

REGULATORY COHERENCE AND CONVERGENCE: A COMPARATIVE ANALYSIS OF BRAZIL, ARGENTINA, MEXICO, COLOMBIA, AND CHILE

Technical Regulations and their supporting standards

Coordinated by
Vera Thorstensen
Luís Fernando Tironi



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REGULATORY COHERENCE AND CONVERGENCE: A COMPARATIVE ANALYSIS OF BRAZIL, ARGENTINA, MEXICO, COLOMBIA, AND CHILE

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Research report

Coordinated by

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This research was developed with resources from the Institute of Applied Economic Research (IPEA) and resulted from the Terms of *Reference titled 18-Economic Commission for Latin America and the Caribbean-95059-Consultant*, under the ECLAC-IPEA Technical Cooperation Agreement. The views and opinions expressed in this research are those of the authors and not necessarily reflect the official policy or position of any agency of the Brazilian government or any international organization.

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LIST OF ACRONYMS

ABIA Brazilian Association of Food Industries
ABIFINA Brazilian Association of Fine Chemical Industry
ABIQUIM Brazilian Chemical Industry Association
ABNT Brazilian Association of Technical Standards
ACE Economic Complementation Agreement
AEA Asociación Electrotécnica Argentina
AITA Asociación de Ingenieros y Técnicos del Automotor
ALADI Latin American Integration Association
ANA Brazilian Water Agency
ANATEL National Agency of Telecommunication
ANCE Asociación de Normalización y Certificación
ANFAVEA Brazilian Association of Automotive Vehicle Manufactures
ANMAT National Drugs, Food and Medical Technology Administration
ANP Brazil National Agency of Petroleum, Natural Gas and Biofuels
ANSI American National Standards Institute
ANTT Brazilian Land Transport Agency
ANVISA Brazilian Health Regulatory Agency
ASTM American Society for Testing and Materials
BPL Good Laboratory Practices
CAC Comité Andino de Calidad
CALMECAC Calidad Mexicana Certificada, A.C.
CAMEX Brazil Foreign Trade Chamber
CAN Comunidad Andina de Naciones
CEN European Committee for Standardization
CENAM Centro Nacional de Metrología
CENELEC European Committee for Electrotechnical Standardization
CGN General Committee on Standards (*Comité General de Normalización*)
CJEF Consejería Jurídica del Ejecutivo Federal
CMC Common Market Council, Mercosur
CNA Brazilian Confederation of Agriculture and Livestock
CNB Committee of Biregional Negotiations
CNBS Brazilian Council on Biosafety
CNCP Centro Nacional Para la Calidad del Plástico
CNI Brazilian National Confederation of Industry
CNN Comissão Nacional de Normalização
CNTBio Brazilian Technical Commission on Biosafety
CONAL National Food Commission
CONMETRO Brazil National Metrology, Standardization and Industrial Quality Council
COPANT Comissão Pan Americana de Normas Técnicas
CORFO Chilean Economic Development Agency
CORPROSAL Commission on Health Products
CRT Consejo Regulador Del Tequila
CSA Commission for Animal Health
CSM Mercosur Sectoral Committees
CSV Commission for Vegetal Health
DECEX Department of Foreign Trade Operations, MDIC
DFPC Controlled Products Oversight Board
DIPOA Department of Inspection of Products of Animal Origin, SDA, MAPA
EFTA European Free Trade Association
ETSI European Telecommunications Standards Institute
EU European Union
FDA US Food and Drug Administration
FDI Foreign Direct Investment
FIESP Federation of Industries of the State of São Paulo
FNDCT Brazilian Fund of Scientific and Technological Development
GMC Common Market Group, Mercosur
GMO Genetically Modified Organisms
GMP Good Manufacturing Practices

GTP CV Permanent Working Group on Plant Quarantine
HS Harmonized System
IAAC Cooperación Integramericana de Integración
IAF International Accreditation Forum
IAS *Instituto Argentino de Siderurgia*
IBAMA Brazilian Institute of the Environment and Renewable Natural Resources
IEC International Eletrotechnical Commission
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
IMNC Instituto Mexicano De Normalización y Certificación, A.C.
INAL National Food Institute
INMETRO Brazil National Institute of Metrology, Quality and Technology
INNTEX Instituto Nacional De Normalización Textil, A.C. (Mexican Institute of Textile Standardization)
INTERTEK (product certification body for electric and electronic equipment)
INTI National Institute of Industrial Technology
INV Wine Production Institute
IPI Brazilian Manufactured Products Tax
IRAM Argentine Standards and Certification Institute
ISO International Standardization Organization
MAD Agreement of Mutual Acceptance
MAPA Brazil Ministry of Agriculture, Livestock and Food Supply
MCR Adjusts the General Norms
MDIC Brazil Ministry of Industry, Foreign Trade and Services
MERCOSUR Common Market of the South
MMA Ministry of Environment
MME Ministry of Mines and Energy
MRA Mutual Recognition Agreement
MRL Maximum Residue Levels
NAFTA North American Free Trade Agreement
NAL Non Automatic Licenses
NIP National Implementation Plan
NM Mercosur Standard
NMC Common Nomenclature of Mercosur (*Nomenclatura Comum do Mercosur*)
NORMEX Sociedad Mexicana de Normalización y Certificación, S.C.
NR Regulatory Standard
NRF Normas de Referência
NYCE Normalización y Certificación Electrónica
OAA Argentine Accreditation Agency
OAS Organization of American States
OECD Organization for Economic Cooperation and Development
OIE World Organization for Animal Health
OIML International Organization of Legal Metrology
ONN Organismos Nacionais de Normalização
ONNCCE Organismo de Normalización y Certificación de la Construcción y Edificación
PGR Procuraduría General de la República
PHPC Personal Hygiene, Perfumery and Cosmetics
POP Persistent Organic Pollutants
PROCONVE Brazilian Program for the Control of Pollution by Motor Vehicles
PROMOT Brazilian Program for the Control of Pollution by Motorcycles and Similar Vehicles
PRONAF Brazil National Program to Strengthen Family Agriculture
PRONAR Brazilian National Program for Air Quality Control
RDC Resolution of the Board of Directors, ANVISA
RENAVAM Brazilian National Registry of Motor Vehicles
RIEMA Brazilian Internal Regulation of Environmental Emergencies
SADER Secretaria Agricultura y Desarrollo Rural
SAI Sistema Andino de Integración
SALUD Secretaria de Salud
SCT Secretaria Comunicaciones y Transportes
SDA Secretariat of Agricultural Defense, MAPA
SDCI Secretariat of Industrial Development and Competitiveness, MDIC

SE Secretaria de Economia
SECTUR Secretaria de Turismo
SEDATU Secretaria de Desarrollo Agrario, Territorial y Urbano
SEDENA Secretaria de Defensa Nacional
SEGOB Secretaria de Gobernacion
SEMAR Secretaria de Marina
SEMARNAT Secretaria Medio Ambiente y Recursos Naturales
SENASA National Service of Health and agro-Food Quality
SENER Secretaria de Energia
SEP Secretaria Educacion Publica
SER Secretaria de Relaciones Exteriores
SFP Secretaria de la Funcion Publica
SFP Secretaria de la Funcion Publica
SGT Working Subgroup, GMC, Mercosur
SHCP Secretaria de Hacienda y Credito Publico
SIEMA Brazil National Environmental Emergency System
SIMI Import Monitoring System (*Sistema Integral de Monitoreo de Importaciones*)
SISMENEC Sistema Mexicano de Metrologia, Normalização e Avaliação da Conformidade
SMC Secretariat of Social Mobility, Rural Producer and Cooperativism, MAPA
SNVS Brazilian National Health Surveillance System
SPA Secretariat of Agricultural Policy, MAPA
SPS Sanitary and Phytosanitary Measures
SRI Secretariat of Agribusiness International Relations, MAPA
STC Specific Trade Concern
STPS Secretaria del Trabajo y Prevision Social
SUS Unified Health System
TBT Technical Barriers to Trade
TPP Trans-Pacific Partnership
UL Underwriters Laboratories de Mexico, S.A. de C.V.
UNECE United Nations Economic Commission for Europe
USCA US-Mexico-Canada Agreement
USMCA United States, Mexico and Canada Agreement
WP 29 UN World Forum for Harmonization of Vehicle Regulations
WTO World Trade Organization

PREFACE

The importance of non-tariff barriers is already identified in the multilateral framework of trade in several rules and activities of the World Trade Organization (WTO) and in the various preferential agreements, including regional integration projects such as Mercosur.

At the same time, the negative impacts of countries' regulatory policies on their trade can be evaluated by comparative analysis between domestic regulatory regimes of trading partners. Such an analysis makes possible to understand the dynamics of bilateral trade flows, as well as their trade relations with third countries.

This book aims at a comparative analysis between Brazilian and Argentine regulatory systems in the context of international trade and integration with some countries of the Pacific Alliance.

This research report is divided into three parts:

Part I - Brazil and Argentina

Part II - Mexico, Colombia, and Chile

Part III - A comparative study between Mercosur and the Pacific Alliance

Part I shows an overview of Brazil and Argentina technical regulatory systems and sectorial analyses for some sectors: automotive and auto-parts; machinery; electrical machinery; medical devices; pharmaceuticals; cosmetics; processed food; plastic and plastic materials; amongst other specific trade issues.

Part II examines the regulatory structure, aspects of regulatory convergence and sectorial analyses for Mexico, Colombia, and Chile.

Part III holds a comparative exercise amongst Brazil, Argentina, Mexico, Colombia, and Chile in terms of technical regulations, technical standards and conformity assessment procedures; and a comparative sectorial analyses to conclude that there is room for improving horizontal regulatory convergence between Brazil-Argentina and Mexico-Colombia-Chile.

It also reveals that some sectors are based on international standards, such as the oil and gas sector for Brazil and Argentina, while others are still heavily based on domestic regulations not necessarily on a basis of international standards such as machinery and electrical equipment for Brazil, Colombia and Mexico.

Good reading !

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PART I
BRAZIL AND ARGENTINA

1. The relevance of regulatory barriers to trade in the context of Brazil and Argentina

At the present time, due to the relative success in the elimination or reduction of tariffs on trade, though successive rounds of multilateral negotiations, efforts of liberalization are focused in other aspects that interfere with trade flows. Now the focus is on the existence of non-tariff barriers, especially technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) or environmental measures that affect the flow of goods. The proliferation of these non-tariff barriers to trade, which in certain situations may constitute a new wave of protectionism, results from the intense regulatory activity of the states, which are demanded by society to regulate, through normative instruments, the most varied dimensions of the economy, including trade.

The importance of non-tariff barriers is already identified in the multilateral framework of trade, in several rules and activities of the World Trade Organization (WTO) and in the various preferential agreements, including regional integration projects such as Mercosur. At the same time, the negative impacts of countries' regulatory policies on their trade can be evaluated by comparative analysis between domestic regulatory regimes of trading partners. Such an analysis makes possible the understanding of the dynamics of bilateral trade flows, as well as their trade relations with third countries. This report aims a comparative analysis between Brazilian and Argentine regulatory systems in the context of international trade and integration.

Brazil and Argentina have important similarities in their economic structures. These similarities are the result of shared characteristics with many developing countries. Both countries share: the colonial condition in the past, the primary-export vocation, the state-induced late industrialization, the process of import substitution. Among the most recent similarities, it should be mentioned the lack of competitiveness in the production of manufactured goods, the economic opening of the 1990s and, after the globalization process after the 80's, the rapid deindustrialization, inferred by the loss of participation of the secondary sector in the gross domestic product. In terms of international trade specifically, both countries have a very common profile among developing countries. Both are major exporters of commodities and other primary or low-processed goods, such as soybeans, meats, and crude oil. The two are importers of manufactured goods, acquiring more sophisticated products with higher technological intensity from European, Asian and North American markets.

However, at the regional level, this general profile of the two countries changes substantially. Brazil and Argentina, within the framework of the Latin American Integration Association and Mercosur, become important exporters of manufactured goods, including more sophisticated ones, such as automobiles, machinery and chemicals. Even in bilateral trade, Brazil and Argentina develop bilateral exchange predominantly of manufactures. In view of this, regional and, in particular, bilateral trade is of great qualitative importance for the two economies.

Despite the similarity of economic trajectory and the undeniable relevance of bilateral trade, Brazil and Argentina do not fully exploit the economic potentials of their commercial partnership. Both the volume of products and the variety of products could be substantially increased with a few domestic or regional initiatives. One of the reasons that hamper the increase of trade between the two countries is the difference in the regulatory framework, such as regulation of technical, sanitary, phytosanitary and environment aspects related to international trade, as well as different conceptions in the standardization and conformity assessment systems. After almost three decades of economic integration, Mercosur is still in the preliminary steps of regulatory convergence. Indeed, there are important differences in the regulatory systems of the two countries, which often lead to difficulties in bilateral, regional

and third-country international trade. These difficulties can explain why the achievements on regulatory convergence in Mercosur are so fragile, even when Brazil and Argentina are the most important partners of Mercosur.

The research

The purpose of this research is to develop a comparative framework between the regulatory systems of Brazil and Argentina in order to verify possible non-tariff barriers to bilateral trade and trade with third countries. Three dimensions were concomitantly evaluated: regulations with a mandatory status, standardization activities with a voluntary status and conformity assessment procedures. These three dimensions provide a general picture of non-tariff barriers experienced by the economic actors of the two countries in international trade.

In order to concentrate efforts on the essential aspects related to trade, some economic sectors in Brazil and Argentina were selected, based on economic and trade relevance. The criteria for choosing these sectors, were of two types: participation in the export agenda of Brazil and Argentina and potential to have non-tariff difficulties in international trade, demanding an effort to advance regulatory convergence among the parties.

Some relevant sectors are analyzed on this research, namely: machinery, vehicles, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry.

Once the sectors were selected, the research focused on the identification of technical regulations (and other mandatory rules, technical standards (voluntary) and conformity assessment procedures established in the two countries. Based on this identification, it examines the possible lack of convergence between the trade regulatory framework of Brazil and Argentina, especially with regard to the supporting standards of both regulations and domestic standards. One goal was to identify the degree of the internalization or the utilization of international standards or the use of global sectoral standards to establish new regulations issued by the State or by regulatory agencies or decentralized institutions, endowed by the State with regulatory powers.

International standards

Two important concepts used in this project are international standards and global sectoral standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), Codex Alimentarius Commission, World Organisation for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*. International standards are generally produced in accordance with the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectoral standards are private standards developed by relevant standardizing bodies and relevant to international trade. Some examples are those produced in the United States of America (US), as the American Society for Testing and Materials (ASTM), American

Petroleum Institute (API), American Society of Mechanical Engineers (ASME) and Underwriters Laboratories (UL). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

Alongside these global technical standards, there are important technical standards produced and used regionally. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), European Telecommunications Standards Institute (ETSI). European standards are essential for the functioning of the EU integrated market and are widely used as the model influencing many standardization and regulatory work in several countries of the world. For Brazil and Argentina, European standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies. Several provisions of the Brazilian technical regulation concerning machinery and mechanical devices safety, and the Argentine regulation for motor vehicles, make direct reference to the European technical standards produced by CEN.

Some legal explanations

To understand the regulatory frameworks of the two countries, the first step is to identify their main regulatory actors: authorities, agencies and government bodies and some private bodies with regulatory responsibilities.

The research identified the main regulatory actors for each country and grouped them on the following categories: public authorities, non-governmental bodies and private actors. Examples of public authorities issuing mainly mandatory rules are ministries, committees inside ministries, secretariats, departments inside secretariats, regulatory agencies and autarchies. Examples of non-governmental bodies issuing mainly non-mandatory rules are the ones that regulate technical standards. The private actors consist of sectoral associations and committees working alone or coordinated with ministries. Despite the private juridical nature of those entities, they can interfere on the regulatory system of the countries and also affect the regulatory activities.

The regulation in Brazil and in Argentina differs according to the allocation of competences established on the constitution of each country. In Brazil, laws can be national, state or municipal. In Argentina, laws can be national, provincial and municipal.

In Brazil, the main regulations are created by the federal government, but their contents reflect on the competences attributed to subnational governments. The different public bodies inside the Brazilian regulatory systems are: National System of Metrology, Standardization, and Industrial Quality (SINMETRO); National Health Surveillance System (SNVS); Unified Agricultural Health Care System (SUASA) and National Environment System (SISNAMA). State and municipal governments are competent in strategic regulatory issues that affect the sectors analyzed in this project. For these reasons, the review of the regulation produced by each system is not exhaustive, but encompasses the most relevant technical regulations in force in Brazil.

In Argentina, provinces retain the competences that were not delegated by the Constitution to the federal government and those reserved by special covenants on the time of their incorporation to the Federation. They are competent, for example, to complement national laws on different issues as the environment. Each province, moreover, creates its own constitution and thus guarantees the municipal autonomy and regulates its scope on the institutional, political, administrative, economic and financial order. In addition, delegating regulatory authority to executive agencies is rarer in Argentina, which gives power to state political bodies, such as Ministries and Secretaries.

Initiatives on convergence

This research aims to analyze the degree of convergence of specific regulatory issues for each of the selected sectors in Brazil and Argentina.

In the process of identifying the elements of regulatory systems and specifying the difficulties involved, the regulatory convergence instruments developed in the Latin American regional context were explored. The initiatives examined were basically two: ALADI and Mercosur. In the area of ALADI, an agreement was negotiated among its members to overcome technical barriers, without this implying a broadening or deepening of commitments made at the multilateral level. The results achieved till now are more political than economic.

In Mercosur, there are important measures of regulatory convergence aiming the inception of a concrete common market. Through the institutional legal framework established by the organization's founding treaties and the community law of the main bodies of the regional organization, members try to overcome technical barriers to trade. In this case, the work of the Common Market Group (GMC, according to initials in Portuguese), as well as of the Working Subgroup n. 3 n.8 and n.11 are specifically highlighted. They have the responsibility for the elaboration of harmonized technical regulatory measures to be approved by the GMC. The option of harmonization adopted by Mercosur depends essentially on the concerted performance of these bodies, establishing a procedure that is only partially technical and political in the majority of times. The research identified that political interests and the capture by segments of interested parts influence the regional production of regulation and obstruct the automaticity of the process that should be technical harmonization. The influence of this non-technical pressure also explains the irregularity in the time of the harmonization measures of the regulation within the bloc.

Given the importance of the regional institutional framework to implement the regulatory convergence initiative between Brazil and Argentina, the direct reference to other regulatory convergence models entrenched in regional integration initiatives was inevitable at some point in the research. The solutions adopted within the European Union in the building of common market were therefore an important comparative model, since it established a successful way to reduce the impacts of the heterogeneity of domestic regulation.

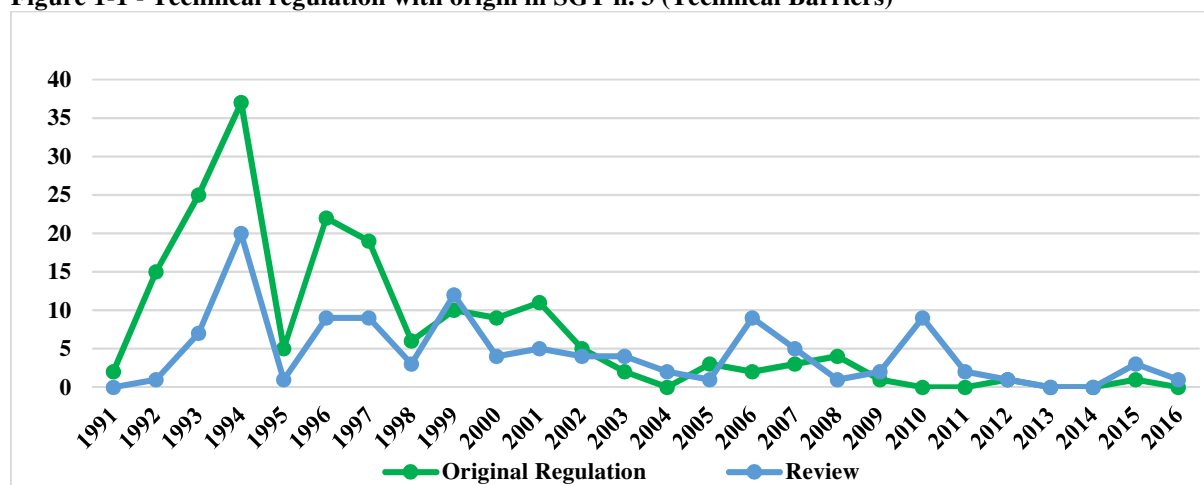
There are substantial differences between the EU and Mercosur systems. There are fundamental points in the three dimensions of the regulatory framework. As regards regulation, the EU regulates only general aspects of products, which are addressed in the form of large family of products. In the case of Mercosur, even if a similar strategy was adopted, much effort is expended in updating and reviewing already harmonized regulations.

Mercosul initiatives on convergence

In fact, Mercosur has a weak regional standardization structure, in contrast to the vigorous performance of the European standardization bodies. Because of the lack of interest in the private sector, the Mercosur Standardization Association (AMN) lost its impetus and produces few standards; only a small number of them are effectively used with the objective of harmonizing regulations of the bloc. In addition, AMN acts together with SGT n. 3 (Technical Barriers) but the technical regulation of Mercosur can have effective origin in other subgroups of work, as, for example, subgroups no. 8 (Agriculture) and n. 11 (Health).

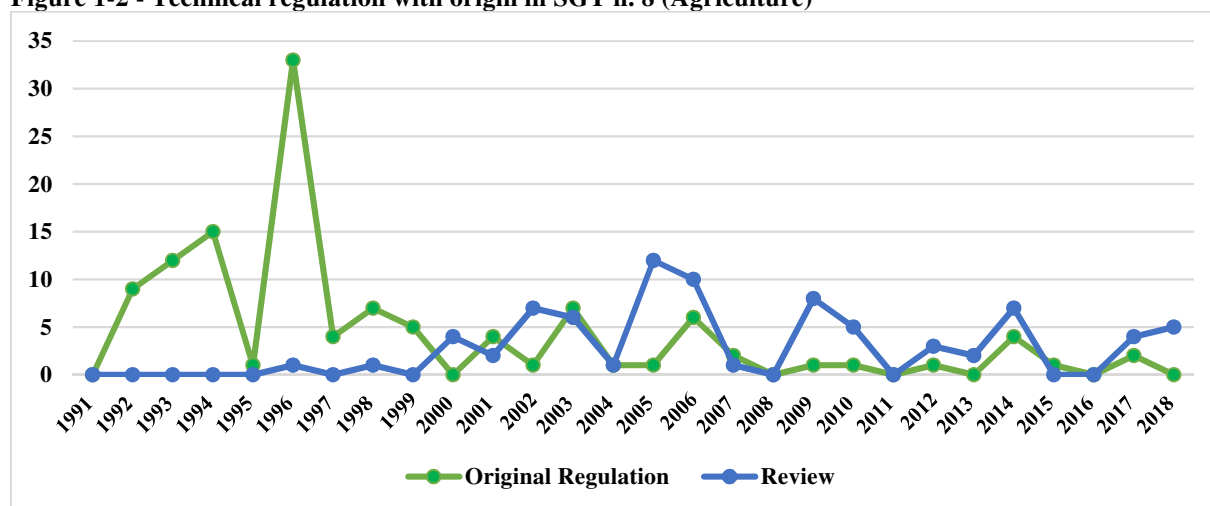
The following graphs present an overview of regulatory activity of SGT n. 3, 8 and 11:

Figure 1-1 - Technical regulation with origin in SGT n. 3 (Technical Barriers)



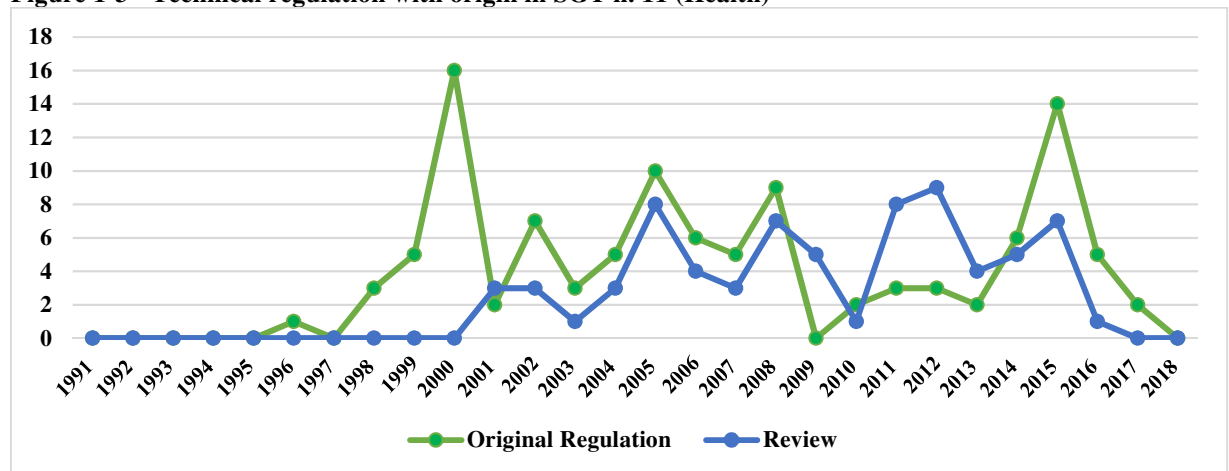
Source: Mercosur. Elaborated by CCGI-EESP/FGV.

Figure 1-2 - Technical regulation with origin in SGT n. 8 (Agriculture)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

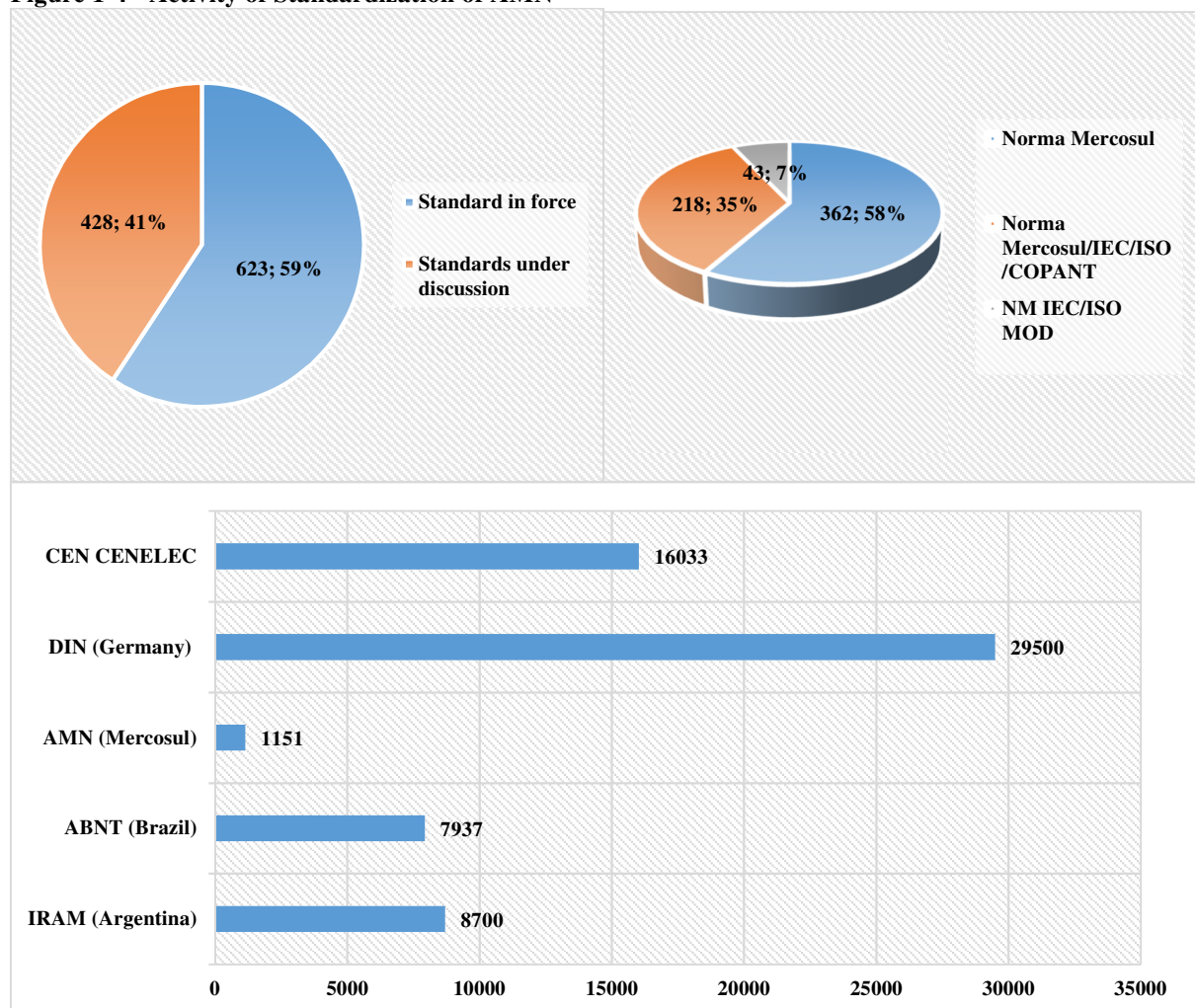
Figure 1-3 - Technical regulation with origin in SGT n. 11 (Health)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

The following graphs present an overview of regulatory activity of AMN, and show a comparison among some standardization bodies.

Figure 1-4 - Activity of Standardization of AMN



Source: AMN, IRAM, ABNT, DIN, CEN/CENELEC. Elaborated by CCGI-EESP/FGV.

This tables present a clear evidence that Mercosur activities on regulatory convergence are facing real problems. After almost 30 years of integration, the results presented in the development of common regulations and common standards are quite small. Time has come for a revision of the regulatory process in Mercosur.

Conformity assessment

The third dimension of regulatory framework is related to the conformity assessment procedures. Again, after almost 30 years of its creation, the fact that there is no common conformity process is a good example on how weak is the Mercosur integration process.

A comparison with the EU experience can clarify the challenges ahead. The EU adopts a self-declaration and a post-market surveillance. Mercosur and its members adopt pre-market control to reinforce the quality of the products released in the market. The burden of this pre-market control is the increase of time and costs of the process, and more difficulties to put products in the market, especially in the markets of the bloc's partner countries.

There are several ways to assess the conformity of a product against a standard. The broader categories of classification of conformity assessment procedures are based on the kind of actor performing the task. Bearing in mind the contractual relationship acquisition of goods and services, two parties are identified a priori: supplier and buyer. If the conformity assessment is carried out by the supplier, this procedure is classified as first party assessment. If the buyer conducts the conformity assessment, there is a second-party assessment. The procedure can also be performed by an external actor to the main contractual relationship and, therefore, formally neutral and disinterested in the accomplishment of the legal business. In this case, the procedure is classified as a third party procedure. The most common third-party procedure is certification, which usually involves an accredited body to perform this type of procedure.

Differences in the functioning of European and Mercosur regulatory framework systems are directly related to the choice of the predominant national and regional conformity assessment procedures. While the EU understands that the completion of the common market would be better served by a system based predominantly on first-party evaluation (supplier's declaration, for example), Mercosur members understands that the predominance of third-party evaluation procedures should be maintained domestically and in regional level. The Mercosur option emphasizes pre-market practices (the product is evaluated before it is put on the market), which hampers the free movement of products within the common market. The EU option makes trade faster and the first-party assessment creates presumption of compliance in any member country of the bloc. The European system works because it is heavily based on post-market control, with the possibility of speedy adoption of legal measures against the supplier falsely claiming to comply with a particular European technical standard. Regardless of the structural aspects that underpin the European model, it seems to be more suited to a logic of integration and consolidation of the single market.

The fact that trade between Brazil and Argentina is still based in a double conformity process is a question to be re-discussed. Again, after almost 30 years of Mercosur, it is time to rethink the experience and adjust the framework.

Although Mercosur is the most advanced institutional framework for regulatory convergence between Brazil and Argentina, it has presented limited results. Parallel initiatives may be important to make the regulatory framework systems of the two countries more compatible.

The objective of this study is to exam the question of regulatory convergence and provide some suggestions to improve the economic integration of Brazil and Argentina envisaging a better integration of Mercosur.

Methodological note on the scope and purpose of this research

This study consists of the analysis of technical regulation, standardization and conformity assessment procedures of different sectors of the Brazilian and Argentine economies. The purpose of the study is to find evidence of the degree of regulatory convergence of some of the main Brazil and Argentine industrial sectors. A first step to this goal is to study the use of international or sectoral global supporting standards in Brazil and Argentina through compulsory technical regulations and as a technical basis for the elaboration of voluntary standards. The utilization of international and global standards in Brazil and Argentina can be considered as an indicative of regulatory convergence.

The sectors were selected based on the importance in Brazilian and Argentinean foreign trade. The study considered the broader classification of the harmonized system (HS - two digits). Official sites of Argentina and Brazil, such as *Instituto Nacional de Estadística y Censos de la República Argentina*, INDEC, <https://www.indec.gob.ar/>), and COMEXSTAT (<http://comexstat.mdic.gov.br/pt/home>) provided information on trade flow, including disaggregated data.

The sectors analyzed on this research are, namely: machinery, vehicles, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry.

- Regulations

The identification and mapping of technical, sanitary and phytosanitary regulation in Brazil and Argentina are twofold: analysis of notifications to an international body and identification of Brazilian and Argentinean domestic regulation through analysis of the activity of the main domestic regulatory agencies. The first part reviews the notifications made by Brazil and Argentina to the WTO Committee on Technical Barriers to Trade (CTBT) and the Committee on Sanitary and Phytosanitary Measures (CSPS). As provided in art. 2.9. of the TBT Agreement and paragraph 5 of Annex B of the SPS Agreement, such notifications, which express compliance with the WTO principle of transparency, would indicate if the regulation or technical standard are different from international standards and potentially relevant to international convergence. Since identification through analysis of notifications allow the contact only to a portion of regulations and standards of a given sector, the research also sought to identify sectoral regulations and standards through an independent search on official websites of Brazilian and Argentinean government, including decentralized bodies.

In practical terms, in the analysis of notifications, the research used three distinct means of searching, since none of them alone would provide satisfactory information. Firstly, the research directly accessed the WTO's information management system (IMS) websites (CTBT: <http://tbtims.wto.org/> and CSPS: <http://spsims.wto.org/>). From this search it was extracted information on regulations and standards notified by Brazil and Argentina. Frequently, such prescriptive documents were in draft stage or public consultation stage, in accordance with the mentioned provisions of the TBT and SPS Agreements. However, not all notifications provided complete information on the notified regulation. In the case of SPS, only the latest notifications contained complete references to the notified regulation, project or consultation.

TBT and SPS notifications were also collected at the sites of focal points of Brazil and Argentina, in compliance with provision WTO TBT and SPS Agreements, regarding the obligations of national enquiry points. Based on the information of these sites, which reproduces and reorganizes the information notified to TBT and SPS Committees the research identified the domestic regulation notified by Argentina and Brazil. In the case of TBT, in the website of enquiry points, the research found not only the form sent to the TBT Committee, but also the file of the normative acts that was object of the notification. It should be noted that a similar website was not found for regulations concerning sanitary and phytosanitary measures.

The third source for the search and analysis of notifications was the website of the Latin American Integration Association (ALADI), which contains a copy of the notifications sent to the TBT Committee in a friendlier virtual environment. The search on the ALADI website was mainly aimed at verifying the fulfillment of the commitments made under the Framework Agreement for Trade Promotion by Overcoming Technical Barriers to Trade (*Acuerdo Marco para la Promoción del Comercio Mediante la Superación de Obstáculos Técnicos al Comercio*, 1997), which acquired the status of Regional Agreement no. 8 (AR 8).

Parallel to the research based on the notifications to the TBT and SPS Committees, a separated search was made for the domestic regulations and standards for each sector. In Brazil and Argentina, many public bodies and agencies issue technical regulations for different economic sectors. Therefore, to identify the main regulation (including those not notified to WTO Committees), the research had to go through different search tools in different governmental websites to put together relevant technical regulations for the economic sectors analyzed. It means that, with current searching tools available to present day, it is not possible to guarantee that tables with those regulations introduced in the reports are exhaustive lists.

The regulatory authority varies according to the sector. Some authorities have the competence to regulate more than one sector, such as ANMAT the National Drugs, Food and Medical Technology Administration in Argentina and ANVISA the Brazilian Health Regulatory Agency in Brazil, that are responsible for the regulation of pharmaceutical and cosmetic goods. The regulation of other industrial sectors sometimes overlaps with standards developed by national standardization bodies. In fact, the regulatory agencies can build the technical regulation with reference to standards or the agency can design itself the technical prescription with no reference to standards.

- Standards

The research also scrutinized the standardization policies in Brazil and Argentina assessing the portfolio of *Instituto Argentino de Normalización y Certificación* (IRAM) standards and *Associação Brasileira de Normas Técnicas* (ABNT). ABNT and IRAM do not provide a public list of all international and global standards adopted in full. The search tool available requires a keyword search that goes from product to product at ABNT and IRAM's website. Therefore, the research had to refine a keyword search in order to gather a list with relevant supporting standards for each of the economic sectors analyzed. IRAM Catalog with all searching tools is available [here](#). ABNT catalog can be found [here](#).

Additionally, it is relevant to point out that accessing the content of standards issued by ABNT and IRAM is not free. In the same way as European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), American Society for

Testing and Materials (ASTM) and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT and IRAM. The costs vary depending on the standard. Therefore, going on an analysis whether the supporting standards are only based or have some degree of modification with international or globalized standards or how different original standards issued by ABNT and IRAM are in comparison with international standards is a very complex task to pull through. For that matter, the research focused on the summaries of each relevant supporting standard to put together a list of supporting standard by analyzed sector and to provide a first assessment on their compatibility with international standards as a measure of the degree of convergence for the regulatory framework of Brazil and Argentina.

In any case, there are no official lists determining which regulations or standards are based on international or global standards and to what extent each one adopts *ipsis literis* the international or global standard; or which are grow-made domestically created.

In order to facilitate the qualitative analysis of regulations and technical standards, the researchers made use of a specific computational tool, the Atlas TI. The Atlas TI is a qualitative research software, used for studies that require comparative analysis of large mass of text and other non-numeric material, making possible the creative and efficient reorganization of the primary research sources.

Finally, it should be noted that the analysis of the degree of utilization of international and global supporting standards in the Brazilian and Argentine regulatory and standardization system provides only an indication of the degree of convergence and internationalization of the industrial regulatory framework, since there was no comparison of technical content between international and Brazilian/Argentine standards and regulations. In other words, the constant reference to international and global standards in Brazilian and Argentine regulations and standards indicates the internationalization and convergence of a certain sector, but the lack of references does not lead to any conclusion in the opposite direction. Therefore, the absence of such reference to international standards does not necessarily indicate the incompatibility between the Brazilian and Argentine and other countries' regulation or standardization. In such cases of tacit compatibility, which were not tracked in this research, the absence of explicit reference to the international standard is compensated by the similarity of technical content of the prescriptive texts. More research is needed to clarify the issue.

2. Overview of Brazil-Argentina Technical Regulatory Systems

2.1. Research project details: connecting trade and technical regulation

2.1.1. Scope

The present study consists of the analysis of technical regulations, technical standards and conformity assessment procedures from different sectors of the Argentine and Brazilian economy, from the perspective of international trade in goods, which is governed by multilaterally agreed rules and principles.

The purpose of the study was to find evidence on the degree of regulatory internationalization / convergence between some of the main sectors of the Brazilian and Argentine economies, in order to identify opportunities to increase bilateral trade and the trade with third countries. The frequency of international (or regional and sectoral) technical standards in the mandatory technical regulation of Argentina and Brazil and as a guideline for the elaboration of voluntary standards in both countries will be considered as an indicator of sector internationalization / convergence.

The sectors were selected based on their importance in the trade agenda of Brazil and Argentina and on the expectation of sectoral regulatory complexity. The study considered the broader classification of the harmonized system (HS - double digits) maintained by the World Customs Organization (WCO). Official sites in Argentina and Brazil, such as the National Institute of Statistics and Census of the Argentine Republic (INDEC)¹, and the Foreign Trade Information Analysis (Comexstat)², provided information on trade flow, including disaggregated data (to four digits).

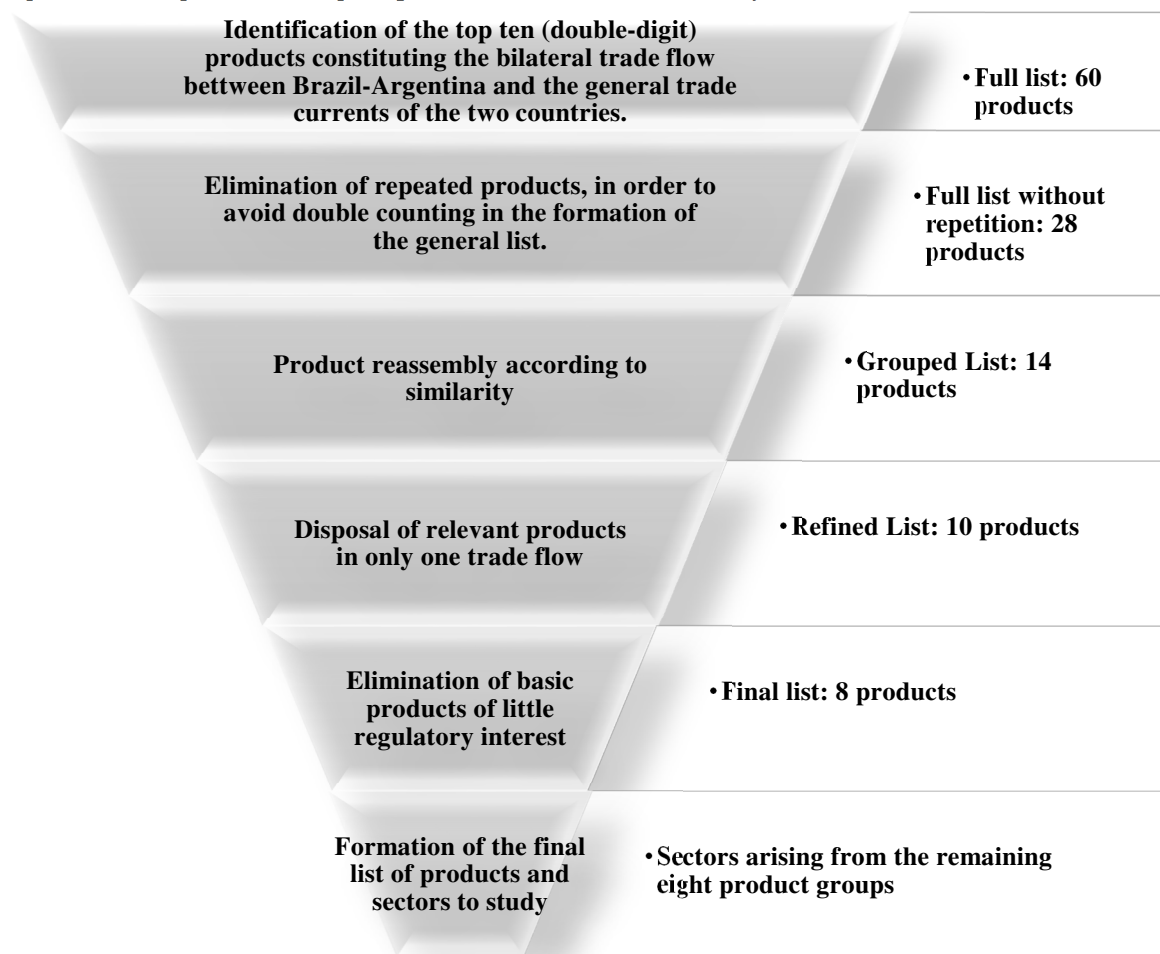
2.1.2. Identification of sectors

The group of products was chosen based on dual criteria, based on bilateral (Brazil-Argentina) and general (Brazil and Argentina with all their trading partners) trade flows, and the presumed regulatory complexity of the sectors. The selection took place in sectors exclusion stages, which were eliminated according to the lower commercial relevance and the expectation of lower regulatory complexity. At the end of this process, eight (8) groups of goods remained, which do not necessarily correspond to eight chapters of the harmonized system. These eight groups of goods, which correspond to eight major sectors of the Brazilian and Argentine economy, will be further analyzed in the regulatory, standardization and conformity assessment dimensions.

¹ Disponível em <https://www.indec.gob.ar/>.

² Disponível em <http://alicesweb.mdic.gov.br>

Figure 2-1 - Stages of choosing the products and sectors to be analyzed



Source: MDIC. Elaborated by CCGI.

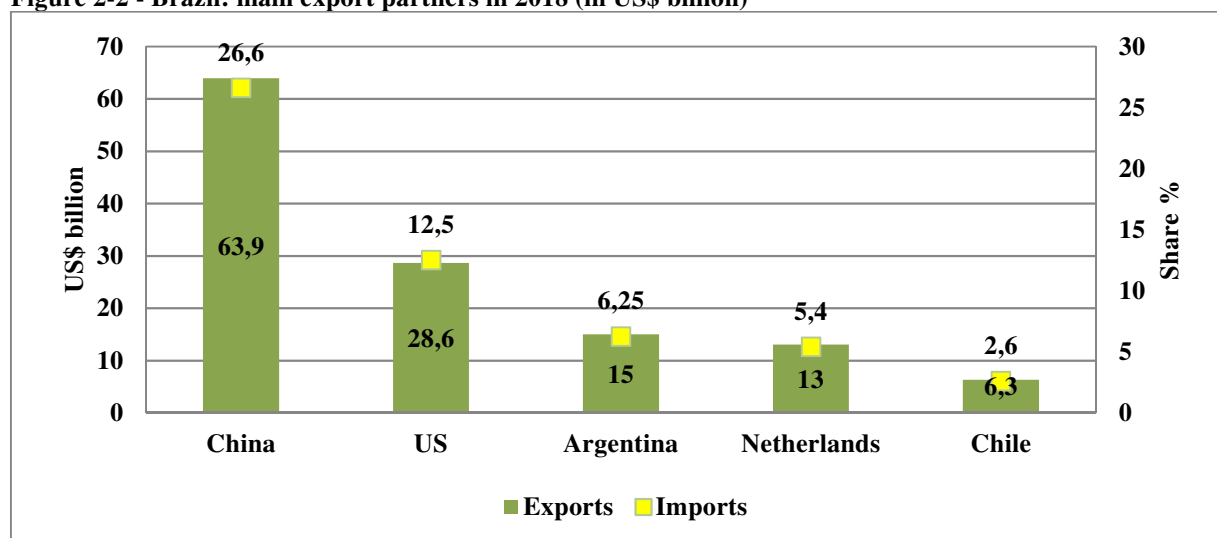
As the project focuses on regulatory aspects that effectively or potentially affect international trade in Brazil and Argentina, the choice of sectors was directly due to the appreciation of trade flows from Brazil and Argentina. The trade profile of both countries was therefore the starting point.

2.1.3. Trade profile: Brazil and Argentina

The trade flow profile between two countries should be assessed in its quantitative aspects and should also consider the characteristics of traded products. It is understood that the diversification of the marketed products agenda and the increased exchange of higher value added products contribute to increase the quality of bilateral trade. Thus, the business profile should be assessed based on the value of the trade and the type of product traded.

In the case of Brazil, in 2017, the main export partners were China, the United States of America, Argentina, the Netherlands and Japan, as shown in the following chart. Together these trading partners accounted for more than half of Brazil's total exports for 2017:

Figure 2-2 - Brazil: main export partners in 2018 (in US\$ billion)

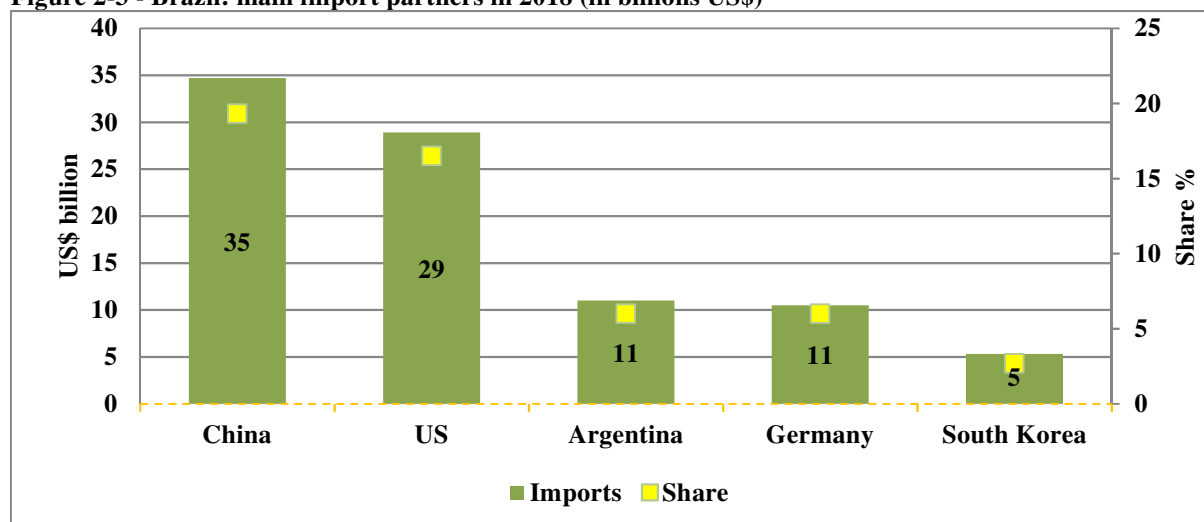


Source: MDIC. Elaborated by CCGI-EESP/FGV.

Although exports to Argentina were only in third position, it should be noted that they consist of higher value-added goods, especially manufactures, especially automobiles and components of the automobile industry. This indicates that when assessing a country's trade, attention should be paid to the composition of the export and import tariff (see [Annex 1](#)).

The main import partners were China, the United States, Argentina, Germany and South Korea. From Argentina, nearly US\$ 10 billion originated in goods, mainly manufactured goods, placing Mercosur's partner ahead of well-functioning economies. such as Germany and South Korea.

Figure 2-3 - Brazil: main import partners in 2018 (in billions US\$)



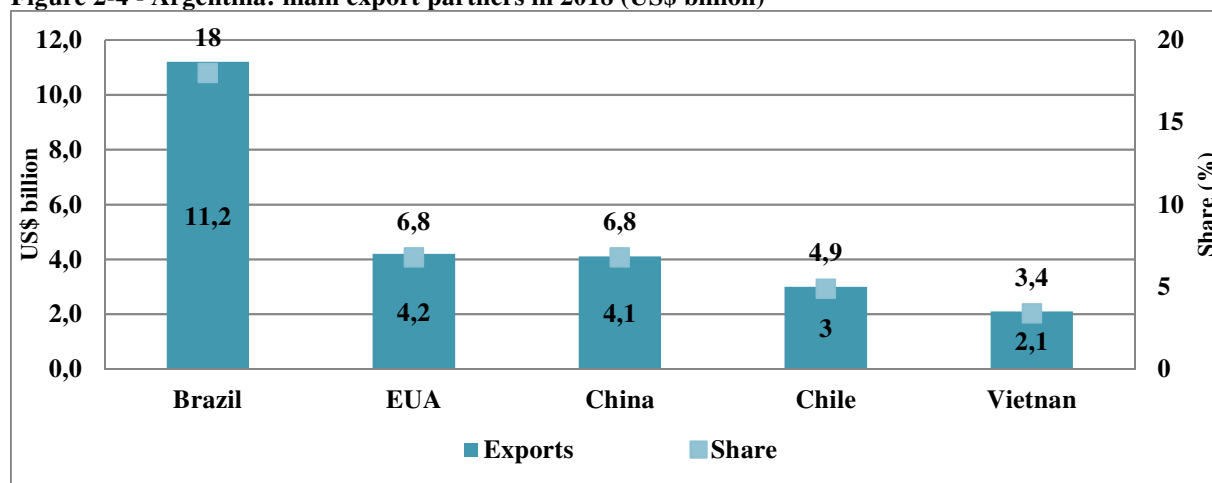
Source: MDIC. Elaborated by CCGI-EESP/FGV.

Considering the partners and the trade flows, this Brazilian trade profile is very similar to Argentina's (see chart below), with some differences in the order of importance of partners. For Argentina, trade within Mercosur acquires vital importance, as Brazil, the bloc's largest economy, is also Argentina's main trading partner, surpassing the two largest world economies in bilateral relations. The conclusion is that, for Argentina, trade with Brazil is qualitatively and

quantitatively more important, evidencing a situation of greater dependence of that country on its South American neighbor than the opposite.

In 2017, Argentina's main export partners were Brazil, the USA, China, Chile and Vietnam, as shown below, which accounted for 37.8 percent of Argentina's total exports for the same year. Exports to Brazil reached almost US \$ 9.3 billion in 2017, surpassing by a few million the combined exports to the US and China. In some years, Brazil absorbs almost a fifth of Argentine exports, acquiring from the neighboring country a very varied list of products.

Figure 2-4 - Argentina: main export partners in 2018 (US\$ billion)

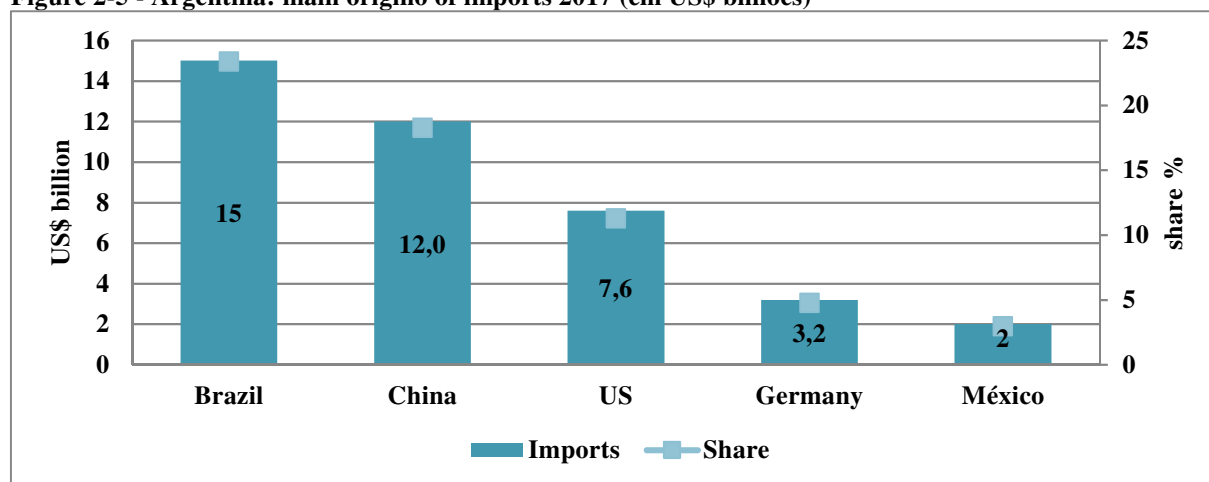


Source: MDIC. Elaborated by CCGI-EESP/FGV.

China and the US are two other major destinations for Argentine exports, and trade with China has grown remarkably in recent years. The world's first and second economies accounted for approximately 7.5% of Argentine exports in 2017. The fourth largest destination for Argentine products is neighboring Chile, which acquired more than \$ 2.5 billion in Argentine products in 2017, accounting for just over 4% of Argentina's exports.

Regarding Argentine imports, the figure below shows that Brazil is the main source (US \$ 17.8 billion), closely followed by China and, in more distant positions, the US, Germany and Mexico.

Figure 2-5 - Argentina: main origino of imports 2017 (em US\$ bilhões)

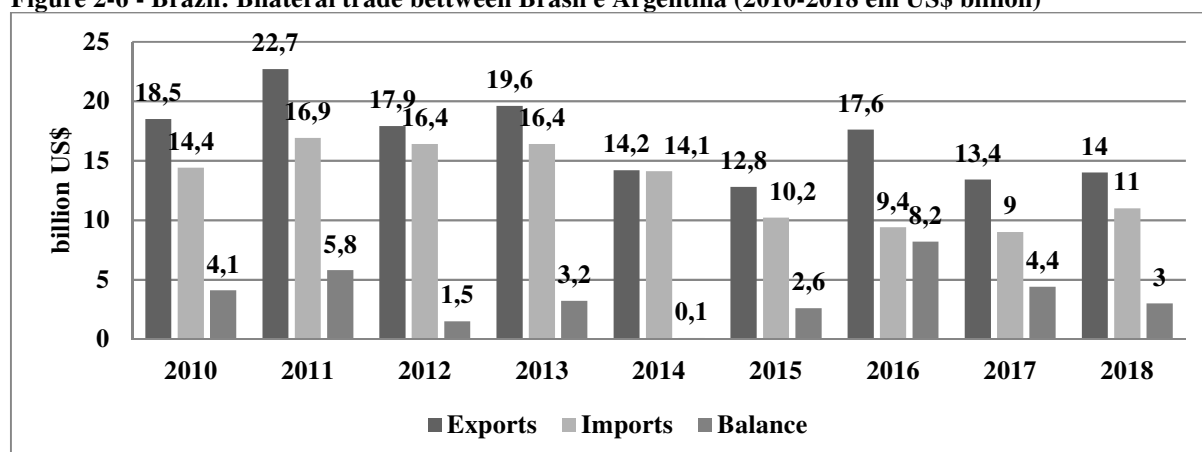


Source: MDIC. Elaborated by CCGI-EESP/FGV.

In assessing the trade profile of Brazil and Argentina, the predominance in volume of the largest world economies (USA and China) is evident, appearing on all lists of the largest importers and exporters in Brazil and Argentina. However, there is also the importance of bilateral trade between the two South American countries, which benefit from their geographical proximity and the existence of a network of trade agreements within the Latin American Integration Association (ALADI). In terms of trade volume, it is noted that bilateral Brazil-Argentina trade is more important for Argentines than for Brazilians, although this importance is more balanced if qualitative aspects are also considered.

The flow of trade between Brazil and Argentina has grown since the early days of the regional integration process, with trade surpluses alternating for both partners. In recent years, Brazil had surplus in all the years, despite the fall in 2014. The trade flow, in turn, decreased between 2011 and 2015, which can be explained by the slowdown of the two economies in those years, in addition to measures aimed at curbing the outflow of dollars from Argentina through the Early Import Declaration (DIAI in Spanish), revoked only after the inauguration of Mauricio Macri's administration. The years 2016 and 2017 were years that showed recovery of bilateral trade between the two countries.

Figure 2-6 - Brazil: Bilateral trade between Brasil e Argentina (2010-2018 em US\$ billion)



Source: MDIC. Elaborated by CCGI-EESP/FGV.

Argentina remains an important trading partner for Brazil, especially within Mercosur, for the export of manufactured goods. The importance of Argentina as a source of Brazilian imports has always been relatively minor, an issue that has long raised discussions about a possible imbalance in favor of Brazil in the integration process, since, apparently, Brazil, despite its larger economy, benefited more from regional integration than its partners. Despite the size of its economy, Brazil does not play a leading role in integration, either as a direct investor or as a deficit trading partner. Brazil, in turn, argues that this situation should be understood with caution, as Brazil has similar or lower development rates than its partners, and is therefore unable to assume the main costs of integration.

However, Brazil's share in Argentine exports and imports is more substantial, despite the brief downturn between 2011 and 2015. According to the National Institute of Statistics and Census (INDEC), an agency of the Argentine government, the Brazilian market was the destination of 21.1 percent of Argentine exports in 2010; whereas in 2017 this share decreased to 16 per cent. Regarding imports originating in Brazil, the share was 31.6 percent in 2010 and 27 percent in 2017. The simultaneous deceleration of the two economies may have contributed to this, but it is not possible to disregard the adoption of measures that hindered the importation of

industrialized products to Argentina, harming the Brazilian exporter, as one of the possible causes of these changes.

Consisting of high value-added manufactured products, the trade between Brazil and Argentina remains fundamental to the industry of both countries. The successful model of trade in vehicles and auto parts could also be envisaged for other sectors, with the aim of simultaneously expanding markets for intermediate goods and creating regional production chains at the South American level, reducing production costs. and improving the competitive conditions of products originating in Mercosur.

2.1.4. Trade flow and selection of sectors

The first stage of the selection was the choice of commercial flow that would be the basis for choosing the products and, consequently, the sectors to be studied. The bilateral flow of trade between Brazil and Argentina was analyzed in conjunction with the general trade flows of the two countries, which were generically termed Brazil-World (import/export) and Argentina-World (import). In order to facilitate the use of these flows, the reference standard has been adopted for trading partner pairs in which the exporting actor always precedes the importer. Thus, exports from Brazil to Argentina, for example, are referred to synthetically as Brazil-Argentina. To refer to the general flow of trade from Brazil and Argentina, we used the term World, which indicates the total imports or exports that both countries make with all their trading partners.

This first selection considered the gross value of imports and exports from Brazil and Argentina for the year 2017. Excluding the repetition of some product genres, sixty most relevant foreign trade items from the two countries were identified: ten products for each of the flows. in both directions: Brazil-Argentina; Argentina-Brazil; Brazil-World; World-Brazil; Argentina-World; World-Argentina.

In this first selection, product differences in trade flows become evident. Some of the most important products in the bilateral trade flow between Brazil and Argentina lose relevance in the overall trade flow of both countries. The revealed comparative advantage index (VCR) is an instrument that helps the understanding of this phenomenon.

Box 1.VCR (RCA) Formula Explanation

Where x_{ijk} represents the exports of product k of a country i to a country j and $X_{ij} = \sum_k x_{ijk}$ represents the total exports (all the products) of country i to a country j . Therefore, the revealed comparative advantage index(RCA) index is:

$$RCA_{ijk} = \frac{\frac{x_{ijk}}{X_{ij}}}{\frac{x_{wjk}}{X_{wj}}}$$

where w refers to "World". Thus, $x_{wjk} = \sum_i x_{ijk}$ is the exports of product k to the country j and $X_{wj} = \sum_i X_{ij} = \sum_i \sum_k x_{ijk}$ is the world exports of all products to country j .

Intuitively, the index compares the importance of a good k among all the exports of country i to country j $\left(\frac{x_{ijk}}{X_{ij}}\right)$ vis-a-vis the importance of this good in the world exports $\left(\frac{x_{wjk}}{X_{wj}}\right)$. Therefore, if $RCA > 1$, the country i is more competitive in the exports of product k to country j than the rest of the world. Moreover, if $RCA < 1$, the opposite occurs: the world is more competitive than country i .

Limitations: Because high export volumes may result from market distortions such as undervalued subsidies or exchange rates, as well as low exports may result from tariffs, non-tariff barriers, among others, RCA has been considered an incorrect name in the It is a better measure of competitiveness than comparative advantage (see [Siguel, 2006](#)).

Based on the VCR index, Brazil's comparative advantage in trade with the world is substantially different from that in bilateral trade with Argentina. In trade with Mercosur's partner, Brazil has a comparative advantage in manufactured goods and a comparative disadvantage in several primary goods, as shown in the table below:

Table 2.1 – Comparative Advantage Index Revealed for Brazil and Argentina

	<i>Argentina→Brazil</i>	<i>Brazil→Argentina</i>	<i>Brazil→World</i>	<i>Argentina→World</i>
<i>Food</i>	2,76	1,08	3,34	6,63
<i>Chemicals</i>	0,38	0,58	0,54	0,93
<i>Plastic and rubber.</i>	1,24	1,3	0,58	0,49
<i>Manufactured goods</i>	0,77	1,08	0,46	0,49
<i>Transport</i>	3,88	2,32	0,89	0,88

Source: MDIC. Elaborated by CCGI-EESP/FGV.

Values greater than 1 (one) indicate comparative advantage of the exporting country over other countries in exporting a particular product to a specific country. According to the table above, Brazil and Argentina, in all proposed trade flows, have a comparative advantage in food exports. However, both countries have an index below 1 (one) in exports of chemicals, plastic and manufactured goods to the rest of the world, which indicates comparative disadvantage. These products, however, now have an index greater than 1 (one) in bilateral trade. Brazil has a comparative advantage in exporting manufactured goods and plastic to Mercosur's partner, and Argentina has a comparative advantage in exporting plastic and rubber to Brazil.

The revealed comparative advantage index sheds light, from the perspective of economic theory, on a de facto trade situation in which countries are endowed with diverse trade potentials. However, it is limited as a selection criterion and, therefore, was used only as an explanatory instrument for the specific composition of bilateral trade between Brazil and Argentina.

As a next step in the product selection process, the duplicates contained in the initial list were eliminated. From the original list of 60 (sixty) product chapters, the duplicated products in more than one commercial chain were removed. The following twenty eight separate product chapters are thus identified: meat and edible meat offal (HS 02); fish and crustaceans, mollusks and other aquatic invertebrates (HS 03); milk and dairy products; poultry eggs; natural honey;

edible products of animal origin, not elsewhere specified or included (HS 04); edible vegetables, plants, roots and tubers (HS 07); cereals (HS 10); milling industry products; malt; starches; insulin; wheat gluten (HS 11); oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruits; industrial or medicinal plants; straw and fodder (HS 12); animal or vegetable fats and oils; products of their decoupling; prepared fats; animal or vegetable waxes (HS 15); sugars and sugar confectionery (HS 17); preparations of vegetables, fruit or other parts of plants (HS 20); waste and scrap from the food industries; prepared animal feed (HS 23); ores, slag and ash (HS 26); mineral fuels, mineral oils and products of their distillation; bituminous materials; mineral waxes (HS 27); inorganic chemicals; inorganic or organic compounds of precious metals, radioactive elements, rare earth metals or isotopes (HS 28); organic chemicals (HS 29); pharmaceuticals (HS 30); fertilizers (HS 31); miscellaneous chemical products (HS 38); plastics and articles thereof (HS 39); rubber and articles thereof (HS 40); pulp of wood or of other fibrous cellulosic material; waste or scrap recycling paper or paperboard (HS 47); paper and cardboard; articles of paper pulp, of paper or of paperboard (HS 48); natural or cultured pearls, precious or semi-precious stones and the like, precious metals, plated or plated metals and articles thereof; jewelry; coins (HS 71); cast iron, iron and steel (HS 72); nuclear reactors, boilers, machinery and mechanical appliances; parts thereof (HS 84); electric machines, apparatus and materials and parts thereof; sound recording or reproducing apparatus, television image and sound recording or reproducing apparatus, and parts and accessories thereof (HS 85); motor vehicles, tractors, cycles and other land vehicles, their parts and accessories (HS 87); optical, photographic, cinematographic, measuring, checking or precision instruments and apparatus; medical and surgical instruments and apparatus; parts and accessories thereof (HS 90).

Table 2.2 - Main products in bilateral and general trade flow of Brazil and Argentina

BILATERAL TRADE BRASIL-ARGENTINA		TRADE WITH OTHER PARTNERS			
BRAZIL → ARGENTINA	ARGENTINA → BRAZIL	BRAZIL		ARGENTINA	
		BRAZIL → WORLD	WORLD → BRAZIL	ARGENTINA → MUNDO	WORLD → ARGENTINA
87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	12 Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder	27 Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	23 Residues and waste from the food industries; prepared animal fodder	87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof
84 Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	10 Cereals	26 Ores, slag and ash	85 Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	10 Cereals	84 Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof
72 Iron and steel	39 Plastics and articles thereof	27 Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	84 Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	85 Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles
39 Plastics and articles thereof	84 Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	87 Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	15 Animal or vegetable fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes	27 Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes
85 Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	11 Products of the milling industry; malt; starches; inulin; wheat gluten	02 Meat and edible meat offal	29 Organic chemicals	12 Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder	39 Plastics and articles thereof
40 Rubber and articles thereof	27 Mineral fuels, mineral oils and products of their	84 Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	31 Fertilisers	71 Natural or cultured pearls, precious or semi-precious	30 Pharmaceutical products

	distillation; bituminous substances; mineral waxes			stones, precious metals, metals clad with precious metal and articles thereof; imitation jewellery; coin	
48 Paper and paperboard; articles of paper pulp, of paper or of paperboard	07 Edible vegetables and certain roots and tubers	17 Sugars and sugar confectionery	30 Pharmaceutical products	03 Peixes e crustáceos, moluscos e outros invertebrados aquáticos	29 Organic chemicals
26 Ores, slag and ash	20 Preparations of vegetables, fruit, nuts or other parts of plants	72 Iron and steel	39 Plastics and articles thereof	38 Miscellaneous chemical products	90 Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof
38 Miscellaneous chemical products	04 Dairy produce; birds' eggs; natural honey; edible products of animal origin, not elsewhere specified or included	47 Pulp of wood or of other fibrous cellulosic material; recovered (waste and scrap) paper or paperboard	90 Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof	2 Meat and edible meat offal	38 Miscellaneous chemical products
28 Inorganic chemicals; organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes.	38 Miscellaneous chemical products	23 Residues and waste from the food industries; prepared animal fodder	38 Miscellaneous chemical products	27 Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	72 Iron and steel

Because some of these products are similar, they can be rearranged into new product groups. Food and agricultural goods can be treated together, as they have similarities in the regulatory dimension, with the predominance of sanitary and phytosanitary aspects. The same regrouping procedure can be applied to chemicals. The result is formation of 14 (fourteen) product groups, as shown in the following table.

Table 2.3 - Product Groups

Regrouped products	
Agricultural Products and HS (HS 02, HS 03, HS 04, HS 07, HS 10, HS 11, HS 12, HS 15, HS 20, HS 23)	Ores, slag and ash (HS 26)
Mineral fuels, mineral oils and products of their distillation; bituminous materials; mineral waxes (HS 27)	Chemicals (HS 28, HS 29, HS 30, HS 31, HS 38)
Plastics and articles thereof (HS 39)	Rubber and articles thereof (HS 40)
Pulp of wood or of other fibrous cellulosic material; waste or scrap recycling paper or paperboard (HS 47)	Paper and cardboard; articles of paper pulp, paper or paperboard (HS 48)
Natural or cultured pearls, precious or semi-precious stones, precious metals, metals clad with precious metal, and articles thereof; jewelry; coins (hs 71)	Cast iron, iron and steel (HS 72)
Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof (HS 84)	Electric machines, apparatus and materials and parts thereof; sound recording or reproducing apparatus, television image and sound recording or reproducing apparatus, and parts and accessories thereof (HS 85)
Motor vehicles, tractors, cycles and other land vehicles, their parts and accessories (HS 87)	Optical, photographic, cinematographic, measuring, checking or precision instruments and apparatus; medical and surgical instruments and apparatus; parts and accessories thereof (HS 90).

Source: MDIC and INDEC. Elaboration CCGI.

Still based on the joint trade agenda of Brazil and Argentina, it can be seen that some product classes have relevance only in certain trade currents. In view of this argument, four product groups can be discarded: rubber and articles thereof (HS 40); pulp of wood or of other fibrous cellulosic material; waste or scrap recycling paper or paperboard (HS 47); paper and cardboard; articles of paper pulp, of paper or paperboard (HS 48); and natural or cultured pearls, precious or semi-precious stones and the like, precious metals, plated or plated metals and their articles; jewelry; coins (HS 71).

These product groups have limited commercial importance and therefore will not be further studied. Rubber and articles thereof (HS 40) is among the main products exported from Brazil to Argentina, but does not have the corresponding importance in the opposite trade flow. Moreover, this type of product is not among the most traded by both countries with the rest of the world. The same is true with paper and cardboard; articles of paper pulp, of paper or of paperboard (HS 48). Pulp of wood or other fibrous cellulosic material (HS 47) is important in Brazilian general exports, but is of little relevance in Argentine general exports and the bilateral trade agenda between the two countries.

2.1.5. Regulatory complexity as a selection criterion

Of the 11 (eleven) remaining product groups, two of them are mainly primary products: ores, slag and ash (HS 26); and mineral fuels, mineral oils and products of their distillation; bituminous materials; mineral waxes (HS 27). The four-digit breakdown indicates that the value of goods processed is quite low for these two product groups.

Table 2.4 - Disaggregated HS 26 and HS 27 Products

PRODUCT	VALUE US\$
2601 - Iron ores and concentrates, including roasted iron pyrites (pyrite ash)	383.537.172.196
2709 - Crude oils of petroleum or bituminous minerals	16.625.024.185
2603 - Copper ores and concentrates	2.485.258.236
2710 - Petroleum oils or oils obtained from bituminous minerals, other than crude; preparations not elsewhere specified or included, containing by weight 70% or more of petroleum oils or oils obtained from bituminous minerals, which must be their constituent	1.778.618.009
2602 - Manganese ores and concentrates, including ferruginous manganese ores and concentrates, with a manganese content of => 20% by weight on the dry matter.	365.636.404
2606 – Aluminum ores and concentrates	237.835.361

Source: MDIC and INDEC. Elaboration CCGI.

Thus, although HS 26 and 27 include primary and processed products, Brazil and Argentina export these products primarily in their primary stage as commodities. These commodities are priced in international markets, as well as highly internationalized regulation.

From the initial list, after the various product deletion and reassembly steps, the remaining product groups were as follows:

Table 2.5 - Final List of Products to Analyze

Agricultural products and food (HS 02, HS 03, HS 04, HS 07, HS 10, HS 11, HS 12, HS 15, HS 20, HS 23)
Chemicals (HS 28, HS 29, HS 30, HS 31, HS 38)
Plastics and articles thereof (HS 39)
Cast iron, iron and steel (HS 72)
Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof (HS 84)
Electric machines, apparatus and materials and parts thereof; sound recording or reproducing apparatus, television image and sound recording or reproducing apparatus, and parts and accessories thereof (HS 85)
Motor vehicles, tractors, cycles and other land vehicles, their parts and accessories (HS 87)
Optical, photographic, cinematographic, measuring, precision checking (HS 90) instruments and apparatus

Source: MDIC and INDEC. Elaboration CCGI.

The remaining product groups will be the basis for choosing the sectors to study. According to the Terms of Reference (ToR) (-18-Economic Commission for Latin America and the Caribbean-95059- Consultant, p.1), the sectors studied will be: agriculture, food industry, chemicals (pharmaceuticals, cosmetics and basic chemicals), steel, mechanical machines, consumer electronics, medical equipment and automotive vehicles.

Deepening regulatory analysis will also focus on international trade, taking into account multilateral trade rules and principles as well as the regional regulatory framework. However, for international trade aspects to be fully addressed, it is necessary to understand the national regulatory framework of each of the sectors addressed.

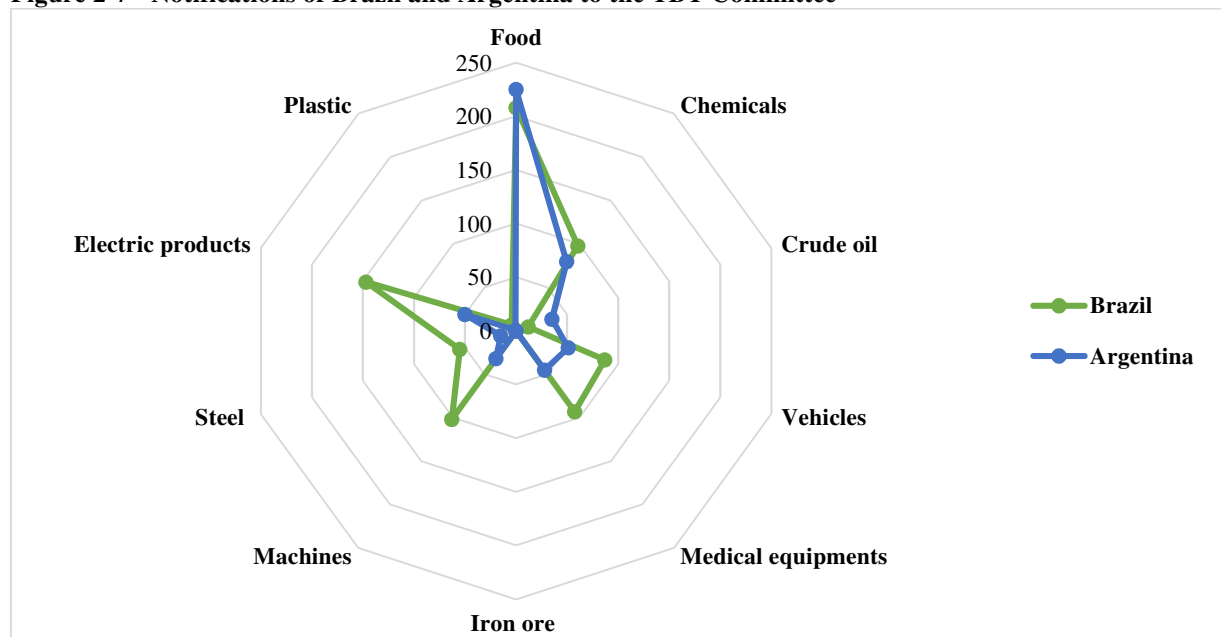
Note: Due to the lower commercial relevance and low regulatory density, we decided to exclude the pulp and paper sector, as explained above. The information technology sector, which was the autonomous sector in ToR, will be analyzed in the field of electronics.

2.1.6. Methodology

The identification and mapping of technical, sanitary and phytosanitary regulations in Argentina and Brazil are twofold: analysis of notifications to an international body and identification of Argentine and Brazilian internal regulations by analyzing the activity of the main national regulatory agencies. In the first part, the notifications made by Argentina and Brazil to the Committee on Technical Barriers to Trade (CTBT) and the Committee on Sanitary and Phytosanitary Measures (CSPS) are analyzed. As provided in art. 2.9. of the TBT Agreement and paragraph 5 of Annex B to the SPS Agreement, such notifications expressing compliance with the principle of transparency of the WTO would indicate a regulation or technical standard other than international standards and potentially relevant to international trade. Since identification through notification analysis allows contact with only part of a given industry's regulations and standards, researchers will also identify sectoral regulations and standards through independent research on official Argentine and Brazilian government websites, including decentralized agencies and agencies. deprived of normalization.

In practical terms, when analyzing notifications, researchers will use three distinct means of searching, since none of them alone would provide satisfactory information. First, researchers will directly access the WTO Information Management System (IMS) websites (CTBT: <http://tbtims.wto.org/> and CSPS: <http://spsims.wto.org/>). Based on this search, information on regulations and standards notified by Argentina and Brazil will be extracted. As illustrated in the chart below, the sectors to be studied have a variable number of notifications:

Figure 2-7 - Notifications of Brazil and Argentina to the TBT Committee



Source: IMS-OMC. Elaboration CCGI.

Such prescriptive documents are often notified at the design or public consultation stage, supported by the provisions mentioned in the TBT and SPS Agreements. However, not all notifications provide complete information about the notified regulation. In the case of SPS

regulations notified by Argentina, only the latest notifications contain complete references to the notified normative act, project or consultation.

TBT notifications will also be collected on the focal point websites of both countries (*punto focal*: <http://www.puntofocal.gov.ar/servicios.htm>; National Institute of Metrology, Quality and Technology, INMETRO:

<http://www.inmetro.gov.br/barreirastecnicas/faq/pontoFocal.asp>) maintained by Brazil and Argentina, respectively, in accordance with the provisions of Article 10 of the TBT Agreement, regarding the obligations of national focal points. Based on the information from the focal point, which reproduces and reorganizes the information notified to the TBT Committee, the research team will identify the national regulation notified by Argentina, through the action of its competent bodies. Similar information is not obtained by accessing the outdated INMETRO website. On the Argentine focal point website, researchers will be able to find not only the form sent to the TBT Committee, but also the archive of the normative act being notified. It should be noted that a similar site has not yet been found for Argentine sanitary and phytosanitary regulations.

The third source for notifications search and analysis will be the official website of the Latin American Integration Association (ALADI: <http://www.aladi.org/sitioAladi/NormasyReglamentosTecnicosP.html>), which contains a copy of the notifications sent to the Committee. TBT, but has a more accessible virtual browsing environment than that offered by the WTO. The search on the ALADI website will have as its main objective to verify the fulfillment of the commitments made under the Framework Agreement for the Promotion of Trade through the Overcoming of Technical Barriers to Trade (Acuerdo Marco for the Promotion of Trade through the Overcoming of Technical Barriers to Trade), 1997), which acquired the status of Regional Agreement no. 8 (AR 8).

In parallel with research based on notifications to the TBT and SPS Committees, research will be conducted into the national regulations and standards of each sector. In Argentina and Brazil, many public agencies and agencies issue technical regulations for different economic sectors. Therefore, to identify key regulations (including those that, due to the competent body's consideration, have not been notified to the WTO Committees), the survey will use a variety of search tools on different government websites to compile industry-relevant technical regulations. economic factors analyzed. In advance, it is reported that with current search tools available in some sectors, it is not possible to ensure that the tables with these regulations introduced in the reports are exhaustive lists.

The regulatory authority varies by industry. Some authorities have competence to regulate more than one sector, such as the National Administration of Medicines, Food and Medical Technology (ANMAT) and the National Health Surveillance Agency (ANVISA), responsible for the regulation of pharmaceutical and cosmetic products. Regulation of certain industrial sectors sometimes overlaps with standards developed by national standardization bodies. However, regulatory agencies may construct the technical regulation with reference to pre-existing technical standards or may draw up the technical prescription without reference to those standards.

The research will analyze the standardization policies in Argentina and Brazil based on the portfolio evaluation of the standards of the Argentine Institute of Standardization and Certification (IRAM) and the Brazilian Association of Technical Standards (ABNT). Both private standardization bodies do not provide a public list of all fully adopted international

standards. The available search tool requires keyword or sector committee search. IRAM and ABNT standards catalogs with all search tools are available on their respective websites.

The research will analyze the standardization policies in Argentina and Brazil based on the portfolio evaluation of the standards of the Argentine Institute of Standardization and Certification (IRAM) and the Brazilian Association of Technical Standards (ABNT). Both private standardization bodies do not provide a public list of all fully adopted international standards. The available search tool requires keyword or sector committee search. IRAM and ABNT standards catalogs with all search tools are available on their respective websites.

In addition, it should be clarified that, for the most part, access to the content of the standards produced by IRAM and ABNT is not free. Similar to the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), the American Society for Testing and Materials (ASTM) and other standardization bodies, access to the full content of the standards is allowed upon payment, values that can reach a few hundred dollars. Costs vary depending on the standard. Research will therefore be limited to examining whether such technical standards are based on international standards (with some degree of modification or literal translations) or whether they are entirely domestic standards originally developed by IRAM and ABNT. In this sense, the analysis will be concentrated on the summaries of each relevant support standard. This procedure will make it possible to build a list according to the sector analyzed, which will enable a first assessment of its compatibility with international standards.

In any case, there are no official lists determining which regulations or standards are based on international standards and to what extent; which *ipsis literis* are adopted; or which constitute discrepant requirements of international standards.

2.1.7. Limitation of the research and the conclusions

Finally, it should be noted that the analysis of the frequency of technical standards in the Argentine and Brazilian regulatory and standardization system provides only an indication of their degree of convergence / internationalization. Cases of frequent references to international standards in Argentine and Brazilian regulations and standards may indicate the internationalization and convergence of a particular sector, but the lack of references will not imply any automatic conclusion in the opposite direction. The absence of references to international standards, in turn, does not necessarily express the incompatibility between Argentine and Brazilian regulations / standardization in relation to rules and standards of other countries, as the cases of tacit compatibility (that are very common) will not be mapped in this research, once requiring further analysis of the technical substance of the standard and the regulation. Therefore, for the purpose and scope of this research, tacit compatibility situations represent original regulations and standards of both countries and will therefore be presumed to be in disagreement with international or foreign technical prescriptions.

2.2. Introduction to infrastructure system

In the study of technical regulation, some concepts should be clarified preliminarily. The technical regulation *stricto sensu* is that rule normally produced by a public body constituted by experts and it is mandatory. It can take the form of a law approved by Congress or it can take the form of any nonstatutory normative act (for example, resolutions, decrees, ordinances). The standard is a voluntary prescription, provided it is not explicitly referred to by technical

regulations. Normally, the private sector elaborates the standard, through its associations and technical experts in standardization, often centralized in a civil association divided into several committees³. Such associations also contribute in the elaboration of international standards, through the participation of international standardization bodies. Procedures for assessing the application of standards are referred to as conformity assessment procedures. They are performed by specialized private organizations that have their operating authorization granted by an accreditation body. There are several conformity assessment procedures. They differ according to the purpose of the process and the type of object assessed. For tangible products, the most important of these are the product certification procedures, which are performed by impartial and reliable third parties. Many of these procedures are mandatory, such as those determined by metrology and quality assurance bodies⁴.

While technical regulations and conformity assessment procedures are important within regulatory systems, technical standards are the central item in any regulatory system. They provide the normative basis for manufacturing processes and prescribe requirements for products. They, when referred to in technical regulations, constitute the true technical prescriptions and they are the only parameters for judging conformity assessment procedures. For this reason, markets that aim a fruitful integration, economic stakeholders, especially companies, should preferably use the same technical standards. This is for example the case of the European Union, where standards are produced at the regional level, by three Community standards bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI)⁵. In the Latin American context, where the discussion has been focused for a long time only on tariff aspects, this regulatory integration presents difficulties, which has had a significant impact on the region's trade, especially in the area of manufactured goods.

The purpose of the report is to present a comparative overview between the regulation in Brazil and Argentina, especially regarding technical regulation, technical standards and conformity assessment procedures aspects. The report describes the main regulatory bodies in both countries, focusing on the role of the regulatory bodies. Additionally, the report focuses on policy and standards bodies in both countries, with the aim of assessing the level of internationalization of the standards used in the two countries, examining the percentages of national standards as compared to international or global ones ISO, IEC, and ITU, as well as European or American standards generally accepted around the world. Finally, the report describes the main mandatory conformity assessment process.

This report covers the following sectors: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or

³ ABNT – AGÊNCIA BRASILEIRA DE NORMAS TÉCNICAS. **Catálogo**. Available in: <<http://www.abntcatalogo.com.br/default.aspx>>. Access on: 24 nov. 2018. IRAM – INSTITUTO ARGENTINO DE NORMALIZACIÓN Y CERTIFICACIÓN. **Sistema Nacional de Normas, Calidad y Certificación**. Buenos Aires. Available in: <<http://www.iram.org.ar/index.php?id=Sistema-nacional-de-normas-calidad-y-certificacion>>. Access on: 23 nov. 2018.

⁴ INMETRO – INSTITUTO NACIONAL DE METROLOGIA. **Manual do Cliente** – Orquestra. Available in: <http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp>. Access on: 23 nov. 2018. INTI – INSTITUTO NACIONAL DE TECNOLOGÍA INDUSTRIAL. **Conoces al INTI?** Buenos Aires. Available in <<http://www.inti.gob.ar/#conoces>>. Access on: 23 nov. 2018.

⁵ EC – EUROPEAN COMMUNITY. Good regulatory practices (GRPs) in TTIP. Disponible em: <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154381.pdf>. Acesso em: 14 dez. 2018.

tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

2.3. Technical Regulation System

2.3.1. Technical Regulation in Brazil

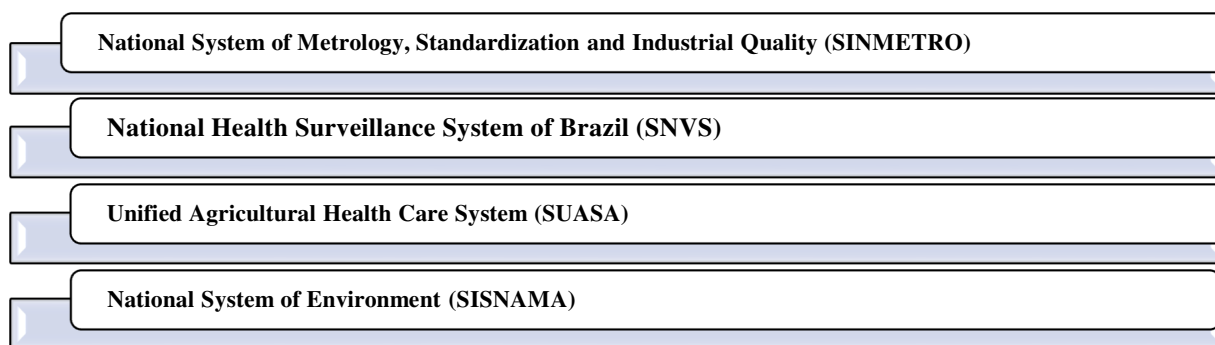
In Brazil, the policies of regulation, standardization, accreditation and certification have some important aspects that affect directly or indirectly the international trade. In each of these policies, there are different governmental and private bodies involved, many of them private actors carrying out a function of public interest. The purposes of such policies are, as a rule, the protection of public health, the environment, the consumer, as well as the guarantee of credibility of conformity assessment procedures. Currently, regulatory policies are fundamental to international trade because they can interfere positively or negatively on trade, affecting imports, exports and investment flows.

In Brazil, regulatory policies in the areas of health, phytosanitary, technical and environmental measures that impact international trade were structured by different actors. Such actors have distinct and complex interconnected relevance. In addition to the direct administration of the three Federation entities (Union, States and Municipalities), other public and private entities have important roles in the regulatory policies.

The structure of the systems derives from the political, institutional and federal organization of Brazil. The regulatory structure is the result of a decentralized policy rationality that overlaps in the distribution of competences and functional roles of the agencies. This follows a logic of institutionalization in Brazil, in which the systems are derived from legal and institutional frameworks built by the Union, with repercussion in subnational levels. In these sense, the perspective of National Regulatory Systems does not provide exhaustive analysis of the regulatory universe in Brazil, but it covers the most important and comprehensive regulation produced in the country.

There are four major national regulatory systems. These systems are composed of several bodies, many of them acting in a coordinated but functionally autonomous way.

Figure 2-8 - Brazilian Systems according to the respective areas



Source: INMETRO. Elaborated by: CCGI – EESP/FGV.

With respect to technical regulation, the Brazilian Federal Constitution of 1988 has reserved the Union the competence to legislate on the measurement system. In this sense, the Ministry of Industry, Trade and Services (MDIC) has the obligation to manage issues related to metrology, standardization and industrial quality. The main agency responsible for such themes is the National Institute of Metrology, Quality and Technology (INMETRO)⁶. INMETRO is a federal authority, linked to MDIC, and it also perform the role of Executive Secretary of the National Council of Metrology, Standardization and Industrial Quality (CONMETRO), an inter-ministerial collegiate, which is the normative body of the National System of Metrology, Standardization and Industrial Quality (SINMETRO).

INMETRO has a central role in the import process of many goods. It maintains a computerized system called Orquestra⁷ for the management of its register of items and its non-automatic import licensing activities. As at March 2016, INMETRO's register contained 32,736 items, up from 13,002 in 2013. The total number of requests for analysis of an import license rose from 197,326 in 2013 to 754,270 in 2016⁸.

Brazil has made more than 1500 notifications to the TBT Committee. The notifications sent by INMETRO notifies public consultations or final publication of metrological and technical regulations on conformity assessment (RTCA). The INMETRO regulation set out the characteristics of a product or process and related production methods, including administrative provisions applicable to compulsory conformity assessment procedures. Such regulation concern terminology, symbols and packaging requirements, marking or labelling applicable to a product, service, goods, people, process or production method.

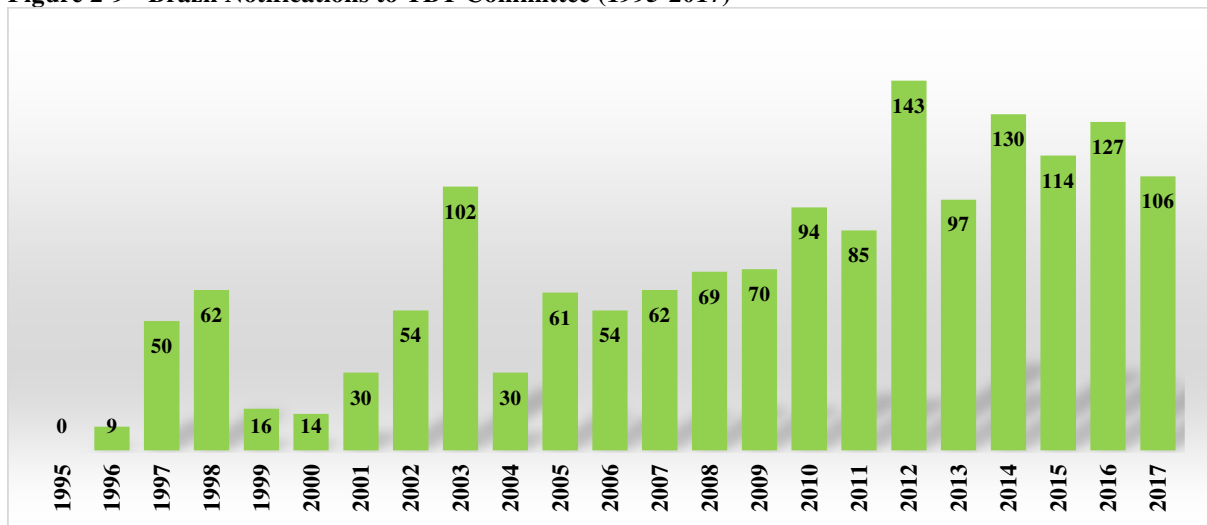
ANVISA and MAPA are the focal points for notifications in the area of SPS. Brazil made more than 1700 notifications to the SPS Committee. The number of notifications increased significantly since 2014, remaining on each of the last four years higher than 100.

⁶ **INMETRO** issues technical regulations for all aforementioned sectors. It is possible to search by keywords, date and number of the technical regulation [here](#).

⁷ More details on Orquestra System can be found in http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp

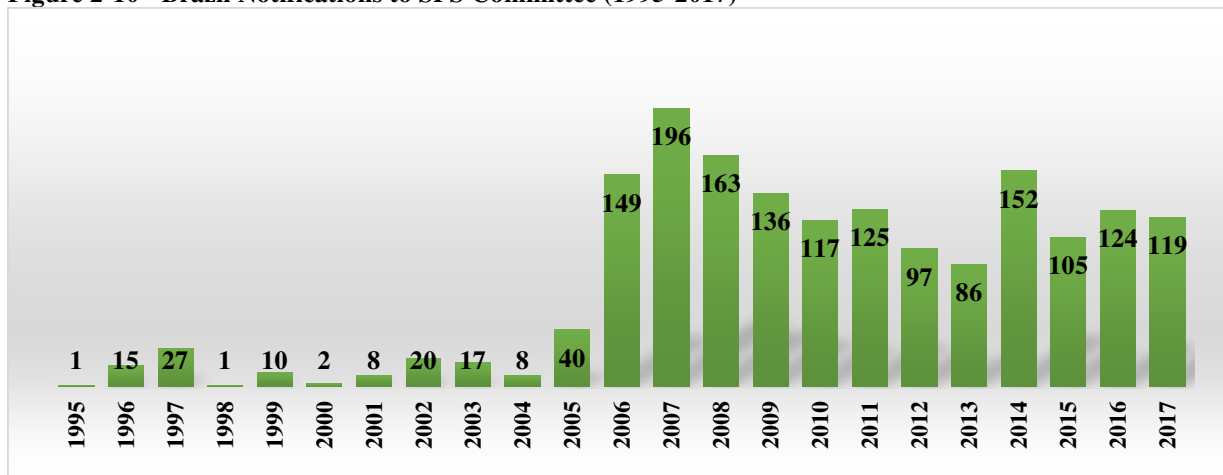
⁸ WTO – WORLD TRADE ORGANIZATION. **Trade Policy Review:** Brazil. Available in: https://www.wto.org/english/tratop_e/tpr_e/tp377_e.htm. Access on: 23 nov. 2018.

Figure 2-9 - Brazil Notifications to TBT Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV

Figure 2-10 - Brazil Notifications to SPS Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV

Before being approved, notifications by the regulatory authority are sent to a technical commission involving various segments of society. After a public consultation with the publication and availability of the text in the Brazil Official Journal, the stakeholders can give opinions and suggest modifications in the text. In the end, the regulation is published and made available to the public.

There is no central mechanism for publishing the drafts of technical regulation, but they are usually disseminated through the websites of the bodies adopting the technical regulations. In all cases a period of 60 days is allowed for the submission of comments. Argentina's notifications to the WTO are published on the *Punto Focal* website⁹ and are also distributed through a subscription service or on request. Comments are generally discussed among the focal points of WTO Members, with intervention by the body with jurisdiction over the matter in question. The issuing body is responsible for adoption and entry into force of the measure. The measure is published in the Official Journal.

⁹ *Punto Focal* online information. Viewed at: <http://www.puntofocal.gov.ar>.

2.3.2. Technical Regulation in Argentina

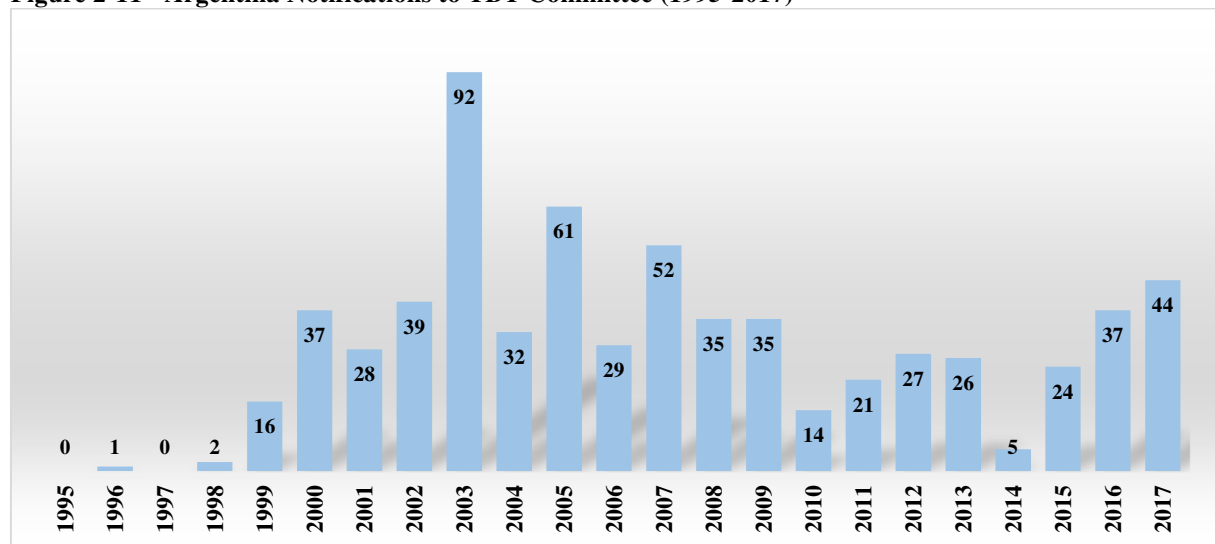
Technical regulations in Argentina are frequently based on MERCOSUR standards and on the standards and recommendations of various international organizations, including the International Organization for Standardization (ISO), the Pan American Commission on Technical Standards (COPANT), the Codex Alimentarius Commission, the International Organization of Legal Metrology (OIML), and the International Electrotechnical Commission (IEC).¹⁰

Various ministries and agencies are responsible for establishing technical regulations in Argentina. The following bodies may enact such regulations: the Secretariat for the Environment and Sustainable Development of the Office of the Chief of Cabinet of the National Government, the National Institute of Industrial Technology (INTI) of the Directorate-General of Domestic Trade, the National Drugs, Food and Medical Technology Administration (ANMAT), among others.

Technical regulations are usually amended or abolished on the basis of technological changes or international standards.

Between 1995 and October 2017, Argentina made 654 notifications to the WTO Committee on Technical Barriers to Trade. These notifications are on drafts of technical regulations (Article 2.9.2), technical regulations adopted to address urgent problems (Article 2.10.1), draft of conformity assessment procedures (Article 5.6.2), conformity assessment procedures adopted to address urgent problems (Article 5.7.1), and concerned measures under Articles 2.9 and 5.6. Moreover, Argentina made 252 notifications to the WTO Committee on Sanitary and Phytosanitary Barriers to Trade.

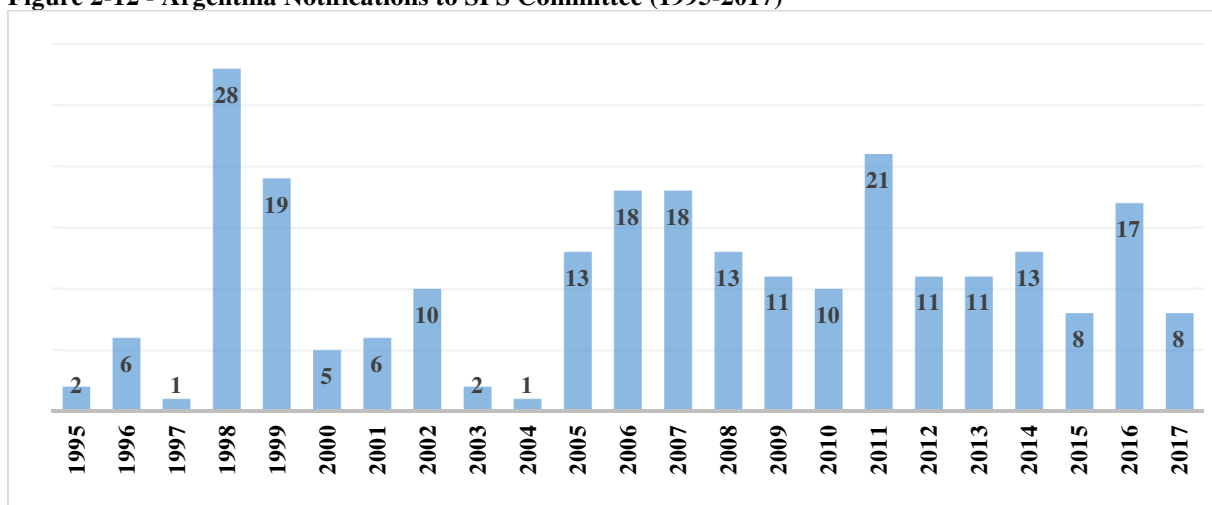
Figure 2-11 - Argentina Notifications to TBT Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV.

¹⁰ Information provided by the Argentine authorities.

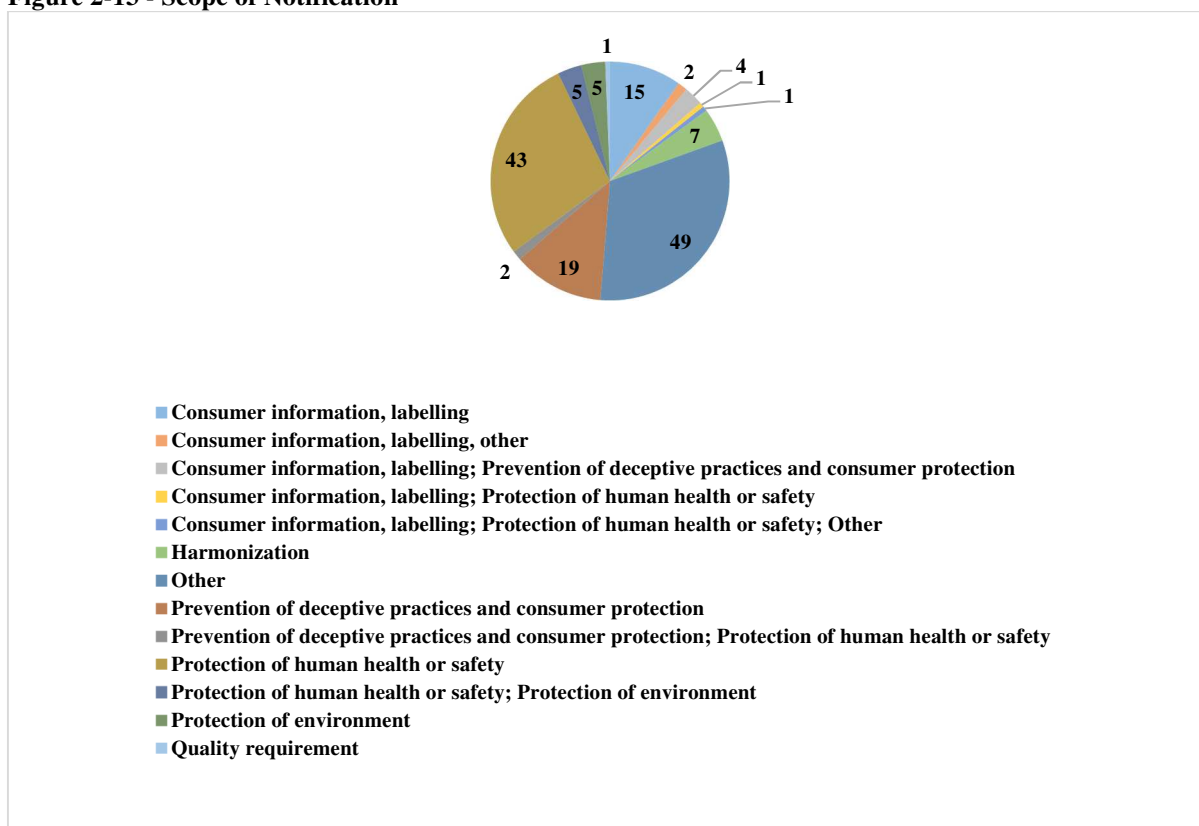
Figure 2-12 - Argentina Notifications to SPS Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV.

Most notifications are regular notifications on various topics, including labelling and consumer protection. The addendums and corrigendum to previous notifications should also be highlighted. These notifications are sometimes necessary because of the economic and productive dynamics of some sectors, whose technical aspects are altered at a faster rate than the ordinary regulatory practice of the State.

Figure 2-13 - Scope of Notification

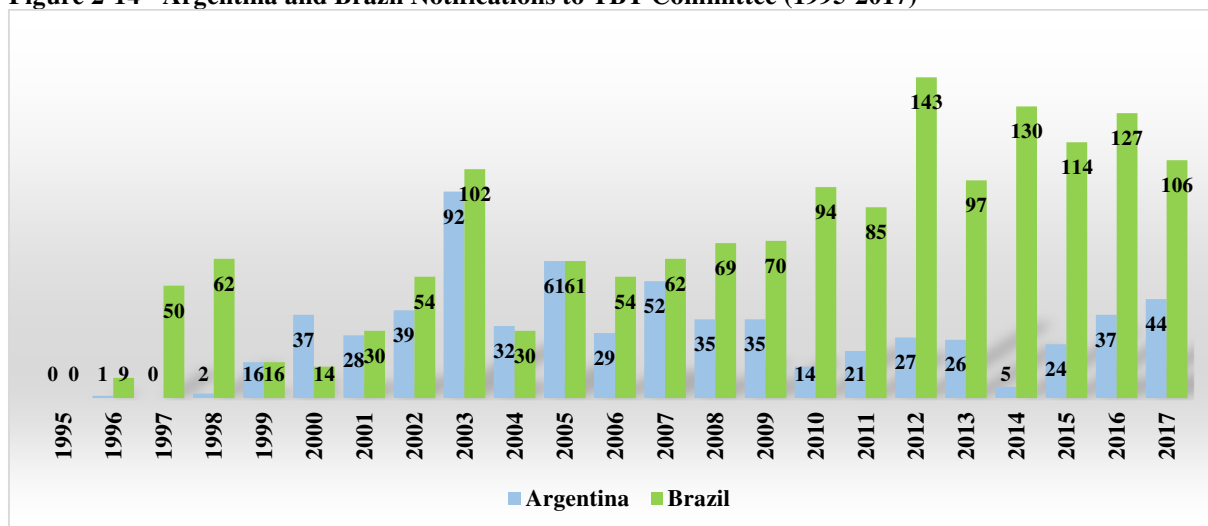


Source: WTO. Elaborated by CCGI-EESP/FGV.

2.3.3. Brazil and Argentina technical regulation: comparison based on notifications to TBT Committee

The number of Brazilian notifications to the TBT Committee is bigger to that of Argentina. This aspect reflects differences in philosophy and the intensity of regulatory activity in both countries, as well as differences in administrative and political organization. The intensity of regulatory activity can also reflect the size of the economy and international trade of the countries.

Figure 2-14 - Argentina and Brazil Notifications to TBT Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV

2.4. Technical Standard Framework

2.4.1. Technical Standards in Brazil

In terms of standardization, the Brazilian Association of Technical Standards is the most important institution. ABNT is a non-governmental entity, founded in 1940. The ABNT mission is to provide to the Brazilian society systematic knowledge, producing normative documents, which allow the production, marketing and use of goods and services in a sustainable and competitive manner in domestic and foreign markets, contributing to the scientific and technological development, environmental protection and consumer protection. It is structured as a National Forum for standardization provided for in Brazilian Standardization System (SBN), under the National System of Metrology, Standardization and Industrial Quality (SINMETRO) and according to strategic guidelines of National Council of Metrology, Standardization and Industrial Quality (CONMETRO).

ABNT is recognized by international standardization bodies such as the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and International Telecommunications Union (ITU), the Codex Alimentarius, the *Bureau Internationale de Poids and Mesures* (BIPM), the International Organization of Legal Metrology (OIML), *International Accreditation Forum* (IAF) and *International Laboratory Accreditation Cooperation* (ILAC).

ABNT core competence is to produce Brazilian standards (ABNT NBR), drawn up by their Brazilian Committees (ABNT/CB), sectoral standardization bodies (ABNT/ONS) and special study commissions (ABNT/EEC).

Standardization is recognized as the process of formulation and implementation of rules for the solution or the prevention of problems, with the cooperation of all concerned, and, in particular, for the promotion of the global economy. Establishing these rules refers to the technology as the instrument to establish objectively and neutrally the conditions which allow the product, project, process, system, person, good or service to meet the intended purposes, considering specifically quality and security issues.

There are different kind of supporting standards issued by ABNT that goes from a fully original standard developed under its Standardizing Committees (CB) to those based on international standards, mainly ISO and IEC. The key is to observe the number of the standard:

- (i) If it is a standard identical to an international standard, it will appear, for example, as *ABNT NBR ISO n° XXX*.
- (ii) If it is based on an international standard, a reference to this international standard will be in the preamble of the standard.
- (iii) If it is an original standard, it will appear as *ABNT NBR n° XXX*.

The production of original standards follows a specific process: (i) the company expresses interest; (ii) a study Commission shall draw up a standard project after analysis of the industry technical Committee and inclusion in the Sectoral Normalization Plan (PNS) by consensual decision; (iii) the project is submitted to national consultation; (iv) the standard is approved, assigned a ABNT NBR and becomes available to society¹¹.

ABNT participates actively in various technical committees, such as ISO TC 176 (quality), ISO TC 207 (environmental) and ISO/CASCO, in addition to the ISO/TMB (Technical Management Board). ABNT signed the WTO/TBT Code of Good Practice in 1995 and follows its Annex Activities related to the accreditation and conformity assessment in SINMETRO are based on the standards and guides ABNT/ISO/IEC.

In addition to ISO, ABNT also represents the Brazil in the Copant (Panamerican Technical Standardization Commission), CMN (Mercosur Standardization Committee) and CEN/CENELEC (European Joint Standardization Organization). ABNT maintains cooperation agreement with the American National Standards Institute (ANSI) and participates, along with the INMETRO and other entities of the SINMETRO and MERCOSUR technical committees.

An overview of the standards catalog adopted by the different committees of ABNT makes it possible to verify the degree of internationalization of Brazilian standards. However, ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to

¹¹ The access of the content of standards issued by ABNT is not free. In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard. Therefore, going on an analysis whether such supporting standards are only based on (with some degree of modification) international standards or how different original standards issued by ABNT are in comparison with international standards is very complex task to pull through. For that matter, the report focused on the summaries of each relevant supporting standard to put together a list of them by analyzed sector and to provide a first assessment on their compatibility with international standards.

product at ABNT's website¹². Therefore, the user had to refine our keyword search in order to gather a list with relevant supporting standards for each of the economic sectors analyzed. For instance, in this report it was consulted standards discussed under ABNT Brazilian Committee nº 3 (CB 03) to find relevant supporting standards for electric-electronic and machinery sectors.

As at March 2017, there were 7,815 standards in force in Brazil. Between January 2013 and January 2017, Brazil adopted 2,557 new standards, some 33% of which were adoptions of international (ISO/IEC) standards.

2.4.2. Technical Standards in Argentina

The standardization system in Argentina is not centralized. There is an important standardization body, which develops most part of standards, but there are also several other sectoral bodies that produce standards for their sector.

In its capacity as the national standardizing body, IRAM develops standards in a participatory, transparent and consensual manner, using international standards as a benchmark. In Argentina, standards are prepared by standards study bodies, comprising representatives of various organizations belonging to the three sectors involved in the production of a standard: producers, consumers and those "responsible for protecting the general interest and the common good". Before a draft standard can become an IRAM standard, it must be considered by the General Committee on Standards (CGN), an independent and honorary body responsible for the comprehensive examination of all the technical documents approved by the various study bodies.

The preparation of standards begins with the production of a draft standard, either by the Executive or by representatives of the sector concerned. The draft is submitted for public discussion for a period of between 30 and 180 days (with exceptions). The draft, with the revisions considered necessary, is then submitted to the General Committee on Standards, which gives it official form and passes it on to the IRAM Directorate General for approval as a standard.

At regional level, IRAM participates in the Pan American Standards Commission (COPANT) and the MERCOSUR Standardization Association (AMN). IRAM is a member of ISO, contributing to develop international standards for different sectors.

There are other important sectoral standardization bodies in Argentina. They usually work together with IRAM, but sometimes they produce standards as single bodies. Two important sectoral standardization bodies are the Association of Automotive Engineers and Technicians (AITA) and Argentine institute of iron and steel industry (IAS).

AITA was created in 1970 with the aim of studying and issuing technical norms for the automotive industry through the agreement of technical cooperation with IRAM. AITA is a technical forum that gathers resources and efforts in order to transform the local automotive industry, the facilities of the government and the academic space in a unique context. It participates actively on the harmonization of norms inside Mercosur and is adhered to FISITA, the International Federation of Societies of Engineers in Automotive Techniques.

¹² ABNT Catalog with all searching tools is available [here](#).

AITA is composed of technical commissions and/or regional nuclei, which are coordinated by professionals and specialists with vast experience and recognized trajectory. They produce works and reports that conform the recommendations and/or specifications of norms and regulations to be applied. The association publishes technical knowledge, experience and skills of engineers and technicians through a cooperative engineering system that is useful to the State, to the industry, to educative institutions, to professionals and to the whole community.

The entity made many efforts to control the quality of safety pieces sold in the replacement market. The common user is not protected as to the possibility of accessing the technical control of what he buys for his vehicle. Resolution 91/2001 regulates the production and trade of many safety pieces. This resolution allows, among others, the agreement IRAM-AITA to certify safety auto-parts. The certification is the process in which the producer complies with the quality system established on model 5 of guide ISO/IEC 28 or IRAM standard 354 that is its equivalent. The products must also comply with the corresponding norm or normative document.

AITA integrates work and cooperation agreements with IRAM, UTN, the National Sub-Secretary of Transport, the National Commission of Traffic and Safety, the Secretary of Environment and Sustainable Development, the Brazilian Association of Automotive Engineering (AEA), the Professional Foundation of Transport (FPT), the Professional Council of Mechanical and Electric Engineering (COPIME) and the auxiliary entity of the provincial agency of transport of Buenos Aires.

Argentine Institute of Iron and Steel Industry (IAS) is an entity constituted in 1972 by Argentine iron and steel companies. IAS does activities of technological development, technical assistance, analysis, and distribution of technical information, organization of courses and conferences and normalization. These activities aim to accompany the development of the iron and steel sector, of its value chain and other industries.

The institute, on the scope of the agreement of technical cooperation subscribed with IRAM, develops the process of creation of norms relative to iron and steel products, its inputs, welding and related aspects. It participates on the study of standards on the regional level, especially with the works of MERCOSUR Standardization Association (AMN) and Pan American Commission of Technical Norms (COPANT).

The Committee of Coordination IRAM-IAS is responsible for guiding the works under the agreement. The committee is composed of representatives of each institution, considering the requirements of producers and users, of government programs and of the technical and scientific area.

The working plan is developed on first instance on IAS through specific study commissions with the participation of interested sectors: users, producers, institutions and public and private bodies. The results are turned to IRAM in order to, once done the common procedure, be approved as Argentine standards identified by the initials IRAM-IAS. This system of study of standards of products and iron and steel inputs between institutes of normalization and iron and steel institutes facilitates the advances on the standardization of the sector.

The environment working group of IAS monitors the liquid and gas effluents, the soil, underground waters and residues. Its equipment of sampling and analysis is in conformity with international standards. Since 2001, the Provincial Body for Sustainable Development oversees

the environment to guarantee that corporations comply with their legal obligations. On the process area, the working group is working on the recovery of industrial residues inside an agreement with the Japanese Agency of Cooperation (JICA).

Argentina's standardization system, therefore, presents an important degree of decentralization. Although there is a main body that, in theory, should bring together the standardization activity of all associations, they continue to produce technical standards autonomously. It is also worth noting that sectoral standardization bodies also maintain relations with similar bodies in other countries, at regional and international levels. Such net of international relationships of the Argentine standardization bodies makes the system more complex.

2.4.3. Brazil and Argentina technical standards: caparison based on standards produced by the main standardization bodies

The use of international standards produced by international standardization bodies may favor the insertion of a country's exports in sophisticated foreign markets. The frequent use of international standards in domestic production processes would be indicative of the level of internationalization of production and economy.

However, all countries have their own standardization policy, coordinated by one or more national standardization body, whose work is performed directly by the domestic productive sectors. This means that countries and economic blocs are reluctant to renounce their prerogative to develop their own standards. One way to avoid incompatibilities between national and regional standards is to adopt, through simple copying or soft adaptation, international standards (eg ISO, IEC) by the national and regional standardization bodies. This is, in fact, a practice widely adopted by those bodies. Thus, a valid way of verifying the internationalization of a productive process can be by analyzing the domestically produced technical standards for different sectors. Whether these standards are replication or adaptation of international standards, the industry is technically closer to developed and demanding markets.

The table below presents the percentage of international standards that are used by the main standardization bodies in Brazil and Argentina.

f sectoral standards

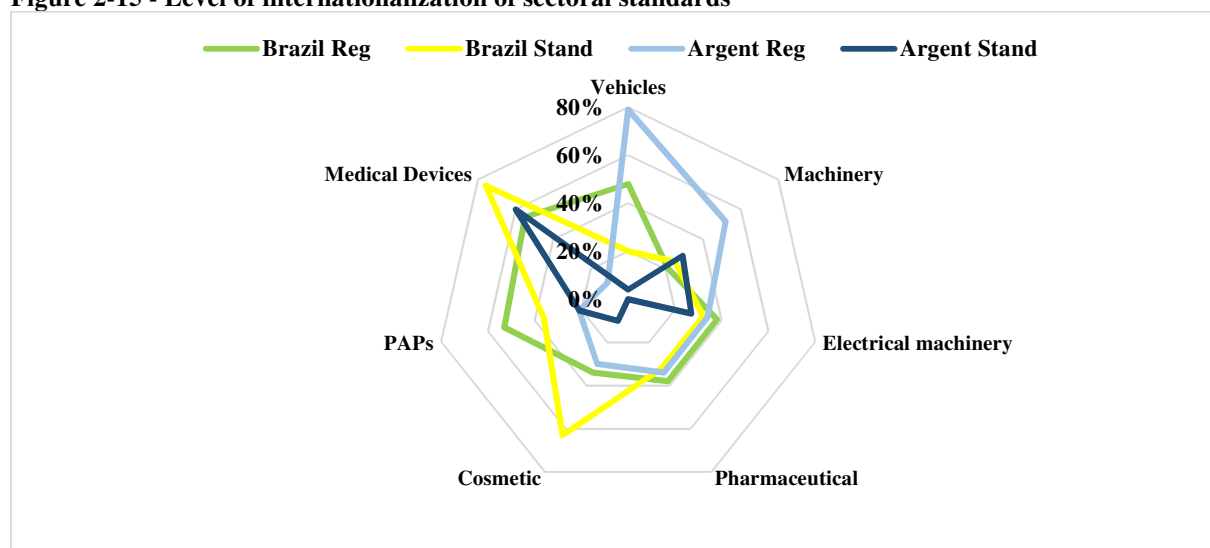
VEHICLES; OTHER THAN RAILWAY OR TRAMWAY ROLLING STOCK, AND PARTS AND ACCESSORIES						
IFICATIONS TO TBT COMMITTEE	ABNT (BRAZIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
52%	350	80%	86	21%	80	96%
48%	84	20%	328	79%	4	4%
HS 84 - MACHINERY AND MECHANICAL APPLIANCES; PARTS						
IFICATIONS TO TBT COMMITTEE	ABNT (BRAZIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
79%	585	75%	38	48%	71	71%
21%	197	25%	41	52%	29	29%
HS 85 - ELECTRICAL MACHINERY AND EQUIPMENT; SOUND RECORDERS AND REPRODUCERS; TELEVISION IMAGE AND SOUND RECORDERS AND REPRODUCERS, PARTS AND ACCESSORIES						
IFICATIONS TO TBT COMMITTEE	ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
62%	935	68%	120	66,3%	73	73%
38%	431	32%	61	33,7%	27	27%
HS 30 - PHARMACEUTICAL PRODUCTS						
IFICATIONS TO TBT COMMITTEE	ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
91%	3	75%	120	66,3%	19	100%
9%	1	25%	61	33,7%	0	0
HS 33 - PERFUMERY, COSMETIC OR TOILET PREPARATIONS						
IFICATIONS TO TBT COMMITTEE	ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE

INTERNATIONAL STANDARDS	1	34%	5	63%	3	30%	1	10%
HS 16, 19, 20, 21 - PROCESSED FOOD - PAPS								
	BRAZIL NOTIFICATIONS TO TBT COMMITTEE		ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	93	47,4%	22	64%	34	79%	33	79%
INTERNATIONAL STANDARDS	103	52,6%	8	36%	9	21%	9	21%
HS 9018, 9022 - MEDICAL DEVICES								
	BRAZIL NOTIFICATIONS TO TBT COMMITTEE		ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	8	45%	35	24%	33	89%	33	89%
INTERNATIONAL STANDARDS	9	55%	111	76%	4	11%	4	11%

Source: ABNT; IRAM; European Commission. Elaborated by CGTI-EESP/FGV

The data in the table are expressed graphically in the figure below. It is clear that in some sectors where the EU had very low or no standard figures, there was a Community option to standardize products in other ways, not using the three EU standardization bodies.

Figure 2-15 - Level of internationalization of sectoral standards



Source: ABNT; IRAM; European Commission. Elaborated by CGTI-EESP/FGV.

The degree of internationalization of standards varies greatly according to the sector. Some sectors, such as medical devices and information technology, are heavily internationalized. Other sectors have a lower degree of internationalization, such as basic chemicals, but it suggests the irrelevance of standardization in a sector strictly ruled by compulsory technical regulations. In the comparison between countries, both Argentina and Brazil have a low degree of internationalization compared to the European Union. In fact, the production of CEN, CENELEC and ETSI standards usually reproduces international standards in their entirety and advance in product performance, environmental protection and consumer welfare requirements. In the comparison between Brazil and Argentina, Brazil has a higher degree in almost all sectors, except machinery and mechanical equipment and basic chemicals. The low level of internationalization of Argentine standards may have been partially affected by the exclusive use of the standards produced by IRAM, disregarding those produced directly by sectoral standards bodies (such as AITA). These aspects, however, would hardly change the general picture for the standardization policy in Argentina.

2.5. Conformity Assessment System

Accreditation is a process that lends credibility to a conformity assessment body or procedure. There is not only one type of conformity assessment, although the certification is the best known of them. Usually, five types of conformity assessment procedures are identified: testing, examination, verification, inspection, calibration and certification. Calibration and verification are metrological verification procedures. The inspection and the examination are procedures performed, under specified conditions, for the purpose of identifying points of interest or properties of a material in a given sample. Certification focus on products, processes, services, management systems and personnel. By definition, it is performed by a third party, that is, an independent, accredited organization to perform the conformity assessment of one or more of these objects.

Certification is one of the most important conformity assessment procedures since it covers a fairly large number of goods and services. Certification may be compulsory or voluntary, depending on the relevant legislative provision. In general, the mandatory certification is that determined by a technical regulation. The certifying bodies, in most cases, are accredited by an official accreditation body, which confers the necessary credibility to the certifying body. In general, there is only one accreditation body by country.

2.5.1. Conformity Assessment in Brazil

According to Conmetro resolution 5/95, Inmetro is competent to coordinate activities as the notification center of technical barriers, denominated Focal Point of Technical Barriers to Exportations. Under this mandate, Inmetro created a conformity assessment program.

In practice, the program operates through the collection of samples of products regulated by conformity assessment procedures and the subsequent send to accredited laboratories that belong to the Brazilian Network of Test Laboratories (*Rede Brasileira de Laboratórios de Ensaio* – RBLE). These laboratories verify the conformity of the samples with the legislation in force.

Another part of the program is the analysis of products with conformity evaluated voluntarily or compulsorily, being essential on the evaluation of the features of the product aspects directly related to safety, human health and the environment (Inmetro, 2018b). The main criteria applied on the program are listed below.

- statistical indexes of complaints on Inmetro;
- identification of the needs of organizational unities of the directorate of conformity assessment and of the general coordination of accreditation;
- priorities verified on the society through the Brazilian Committee of Conformity Assessment (*Comitê Brasileiro de Avaliação de Conformidade* – CBAC);
- requirement of regulations of conformity assessment;
- solicitation of the directorate of conformity assessment;
- expectation of the regulatory bodies;
- historic of conformity assessment programs and
- index of irregularities on oversight.

After the definition of the criteria, the systematic procedure of conformity assessment normally involves, among other actions:

- performance of tests;
- performance of inspections through the interpretation of results of tests and inspections;
- performance of audits on the management system of supplier quality through follow-up audits and the definition of systematic treatment of non-conformities identified and
- evaluation and follow-up of the product on the market¹³.

The choice among the aforementioned mechanisms is done considering different aspects. Examples of these aspects are the risk present on a possible consumption accident, the impact and the frequency of a failure, the volume of production, the speed of technological

¹³ INMETRO – INSTITUTO NACIONAL DE METROLOGIA. **Manual do Cliente** – Orquestra. Available in: <http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp>. Access on: 23 nov. 2018.

improvement on the sector, the size of the manufacturers involved, geographical dispersion, the impact on the competitiveness of a product and the degree of difficulty in monitoring the market.

The results arising from the execution of conformity assessment programs are evaluated by the directorate of conformity assessment, as foreseen on Inmetro specific norm NIE-DQUAL-145.

Another key instrument of conformity assessment is the monitoring on the market by external agents. The main objective of this activity is to amplify the necessary structure in support of the increasing demand that appeared due to the increase of products and services that underwent a conformity assessment procedure (Inmetro, 2018c). The activity also provides the follow-up of the society in relation to these products with impact on the human health and security as well as on the environment. The monitoring is justified by the increasing diffusion of a culture of certification of products and services and the expertise dissemination on conformity assessment, quality and consumer relations.

In the activity of conformity assessment of products evaluated by the external agent, Inmetro is competent to analyze the data supplied and take decisions regarding them¹⁴.

The conformity assessment program, thus, comprises a sequence of different moments. The initial evaluation of the conformity of the object is followed by a group of actions of follow-up and control to allow the manager of the program to be certified that the product is effectively on sale in conformity with the established rules¹⁵. In comparison with the initial evaluation, this later phase is more complex and requires higher systematization.

As at January 2017, 382 calibration laboratories and 1,046 testing laboratories were accredited in Brazil. There were also 879 entities with active accreditations to perform conformity assessments (certification, inspection, performance verification). Among the Brazilian-accredited entities, 10 laboratories and 4 certification bodies were located overseas.

2.5.2. Conformity Assessment in Argentina

Conformity assessment is ruled by the Laws on Consumer Protection (Law 24240/1993) and Fair Trade (Law 22802/1983). They stipulate that products must be supplied in a form such that, when used under predictable or normal conditions, pose no risk to the health or person of the consumer. The products whose use could pose a risk to the health or person of the consumer must be traded in conformity with the rules established by the national implementing authority or reasonable rules to guarantee consumer safety. The Secretariat for Domestic Trade is the national implementing authority and it is responsible for creating mandatory safety requirements.

In Argentina, accreditation is responsibility of Argentine Accreditation Agency (OAA). Accreditation means the formal recognition of competence and impartiality of laboratories, suppliers of proficiency testing, producers of reference materials and certification and/or inspection organisms. It is done through an independent evaluation based on international

¹⁴ INMETRO – INSTITUTO NACIONAL DE METROLOGIA. **Manual do Cliente** – Orquestra. Available in: <http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp>. Access on: 23 nov. 2018

¹⁵ INMETRO – INSTITUTO NACIONAL DE METROLOGIA. **Manual do Cliente** – Orquestra. Available in: <http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp>. Access on: 23 nov. 2018

standards used as normative requisites. It shows that these entities can be trusted to do tests, proficiency testing programs, production of reference materials, calibrations, inspections and certifications.

Regarding information to exporters, many countries in the world have regulations that require compulsory accreditation of certification organisms, inspection organisms and/or test laboratories that certify, inspect and test products traded on the local market. The accreditation body may have signed a multilateral agreement with ILAC, IAF or IAAC.

The accreditation bodies that signed the agreements must trust on the accreditation conceded by other signers and thus consider that the certificates, inspection or informs issued by entities accredited by the OAA have the same level of trust of the ones issued by accredited entities in each signatory country.

The main benefits derived from the accreditation process are listed on the following table.

Table 2.7 - Benefits derived from accreditation

ACTOR	BENEFIT
Government and regulators	OAA is an instrument of high trust to regulatory authorities in issues of health, security, food and environment. Guarantee of the compliance of requirements established to guarantee security of people and environmental protection.
Companies	Based on agreements of multilateral recognition, products and services backed up by certifications, inspections and laboratory tests duly accredited are accepted on the global market, eliminating technical barriers to trade. A contribution to improve competitiveness between companies, to increase economic growth and to generate employment. A basis to a trustworthy selection of suppliers.
People	Confidence to the public in goods and services and consumption. Reduction of failures in products. Security of people and environmental protection.

Source: OAA. Created by CCGI – FGV/EESP.

Certification is one of the responsibilities of the INTI, which also regulates and develops the metrology sector in Argentina. INTI certification organism was created by resolution of the Directive Council n° 32/2001 to certify products on the voluntary and regulated scopes. Its activities were later extended to certify processes and labor competences. The main goal of INTI certification organism is to do all the management to concede the certification. The National Directorate of Internal Trade recognized INTI as the certification organism inside the scope regulated by provision n° 775/99. OAA recognizes the competence of INTI certification organism to do the certification of products and people.

INTI acts as an independent third party regarding the compliance of standards, allowing a differentiation to transmit confidence to users and buyers. INTI has a quality policy that was implemented and kept on all the levels of the certification organism. The certification process is composed of four phases: requirement of certification, conformity assessment procedure, issuing of certificate and follow-up or oversight.

INTI and OAA signed a covenant in 2015 through which the certification organism is re-accredited to certify people that want to demonstrate their theoretical and practical knowledge on the methods of: magnetic particles, penetrant liquids, measurement of thicknesses by ultrasound. These certification processes are done according to requisites established by the standard IRAM-ISO/IEC 17024:2013.

The Secretariat for Domestic Trade established mandatory certification regimes for certain products and also must assess the technical and legal requirements of those regimes. One of the certification regimes encompasses symbols that must displayed in manufactured products. The

symbols must be marked on each unit of the product, either on the unit itself or on its packaging or labelling together with the certificate number corresponding to the product in question.

Table 2.8 - Mandatory certification regimes

PRODUCT	RESOLUTION NO. (UNLESS OTHERWISE INDICATED)	CERTIFICATION BODY
Domestic appliances/energy labelling	319/99 (as amended)	INTI
Devices, equipment, accessories and containers for gaseous fuels	676/99(as amended)	INTI
Safety auto parts	91/2001	INTI
New bicycles	220/03 (as amended)	INTI
Animal identification tags	Order No. 1.325/06	SENASA / INTI
Cement	130/92	INTI
Bicycle tyres and tubes	153/05 (as amended)	INTI
Low-voltage electrical equipment	92/98 (as amended)	INTI
Phthalates	583/2008	Ministry of Health / INTI
Toys	163/05 (as amended)	INTI
Anti-hail nets	Law No. 26.459	INTI
Retreads	205/2010	INTI
Paper sold packaged	653/99 (as amended)	INTI
Cells and batteries	14/2007	Secretariat for the Environment and Sustainable Development / INTI
Lead in paints, lacquers and varnishes	7/09 (as amended)	INTI
Printed graphic products	453/2010	INTI
Assembly shops for cng	2.603/2002	INTI
Dyes, lacquers and varnishes used in the printing industry, as regards their lead content	453/10, 39/11 and Order No. 26/12	INTI

Source: WTO. Elaborated by CGTI-EESP/FGV.

Resolutions set forth technical regulations and standards with which the products must comply to be certified and the procedure to obtain such certification. Some of these formalities can be suspended temporarily or definitively or for specific products.

Institutions that participate in the test and the certification of regulated products must be accredited by the OAA and recognized by the competent authority. The certifying body and the laboratory whose work involves elaborating conformity certificates and test reports must be recognized by the Secretariat for Domestic Trade. The requirement to obtain accreditation is to follow ISO/IEC guidelines.

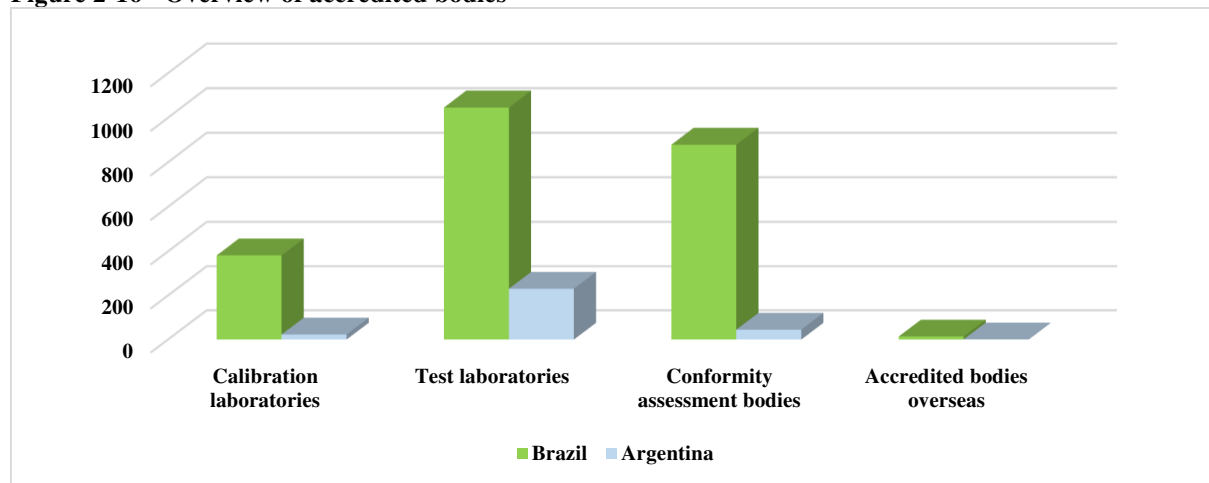
The institutions that participate in testing and certifying regulated products are IRAM and INTI. IRAM has an important role in the certification of products, processes and services over a very wide range of economic activities. The certification is done through IRAM seals and IRAM conformity marks. INTI's certifying body can certify products under the voluntary or regulated regime. OAA can accredit organizations that participate in the test and the certification of regulated products. OAA is also competent to carry out any accreditation activity incorporated in international practice or defined by the regulatory authorities.

Argentina has 23 calibration laboratories, 231 testing laboratories and 45 conformity assessment bodies. The country recognizes foreign certifying entities and laboratories of countries under two conditions: the relevant reciprocity agreements must be in effect and the entities must be accredited by the respective national accreditation body. In this aspect, OAA integrates many international organizations and is a signatory to multilateral recognition agreements (ARM) at international level.

2.5.3. Brazil and Argentina conformity assessment procedures: comparison based on certification bodies

The conformity assessment procedures are very similar in Brazil and Argentina. There is a greater number of conformity assessment bodies and laboratories in Brazil, which is explained by the existence of greater demand in the Brazilian market, which is larger than Argentina's. Brazil also has a greater presence abroad in conformity assessment services, mainly product certification.

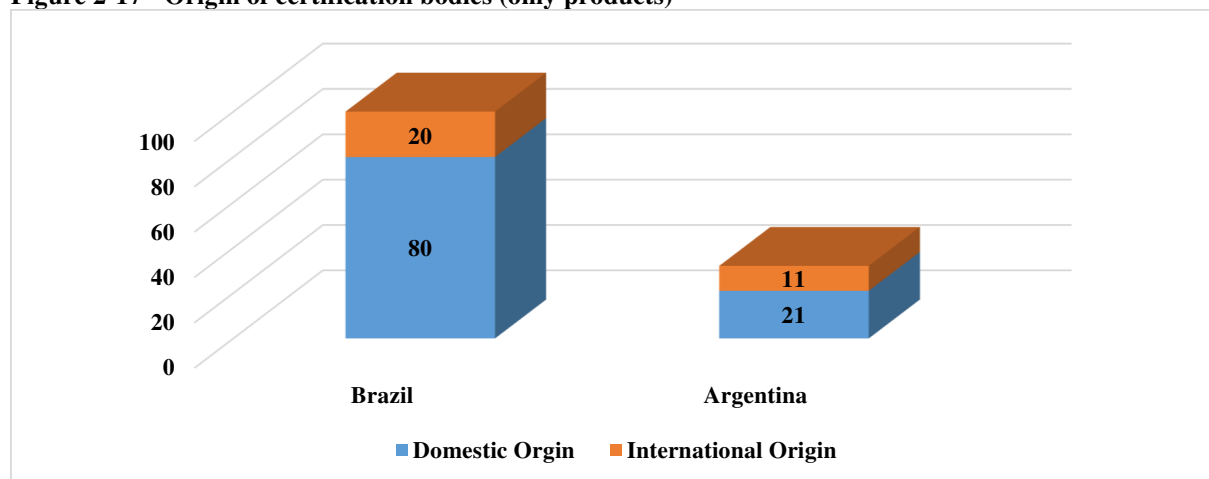
Figure 2-16 - Overview of accredited bodies



Source: INMETRO, INTI, OAA. Elaborated by CGTI-EESP/FGV

The participation of foreign certification bodies seems to be higher in Argentina. This is different if one considers the total numbers of such bodies in both countries.

Figure 2-17 - Origin of certification bodies (only products)



Source: INMETRO, INTI, OAA. Elaborated by CGTI-EESP/FGV.

The great number of totally Brazilian certification bodies clearly dilutes the foreign presence in the sector in Brazil. The most important international organizations (eg Intertek, TUV and UL) are present in both countries, working with the certification of various products.

2.6.Regional Regulatory Cooperation

Brazil and Argentina are inserted in regional initiatives for regulatory cooperation. The most important initiatives were developed in Latin American Integration Association (ALADI) and in Mercosur.

2.6.1. Regulatory Cooperation in ALADI

The theme of regulatory convergence is not central to Latin American integration. Although there are normative and policy initiatives that address the issue, it is not a priority for the Latin American Integration Association (ALADI) member states, the most comprehensive integration arrangement on the American continent.

This little importance that the theme receives in Latin America arises from two characteristics of integration projects in the subcontinent: the period in which they began and the lack of flexibility of integration structures.

Regulatory convergence is the approximation between regulatory systems of two or more autonomous customs territories, which results in the removal of non-tariff barriers to trade. The creation of a free market presupposes not only negative conduct by States, which must refrain from creating tariff and non-tariff barriers, but also positive conduct, which demands the removal of obstacles to the free transit of goods, including obstacles of a regulatory nature . One way to remove regulatory barriers is to approximate Member States' regulatory systems, particularly with regard to their technical regulation, their conformity assessment procedures and their standardization policies (creation of standards, for example, those elaborated by the Brazilian Association of Technical Standards, ABNT, and the International Standardization Organization, ISO).

There are two purposes of the de Latin American Association of Intergration (ALADI), according to provision of art. 1 of the Treaty of Montevideu (1980) and the formation of a common market in Latin America. The members are committed to eliminating, progressively, barriers to trade, including non-tariff restrictions to regional trade (Article 13 of the Montevideu Treaty). The purpose demands regulatory cooperation between the countries of the region (Article 2 of the Montevideu Treaty).

The most important instrument for regulatory cooperation in ALADI is the Framework Agreement for the Promotion of Trade through Overcoming Technical Barriers to Trade, signed in 1997 and in force since 1998. The aim of the agreement is to ensure that the development, adoption and application of technical regulations, standards and mandatory conformity assessment procedures do not constitute unnecessary barriers to intraregional trade (art. 1 of the Framework Agreement). In line with the TBT Agreement of the WTO (see art. 2 of the TBT Agreement), States have sought to achieve this by harmonizing technical regulations that can achieve trade without reducing levels of protection animal and plant life and health, the environment, safety and the consumer (art. 3).

In the harmonization process, which is the form of regulatory cooperation explicitly adopted by ALADI members, the regulatory and standardization work developed in the region is used as the main parameter for the design of domestic technical regulations. The imminent approval of regulation or standard is considered for regulatory and standardization activity of States (Article

6). Priority shall be given to the harmonization of technical regulations which may constitute unnecessary technical barriers to intraregional trade (Art. 7).

The idea of convergence adopted by ALADI countries was therefore to make use of international and regional regulatory and standardization parameters, in order to avoid incompatibilities between the regulatory systems of the States parties. In practice, this arrangement indicates that States should make efforts to produce technical regulations within ALADI legal framework and then internalize these regulations so that they can be applied at the domestic level, repealing earlier national rules on the same subject. In addition, voluntary standards used in production processes should be those produced by international (eg ISO, IEC) and regional standardization bodies (eg COPANT, AMN) even though they have to be submitted to nationalization process in the domestic standardization bodies.

According to art. 8 of the Framework Agreement, the establishment and strengthening of conformity assessment systems and the mutual recognition of conformity assessment systems among ALADI countries are key instruments for the regulatory cooperation. The main bases for such cooperation are recommendations from specialized international bodies such as ISO and other international forums that bring together accreditation bodies such as the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). Cooperation in this area would avoid double accreditation of conformity assessment bodies, reducing the cost of regional trade.

Besides the construction of conformity assessment systems, the art. 10 of the Framework Agreement set forth a harmonized regime regarding liability for the veracity of certificates and other documentation issued by the accredited institutions and penalties applicable in cases of fraudulent certification.

Within the framework of conformity assessment systems and the harmonized regime, the signatory countries are working to encourage the participation of their official accreditation bodies in the Inter-American Accreditation Cooperation (IAAC) and to participate in multilateral recognition agreements. Such measures are intended to enable the mutual recognition of conformity assessment structures of countries (Art. 12).

The IAAC is a regional association of accreditation bodies and other related organizations interested in conformity assessment in the Americas. Briefly, it is verified that the IAAC promotes direct cooperation between accreditation bodies in the American continent. Its overall objective is to develop conformity assessment frameworks to achieve product, process and service improvement by reducing the risk to business owners and consumers by enhancing trust in accredited certificates. Accreditation has the purpose of assuring users of the competence and impartiality of the accredited body.

The IAAC has multiple goals and carries out various functions within the American continent in regulatory matters. First, the IAAC administers the Multilateral Recognition Agreements between the accreditation bodies of the members States. The IAAC also promotes the harmonization of accreditation programs for its members in order to eliminate the need for separate accreditations in each country. Thirdly, the entity promotes collaboration and cooperation throughout the world between accreditation bodies and between their members and other relevant bodies and groups. Fourth, the IAAC assures the representation of the Americas in international accreditation forums and provides a wide variety of training activities.

Therefore, the interaction between ALADI and IAAC is important and can facilitate the cooperation efforts in Latin American region.

In the regulation of metrology, as provided in art. 13 of the Framework Agreement, the signatory countries should adopt the international system of units and to establish the strategies, deadlines and instruments necessary to bring the national structures into line with the technological change resulting from the adoption of the international system of units.

In compliance with the principle of transparency, which is fundamental in regulatory cooperation initiatives, the signatory countries work with the General Secretariat of ALADI, the Pan American Technical Standards Commission (COPANT) and other relevant regional entities. They effort to develop and integrate information systems on draft technical regulations, technical standards and conformity assessment systems. The system shall be able to respond promptly to requests regarding the technical regulations, standards and conformity assessment procedures in force.

The permanent contacts between the national standardization, regulation and conformity assessment bodies of the signatory countries is intended to strengthen the above mentioned instruments of regulatory convergence. From the dialogue of these different institutions, signatory countries can formalize, through additional protocols, the instruments of harmonization and other concerted actions. They also can structure a conceptual framework for technical regulation and standardization, as well as conformity assessment.

In parallel to the provisions formalized under the Framework Agreement, Mercosur countries have created additional measures to strengthen regulatory cooperation.

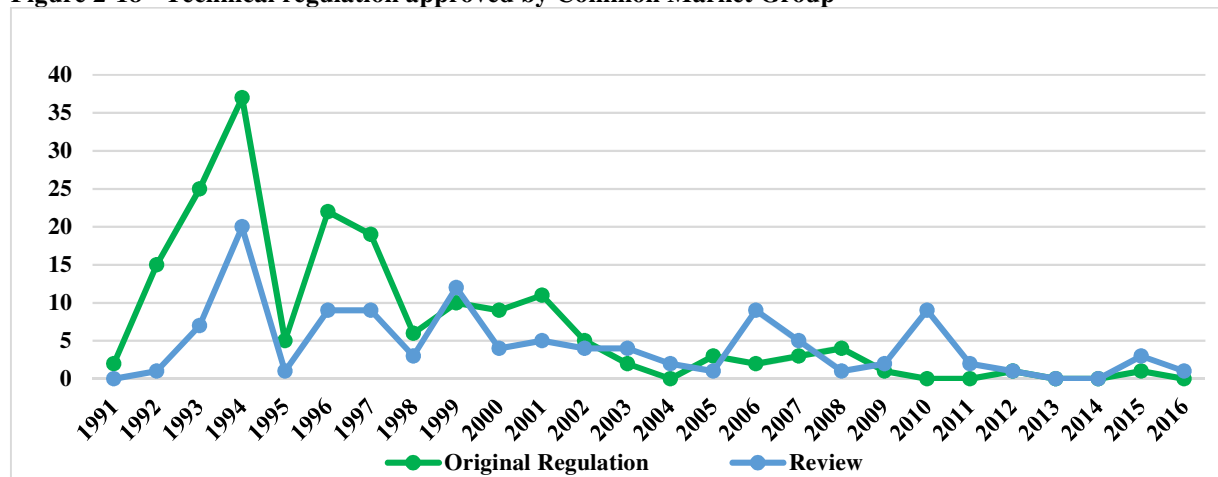
2.6.2. Regulatory Cooperation in Mercosur

In terms of technical barriers, regulatory convergence initiatives among the Mercosur countries were adopted within the framework of the Sub-Working Group (SGT) No. 3 and the Mercosur Standardization Association. These two bodies were responsible for the production of a series of technical standards, which should be internalized by the Member States.

The SGT No. 3 is one of the eighteen subgroups of work subordinated to the Common Market Group, sharing space with subjects such as communications, institutional aspects, financial affairs, transport, environment, industry, agriculture, energy, labor, health, investment, trade electronic, productive integration, mining and geology.

Each of these subgroups is integrated and coordinated by representatives of specialized government bodies. Thus, SGT No. 3, called Technical Regulations and Conformity Assessment, has its General Coordination of International Articulation attributed to the National Institute of Metrology, Standardization and Industrial Quality (INMETRO). The other Mercosur members assign this function to higher political bodies, generally endowed with a ministerial condition. Thus, in Argentina, this function was attributed to the Sub-secretary of Consumer Defense, directly linked to the Ministry of Economy and Production (MECON); in Paraguay, the Ministry of Industry and Commerce (MIC) operates directly in the subgroup; or Ministry of Industry, Energy and Mining (MIEM) occupies this place in Uruguay; and in Venezuela, the Ministry of People's Power for Trade carries out this technical function (see MERCOSUR, 2017).

Figure 2-18 - Technical regulation approved by Common Market Group

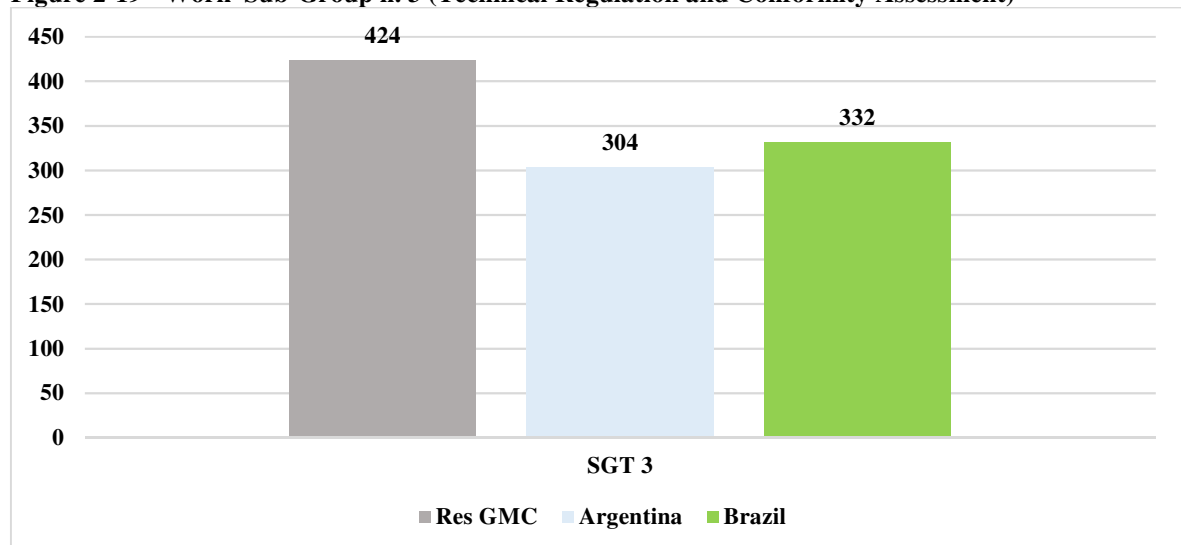


Source: Mercosur. Elaborated by CCGI-EESP/FGV.

The SGT n. 3 and the GMC works based on the principle of strong harmonization of technical regulation. Moreover, the technical regulation approved by the GMC has to be internalized by member countries. Such aspects make inefficient the Mercosur regulatory system. Several regulations are not incorporated by the member states, including Brazil and Argentina.

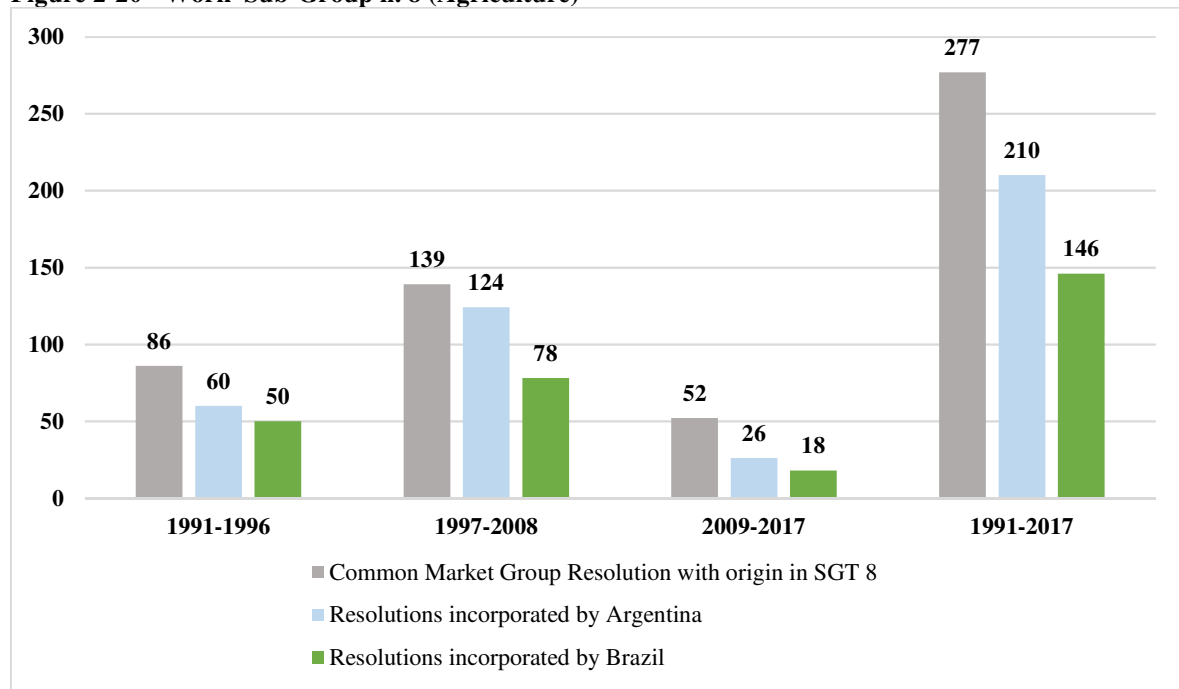
In addition to the approval of draft technical regulations produced by SGT n.3, the work of other sub-working groups should be observed. The activities of SGT n.8 and SGT n. 11.

Figure 2-19 - Work Sub-Group n. 3 (Technical Regulation and Conformity Assessment)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

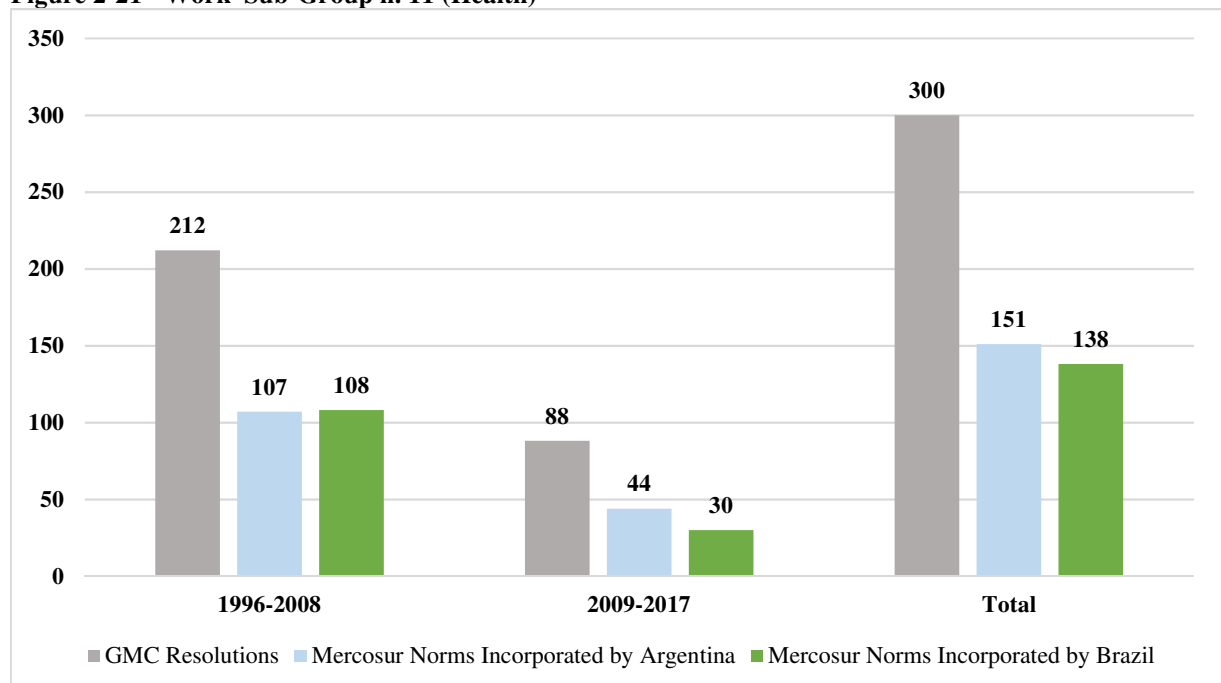
Figure 2-20 - Work Sub-Group n. 8 (Agriculture)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

In relation to subgroup n. 3, group 8 shows a smaller number of regulations approved by the GMC. Argentina stands out in the internalization of the rules originating from this subgroup.

Figure 2-21 - Work Sub-Group n. 11 (Health)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

It is worth mentioning an agreement reached with the members of the Brazilian Network of Legal Metrology and Quality. The agreement, created under SGT No. 3, aims to contribute to legal metrology being applied uniformly by the various countries of the world. It is understood

that cooperation between MERCOSUR and the International Organization of Legal Metrology (OIML) should be strengthened.

In addition to the production of technical regulations, it should be noted that the Mercosur Association of Standardization, a private body that develops technical standards at the regional level. As provided in art. 4.4. of Resolution 45/2017 of the Common Market Group, the development of technical standards may be requested from AMN by the Common Market Group. These technical standards can be used to support regional technical regulation. Although the AMN is not an official body of Mercosur, it has signed an agreement with the bloc, in order to act as a standardization body responsible for the creation of Mercosur standards. The AMN participants are the main standardization bodies of Mercosur member countries.

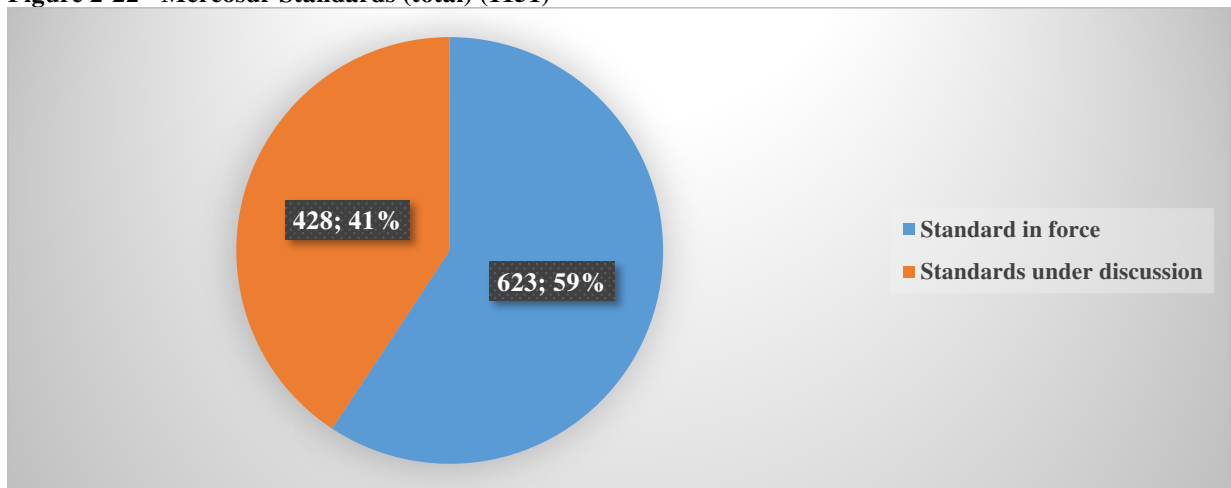
Table 2.9 - Mercosur Sectorial Committee

CSM	NAME	SECRETARY
01	Mercosur Sectoral Committee of Electricity	ABNT
02	Mercosur Steel Sector Committee	IRAM
03	Mercosur Sectoral Committee of Electronics and Telecommunications	ABNT
04	Mercosur Sector Committee of Toys	IRAM
05	Mercosur Sector Committee for Cement and Concrete	ABNT
06	Mercosur Sectoral Committee of Machinery and Mechanical Equipment	ABNT
07	Mercosur Automotive Sector Committee	IRAM
09	Mercosur Sectoral Committee of Plastics for Civil Construction	ABNT
12	Mercosur Sector Committee of Pulp and Paper	ABNT
13	Mercosur Sector Committee for Quality	IRAM
16	Mercosur Sectoral Committee for Environmental Management	ABNT
17	Mercosur Sectoral Committee on Accessibility	UNIT
18	Mercosur Sectoral Committee of Graphic Technology	ABNT
20	Mercosur Sectoral Committee for Clinical Analysis and In Vitro Diagnostics	ABNT
21	Mercosur Sectoral Committee of Flat Glass	ABNT
22	Mercosur Sector Committee for Conformity Assessment	IRAM
23	Mercosur Sectoral Committee of Tourism	ABNT
24	Mercosur Sector Committee for Non-Destructive Testing	IRAM
25	Mercosur Sectoral Committee for Packaging and Packaging	INTN
26	Mercosur Sectoral Committee on Food Safety	IRAM
27	Mercosur Sector Quality Committee for software	UNIT
28	Mercosur Sectoral Committee on Information Security	ABNT

Source: AMN. Elaborated by CCGI-EESP/FGV.

AMN's sector committees have so far produced few standards. The graph below shows the standards produced by AMN and establishes a comparison with other standardization bodies, including regional organizations, such as CEN and CENELEC.

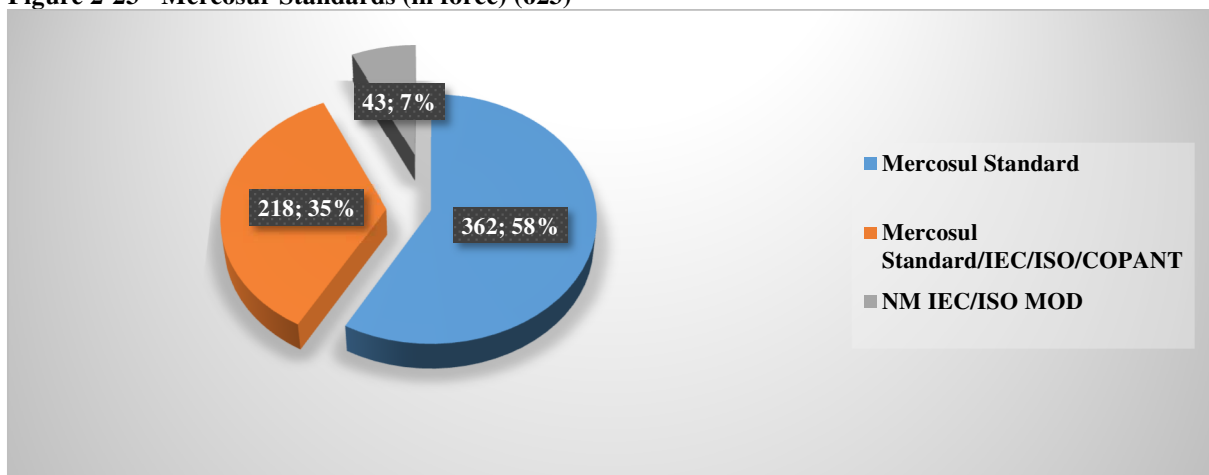
Figure 2-22 - Mercosur Standards (total) (1151)



Source: AMN. Elaborated by CCGI-EESP/FGV.

It is also important to highlight that, in AMN's catalog of standards, the Association's standards of origin predominate, in the detection of international and regional (continental) standards.

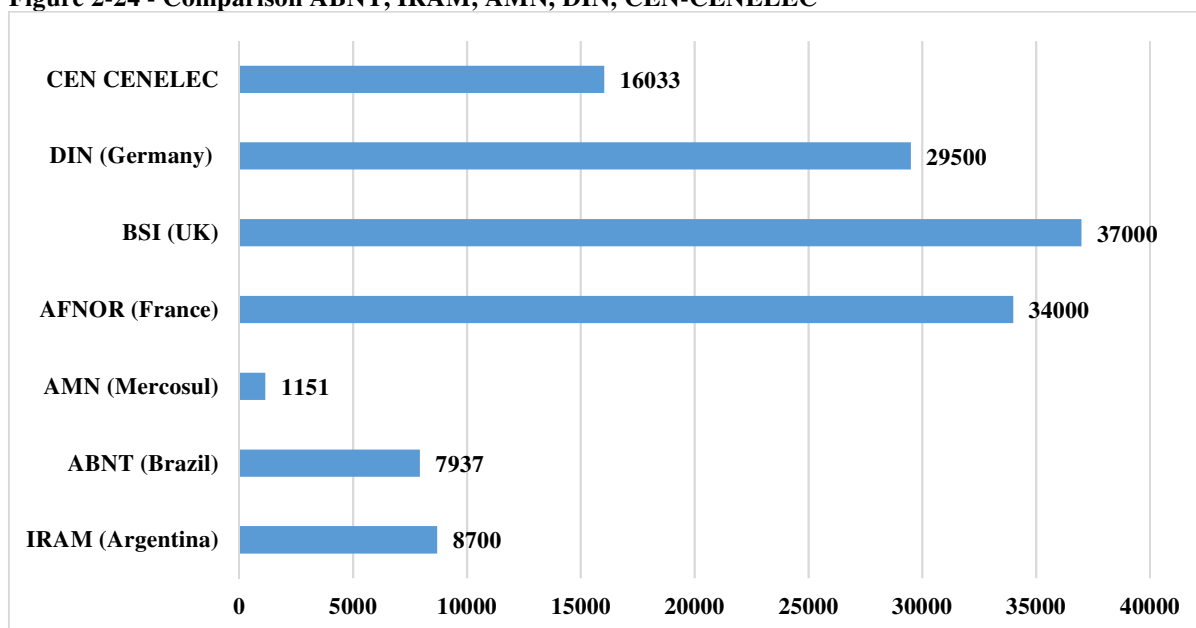
Figure 2-23 - Mercosur Standards (in force) (623)



Source: AMN. Elaborated by CCGI-EESP/FGV.

In addition, it is worth noting the weak standardization activity of the national standardization bodies of the two main Mercosur partners. Although the production of technical standards in Argentina and Brazil is superior to that of AMN, it is well below the production of the German standardization body.

Figure 2-24 - Comparison ABNT, IRAM, AMN, DIN, CEN-CENELEC



Source: AMN. Elaborated by CCGI-EESP/FGV.

Concerning standardization, is also important the agreement established with the European Union to determine the so-called ECONORMS for the convergence of technical regulations between the European Union and MERCOSUR in the fields of Metrology and Conformity Assessment.

TBT issues were mainly debated on the negotiations for the creation of a free trade area between Mercosur and the European Union. Discussions on standards, technical regulations and conformity assessment procedures happened on the Technical Group 1 of the Committee of Biregional Negotiations (CNB). Negotiation meetings happened during the whole year of 2004, in which a consensus was reached about the redaction of section 4 of the agreement between Mercosur and EU – Norms, Technical Regulations and Conformity Assessment. The issue of free circulation of products was also debated from the acceptance of the mark CE by Mercosur on the following sectors: wood, wood furniture, machines and electrical products.

Aiming to implement the action plan on business facilitation, Mercosur and the EU created a project of technical cooperation involving the productive sectors on the value of 4 million euros. This project benefits regulation, standardization, accreditation and certification bodies and the test and calibration laboratories identified by the authorities of Mercosur State parties.

The regulatory systems of Argentina and Brazil have many similarities. Regulatory agencies have technical autonomy to regulate their respective areas of competence, even if they are sometimes subject to budget constraints and are captured by political interests. In Argentina, the production of technical standards, which is conducted by IRAM, is more decentralized than in Brazil, since many standards are published directly by the standardizing bodies of industry associations (for example, AITA, IAS). The conformity assessment system, especially the accreditation procedures for certification bodies, is similar in both countries. Brazil has a larger number of products that require compulsory certification, but this list is quite variable and usually regulated by non-statutory laws. With regard to the internationalization of the regulatory system through the use of international standards, the two countries have a predominance of domestic standards, which may hinder the insertion of their products in the international market

and even create obstacles to bilateral trade. Efforts to produce regional regulations and technical regulations, including regulatory convergence efforts within ALADI and Mercosur , have been insufficient to guarantee the free movement of goods between members and, above all, to ensure exports from the region to other markets in the world.

3. Automotive and auto-parts sector¹⁶

3.1. Automotive and auto-parts sector (Brazil)

3.1.1. Overview

The domestic production of vehicles, auto-parts, agricultural machinery, and highway construction machinery, among others, is guided both to domestic and to the foreign market, making the automotive segment a strategic sector in Brazil. The goods produced in this sector are of high value added to Brazilian trade profile, contributing to the diversification of the country's export basket, concentrated in commodities.

Since the 1990s, Brazilian automotive industry has become more modern and competitive, due to the increase of foreign direct investments (FDI) supported by specific policies to the sector. Brazilian automotive industry revenue, in 2015, was USD 59.1 billion, while FDI in the sector, including the auto-part segment, were of USD 68 billion from 1994 to 2012¹⁷.

Historically, the Brazilian automotive sector was marked by a strong presence of North American and European manufacturers; more recently South Korean, Japanese and Chinese manufacturers increased their participation in the Brazilian market, becoming relevant players in the policy arena. Such industry profile result in the technical regulation trends of the sector.

The increase of FDI from traditional and non-traditional investors was mainly a result of the increase of the domestic consumer market, but it also favored exports by the country and its integration to the global value chains of the sector. In the first decade of the 21st century, the Brazilian automotive industry had a good performance, especially in the motor vehicles sector. In 2013, the production of vehicles achieved its peak with 3.738.448 units, and Brazil was recognized as the 9th major producer of vehicles in the world. In the following years, there was a continuous decrease in those numbers, reaching in 2016 the registry of 2.175.284 units of vehicles. A synthesis of the Brazilian automotive sector trade performance with the world, from 2001 to 2016 is summarized in Table 1.

Vehicles and auto-parts segments are integrated sectors, and both segments compose the main profitable goods of Brazilian automotive industry. The agricultural machinery and highway construction machinery segments, in which Brazil has a trade surplus, represent a smaller quota of all Brazilian trade.

Table 3.1 - Brazilian Automotive Industry Trade Balance

Year	Vehicles	Auto parts	Agricultural machinery	Highway construction machinery	Others	Total

¹⁶ The fragments referring to the Brazilian sectors were withdrawn and adapted from another research report, developed by CCGI/EESP-FGV and available at: <https://ccgi.fgv.br/pt-br/eu-brazil-business-development-technical-regulations>. The considerations on the sectors of Brazil and Argentina were also formulated based on research and independent and benefited by the exhibitions that took place during the event: Regulatory Dialogue Brazil-Argentina, held on June 11, 2019: <https://ccgi.fgv.br/sites/ccgi.fgv.br/files/u5/Anais-Conferencia-Diologo%20Regulatorio-BR-ARG-11-6-18.pdf>

¹⁷Based on the numbers prepared by *Associação Nacional dos Fabricantes de Veículos Automotores. Brazilian Automotive Industry Yearbook*. ANFAVEA. 2017. Available at: <<http://www.virapagina.com.br/anfavea2017/files/assets/common/downloads/publication.pdf>>. **Yearbook**. ANFAVEA. 2017, p. 17-53. Available at: <<http://www.virapagina.com.br/anfavea2017/files/assets/common/downloads/publication.pdf>>. Last accesses on: Feb 23rd, 2017.

	Exp.	Imp.	Exp.	Imp.	Exp.	Imp.	Exp.	Imp.	Exp.	Imp.	Exp.	Imp.
2001	2.640,1	2.017,0	3.910,7	4.416,5	167,2	30,7	315,3	94,6	428,4	84,6	7.461,7	6.643,4
2002	2.633,4	1.093,5	4.163,0	4.147,3	263,8	12,1	352,2	93,0	379,4	16,5	7.791,8	5.362,4
2003	3.566,5	828,0	5.137,3	4.503,9	502,2	13,5	467,9	166,9	482,0	5,1	10.155,9	5.517,4
2004	4.950,7	880,4	6.431,5	5.824,8	810,7	65,2	954,5	149,1	648,8	21,2	13.796,2	6.940,7
2005	7.076,8	1.350,6	7.855,0	7.070,2	827,0	38,0	1.320,9	302,9	993,8	73,8	18.073,6	8.835,5
2006	7.320,7	2.633,6	9.314,6	7.236,8	701,7	35,0	1.540,4	502,5	1.129,7	28,1	20.007,1	10.436,0
2007	7.800,3	4.083,5	9.939,8	9.772,2	1.018,2	103,1	1.646,2	362,1	1.257,8	68,8	21.662,3	14.389,7
2008	8.409,6	6.865,3	10.880,5	13.557,9	1.369,6	195,6	1.870,1	931,6	1.483,8	38,4	24.013,6	21.588,8
2009	4.621,1	6.971,1	7.071,7	9.508,1	654,2	136,3	618,1	861,5	788,4	46,6	13.753,5	17.523,6
2010	6.909,6	10.869,5	10.691,7	14.855,3	948,7	177,9	1.384,6	1.144,8	1.050,7	116,5	20.985,3	27.164,0
2011	7.656,8	14.709,4	12.537,5	17.999,3	1.048,5	280,8	2.215,1	1.507,4	1.323,6	166,9	24.781,4	34.663,8
2012	6.784,6	12.701,3	11.625,5	18.129,0	906,0	483,8	2.258,2	1.658,5	1.155,4	196,2	22.729,7	33.168,9
2013	8.739,5	12.622,1	10.748,4	21.347,0	912,3	228,4	1.864,8	1.258,9	1.162,9	128,9	23.427,9	35.585,4
2014	5.531,7	10.931,3	9.185,0	19.386,8	764,3	219,2	1.956,9	907,5	1.036,5	134,9	18.474,4	31.579,7
2015	5.822,2	7.059,2	8.222,6	14.601,1	500,4	108,2	1.401,6	548,7	924,4	92,2	16.871,1	22.409,3
2016	7.639,1	4.408,2	7.315,3	12.933,9	483,8	77,6	1.432,8	244,9	985,1	107,1	17.856,1	17.771,7

Source: ANFAVEA, 2017, p. 46.

The trade balance of vehicles has floated substantially since 2013. If in 2014, the balance of trade registered a deficit of about USD 5,3 bi; in 2015, there was a lower deficit of about USD 1,2 bi; and in 2016, exports slightly grew up, inverting the trend of the last two years for a trade surplus of USD 3,2 bi.

The auto-parts segment, on the other hand, has registered a consistent deficit since 2008. In 2008, the numbers are of a deficit about USD 2,7 bi; in 2012, although exports grew, imports also increased, favoring a trade deficit of about USD 6,5 bi. More recently, in 2016, exports and imports decreased; but still with a trade deficit around USD 5,6 bi.

In the bilateral trade with the European Union, Brazil holds a trade deficit in all segments of the automotive sector, as Table 2 below:

Table 3.2 - Automotive Trade between Brazil and EU

Year	Vehicles		Auto parts		Agricultural machinery		Highway construction machinery		Others		Total	
	Exp	Imp	Exp	Imp	Exp	Imp	Exp	Imp	Exp	Imp	Exp	Imp
2001	147,7	215,9	820,7	2.101,1	3,1	6,4	37,0	24,3	9,3	23,0	1.017,8	2.370,7
2002	96,3	191,9	938,0	2.033,7	11,8	3,1	38,5	20,3	13,1	6,3	1.097,7	2.255,3
2003	120,2	232,3	1.220,3	2.210,7	17,4	3,5	49,9	28,6	22,8	3,4	1.430,6	2.478,5
2004	157,9	171,3	1.510,6	2.745,7	16,5	4,1	68,3	20,5	7,6	9,4	1.760,9	2.951,0
2005	844,2	278,2	1.752,7	3.389,6	26,9	7,4	73,8	36,7	23,5	56,0	2.721,1	3.768,0
2007	898,7	489,5	2.168,8	4.384,6	22,2	15,3	131,6	74,1	20,8	12,5	3.242,1	4.976,0
2006	767,4	517,3	1.925,4	3.198,0	18,3	10,8	100,8	117,4	8,2	12,6	2.820,1	3.856,1
2008	1.257	818,9	2.345,0	5.933,2	14,6	44,5	137,6	184,4	36,4	13,4	3.791,1	6.994,4
2009	724,1	740,6	1.347,9	3.539,1	7,9	26,3	23,1	128,5	2,8	9,2	2.105,8	4.443,7
2010	562,2	1.397,0	1.935,6	5.689,0	8,0	32,1	73,7	213,5	2,8	27,3	2.582,4	7.359,0
2011	123,8	2.074,7	2.101,9	6.844,8	19,4	35,4	152,5	292,6	5,3	39,9	2.402,9	9.287,3
2012	35,5	1.387,0	1.880,8	6.392,1	14,0	60,2	111,9	341,0	4,9	63,5	2.047,0	8.243,8
2013	63,8	1.759,5	1.947,4	7.738,8	4,1	64,6	59,4	213,5	4,5	73,7	2.079,1	9.850,1
2014	25,5	1.678,6	1.718,1	6.590,7	3,5	45,2	117,0	161,5	3,9	77,6	1.868,0	8.553,6
2015	8,6	1.073,0	1.589,5	4.444,7	1,6	32,9	32,2	53,8	4,1	39,1	1.636,1	5.643,5

Source: ANFAVEA, 2017, p. 48.

The most expressive deficit is in the vehicles segment: in 2013 and 2014, around USD 1,7 bi; and, in 2015, USD 1,1 bi. But, the trade deficit of all segments combined, for the year of 2015, is much higher, resulting in USD 4,0 bi.

It is hard to calculate the impacts of technical barriers to trade and investment inflows and outflows. However, according to the numbers above and their flotation in the last years, it seems that they had not a decisive weight at the end.

The numbers above are also driven changes in the high-level policy for the automotive sector, such as national industrial policy and regional arrangements.

3.1.2. Mapping technical regulation

The most important authorities that regulates this sector are: Brazilian National Environmental Council (CONAMA), the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), the Brazilian National Traffic Council (CONTRAN) and the Brazilian National Institute of Metrology, Quality and Technology (INMETRO). They are responsible for regulating the automotive sector issuing technical regulations and standards related to the reduction of the emission of pollutants and car safety. The Brazilian Association on Technical Standards (ABNT) is the only private organization with an important role in promoting private and international standards in this area.

A brief analysis of the profile of technical regulations notified by the Brazilian government to the WTO under the Agreement on Technical Barriers to Trade (TBT) provides the overview of automobiles sectoral regulation in the country. The projects of technical regulations that impact international trade are notified to the TBT Committee. In addition to INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly IBAMA and CONTRAN.

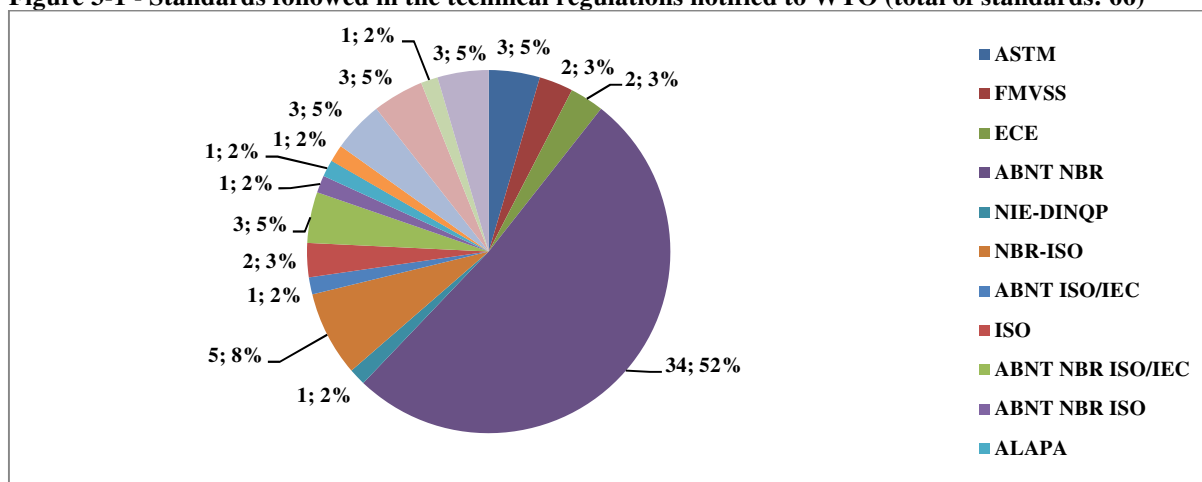
From January 1st, 1995 until March 30th, 2017, there were 29 notifications from Brazil, concerning the Automotive Sector, on TBT. In 2017, twenty of them were still in force. INMETRO¹⁸ has traditionally been by far the main body having technical regulations notified to the WTO, but CONTRAN has been more active in the last two years.

The main objectives of the technical regulations notified to the TBT Committee deal with safety issues -i.e. human safety-, metrology, environment and other topics are of minor relevance.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on auto sector.

¹⁸ INMETRO has made available to the public a searching tool in which it is possible to search by keywords, date and number of the technical regulation [here](#).

Figure 3-1 - Standards followed in the technical regulations notified to WTO (total of standards: 66)



Source: WTO database. Prepared by CCGI-EESP/ FGV (March 2017).

The standards ABNT NBR correspond to fifty-two percent of the total notified. ABNT standards do not explicitly endorse any international standard¹⁹.

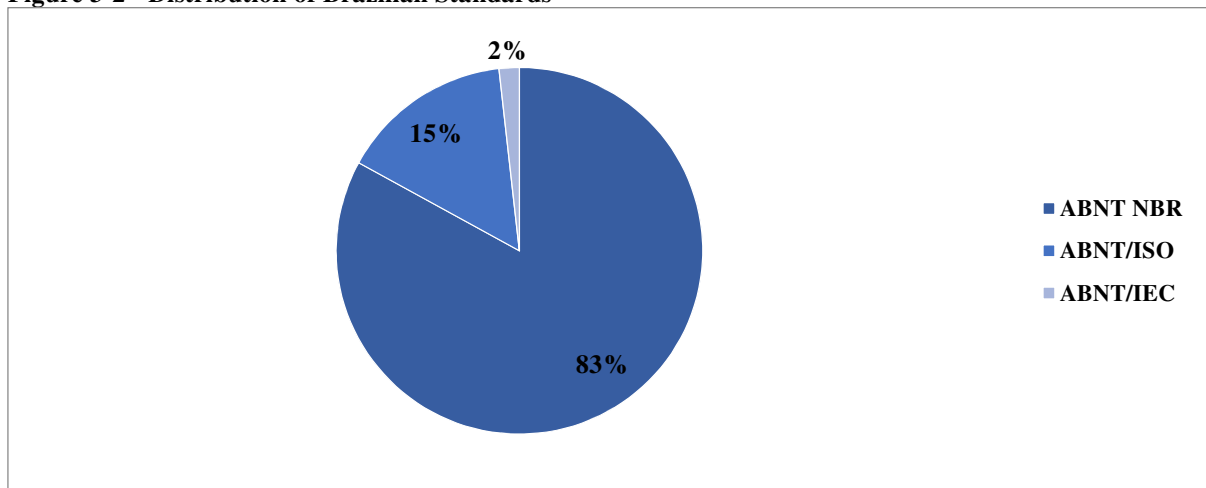
The ISO and ISO/IEC standards have also a important role, if compared to other. The ISO and ISO/IEC standards are usually adopted by certain governmental agencies or incorporated to ABNT standards. Only one notification (G/TBT/N/BRA/702, dated as of 2017) mentions expressly UNECE (ECE) and FMVSS. In such notification they were taken as alternative options by the Brazilian technical regulation. This does not mean that such standards are not important as a pattern for Brazilian regulation. As demonstrated in this report, some regulations not reported to WTO are based on European and American standards.

3.1.3. Mapping technical standards

The technical standards produced by ABNT are voluntary compliance (see [Annex 2](#)). Many of them, however, become mandatory when referred to in technical regulations. In addition, according to the Consumer Protection Code, the standards developed by ABNT are applied in a subsidiary manner as a parameter of quality of the products offered in the market.

¹⁹ A relevant number of technical regulations (especially those on conformity assessment procedures) refer to supporting standards, usually issued by **ABNT**, a private body. There are different kinds of supporting standards issued by ABNT. These standards range from a fully original standard developed under its Standardizing Committees (CB) to a standard based on international standards, mainly ISO and IEC. Usually (i) if it is a standard identical to an international standard, it will appear, for example, as ABNT NBR ISO n° XXX; (ii) if it is based on an international standard, a reference to this international standard will be in the preamble of the standard; and, (iii) if it is an original standard, it will appear as ABNT NBR n° XXX. ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website. ABNT Catalog with all searching tools is available here. In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party has to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard.

Figure 3-2 - Distribution of Brazilian Standards



Source: ABNT. Prepared by CCGI-EESP/ FGV (March 2017).

3.1.4. Mandatory conformity assessment procedures

Brazil requires imported and domestic new auto-parts to be certified by accredited laboratories²⁰. Brazil may accept certifications issued in other countries and tests approved by foreign institutions in the following cases: i) if the foreign certification body is accredited by INMETRO; and, ii) if the foreign accreditation body is both a member of the International Laboratory Accreditation Cooperation (ILAC) and, is signatory of the ILAC Mutual Recognition Arrangement²¹.

However, there is no guarantee that specific technical regulations of auto parts will be accepted by CONTRAN if issued by a regulatory body different from INMETRO.

In the case of imported or new vehicles manufactured in Brazil, CONMETRO/INMETRO and CONAMA/IBAMA are the two ministerial councils and regulatory bodies responsible for regulating and issuing standards related to car safety and emissions homologation. The National Telecommunications Agency (ANATEL) is responsible for radio frequency devices certification. CONTRAN/DENATRAN is responsible for the whole process of national registration to new-domestic and new-imported vehicles. Therefore, at the end of the process, it concedes or not the vehicle homologation.

IBAMA accepts environmental performance tests as equivalent to domestic ones if conducted in the presence of IBAMA staff members. In this case, the new vehicle type can receive IBAMA approval. DENATRAN holds a different procedure for passive safety tests. It may exempt the importer from the requirement of conducting tests in the presence of DENATRAN/INMETRO staff members if an ILAC signatory body accredits the foreign laboratory that conducted the tests.

In what concerns other safety requirements, including active ones, the declaration of conformity with the national legislation and the statement that the company operates a management system

²⁰ INMETRO is the regulatory agency responsible for accrediting laboratories for certification processes.

²¹ The list of signatories to ILAC Mutual Recognition Arrangement may be found at: <http://ilac.org/ilac-mra-and-signatories/>. Last access: April, 17, 2017.

that controls the operations of the laboratories that performed the tests may meet the need for local homologation and labelling²². The homologation process takes the following steps:

A) obtain the LCVM (License for use of Vehicle Configuration or Motor) issued by IBAMA. The LCVM certifies that the car complies with current environmental regulations²³. Motorcycles and similar vehicles shall complete the same process (License to Use the Configuration of Mopeds, Motorcycles and Similar). It evaluates two aspects of the vehicle: emission and engine noise levels, which have to be within the limits established by Brazilian legislation²⁴.

B) request the CAT (Traffic Adequacy Certificate) by providing documents (technical tests, essays performed by a recognized laboratory) in order to obtain a registration for the vehicle in the National Registry of Automotive Vehicles (RENAVAM).

Both steps combined usually take between 40 to 90 days, according to experts and practitioners in this field. Regarding the official LCVM deadline, according to Article 9 of Ordinance n. 86/1996, IBAMA will issue the LCVM, the Declaration of Attendance and the Certificate referred to in Article 4, in a period of 60 working days, from the date of delivery of all information necessary to meet fully the requirements established in this Ordinance. The official deadline for issuing the CAT, according to Article 5 of DENATRAN Ordinance n. 190/09, is 20 working days from the receipt of the request.

3.2. Vehicles and auto parts (Argentina)

3.2.1. Overview

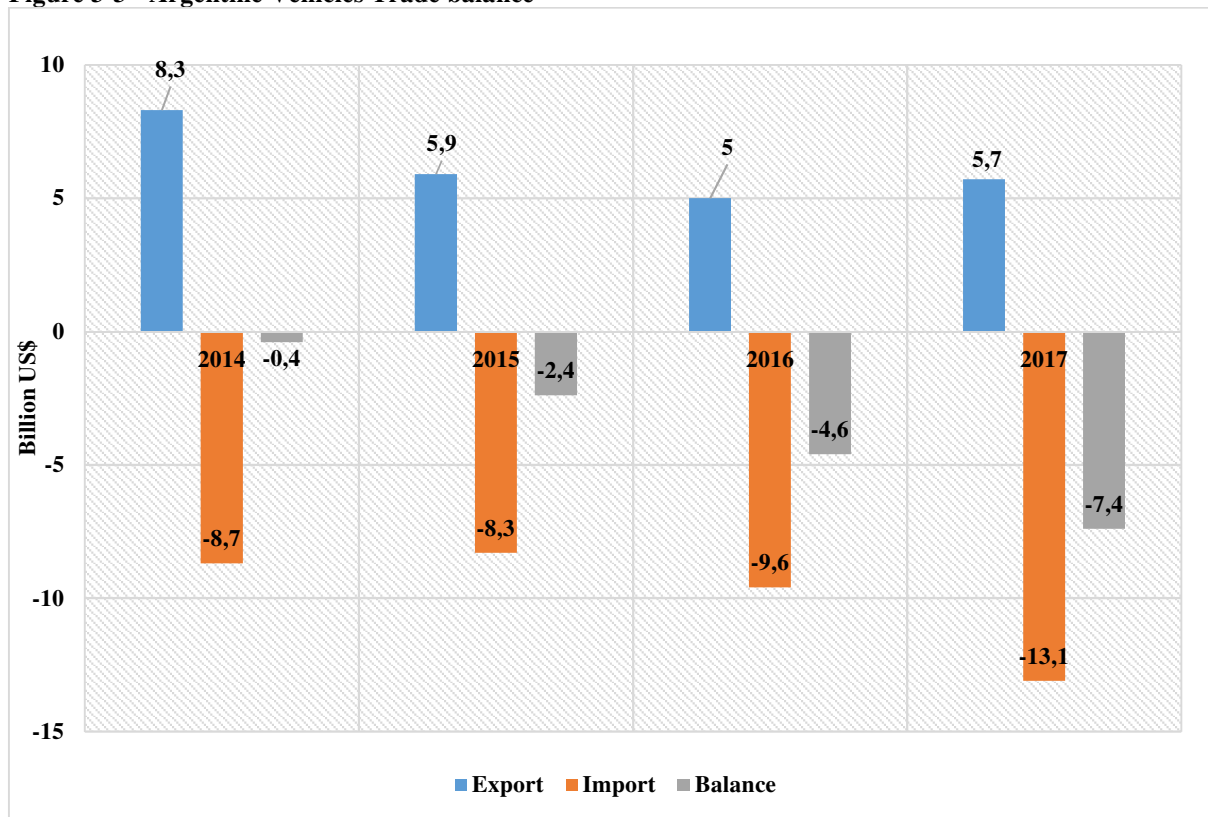
The production of vehicles is fundamental for the Argentine industrial sector and for its foreign trade in manufactured goods. The automotive production chain is quite large and generates skilled jobs in the domestic industry. For the country's foreign trade, especially the trade within Mercosur, the automotive sector is also important to diversify the exports of the country that is traditionally characterized by the predominance of commodities. Relevant part of the successful bilateral trade partnership between Brazil and Argentina results from intense flows of manufactured goods from the automotive sector. In 2017, Argentina exported almost US\$ 6 billion in automotive vehicles, mainly to Brazil. Vehicles and auto-parts are the main Argentine products exported to Mercosur.

²²See DENATRAN Ordinance n. 190/2009.

²³ IBAMA Ordinance n. 086/1996 in its Article 1, determines: imported automotive vehicles are required to meet the same pollutant emission levels and noise levels established for domestic vehicles. License for the Use of the Vehicle or Motor Configuration - LCVM, issued by IBAMA, as determined by Articles 4 and 5 of Federal Law n. 8,723/1993.

²⁴ The emission levels are provided for in Federal Law n. 8,723/1993. The noise levels are set out in CONAMA Resolution n. 252/1999.

Figure 3-3 - Argentine Vehicles Trade balance



Source: INDEC. Elaborated by CCGI/FGV-EESP

This trade, however, could be stimulated by the adoption of more active policies of regulatory convergence between Mercosur 's two main trading partners. For this convergence to materialize, there must be a progressive approximation of technical regulations, standards and regulatory authorities of the automotive sector of the two countries.

The Asociación de Fabricantes de Automotores (Adefa) has an important role in Argentine Vehicles Industry. Adefa is part of the Organisation Internationale des Constructeurs d'Automobiles (OICA), based in Paris and it was created in 1960. It includes manufacturers of automobiles, light vehicles, trucks and buses.

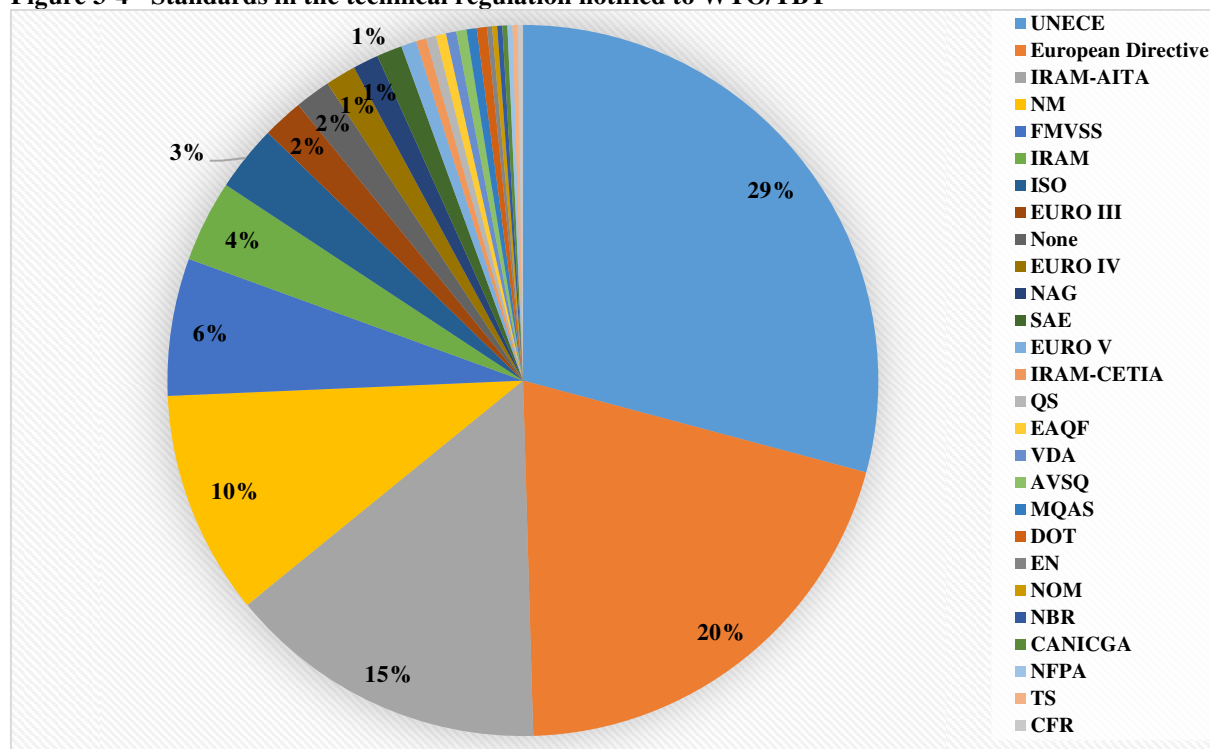
In regulatory matters, the automotive sector in Argentina is governed in two main dimensions: safety (active and passive) and environment. In the first case, the safety of the driver, the passengers and third parties in relation to the use of vehicles is sought. These are aspects related to the correct operation of the vehicle, its safety items and signs. In the second case, the aim is to mitigate the effects of fuel consumption by motor vehicles. For both cases international norms and rules are used as parameters for the design of Argentine regulation.

3.2.2. Mapping of regulations

In regulatory matters, the automotive sector in Argentina is governed in two main dimensions: safety (active and passive) and environment. In the first case, the safety of the driver, the passengers and third parties in relation to the use of vehicles is sought (see [Annex 2](#)). These are aspects related to the correct operation of the vehicle, its safety items and signs. In the second case, the aim is to mitigate the effects of fuel consumption by motor vehicles. For both cases international norms and rules are used as parameters for the design of Argentine regulation.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the machinery and mechanical sector.

Figure 3-4 - Standards in the technical regulation notified to WTO/TBT



Source: WTO. Elaborated by CCGI-EESP/FGV

There are different organizations responsible for issuing technical regulation in machinery sector in Argentina. The most important ones being:

a) **Ministry of Production (prior Ministry of Industry, Trade and Mining):** The Argentine Ministry of Production is the government agency responsible for defining standardization and quality control of industrial production. It also designs and executes the plans related to the promotion of the country's industrial production, as well as foreign trade. Many other secretariats and organization related to this Ministry are in charge of creating technical regulation in machinery sector.

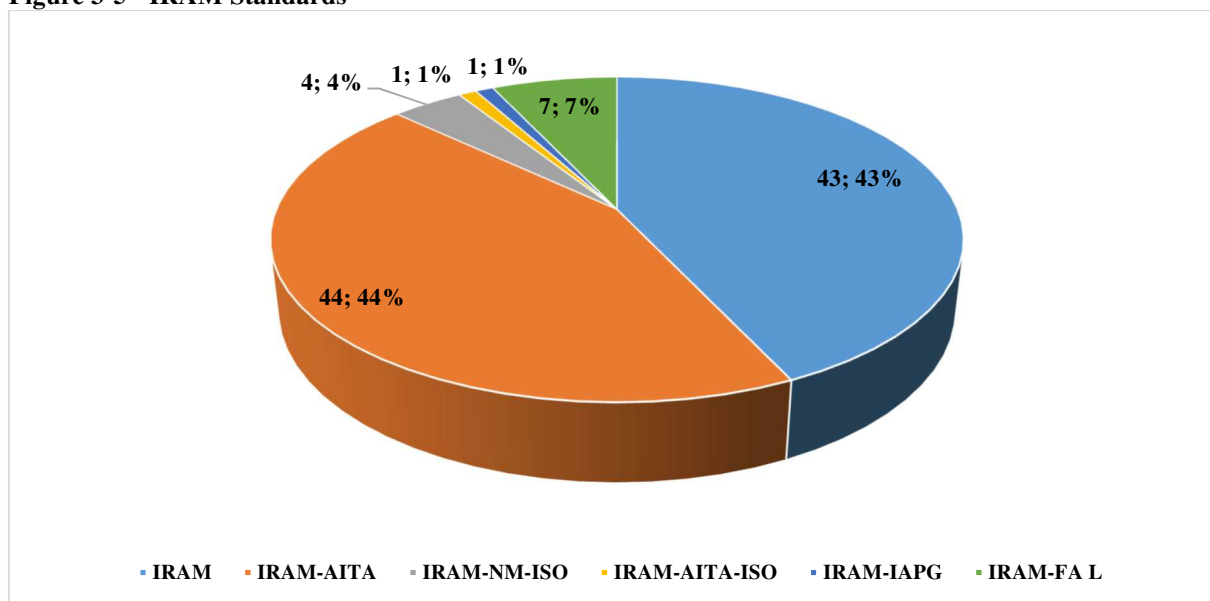
b) **Ministry of the Environment and Sustainable Development:** It is responsible for assisting the President in the formulation, implementation and execution of the environmental policy and its sustainable development as a State policy, within the framework of the provisions of article 41 of the National Constitution, in the technical aspects related to the environmental policy and the environmental management of the Nation, proposing and elaborating regulatory regimes related to the environmental order of the territory and its environmental quality.

c) **Ministry of Transport:** Responsible for everything inherent to air, rail, automotive, fluvial and maritime transport, and to the road activity.

3.2.3. Mapping Technical Standards

In Argentina, IRAM and AITA develop the most part of standards for vehicles. Some of such standards are based in international standards, but the vast majority are homegrown standards.

Figure 3-5 - IRAM Standards



Source: IRAM. Elaborated by CCGI-EESP/FGV .

The number of international technical standards adopted by the Argentinean standardization bodies is quite low. Domestically, it must be stressed the standardization works of IRAM and AITA. IRAM is a general standardization body in Argentina. AITA is an organization specializing in the production of technical standards for automobiles.

3.2.4. Mandatory conformity assessment procedures

According to Section I of the Annex P of Decree n° 779/95, to obtain the homologation of motor vehicles, the manufacturer, importer, natural or legal person or last intervener in the manufacturing process (for armed vehicles in stages), must present the LCM application and the detailed documentation, containing information of descriptive character, technical character, on the brake system, on tires and wheels, on rearview mirrors, on safety belts, on lighting devices and signaling and on the identification of the vehicle. The interested company must submit the homologation request with a minimum of 60 days before the product commercialization.

The Law n° 24.449, together with Decree n° 779/95, designates the Ministry of Industry to establish a system of Certification for Homologation of Safety Auto parts (CHAS) for any component or part destined to spare parts of automotive vehicles, coupled or semi-coupled, that are manufactured or imported in the country for the replacement market.

The Ministry of Industry issued the Resolution n° 91/2001, which regulates the replacement market for auto parts for automotive vehicles. It seeks the least restrictive regulation for the Argentinian market of auto parts replacement compatible with protecting consumer's safety. The system generated from Resolution n° 91/2001 rules that every auto part that is commercialized in the country must demonstrate that complies with strict active and passive safety regulations. For domestic producers this implies presenting certificates of compliance

with specific IRAM standards. The auto parts imported the same IRAM certificates or certificates of adaptation to the international standards of the TRANS/WP29/349 system.²⁵

The Decree n° 779/95 and its amendments designated the former Secretariat of Natural Resources and Human Environment (*Secretaría de Recursos Naturales y Ambiente Humano*), currently Ministry of Environment and Sustainable Development (*Ministerio de Ambiente y Desarrollo Sustentable*), as the competent authority for all aspects related to the emission of pollutants, noises and parasitic radiations, coming from automotive vehicles. By the Decree n° 13/2015, the Secretariat of Environmental Control and Monitoring (*Secretaría de Control y Monitoreo Ambiental*) of the Ministry was appointed as the competent authority in the contamination control.

By virtue of this, it was possible to implement a database on emissions and fuel consumption of the different automotive vehicles commercialized in the Argentinean market in the Operative Technical Unit of Vehicle Emissions, dependent on the Pollution Monitoring Directorate of the Subsecretariat for Environmental Control and Inspection and Pollution Prevention, dependent on the aforementioned Secretariat of Environmental Control and Monitoring. The Secretariat must issue the certificates of approval related to the emission of polluting gases and sound level that the manufacturers must submit to the Secretariat of Industry and Services, to request the License of Model Configuration (LCM).

Under the limits and procedures of emissions certification, implemented by the Resolution n° 1464/2015, of the former Secretariat of Environment and Sustainable Development, for the control of emissions of light commercial and passenger vehicles (of categories M1 and N1 according to reference regulations), the European Directives n° 715/2007 and n° 692/2008 of the European Parliament and the Council for light vehicles, as well as the United Nations regulations, are taken as reference for the homologation of polluting emissions of automotive vehicles and fuel consumption. It was based on this normative framework that the IRAM-AITA 10274 standard could be adopted, establishing the procedures for the measurement of CO2 emissions and fuel consumption.

According to the Article 1 of the Resolution n° 797/2017, until January 15, 2018, all manufacturers and importers of light automotive vehicles belonging to categories M1 and N1 (defined in Annex II of Directive n° 70/156/CEE), must declare before the Operative Technical Unit of Vehicle Emissions, with respect to all models in commercialization within the national territory that have a Gaseous Emissions Approval Certificate in force (*Certificado de Aprobación de Emisiones Gaseosas* - Decree n° 779/95 and subsequent resolutions), the values of CO2 emissions and fuel consumption, according to the test procedure based on the European cycle admitted for homologation, production control or internal research and development report, specified by the IRAM-AITA 10274 standard, the ECE R.101 regulation or the European Directive n° 715/2007 and subsequent rules, as appropriate in each case. These values will only be informative and taken as a sworn statement, for this reason lacking any type of certification by third parties.²⁶

²⁵ Resolution n° 91/2001. Available at: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/65000-69999/68923/texact.htm>

²⁶ Resolution n° 797/2017. Available at: http://www.cira.org.ar/index.php?option=com_content&view=article&id=7974:resolucion-797-e-2017&catid=112&Itemid=500

As of January 15, 2018, all new gaseous pollutant emissions certification, which was presented to the Operative Technical Unit of Vehicle Emissions, of light automotive vehicles, belonging to categories M1 and N1, required to process the License of Model Configuration (LCM) of new models, must incorporate the certified values of CO₂ emission and fuel consumption for the use of the approved fuel type(s), according to the procedure specified by the IRAM-AITA 10274 standard, the ECE R.101 regulation or the European Directive n° 715/2007 and subsequent rules, as appropriate in each case.

Thus, in Argentina the Euro V norm for auto vehicles should already be in force and this means that the maximum that diesel cars can emit is 0.18 g/km of nitrogen oxides and 0,50 g/km of carbon monoxide. While for a naphtero, these values are 0.06 g/km of NO_x and 1 g/km of monoxide.²⁷

²⁷ RUSSO, Victor. En la Argentina, por ahora, la norma es menos exigente. Clarín, 22 Sep. 2015. Available at: https://www.clarin.com/mundo/volkswagen-escandalo-falsificacion_de_datos-ecologia_0_H1pcjfKvQe.html

4. Machinery

4.1. Machinery (Brazil)

4.1.1. Overview

The machinery and mechanical equipment sector in Brazil is a traditional sector of Brazilian industry. Its origins go back to the period of import substitution, which also explains its strong concentration in the southeast region of the country, the core of the state-induced industrialization process. The sector is made up of different types of companies, most notably transnational companies, which, with an intense outsourcing policy, feed a large number of medium and small enterprises with national capital. In terms of international trade, Brazil is a net importer of machinery and mechanical equipment, although Latin America, especially the Mercosur partners, are important destinations for Brazilian exports of this type of product.

The machinery and mechanical equipment sector has had an important role in the recent economic growth of Brazilian economy and in international trade. In the last four years, the values of trade in machinery and equipment varied between US \$ 30 and US \$ 50 billion, narrowing substantially between 2013 and 2016.

Table 4.1 - Trade of Machinery and Equipment (US\$ billions)

Year	Brazil-World	
	Exports	Imports
2013	12,9	35,7
2014	12,7	31,9
2015	11,4	24,8
2016	11,6	21,1

Source: MDIC/AliceWeb. Prepared by CCGI-EESP/ FGV (May 2017).

4.1.2. Mapping Technical Regulation

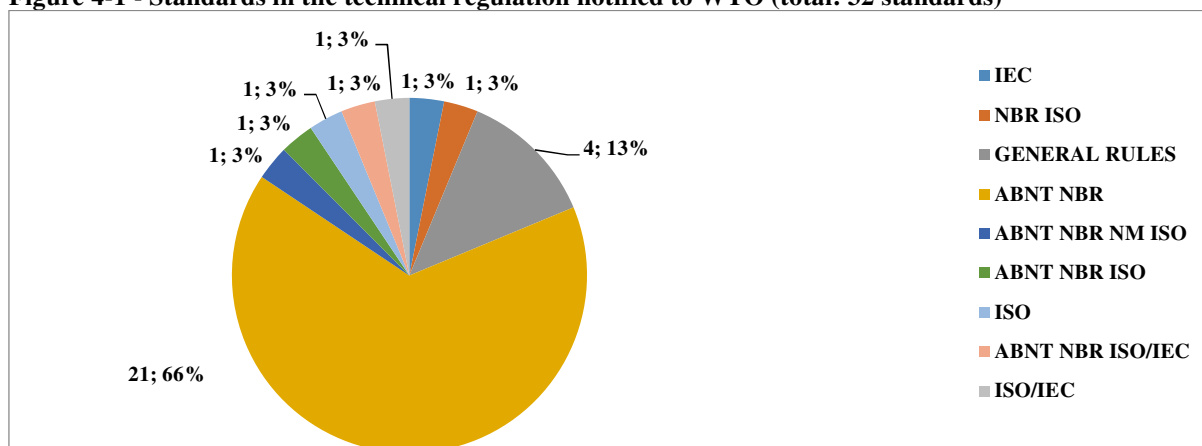
The Brazilian main regulation for machinery deals with worker safety, machine safety and consumer safety (see [Annex 4](#)). The Brazilian National Institute of Metrology Quality and Technology (INMETRO) regulates machinery appliances in the perspective of the final consumer. INMETRO normally notifies in detail its regulation to the TBT Committee of the WTO.

A brief analysis of the profile of technical regulations notified by the Brazilian government to the WTO under the Agreement on Technical Barriers to Trade (TBT) provides an overview of machinery and mechanical appliances sectoral regulation in the country. INMETRO notifies projects of technical regulations that impact international trade. Besides INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly Ministry of Mines and Energy (MME).

From January 1st, 1995 until March 30th, 2017, there were 45 notifications from Brazil, concerning the Machinery and Mechanical Sector, on TBT. INMETRO has traditionally by far been the main body having technical regulations notified to the WTO, however, as we may notice from the following Figure, MME has been more active in the last two years.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on the machinery sector.

Figure 4-1 - Standards in the technical regulation notified to WTO (total: 32 standards)



Source: WTO database. Prepared by CCGI-EESP/ FGV (March 2017).

The standards ABNT NBR correspond to 66 per cent (21 standards) percent of the total notified (32 standards). Such standards are issued by the Brazilian organization ABNT, without explicitly endorsing any international standard.

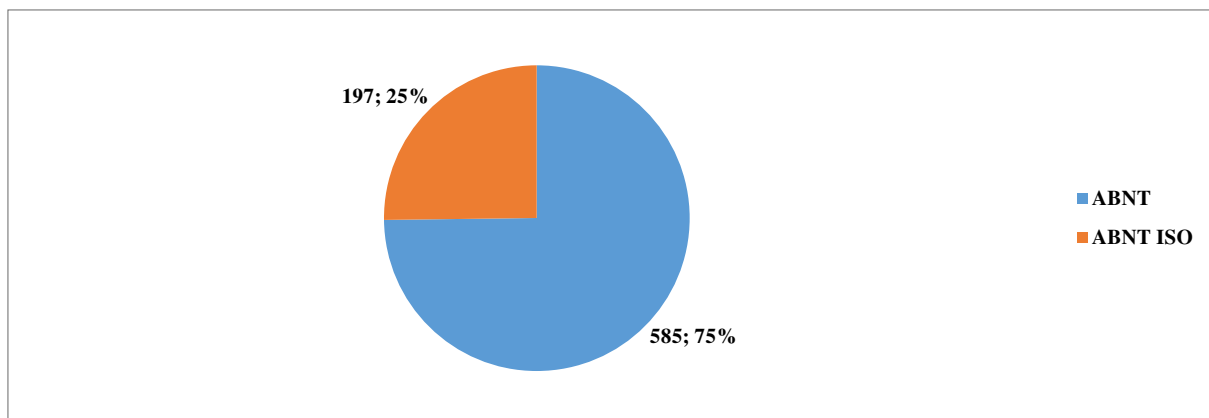
4.1.3. Mapping Technical Standards

In general, the ABNT uses ISO standards as a basis for elaborating its own standards (see [Annex 4](#))²⁸. ISO standards are also a basis for many INMETRO technical regulations and they are even mentioned in the MTE's regulations. Usually, ABNT standards are voluntary but when referred to in a technical regulation they become mandatory standards. In the absence of a technical standard, ABNT standards become a reference of product quality to the market.

A quarter of the standards (there are 197 ISO NBR standards and 585 pure ABNT NBR standards) used by Brazilian manufacturers derives from ISO standards. This number is due in part to the maintenance of some longstanding ABNT NBR standards, elaborated in a period in which there was no obligation or incentives to follow and adopt international standards. After the WTO Agreements entered into force, standards developed in Brazil started adopting international standards. This percentage of ISO standards have grown in recent years.

Figure 4-2 - Brazilian Standards for Machinery and Mechanical Appliances (total: 782)

²⁸ A significant number of technical regulations refer to supporting standards, usually developed by technical committees of ABNT, the main standardization body in Brazil. There are different types of standards issued by ABNT. These standards can be fully developed by the technical of the Standardization Committees (CB) or can be based on international standards, mainly ISO and IEC, but also ASTM and AMN. A Brazilian standard identical to an international standard, will appear, for example, as ABNT NBR ISO No. XXX; (ii) If it is based on an international standard, a reference to this international standard shall be included in the foreword to the Brazilian standard; and (iii) if it is an original standard, it will appear as ABNT NBR No. XXX. ABNT has no organized information on all international standards adopted wholly or modified by any of its committees, although it has general figures on the use of those standards. The available research tool is based on me research by keywords or in the enumeration of the norms produced by a given committee. In the same way as CEN, CENELEC, ASTM, IRAM and other standardizing entities, the interested party must pay a fee to have full access to the content of the standards issued by ABNT.



Source: ABNT. Prepared by CCGI-EESP/ FGV (March 2017).

The increasing application of international standards by ABNT is shown on the following graphic.

4.1.4. Mandatory conformity assessment procedures

In Brazil, the certification consists on a series of acts done by a third party body (an independent body) to confirm and declare that a good, service, person or system is in conformity with specified technical requirements, whether domestic, foreign or international. In other words, the certification process starts with the awareness that getting a certificate is necessary to show the quality of a product and to keep the level of competitiveness in a given market, involving the use of technical standards. It also involves the diffusion of the concept of quality through all the sectors of a company, including its internal operative aspects and the relationship with the society and the environment²⁹.

Third party bodies normally receive the name of certification organisms (OC) or accredited certification bodies (OCC). In Brazil, the National Institute of Metrology (INMETRO)³⁰ is responsible for the accreditation. The certification can be voluntary, whose decision is exclusive of the company that manufactures the product or supplies the service; or compulsory, established by the government to the trade of goods and services³¹. The following table contains the machines with compulsory certification.

²⁹ ABIMAQ. *Avaliação de conformidade*. Available at: <<http://www.abimaq.org.br/site.aspx/Avaliacao-da-Conformidade>> (accessed on 27 February 2018).

³⁰ INMETRO has made available to the general public a searching tool in which it is possible to search by keywords, date and number of the technical regulation [here](#).

³¹ ABIMAQ. *Avaliação de conformidade*. Available at: <<http://www.abimaq.org.br/site.aspx/Avaliacao-da-Conformidade>> (accessed on 27 February 2018).

4.2.Machinery (Argentina)

4.2.1. Overview

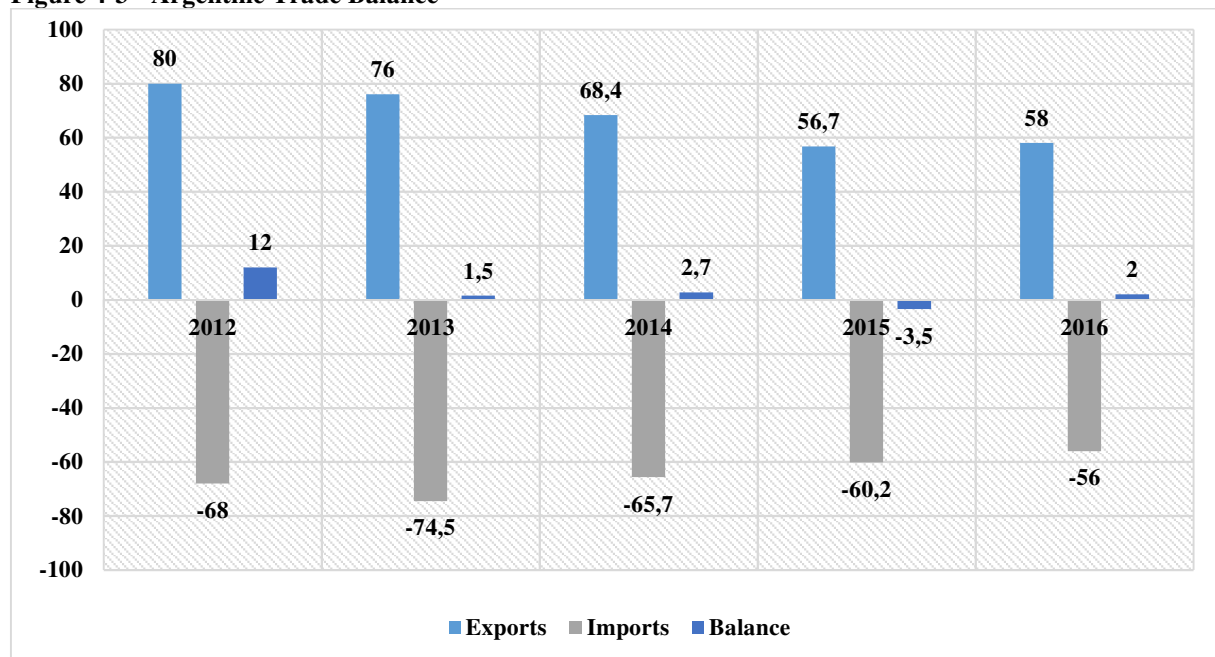
The machinery sector formation in Argentina dates back the second phase of the 1930s' import substitution policy and in the following decades, especially in Perón and Frondizi governments, production in this field was intensified. More recently government demands have forced equipment manufacturers to incorporate more local content, with multinationals using more than 50 percent of local components.³²

Farm machinery counts on approximately 730 companies, 10% of which have been operating for over 50 years in the country. It accounts for around 60 percent of the total sector and includes: seeders, sprayers, and tools.³³

The direct foreign investments of large transnational corporations were important for this development. They were mostly directed to Buenos Aires city, the largest industrial cluster in the country, where many machinery industries, like other industries of capital goods, were located. Other cities such as Córdoba, Rosario, Tucumán, Mendoza also host them.

In general, the foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of machinery and other industrial equipment.

Figure 4-3 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

However, as any other sector that has its origin in protectionist development policies, the machinery sector always had problems competing with similar products in the international

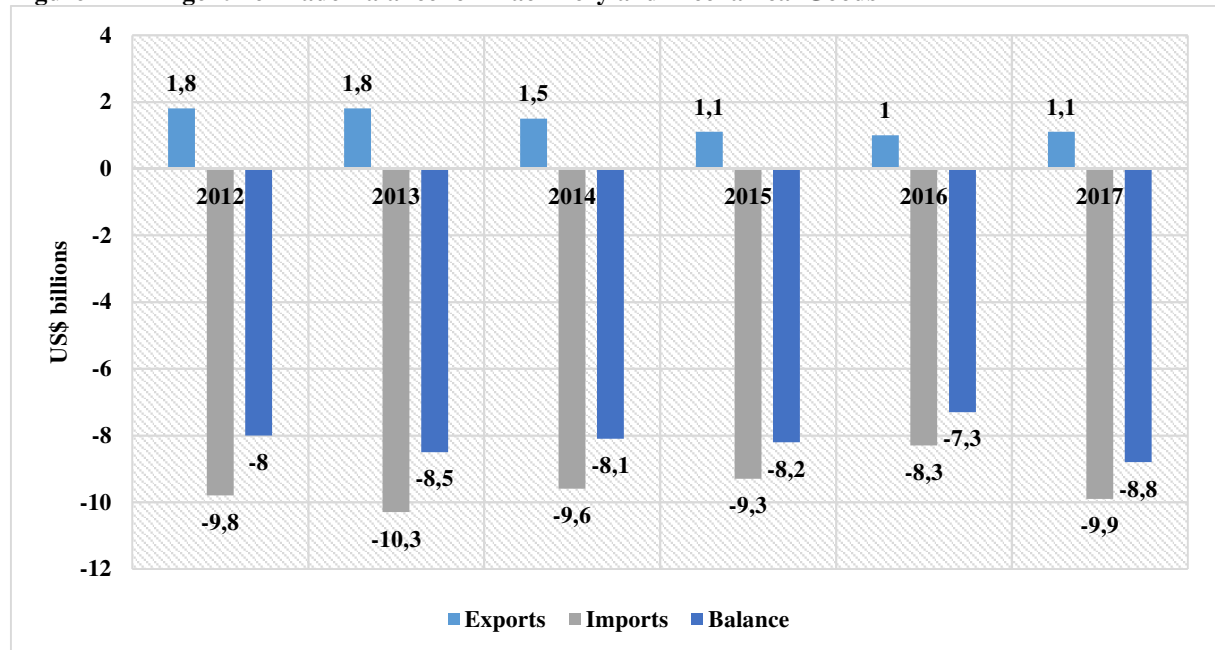
³² Information gathered at the Doing Business in Argentina: 2015. Available at <https://www.pwc.com/ar/es/doing-business/assets/doing-business-arg-2015.pdf> Visited on April, 18, 2018.

³³ Information gathered at the Doing Business in Argentina: 2015. Available at <https://www.pwc.com/ar/es/doing-business/assets/doing-business-arg-2015.pdf> Visited on April, 18, 2018.

market and, more recently, this sector lost space in domestic market as well. Such problem became more evident in the last decades with the strong process of de-industrialization that the country faces.

Argentina is heavily deficient in the trade of machinery and other industrial equipment and is considered an importer of machines. The weight of these products in exports is of little relevance, although the sector has strategic importance as provider of capital goods for other industrial sectors.

Figure 4-4 - Argentine Trade Balance for Machinery and Mechanical Goods



Source: INDEC. Elaborated by CCGI-EESP/FGV.

Thus, is the total amount of Argentine imports of machinery and mechanical products between 50 and 80 billion negatively affects the country balance of trade, as shown at the above figure.

4.2.2. Mapping Technical Regulation and Main Regulatory Authorities

There are many organizations responsible for issuing technical regulation in machinery sector in Argentina (see [Annex 4](#)). The most important ones being:

a) **Ministry of Production**³⁴: The Argentine Ministry of Production is the government agency responsible for defining standardization and quality control of industrial production. It also designs and executes the plans related to the promotion of the country's industrial production, as well as foreign trade. Many other secretariats and organization related to this Ministry are in charge of creating technical regulation in machinery sector.

b) **National Institute of Industrial Technology (INTI)**³⁵: The INTU is an Argentine body created by Decree Law 17.138 of December 27, 1957 to focus on science and technology matters. It is an autarchic entity that operates under the Ministry of Production, whose mission is to accompany and promote the growth of Argentine small companies, promoting federal industrial development through innovation and technology transfer. Nowadays, INTI has six

³⁴ Further information in <https://www.argentina.gob.ar/produccion>.

³⁵ Further information in <https://www.inti.gob.ar>

thematic areas in its headquarters in Buenos Aires, each with two or more INTI Centers and each with one or more fields of action and services.

c) **Ente Nacional Regulador del Gas - ENARGAS**³⁶: ENARGAS is an autarchic organism created by Law No. 24,076 - Regulatory Framework of the Gas Industry - in 1992. It is within the scope of the Ministry of Energy and Mining and is responsible for fulfilling the functions of regulation, control, inspection and resolution of disputes, which are inherent to the public transport and gas distribution service. Besides regulating the transport and distribution of natural gas it also issues regulations to adjust other laws in terms of safety, standards and technical procedures, measurement and billing of consumption and control and use of meters, besides other responsibilities related to specific machines.

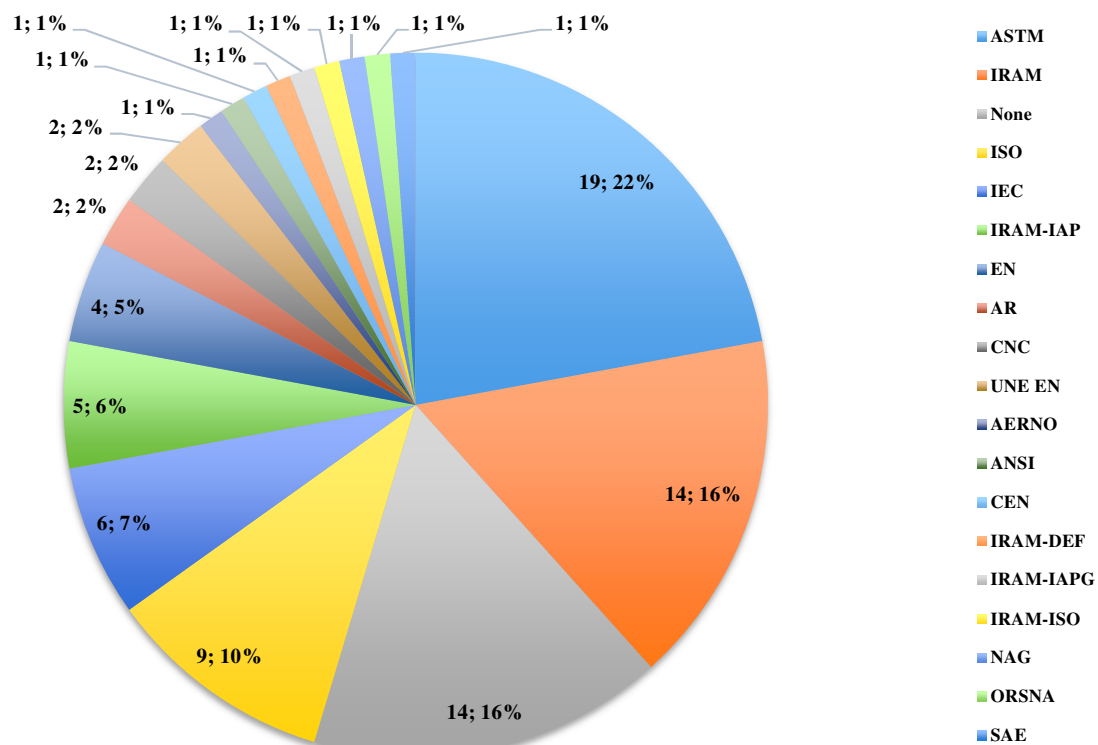
d) **Ente Nacional Regulador de la Electricidad – ENRE**³⁷: While the Ministry of Energy is responsible for setting policies regarding electrical issues, the Ente Nacional Regulador de la Electricidad (ENRE), an autarchic organism created by the Ley N° 24,065- Regulatory Framework of the Energy Sector - in 1992, is responsible for the regulation and general supervision of the sector under federal control. So ENRE and provincial regulators set technical regulations regarding the compliance of safety, quality, technical and environmental standards in machinery sector. Its competencies are clear: to issue regulations to which the producers, transporters, distributors and users of electricity must conform with in terms of safety, standards and technical procedures, measurement and billing of consumption, control and use of meters, interruption and reconnection of supplies, access to third-party properties and quality of services provided.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the machinery and mechanical sector.

³⁶ Further information in <https://www.enargas.gob.ar>

³⁷ Further information in <https://www.argentina.gob.ar/enre>

Figure 4-5 - Standards in the technical regulation notified to WTO/TBT



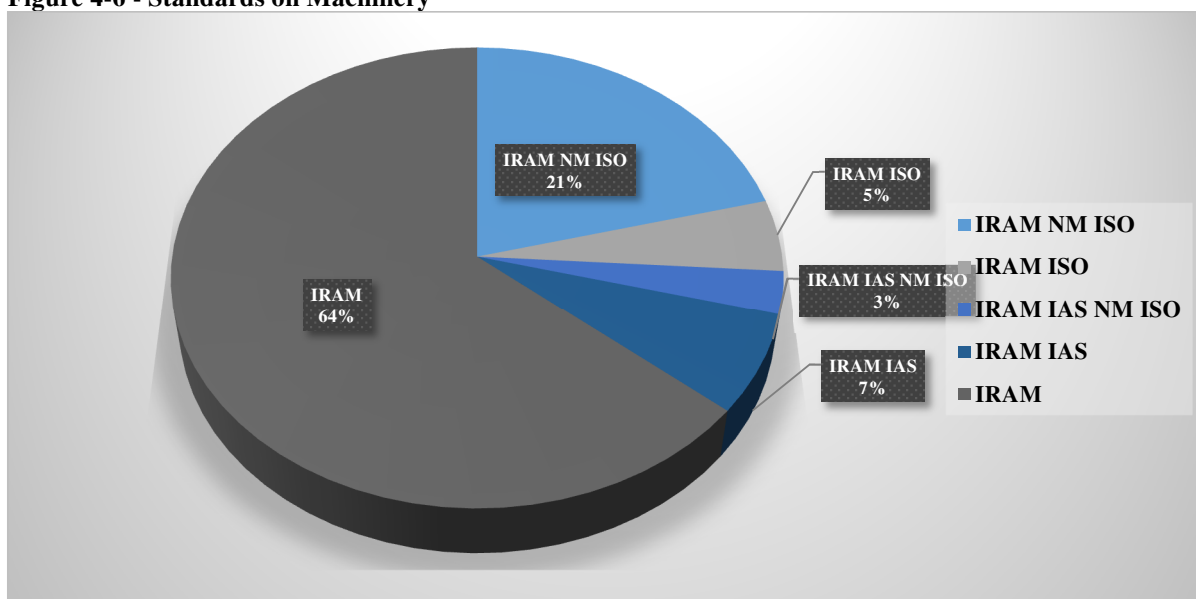
Source: WTO database. Prepared by CCGI -EESP/ FGV (March 2018).

The American Society for Testing and Materials (ASTM) standards correspond to 22 percent of the total notified, most of them by ENARGAS, which applied 14 different ASTM standards in one regulation. ASTM is an American association, created in 1898, but named, since 2001, ASTM International. Currently, the organization is responsible for more than 12,000 technical standards and has more than 30,000 members distributed in 140 countries. ASTM develops standards for various industrial sectors and in its directory there are 325 accredited laboratories for the compliance evaluation with standards developed by ASTM.

4.2.3. Mapping Technical Standards

The Argentine technical standards are produced by the Argentine Institute for Standardization and Certification (IRAM) (see [Annex 4](#)). Many of these standards are based on international standards, such as standards produced by the International Standardization Organization (ISO). Argentine standards that are mirrored in subregional standards (Mercosur) and industry standards (e.g. ASTM, UL) should also be highlighted.

Figure 4-6 - Standards on Machinery



Source: IRAM. Elaborated by CCGI -EESP/FGV.

In the machinery sector, standards produced by Mercosur Standardization Association (AMN) are relevant. It is interesting to note that almost all Mercosur standards on machinery and mechanical equipment are replicas of ISO standards.

4.2.4. Mandatory conformity assessment procedures

Resolution 595/99 regulates the intervention of the Argentine Association of Producers of Machines, Accessories and Similar Goods on the assessment of goods. The association, as an observer, will accompany the customs officers on the assessment practiced on the destinations of imports to consumption. A red signal of selectivity must have been attributed to the imports. The association must intervene on goods of the following tariff positions: 8456 to 8463, 8465, 8466, 85152100, 85152900, 85153100, 85153900, 85158010, 85158090, 85159000, 84122110, 84122190, 84122900, 84123110, 84123190, 84135010, 84135090, 84136011, 84136019, 84136090, 84811000, 84812090, 84813000, 84814000 and 84819090.

The association will indicate the names of technical personnel authorized for the task. The absence of the representatives on the assessment will not block the execution. The requiring association will arbitrate the necessary means to know the assessments to be done. The customs of Buenos Aires, Ezeiza and of the Interior will provide the necessary information to the performance of the assessment.

In general terms, the machinery sector has also to comply with Resolución SC N° 404/2015, according to which every certification and inspection bodies and any laboratory whose work is intended for the issuance of certificates of conformity and test protocols for compliance with mandatory certification schemes for products and services, established by the secretariat of commerce of the Ministry of economy and public finance, must have be duly registered. The following requirements must be met:

- Comply with the guidelines established in the IRAM ISO / IEC 17065: 2013 Standard;
- Have legal status in the country;

- Have been accredited by the Argentine Accreditation Body belonging to the National System of Standards, Quality and Certification, created by Decree No. 1,474 dated August 23, 1994;
- Have a staff of personnel based in the country that evidences background with a seniority and minimum experience of five (5) years in product certification by conformity mark and of three (3) years in the sector of activity for which aspires to be recognized;
- Have a decision-making certification committee with a seat in the country;
- No operation as a testing laboratory or inspection body;
- Assume civil, commercial, administrative and criminal liability arising from the certification functions, and the commitment to hire, in addition, civil liability insurance.

5. Electrical appliances

5.1. Electrical Appliances (Brazil)

5.1.1. Overview

Electrical goods are all goods and their parts that are powered by electricity. Electrical goods can be divided into three subsector: major appliances or white goods; small appliances; and consumer goods or brown goods.

Major appliances encompasses refrigeration equipment such as freezers, refrigerators and water coolers; cooking equipments such as cookers (range, stoves, ovens, cooking plates and cooktops) and microwave ovens; washing and drying equipment such as washing machines, clothes dryers and drying cabinets, and dishwashers; and air conditioners and air heaters, and water filters.

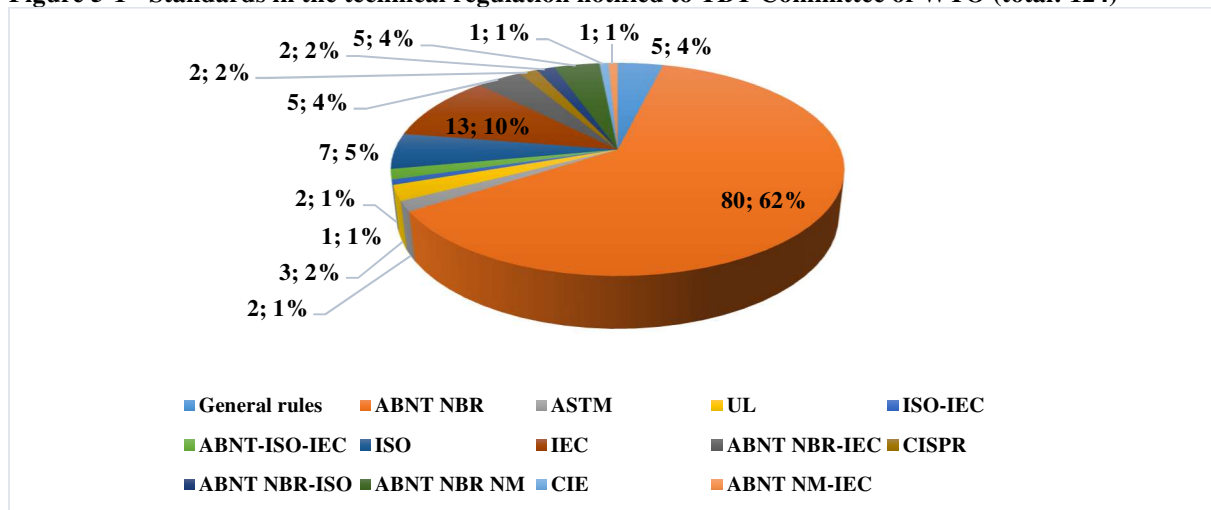
Small appliances includes lightbulbs and light fixtures, fans (table, ceiling and others), portable wineries, water jet washers, sewing machines, drills, vacuum cleaners, blenders, mixers, juice centrifuges, food processors, floor waxers, shaving appliances, hair cutting machine, depilatory devices, electric heating appliances, electric iron, grills, coffee or tea makers, toasters, deep fryers and other household equipment.

Consumer goods, small appliances or home electricals, are electrical or digital equipment for daily use. They are entertainment goods such as: musical instruments, flatscreen TVs, DVD players, DVD movies, iPods, video games and consoles, remote control cars, radio and audio devices, home theaters, cameras; communication and telecommunication goods: telephones, cell phones, smartphones, tablets, e-mail-capable devices and laptops, and home and office goods such as: laptops, desktop computers, printers, scanners, paper shredders.

5.1.2. Mapping of technical regulation

In Brazil Federal government, many ministries and numerous agencies have jurisdiction for establishing regulations to this sector, ensuring safety of goods, energy efficiency and regulating imports of such goods. The Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), and Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, the Energy Efficiency Indicators Management Committee (CGIEE), regulate the National Policy on Conservation and Rational Use of Energy. The Ministry of Labour and Employment (MTE) regulates safety in labour environment and production, as well as sectoral agreements between labour associations of a specific product or section and its employees. The National Institute of Metrology, Quality and Technology (INMETRO) and the National Agency of Telecommunication (ANATEL) are the primary regulators of electrical goods. In any case, the Brazilian Law requires all regulatory documents to be available online. The list of main regulation on electrical and electronic appliances is on [Annex 1](#).

Figure 5-1 - Standards in the technical regulation notified to TBT Committee of WTO (total: 124)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

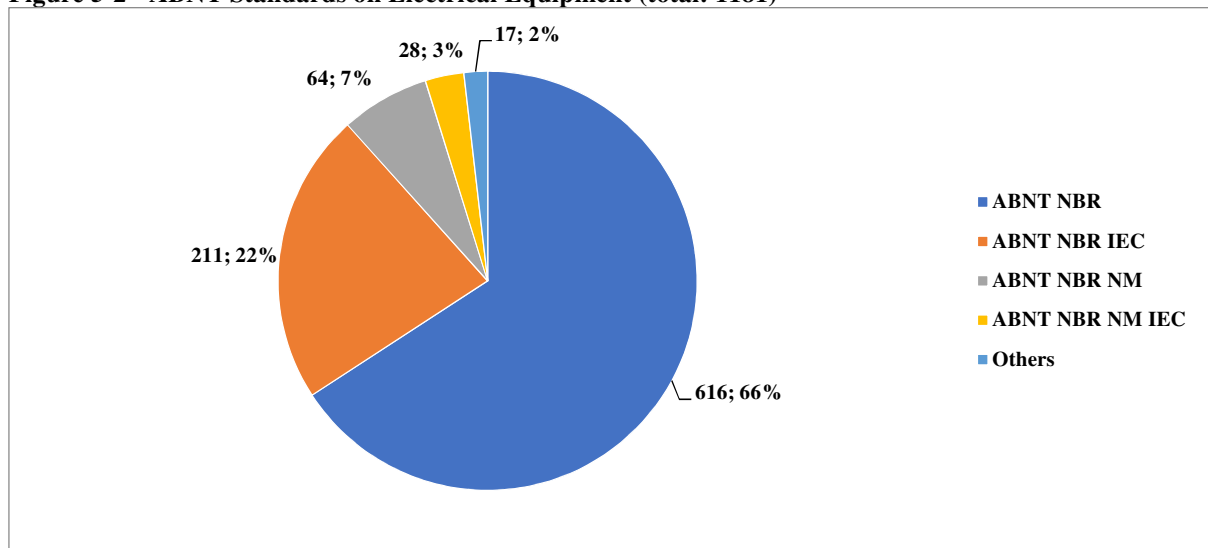
Figure 3 above demonstrates that 62 percent of all notified regulation is based on standards issued by ABNT. The other 38 percent is divided into ASTM, UL, ISO, IEC, ISO-IEC, CISPR, CIE and general rules, which means standards or regulation borrowed from other sector.

5.1.3. Mapping of technical standards

ABNT³⁸ issued about 1181 standards for electronic products or parts ([Annex 1](#)). The Committee on Electricity (ABNT/CB-003) has 936 norms, while the Committee on Computers and Data Processors (ABNT/CB21) has 51 norms. Committee on Air Refrigerators and Heaters (ABNT/CB55) has 42 norms, the Commission on Digital Television (ABNT/CEE-85) has 146 norms. Commission on Energy Management (ABNT/CEE-116), has 5 norms all of them ISO-based, and the Commission for Mitigation of Electric Interferences (ABNT/CEE-212) has only one standard. The following graphic illustrates the different types of ABNT standards on electrical equipment.

³⁸ A relevant number of technical regulations (especially those on conformity assessment procedures) refers to supporting standards, usually issued by ABNT, a private body. There are different kind of supporting standards issued by ABNT that goes from a fully original standard developed under its Standardizing Committees (CB) to those based on international standards, mainly ISO and IEC. Usually, (i) If it is a standard identical to an international standard, it will appear, for example, as *ABNT NBR ISO n° XXX*; (ii) If it is based on an international standard, a reference to this international standard will be in the preamble of the standard; and (iii) If it is an original standard, it will appear as *ABNT NBR n° XXX*. ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website. ABNT Catalog with all searching tools is available [here](#). In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard.

Figure 5-2 - ABNT Standards on Electrical Equipment (total: 1181)



Source: ABNT. Prepared by CCGI -EESP/FGV.

5.1.4. Mandatory conformity assessment procedures

Before a electronic product can be placed on the Brazilian market, it shall be registered with INMETRO and receive a registration number which shall be placed on the label of the product. Therefore, INMETRO is responsible for the compliance and registration of any electronic processing facility established in Brazil. Brazil does not have any policy for pre-market notification process. Each company registration or authorization to sell is the first step to have access to INMETRO services. There are, then, two registry and conformity assessment paths. The first is the Brazilian Labeling Program (*Programa Brasileiro de Etiquetagem* - PBE). PBE relates to energy efficiency and is part of the implementation of the National Plan for Energy Efficiency (*Plano Nacional de Eficiência Energética* (PNEf)), as regulated by the CGIEE. The current National Energy Plan (PNE2030) sets goals and establishes the PBE new requirements. All products at free zones establishments where electro- electronics are manufactured and packaged are under the PBE program. The second path is through Ordinance 371/2009, which establishes basic compulsory standards for all electronic products that does not fall under Inmetro's PBEs.

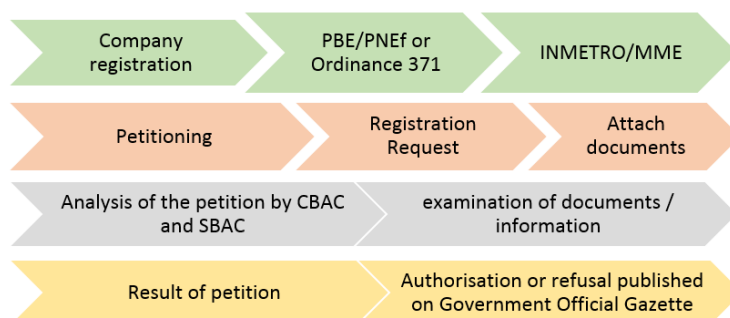
The conformity assessment procedure is compulsory for various electrical and electronic products. In certain cases, certification may be replaced by a supplier's declaration. Conformity assessment procedures are determined in INMETRO ordinances. These procedures often adopt international standards, especially those issued by the IEC, which is frequently mentioned in Brazilian technical regulations. The following table summarizes by products the conformity assessment mechanism, the issuing regulatory agency, the ordinance number and standards and other regulation mentioned. In total, 28 percent of all Brazilian Technical Regulation use Brazilian standards, while 72 percent are based on international standards.

Moreover, the Good Manufacturing Practices (GMPs) include a set of measures that should be adopted by the electro-electronic companies, in order to ensure the quality of the products. Each type of product has its own specifications, but all shall comply with the Ministry of Labor regulations. The certification procedure consists of official certification bodies, or officially recognized certification bodies ensure, recognizing that the electro-eletronic products or parts, or their control systems, are in conformity with the requirements of a standard. Where possible,

alternative measures are considered for certification, such as, special inspection systems or equivalent requirements of trade partners are alternative measures considered when possible.

This registration flow is illustrated bellow:

Figure 5-3 - Brazilian Electronic and Electric Goods Registration Flow



Source: INMETRO, 2017.

Bilateral or multilateral treaties such as mutual recognition agreements may be stipulated. INMETRO, the only accreditation body in Brazil, usually negotiates such agreements. The Conformity Assessment Brazilian System (SBAC) and Conformity Assessment Brazilian Committee (CBAC) are regulated by CONMETRO Resolution 4/2002. Importers and like producers of electro-electronic goods under the compulsory list shall register their products and pay fees, which vary according to the type of product and the size of the company. The competent public body for dealing with imports and their conformity with domestic regulations is the Department for Foreign Trade Operations (*Departamento de Operações de Comércio Exterior* – DECEX). All products shall have an Import License (*Licença de Importação* – LI) previous to its shipping at the Integrated System of Foreign Trade (*Sistema Integrado de Comércio Exterior* – SISCOMEX). If it is a good exclusive for industrial use, or if it is a like product to those listed at Ordinance 371/2009 of INMETRO or even if they are just samples, INMETRO can issue a Declaration of Import Liberation (*Declaração de Liberação de Importação*), in accordance with terms set at Ordinance 199/2011.

5.2. Electrical Appliances (Argentina)

5.2.1. Overview

The Argentine electrical sector results from import substitution industrialization, which began in the 1930s and deepened in the following decades, especially in the governments of Perón and Frondizi. The direct foreign investments of large transnational corporations were also important for the sector development. Most of them located in the Buenos Aires, the largest industrial cluster in the country, and in cities such as Córdoba, Rosario, Tucumán, Mendoza, and Tierra del Fuego.

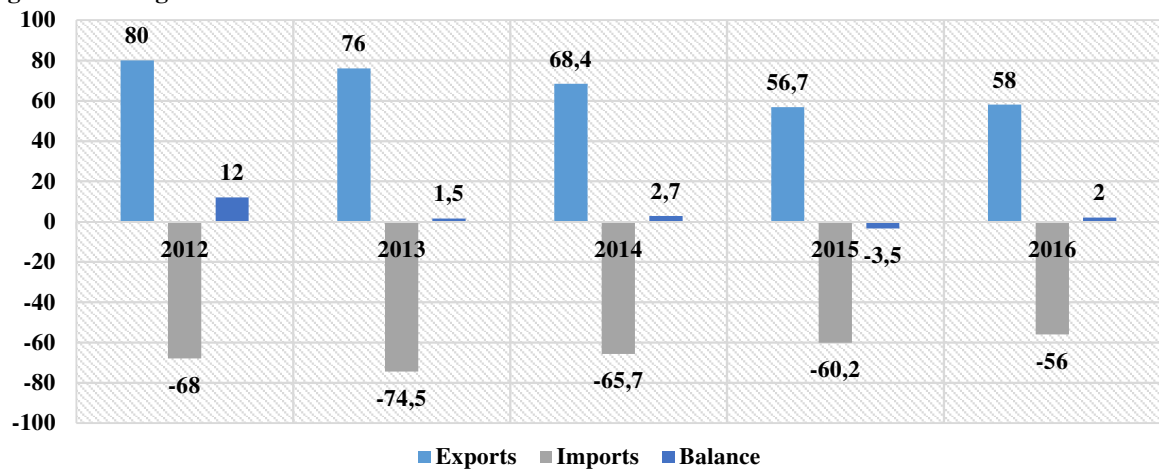
Like other sectors resulting from protectionist development policies, the electrical sector in Argentina always had problems in competing with similar products in the international market and, more recently, lost space in domestic market. This problem became more evident in the last decades when the global economy became more connected and interdependent, while

Argentina had to cope with a strong process of de-industrialization.

Nowadays, Argentina is an importer of electrical and electronic products, although the sector has some expression in the assembly of electrical and electronic products, including telecommunications, based on imported components. The weight of these products in the Argentine exports is also of little relevance, although the sector has strategic importance in manufacturing chain of some products, such as vehicles and building sector.

As it can be seen in its trade balance the foreign trade in Argentina is relatively stable. Over the last five years, according to data collected on INDEC, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods.

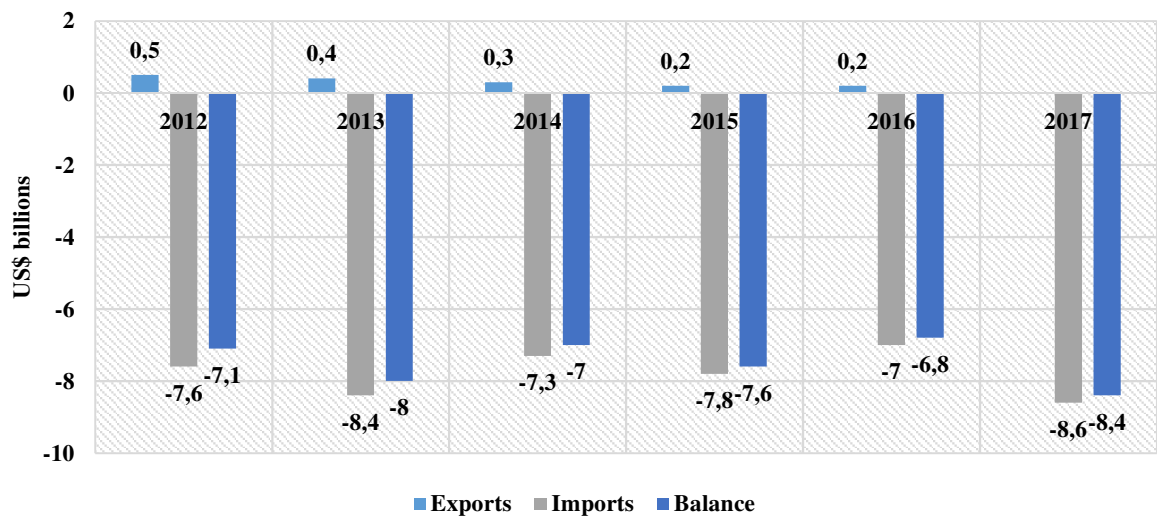
Figure 5-4 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

Regarding the electrical trade balance, in the last five years, Argentina has presented a significant deficit. This characteristic indicates a strong dependence on imports of this type of product, which total between 50 and 80 billion.

Figure 5-5 - Argentine Trade Balance for Electrical Products



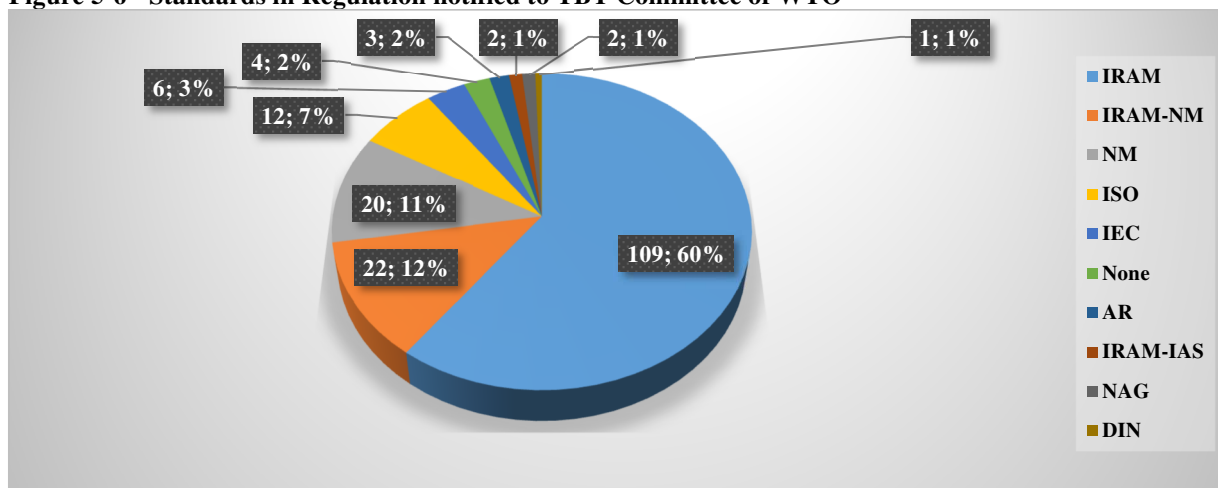
Source: INDEC. Elaborated by CCGI-EESP/FGV.

Argentina develops domestically an important part of the technical standards used in the production process of electrical and electronic appliances, although it also uses sporadically international standards produced mainly by the International Standardization Organization (ISO) and International Electrotechnical Commission (IEC). The technical regulation derives mostly from the activity of *Asociación Electrotécnica Argentina* (AEA). The AEA is a private non-profit entity that performs an important normalization function and, through state delegation, specific regulatory activity. The standards are developed by the *Instituto Argentino de Normalización y Certificación* (IRAM).

5.2.2. Mapping of technical regulations

Technical regulations notified by the Argentine government to the WTO under the Agreement on Technical Barriers to Trade (TBT) may also elucidate the big picture of electrical sectoral regulation in the country. All projects of technical regulations that impact international trade, have to be notified to the WTO. From January 1st, 1995 until March 8th, 2018, there were twenty-two notifications. The provisions of technical regulation usually use standards produced by international or Argentine standardization bodies.

Figure 5-6 - Standards in Regulation notified to TBT Committee of WTO



Source: WTO. Elaborated by CCGI-EESP/FGV.

As stated before the main subject contained in such technical regulation notified to TBT Committee is the user's safety of electrical products.

There are many organizations responsible for issuing technical regulation in electrical sector in Argentina. Most of them, such as Secretariat of Trade, National Directorate of Domestic Trade and Ministry of Competition, Deregulation, National Directorate of Domestic Trade, and Consumer Protection are part of the Ministry of Production. Other ones are the Ministry of Energy and Mining, the National Regulatory Agency for Gas (ENARGAS) and the National Regulatory Entity for Electricity (ENRE).

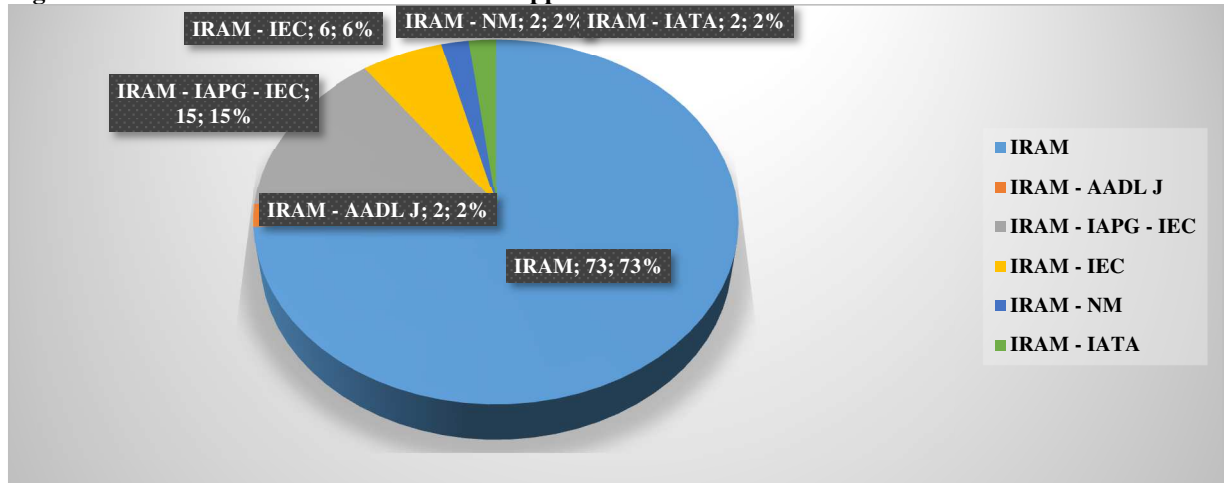
Most of the technical regulations concerning electrical equipment concern the safety of workers who operate the electrical appliance. With regard to the correct functioning of the apparatus, the most important are the voluntary standards produced mainly by *Instituto Argentino de Normalización y Certificación* (IRAM), *Asociación Electrotécnica Argentina* (AEA) and international standardization bodies. More regulation in [Annex 1](#).

5.2.3. Technical Standards

The technical standards used by the sector are usually domestically produced by IRAM and *Instituto Argentino del Petroleo y del Gas* (IAPG) (see [Annex 1](#)). Some of them are based on technical standards produced by international standardization bodies such as ISO and IEC. These standards are voluntary but are compulsory if specifically referred to by a technical regulation. They must be used in conjunction with the mandatory requirements of the AEA.

Most of the standards used in the electrical sector are homegrown standards. Considering as international the IEC standards and those produced by some Committee of the Mercosur Standardization Association (AMN), it is observed that they correspond to a little more than 20% of the IRAM standards, which may indicate a low degree of internationalization of the sector.

Figure 5-7 - IRAM Standards for Electrical Appliances



Source: IRAM. Elaborated by CCGI-FGV/EESP.

As electrical appliances are used in productive processes in various sectors of the economy, many technical standards are designed by standardization bodies apparently unconnected to the electricity sector. For example, the standards produced by *Instituto Argentino del Petroleo y del Gas* (IAPG) and *Asociación de Ingenieros y Técnicos del Automotor* (AITA) can be highlighted as important standards for the correct use of electrical appliances.

5.2.4. Mandatory conformity assessment procedures

In terms of conformity assessment, it should be highlighted the *Resolución* (Resolution) 171/2016, which contains important definitions of technical expressions and prescribes the necessity of certification of low voltage electrical products.

In the *Resolución*, it is clear the importance of IRAM, which acts as the main normalizing body and as an important certification body (articles 4 and 5). The conformity assessment models are provided in art. 5 and may be divided in three models: terms of type, conformity mark and batch. These modalities are provided in detail in Article 1 of *Resolución* No. 197 of December 29, 2004 of the former SECRETARIAT OF TECHNICAL COORDINATION of the former MINISTRY OF ECONOMY AND PRODUCTION.

The way certification is done is based on standards produced by IRAM, which confers an advantage to Argentine conformity assessment bodies. The Argentine network of conformity assessment bodies is made up of organizations originally from Argentina and other international bodies.

6. Medical devices

6.1. Medical Devices (Brazil)

6.1.1. Overview

The proliferation of medical devices in the world symbolizes technological advances for diagnostic and treatment purposes. However, it can also represent risks to patients and users of these products. Thus, it requires both control and protection, including a “regulation of health risk” approach, instead of a mere general market regulation rationale.

Brazil is the largest medical device market in Latin America. This industry is capable of supplying 90% of the internal market needs and exports to more than 180 countries generating around 60,000 jobs in the country³⁹. According to the Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment (*Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios - ABIMO*), Brazil has 418 companies related to health products, including manufacturers, importers and distributors.

The Brazilian medical devices sector is segmented into: Dentistry (equipment, consumer and instrumental material), Laboratory (equipment, reagents and consumer products), Radiology (apparatus, accessories and consumables), Medical and hospital equipment (non-electrical, electro-medical, surgical instruments, physiotherapy and general equipment), Implants (orthopedic, neurological, cardiac and others) and Consumer materials (hypodermic, textile, adhesives and others).

In Brazil, the Federal Law 6,360/1976 is the main regulatory legal norm controlling this sector. It establishes that medical devices may be solely manufactured or imported for use or for sale exhibitions, after the Ministry of Health (MS) has announced whether or not registration is mandatory. In addition, certificate of conformity can be required for some medical devices, especially for electro-medical equipment.

Nowadays, the competence to guarantee the sanitary safety of medical devices is under the Brazilian Health Regulatory Agency (ANVISA) responsibilities, even though product certification remains under the Brazilian National Institute of Metrology, Quality and Technology (INMETRO) obligation.

6.1.2. Mapping Technical Regulation

The main agencies dealing with technical regulations from medical devices sector are ANVISA and INMETRO (see [Annex 5](#)). There is only one non-governmental body with a relevant role in promoting private and international standards, which is the Brazilian Association on Technical Standards (ABNT)⁴⁰. The role and standards published by this association are also covered in this report.

³⁹ Data available at Brazilian Health Devices web site in <http://brazilianhealthdevices.com.br/market> 5/4/2017.

⁴⁰ All acronyms will be used in its Portuguese version, simplifying the references to national regulation applying such acronyms.

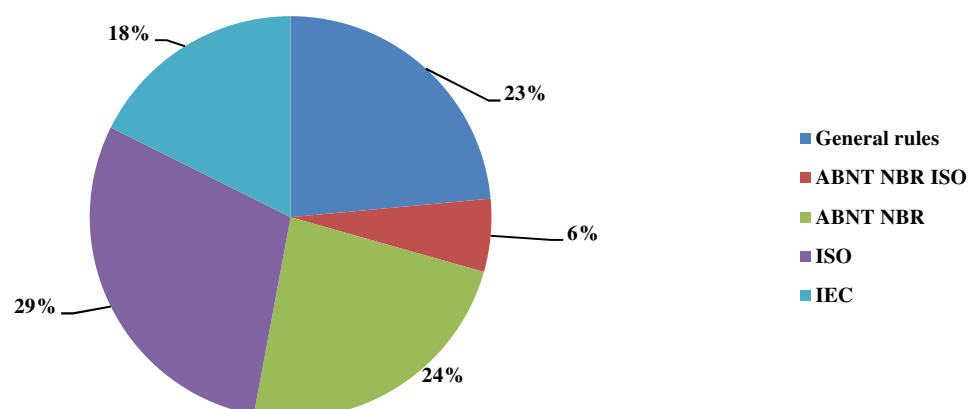
While ANVISA⁴¹ determines that all suppliers of medical products shall obtain its approval prior to selling them in Brazil and after classifying them by the risk-level they represent to the health of consumers, patients, operators, or third parties involved, INMETRO maintains the national measurement standards in the country, evaluates compliance requirements for products manufactured in or imported into Brazil and implements the national policies on metrology and quality⁴².

Projects of technical regulations that impact international trade are to be notified to the Committee on Technical Barriers of the World Trade Organization (WTO). In addition to INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly Ministry of Mines and Energy.

From January 1st, 1995 until March 30th, 2017, there were 23 notifications from Brazil on TBT. In May 3rd, 2017, 13 of them were still in force. INMETRO has traditionally by far been the main body having technical regulations notified before the WTO.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on the sector.

Figure 6-1 - Standards in technical regulations notified to WTO (%) (total: 13)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

The standards ABNT NBR correspond to sixty-two percent of the total notified. Such standards are issued by the Brazilian organization ABNT, without explicitly endorsing any international standard. The ISO and ISO/IEC standards have also a relevant role, in comparison to other. The ISO and ISO/IEC standards are frequently adopted by certain governmental agencies or incorporated do ABNT's standards.

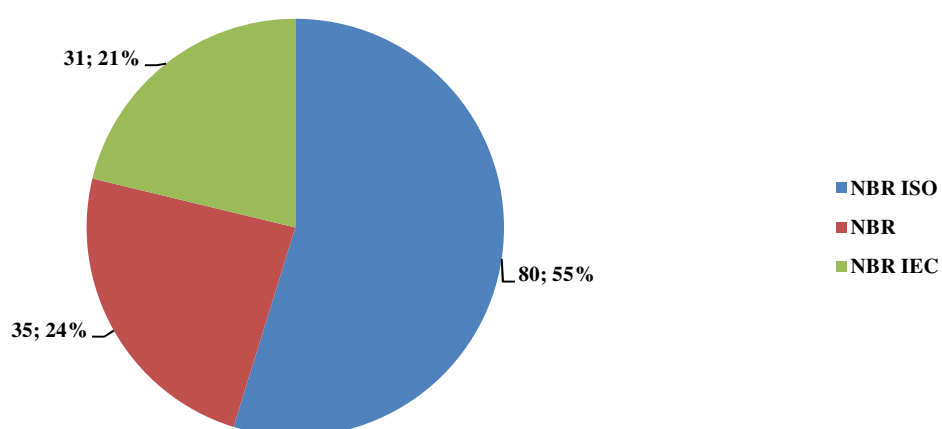
⁴¹ Resolution 59/2000.

⁴² Information available at: <http://inmetro.gov.br/english/institucional/index.asp>.

6.1.3. Mapping Technical Standards

The Brazilian Association of Technical Standards (ABNT) develops Brazilian standards and adopts international ones into Brazilian regulatory scheme characteristics. Specifically, for medical devices, currently ABNT has 146 standards, of which 35 are elaborated in Brazil (NBR), 31 are a translation from standards developed by the International Electrotechnical Commission (NBR IEC) and 80 are a translation from standards developed by the International Organization for Standardization (NBR ISO) (see [Annex 5](#)). As technical standards, they are not compulsory in isolation, but ANVISA Resolution no. 444/1999 makes them compulsory for certification of conformity and requires registration before the release in the market.

Figure 6-2 - Standards and supporting standards of ABNT (%) (total: 146)



Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

With respect to the use of technologies involving ionizing radiation, since 1988, the Brazilian National Commission for Nuclear Energy (CNEN) has defined technical requirements for radioprotection through the CNEN-NE-3.01 standard, establishing Radioprotection and Safety Requirements specifically for Medical Services Nuclear and Radiotherapy respectively in 1989 and 1990 through standards CNEN-NN-3.05 and CNEN-NE-3.06.

However, legislation regarding radiological protection in medical and dental radiodiagnosis was only established in June 1998 by the Ministry of Health and the Secretariat of Sanitary Surveillance through Ordinance No. 453, which also contains technical requirements for the implementation of metrological reliability of these devices.

6.1.4. Mandatory conformity assessment procedures

Concerning ANVISA's registration process⁴³, first, these instruments have to be listed in one of the four classes in ascending risks: classes I, II, III and IV representing low-, medium-, high- and very-high-risk devices. If it is listed as Class I or Class II it is not required registration, unless it has potential risk involved. Class III and Class IV devices require listing and

⁴³ According with Resolution 185/2006.

registration and in the registration process it shall be specified all parameters and specifications of the device⁴⁴.

ANVISA medical device approval process involves the following steps: **Step 1:** Determine device classification using ANVISA's rules (Annex 2: ANVISA: Products Classification); **Step 2:** For all classes: Appoint a company that holds a Company Working Allowance permit from ANVISA as the Brazil Registration Holder (BRH); **Step 3:** For all classes: Provide Letter of Authorization to the BRH, who will submit the registration application to ANVISA. The BRH maintains control of the device registration and Brazil Good Manufacturing Practice (BGMP) certification; **Step 4:** For all classes: Certain devices⁴⁵ require INMETRO Certification. Testing for electro-medical products performed outside Brazil is usually accepted, if performed by an ILAC-certified lab (CB Scheme is not accepted). Third edition of IEC 60601 testing is mandatory. All tests performed outside of Brazil must be less than two years old when they are submitted to INMETRO Certifier; **Step 5:** For Class I and II (*Cadastro*): Class I and II device manufacturers must comply with BGMP requirements. However, ANVISA will not conduct an audit. For Class III and IV (*Registro*): Class III and IV manufacturers must be audited for BGMP compliance by ANVISA as outlined in RDC 16/2013. BGMP fees are due every two years; **Step 6:** For Class I and II (*Cadastro*): Prepare Technical Dossier and application for registration. Send legal documents, as well as proposed RDC 185/2001-compliant labeling (IFU and labels) to BRH. These files are maintained by the BRH in case of ANVISA on-site inspections. For Class III and IV (*Registro*): Prepare Technical File, including clinical data, clinical studies (if applicable), information on the device in accordance with Annex III, Part A, B, and C in RDC 185/2001, and proposed labeling (IFU and labels) per Annex III Part B; **Step 7:** For all classes: BRH prepares and submits the application to ANVISA. All documents must be submitted in Brazilian Portuguese; **Step 8:** For all classes: ANVISA reviews registration application. Upon approval, ANVISA will publish registration number in the Diário Oficial da União (DOU); **Step 9:** Class I and II registrations do not expire. Class III and IV registrations are valid for 5 years. Registration renewals must be initiated one year, and no later than six months, prior to expiration; **Step 10:** For all classes: Appoint a qualified importer/distributor to bring the device into Brazil.

Besides those health products must have proven safety and effectiveness. It shall be submitted a specific clinical testing with the product to be registered by ANVISA in the following situations:

- Innovative health products, regardless of their risk class (innovation in design, raw material, indications for use, among others);
- Health products of risk class III and IV that require safety and effectiveness verification using specific clinical data of the product submitted, due to their unique nature and performance linked to the material design and manufacturing process.

The Resolution [RDC no. 56/2001](#) establishes the need of compliance with essential requirements of safety and effectiveness of health products. It determines that these requirements must be based on clinical data, especially for health products of risk class III or IV, as follows:

⁴⁴ Medical products submitted to clinical research are hereby exempt from registration, provided that they comply with the legal provisions of the competent health surveillance authority on the performance of this activity, prohibiting such products to be commercialized and used for other purposes.

⁴⁵ Includes a variety of devices, such as breast implants, sterile hypodermic syringes, sterile needles, examination/surgical gloves, condoms, certain mattresses, blood bags, intrauterine devices, protective (laser) glasses, and those electro-medical devices outlined in IN 4/2015.

- compilation of scientific bibliography of indexed publications related to clinical researches on the product's intended use and, if applicable, related to written reports containing a critical review of this bibliography; or
- results and conclusions of a clinical research specifically conducted on the product.

The Resolution [RDC no. 40/2015](#) determines the requirements of registration of medical products, established in Article 4, Paragraph 1, ANVISA may request the submission of additional documentation and information for “technical reasons, in order to prove the safety and effectiveness of products due to potential public health risks, and for those products considered strategic by the Ministry of Health.”

In these cases, a clinical assessment report must be submitted at the time of application for listing and registering, contemplating clinical trial(s) that provides valid and sufficient scientific evidence for verification and confirmation of the safety and effectiveness. Several methodologies and study designs can be used to prove the safety and effectiveness of a medical product.

“The specificities of the product and risks associated with its use shall be taken into account, thus contemplating randomized clinical trials with control group” and well-documented series of case studies. “The selected methodology must be appropriate to provide valid safety measures and clinical performance” and the “level of evidence required to approve the product will depend on its indication for use, characteristics of the device, its level of innovation, among other aspects”⁴⁶.

In general, the clinical development of a health product is divided into the following phases: pilot and pivotal. “The purpose of the pilot or feasibility phase, which begins with the first clinical use of the product, is to establish the safety of the product, initial parameters of effectiveness, and assist in the development of the subsequent pivotal study”. The pivotal study confirms that the product is safe and effective for its target population. “Pivotal studies are usually well-controlled experimental studies using either control or partially controlled groups. Pivotal clinical studies with confirmatory methodological characteristics of safety and effectiveness will be requested.” Non-pivotal studies may be accepted in some cases, depending on the specificity of the product, as previously clarified (e.g. health products indicated to treat a rare clinical condition).⁴⁷

Clinical trials must include clinical condition(s) and target population for the medical products. The duration of the clinical study shall be adjusted to assess the expected effectiveness of the product as well as the occurrence of events and acute and late side effects. Robust outcomes shall be used, preferably clinical endpoints or the combination of clinical and surrogate or imaging endpoints, and the study design shall contain the methodology that allows a direct relation between the findings and the performance of the product tested. The rationale shall be demonstrated in order to determine the sample size of the study (number of participants), and the same must be obtained through statistical grounds and adjusted to the clinical development stage of the product.

⁴⁶ Technical note no. 004/2016/GGTPS/DIREG/ANVISA

⁴⁷ Technical note NO. 004/2016/GGTPS/DIREG/ANVISA

The results of clinical trial(s) shall be submitted to ANVISA in the form of report, as well as publications in scientific journals related to these trials, if already available in the scientific literature. The following information must be contained in the documentation, when applicable:

- Objectives of the research;
- Description of the study design;
- Inclusion and exclusion criteria;
- Hypothesis of the study;
- Definition of primary and secondary outcomes (safety and effectiveness endpoints);
- Criteria for the study success;
- Allocation of type I error (alpha) for the hypothesis evaluated;
- Type II error;
- Demonstration of the statistical analysis plan;
- Rationale to determine the sample size;
- Statistical methods used;
- Submission of results and data evaluation;
- Safety and effectiveness evaluation plan for the ITT population (intention-to-treat) or PP population (per protocol);
- Method, in case of blinding;
- Evaluation of adverse events.

Finally, the studies submitted to ANVISA must comply with ethical and Good Clinical Practices principles. Clinical trials performed in Brazil shall comply with [RDC no. 10/2015](#) or with standards that preceded it⁴⁸.

ANVISA suspends the registration of medical devices in the following cases:

- a) when the validity of any document is suspended for safety reasons and is duly justified;
- b) when the non-compliance with any requirement has been proven;
- c) when the product is being investigated by the competent health surveillance authority due to irregularities or defects found in the product or in its manufacturing process, representing a risk to the health of consumers, patients, operators, or third parties involved.

ANVISA cancels the registration of medical products in the following cases:

- a) when there is proof that the information in any document has been forged or when any of these documents has been cancelled by ANVISA;
- b) when the product or its manufacturing process has been proven by Anvisa to be a risk to the health of consumers, patients, operators, or third parties involved.

To investigate this cases ANVISA counts on a surveillance system for adverse events and technical complaints related to health products in post-marketing phase, aiming to recommend the adoption of measures to ensure people's health protection and promotion. This is called technovigilance whose requirements are determined by the RDC no. 67/2009.

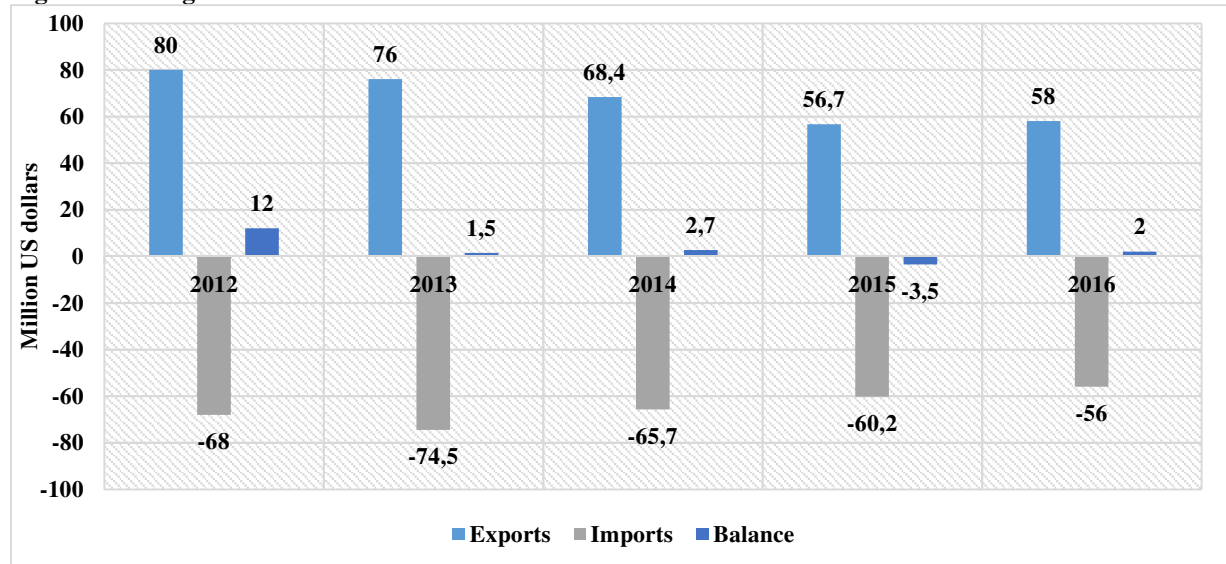
⁴⁸ For details on Good Manufacturing Practices see Annex 3.

6.2. Medical Devices (Argentina)

6.2.1. Overview

The foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of electrical materials and equipment.

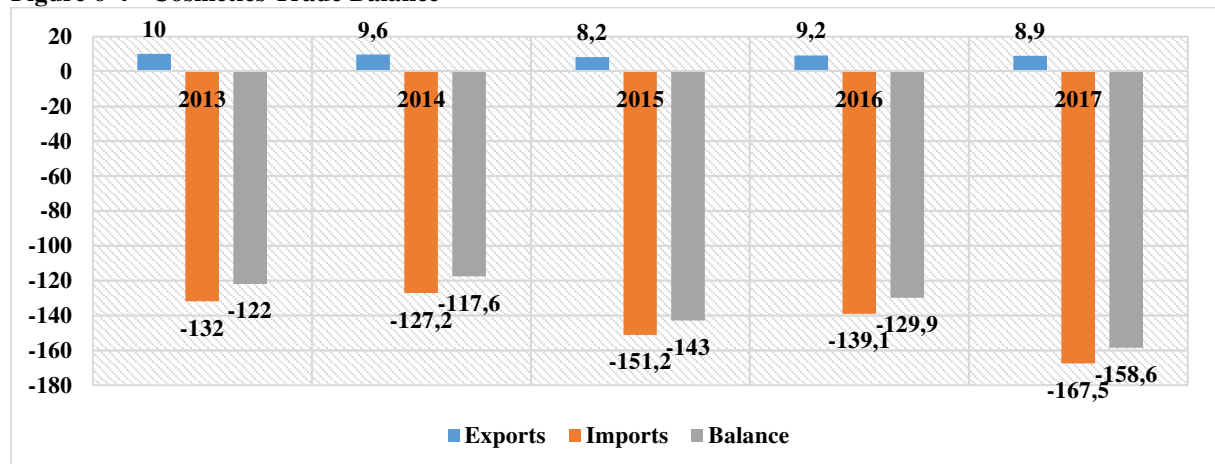
Figure 6-3 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

The medical devices sector presents significant deficits. Despite the production of some types of medical devices on the country, health services are heavily dependent on imported equipment. During the last five years, trade deficits have been higher than US\$ 115 million. Exports oscillated around US\$ 8,2 million and US\$ 10 million. Imports, on their turn, oscillated around US\$ 127,2 million and US\$ 167,5 million.

Figure 6-4 - Cosmetics Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV

6.2.2. Mapping Technical Regulation and Authorities

Argentine laws and regulations aim to provide access to qualified and efficient health services and to define criteria of use of existing technologies. The main issues regulated by national laws are the importation of medical devices and the conditions for the use of medical devices.

Law 21908/1978 establishes the rights of importation of equipment of medical use. The systems, equipment and apparel of medical use of advanced technology are exempted of payment of importation taxes and the value added tax when they satisfy the following requisites:

- they constitute a relevant improvement of the existent techniques about medical research, diagnosis or any step of the process of medical attention;
- they are considered of high cost;
- their production is not on the country and
- they are conceded at no cost in favor of the State to be used in no less than 20% of useful time or of the complete and integral benefits of such systems, apparel or equipment during their useful life.

The State Secretariat of Public Health has a relevant role as it will extend, on each case, a certificate of necessity aiming to guarantee a rational distribution and exploitation of the resources. It will formalize an agreement that will regulate the concessions at no cost in favor of the State to be used in no less than 20% of useful time or of the complete and integral benefits of such systems, apparel or equipment during their useful life. The State Secretariat of Public Health, the respective sanitary authority and the entity that provides the service will be part of the agreement. Such agreement, legally formalized, will be the previous condition that will allow the ministerial resolution of franchising importation.

Resolution 30/1997 updates norms that regulate the importation of products considered medical apparel and equipment subject to the intervention of ANMAT. In order to regulate the importation of medical apparel and equipment, the procedure foreseen on the resolution will be applied to the tariff positions of the Common Nomenclature of Mercosur (*Nomenclatura Común del Mercosur*, NCM) foreseen on the following positions: chapter 28 (only diagnosis reagents), chapter 29 (only diagnosis reagents), 3002.90.10, 3005.10.20, 3005.10.30, 3005.10.40, 3005.10.50, 3005.10.90, 3005.90.11, 3005.90.12, 3005.90.19, 3005.90.20, 3005.90.90, 3006.10, 3006.40, 3822.00.00 (only diagnosis reagents), 3926.20 (only for medical use), 3926.90.30, 4015.11, 4015.19 (only for medical use), 9004.90.10, 9018.11, 9018.12, 9018.13, 9018.14, 9018.19, 9018.20, 9018.31, 9018.32, 9018.39, 9018.41, 9018.49, 9018.50, 9018.90, 9019.10, 9019.20, 9021.11, 9021.19, 9021.21, 9021.29, 9021.30, 9021.40, 9021.50, 9021.90, 9022.12, 9022.13, 9022.14 and 9022.21.

Decree law 2469/58 establishes conditions for the use of every medical instrument or equipment with diagnosis or therapeutic goals. Every element, material, instrument or equipment of medical use that is applied with diagnosis or therapeutic goals must be used by enabled professional and under its responsibility.

Law 14583/2013 is the main provincial law that regulates medical equipment. It establishes a regulation and oversight regime of medical equipment in use in relation with its technical fitness in terms of security and efficacy on public and private health institutions on the province of Buenos Aires. Every following reference to the regime will be done under the simplified denomination VATEM (Verification of Technical Fitness of Medical Equipment).

The adopted definition of medical equipment is the one created by the National Administration of Medicine, Food and Medical Technology foreseen on disposition ANMAT 2318/2002. The medical equipment is categorized according to the intrinsic risk they represent to the health of the consumer, patient, operator or interested third parties. The categorization norms established by the application authority must be applied to categorize medical equipment.

The law also creates the Provincial Registry of Medical Equipment in Use and of Lenders. The health institutions must annually present an official declaration to the corresponding sanitary region that includes the name of medical equipment in use on each establishment.

The main institutions that regulate the use of medical instruments or equipment with diagnosis or therapeutic goals are the Ministry of Social Assistance and Public Health, the Coordinating Unity of Evaluation and Execution of Health Technologies, the Medical Argentine Association and the Executive Power.

Inside the Medical Argentine Association, the Directive Commissions of the Medical Argentine Association (*Asociación Médica Argentina*, AMA) and the Society of Ethics in Medicine created the Code of Ethics of the Argentine Medical Association for Health Equipment. The main goal of the code is to serve as a guide for the performance of AMA's associates and for all other members that wish to adhere to the code.

Chapter 21 of the code regulates conditions of sale and use of medical equipment. The companies that produce or trade medical equipment must guarantee the quality of the offered product, comply the term conceded by the guarantee, train, if necessary, the personnel involved on its use, offer the reparation or substitution of the damaged elements and install the equipment according to norms in force about labor safety.

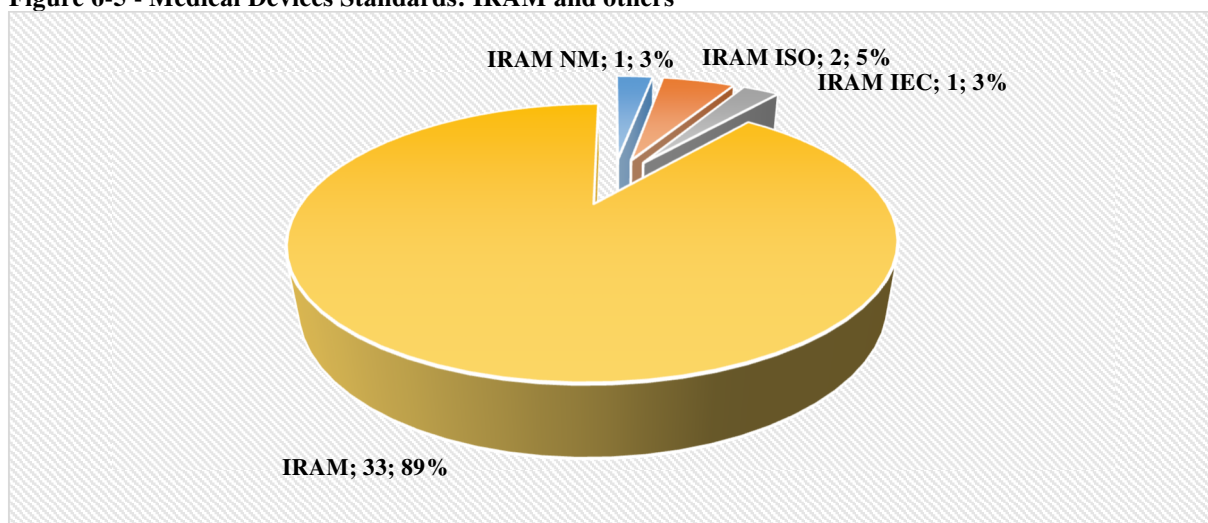
The companies involved on the provision of medical equipment must respect the norms foreseen on the national legislation about the issue. The conduct that can induce mistake, error, confusion or obscurity about the secondary effects of medical equipment will be considered a violation of ethics. The intermediates that trade medical equipment are also responsible for the quality of such products.

Considering the current technological developments to the practice of invasive methods, the companies that produce and trade them and the people that work on them must guarantee the safety of patients and of the doctors.

6.2.3. Mapping Technical Standards

In Argentina, there are several standards applicable to medical equipment. The vast majority of standards consist of standards originally produced by IRAM. A small minority of standards consist of the adoption of international standards.

Figure 6-5 - Medical Devices Standards: IRAM and others



Source: IRAM. Elaborated by CCGI-EESP/FGV.

6.2.4. Mandatory conformity assessment procedures

The medical equipment in use, established by the application authority, must be object of technical verification, test or calibration according to the applicable norm or standard and/or indication of the producer according to the periodicity established by the application authority. The technical verification, test or calibration must be done by laboratories accredited by the Argentine Accreditation Organism (O.A.A.), belonging to national universities on the province of Buenos Aires, the National Institute of Industrial Technology (I.N.T.I.) and other agents authorized by the application authority, being obliged to comply with norms established on the issue for the territory of the province of Buenos Aires.

The application authority must extend a certificate of assessment of medical equipment in use for cases in which the parameters obtained in the technical assessment, test or calibration are adjusted to the corresponding norm/standard. The authority must also determine the period of enforcement of the document that must be updated on equal periods.

The certificate can be without effect at any moment if it is proved that the equipment does not comply totally or partially the requisites foreseen on the law. When there is a drop of an indispensable equipment for the specialty and there is no other equipment to continue the supply of the service, the establishment must interrupt the internment of patients of this specialty.

The application authority will register and archive the informs in which there is a technical protocol of assessment under norm/standard, the result of the inform, the date of emission, the norms applied, the observations and the responsible person. The application authority must also, on a regular and systematic form, do inspections conformity assessment of medical equipment in use.

7. Pharmaceuticals

7.1. Pharmaceuticals (Brazil)

7.1.1. Overview

The medicines and pharmaceutical sector is a relevant sector for Brazil. The exports and imports of pharmaceutical products have contributed to strengthen the Brazilian economy and to foster international trade. In the last four years, the values of trade in pharmaceutical products oscillated between US\$ 7,5 and US\$ 9 billion and went down from 2013 until 2016 (MICS, 2017). It can be observed in the table below:

Table 7.1 - Trade of Pharmaceutical Products (US\$ billions)

Year	Brazil-World	
	Exports	Imports
2013	1,5	7,4
2014	1,6	7,4
2015	1,3	6,5
2016	1,2	6,4

Source: MDIC/AliceWeb. Prepared by CCGI-EESP/ FGV.

Moreover, the number of medicines, biological products and active pharmaceutical ingredients registered in National Health Surveillance Agency (ANVISA) raised significantly from 2014 to 2016. Considering innovation and technology applied to health, 15 goods applied in the treatment of cancer were registered in 2016 in the category of new medicines, new biological products and radiopharmaceuticals. Still in the field of innovation, it is worth mentioning that 28 of the goods registered in the category of generic drugs were produced with new active substances, 5 with new pharmaceutical forms and 2 with new concentrations. The register of generic drugs helps to promote the access to medicines by the population, considering its lower price in relation to the reference product (Anvisa, 2017, p. 21).

The participation of ANVISA in the evaluation of requirements of priority of analysis was also relevant. The priority of analysis is a regulatory instrument that allows the drastic reduction of the queue time and reduces the necessary term to the evaluation of petitions of public interest (Anvisa, 2017). In 2016, 428 requirements of priority of analysis were evaluated and more than 60% of them were deferred by ANVISA.

A panel created by ANVISA with data and comparisons with previous years reveals moreover the increasing number of clinical trials authorized in Brazil and of consent on patent. In 2016, ANVISA conceded 882 registers against 773 in 2015 and 366 in 2014. It reveals a more than double increase.

The variants of registered medicines are encompassed by biologics, energized, specific, Phytotherapeutic medicine, generic, active pharmaceutical ingredient, new medicines, radiopharmacology or similar. The increase is highlighted in the generic sub-sector. It took off from 146 in 2014 to 343 in 2015 and 404 in 2016. Similar medicines are also in a high level, 299 in 2015 and 317 in 2016.

Moreover, it can be inferred that the pharmaceutical industry has shown significant progress in the last years. From 2007 to 2011, the retail drug sales increased 82,2%, from R\$ 23,6 billion to R\$ 43 billion and the prospection is that from 2016 to 2026, three main submarkets

will grow: (i) Patented therapies - original brands of prescription drugs; (ii) Generic pharmaceuticals (generics) and (iii) OTC medicines - over-the-counter treatments.

7.1.2. Mapping Technical Regulation

(i) Constitution: The Brazilian Constitution, enacted in 1988, guarantees the right to universal, equal access to actions of promotion, protection and recovery of health (art. 196). It is competence of the Union, the States and the Federal District to legislate concurrently on health (art. 24, XII) and according to art. 30, I and VII, it is competence of the Municipal government to legislate about issues of local interest (including health) and health actions and public health services.

(ii) Main Regulations: There are several basic laws enacted that cover health, and are related to medicines and pharmaceutical products. The Law n° 5.991/73 provides the sanitary control of drugs, medicines, pharmaceutical and correlated inputs.

According to the Law n° 6.360/76 (amended from time to time, with the last amendment by Law 13.411/2016), the medicines, drugs, pharmaceutical inputs and correlated in the Law n°. 5.991/73 (Law of Sanitary Control) as well as other hygienic products, cosmetics, among others will be subjects to the Health Surveillance (*Vigilância Sanitária*).

Moreover, the Law n° 9.787/99 provides about the generic medicine. For this law, generic medicine is a drug similar to a reference or innovative product, intended to be interchangeable, usually produced after the expiration or waiver of patent protection or other exclusive rights, proven to be effective, safe and Brazilian Common Denomination (*Denominação Comum Brasileira* – DCB) or, in its absence, International Common Denomination (*Denominação Comum Internacional* – DCI). In accordance with the Decree n° 3.181/99, the DCB and DCI are required to packaging, labels, package inserts, leaflets, texts, or any other type of dissemination material and medical information relating to medicinal products and, the generic name of the medicinal product must be in the same printing field and below the trade name or brand name. The criteria of the DCB are regulated by ANVISA. The internal norms of ANVISA that regulate the Package leaflet and labeling are: Ordinance 344/1998, Ordinance 6/1999, Resolution n° 510/1999, RDC 92/2000, RDC 168/2002, RDC 137/2003, RDC 333/2003, RDC 297/2004, RDC 47/2009, RDC 71/2009, RDC 50/2009, RDC 26/2011, RDC 21/2012, RDC 60/2012, RDC 61/2012, RDC 59/2014 and Resolution 572/2002⁴⁹.

⁴⁹ BRASIL. Lei n° 6.360, de 23 de Setembro de 1976. Dispõe sobre a Vigilância Sanitária a que ficam sujeitos os Medicamentos, as Drogas, os Insumos Farmacêuticos e Correlatos, Cosméticos, Saneantes e Outros Produtos, e dá outras Providências. *Diário Oficial [da] República Federativa do Brasil*, Brasília, 24 de Setembro de 1976. Acesso em: <http://www.planalto.gov.br/ccivil_03/leis/L6360.htm>. Acesso em: 15 mai.2017; BRASIL. Lei n° 5.991, de 17 de Dezembro de 1973. Dispõe sobre o Controle Sanitário do Comércio de Drogas, Medicamentos, Insumos Farmacêuticos e Correlatos, e dá outras Providências. *Diário Oficial [da] República Federativa do Brasil*, Brasília, 19 de dezembro de 1973. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/L5991.htm>. Acesso em: 15 mai. 2017; BRASIL. Lei n° 9.787, de 10 de Fevereiro de 1999. Altera a Lei no 6.360, de 23 de setembro de 1976, que dispõe sobre a vigilância sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/L9787.htm>. Acesso em: 15 mai. 2017; BRASIL. Decreto n° 3.181, de 23 de Setembro de 1999. Regulamenta a Lei no 9.787, de 10 de fevereiro de 1999, que dispõe sobre a Vigilância Sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Disponível em: <http://www.planalto.gov.br/ccivil_03/decreto/d3181.htm>. Acesso em: 15 mai. 2017.

The Law n° 9279/96 provides that medicines and pharmaceutical products are target by the Law of Industrial Property Rights. Art. 230 infers that a patent application for substances, materials or products obtained by chemical means or processes and substances, materials, mixtures or food products, chemical or pharmaceutical products, as well as the respective processes of obtaining or modifying them may be filed by whom has protection guaranteed in the treaty or convention in force in Brazil.

It is important to highlight that the Law n° 8.080/90, enacted to regulate art. 196 of Brazilian Constitution, creates the Unified Health System (“SUS”), which is financed by the Federal, State and Municipal Governments and the Federal District, among other sources.

(iii) Regulatory Authority: Within the Health Surveillance, the regulatory initiatives are several, all promoted by National Agency of Health Surveillance (*Agência Nacional de Vigilância Sanitária* – ANVISA), an autarchy with special regime bind to the Ministry of Health. The law that creates ANVISA is the Law n° 9.782/99.

The register is in the Law n° 6360/76, which provided that the product will be register only after scientific evidence and analysis, recognizing the product as safe and effective for the use. In the case of a new product, extensive information should be provided on its composition and its use, in order to evaluate its nature and determine the degree of safety and efficacy. More specific rules are available in the RDCs 60/2014, 124/2004, 37/2014, 31/2014, 134/2003, 210/2004, 250/2004, 98/2016, 5/2014 and the Normative Instruction 5/2014 and 2/2011⁵⁰.

For the operation of companies that intend to carry out activities of extracting, producing, manufacturing, transforming, synthesizing, packaging, repackaging, importing, exporting, storing, dispatching, distributing, contained in Laws n° 6.360/76, Decree n° 79.094/77 and Law n° 9.782/99, Decree n°. 3.029/ 99, correlated to the Medicines, Drugs and Pharmaceutical Supplies is required the Authorization of ANVISA.

The management and administration of the Agency shall be exercised by a Collegiate Board of Directors, composed of up to five members, one of whom shall be its Chief Executive Officer. The Executive Officers shall be Brazilian, nominated and appointed by the President of the Republic after prior approval by the Federal Senate, for a three-year term of office, with a single renewal. It is also forbidden for managers to have a direct or indirect interest in a company related to the Health Surveillance area provided for the Law n° 9.782/99 as provided in the regulations.

The Law n°10.742/03 encompasses the regulation to the pharmaceutical sector and creates the Regulatory Chamber of Medicines Market (*Câmara de Regulação do Mercado de Medicamentos* – CMED, see Annex IV). The producers of medicines must observe, for the adjustment and determination of their prices, the rules defined in this Law. Drug pricing will be based on a ceiling price model calculated on the basis of an index, a factor of productivity, and an intra-sector and cross-sector relative price adjustment factor.

(iv) Programs and Supports: In May 2004, the Brazilian National Bank of Economic and

⁵⁰ BRASIL. Lei n° 6.360, de 23 de Setembro de 1976. Dispõe sobre a Vigilância Sanitária a que ficam sujeitos os Medicamentos, as Drogas, os Insumos Farmacêuticos e Correlatos, Cosméticos, Saneantes e Outros Produtos, e dá outras Providências. *Diário Oficial [da] República Federativa do Brasil*, Brasília, 24 de Setembro de 1976. Available at: <http://www.planalto.gov.br/ccivil_03/leis/L6360.htm>. Accessed on: May 15th, 2017

Social Development (“BNDES”) launched the Programme for Supporting the Development of the Pharmaceutical Productive Chain (*Programa de Apoio ao Desenvolvimento da Cadeia Produtiva Farmacêutica - PROFARMA*), as an instrument of the Industrial, Technological and Foreign Trade (PITCE), valid from 2004 to 2007. The result achieved was 49 projects supported and the supportive amount of R\$ 1.03 billion. The main purposes of the programme was: (i) encourage the increase of the medicine production and its inputs in the country; (ii) improve the quality of medicines standards; (iii) reduce the commercial risks of the pharmaceutical production chain; (iv) stimulate research, development and innovation in the country; and (v) strengthen the economic, financial, commercial and technological position of the national industry.

(v) Transport of Pharmaceutical Products: The transport of medicines is regulated by private and public rules. The Resolution n° 433/05 from the National Council of Pharmacy provided that it is competence of the pharmaceutical professional in a medicine transport company to watch over the compliance with sanitary regulations, to allow only the transport of registered medicines and authorized companies, to install a good practices manual for the transport of medicines, pharmaceutical products and products for health, to train the human resources involved, to elaborate cleaning procedures to register and control the temperature of the vehicles, to clean the vehicles and deposit terminals and to inspect the loading and unloading activities, among others. In addition, the Ministry of Health in the Ordinance 1.052/MS/SVS/99 provided that it is necessary firstly an authorization for the functioning of an enterprise that aims to transport medicines and pharmaceutical products and the same Ministry enacted also the Resolution n° 329/99 enabling a Form of Inspection to Transport Medicines, Drugs and Pharmaceutical Inputs indispensable for the transportation of this kind of products⁵¹.

(vi) Exports and Imports: The ANVISA controls also the regime of exports and imports of medicines and pharmaceutical products. The RDC 60/2004 provided that the company authorized by ANVISA, whom registers the respective product for the need for control and quality of these services until the availability in the market, must adopt appropriate measures to avoid or prevent health prejudices to population. Other regulations are also important such as RDC n° 11/2007 and n° 81/2008⁵².

(vii) Good Practices: There is also the requirement of a certificate of good practices, provided in the RDC n°39/2013, n° RDC 15/2014, RDC n°56/2014 and Ordinance n° 4/2008, attesting that a particular establishment complies with Good Distribution and Storage Practices or Good Storage Practices.

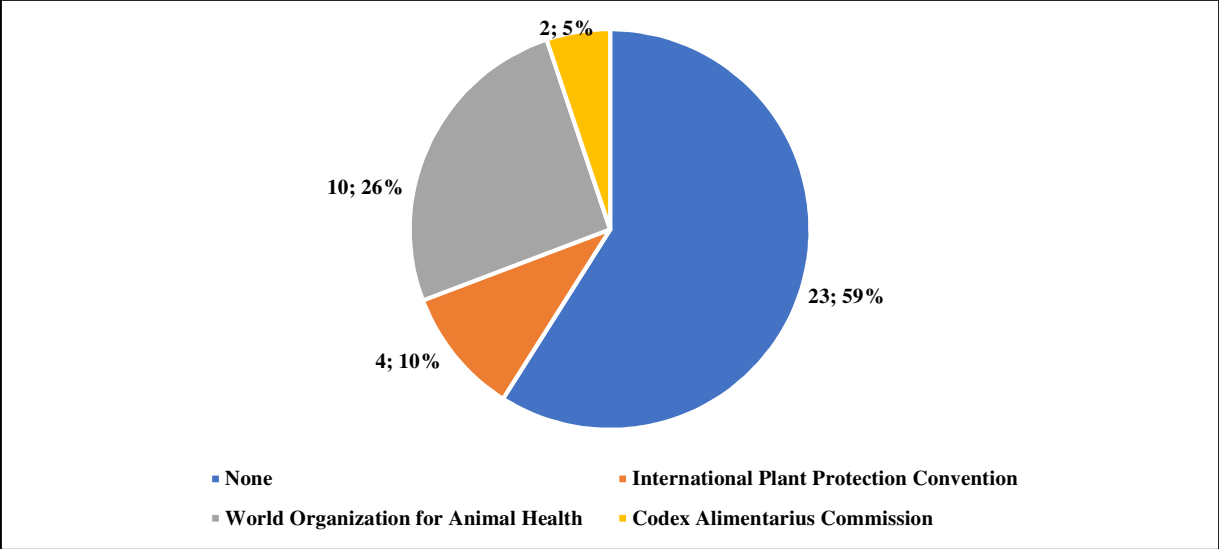
⁵¹ CONSELHO FEDERAL DE FARMÁCIA. Resolução n° 433 de 26 de Abril de 2005. Regula a atuação do farmacêutico em empresa de transporte terrestre, aéreo, ferroviário ou fluvial, de produtos farmacêuticos, farmoquímicos e produtos para saúde Available at: <<http://www.cff.org.br/userfiles/file/resolucoes/433.pdf>>. Acesso em: May 15th, 2017; BRASIL. Ministério da Saúde: Secretaria de Vigilância Sanitária. Portaria n° 1.052, de 29 de Dezembro de 1998. Available at: <http://bvsms.saude.gov.br/bvs/saudelegis/svs/1/1998/prt1052_29_12_1998.html>. Accessed on: 15 mai. 2017; BRASIL. Ministério da Saúde: Agência Nacional de Vigilância Sanitária. Resolução n° 329, de 22 de Julho de 1999. Institui o Roteiro de Inspeção para transportadoras de medicamentos, drogas e insumos farmacêuticos. Available at: <http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/1999/res0329_22_07_1999.html>. Accessed on: May 15th, 2017.

⁵² BRASIL. Ministério da Saúde Agência Nacional de Vigilância Sanitária Diretoria Colegiada Resolução-RDC n° 61, de 19 de Março de 2004. Available at: <http://www.codigoslex.com.br/doc_360114_RESOLUCAO_N_61_DE_19_DE_MARCO_DE_2004.aspx>. Accessed on: May 15th, 2017.

(viii) Labeling: The Ordinance n° 510/99 of the Ministry of Health, the RDC n° 92/00, RDC n° 168/02, RDC n° 137/03, RDC n° 47/09, RDC n° 60/2012, RDC n° 71/09, RDC n° 61/2012, Ordinance n° 572/02 and n°230/04 of the Ministry of Health provides regulation concerning the labeling of medicines and the content of the package inserts.

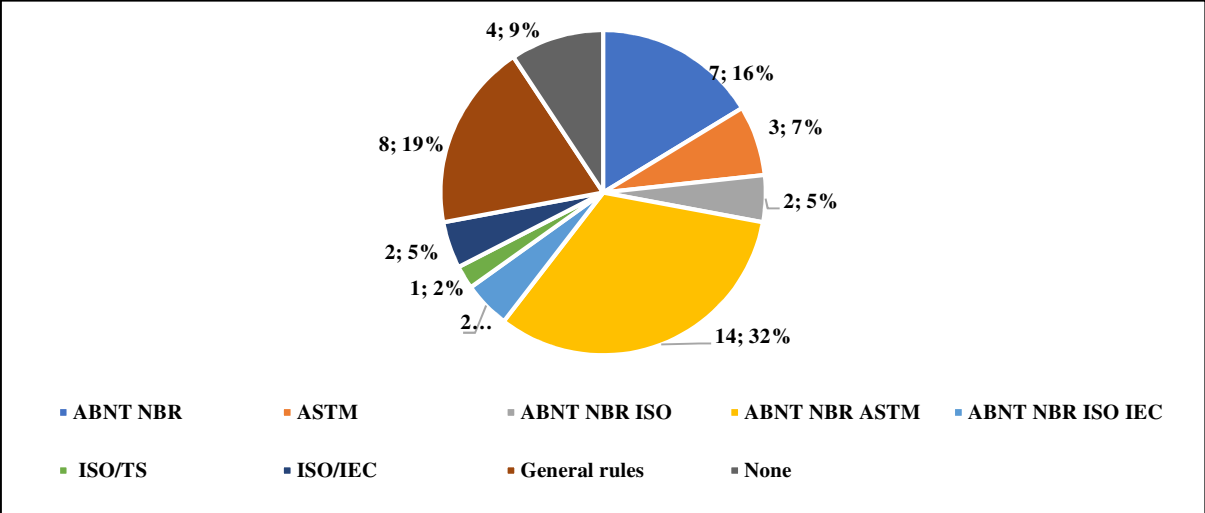
The following figure shows picture general framework of the international standards adopted by the Brazilian technical regulation on chemical sector. To the SPS Committee, Brazil notified 39 times; to the TBT Committee, another 43 times diverse regulations on chemical sector.

Figure 7-1 - Notifications to SPS Committee of WTO (total: 39)



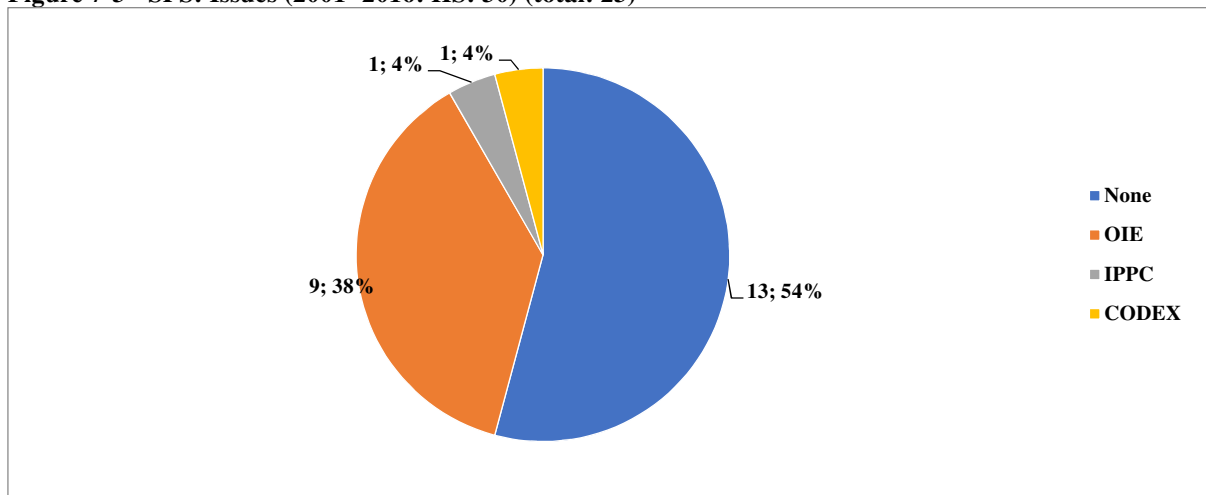
Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

Figure 7-2 - Notifications to TBT Committee of WTO (total: 43)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

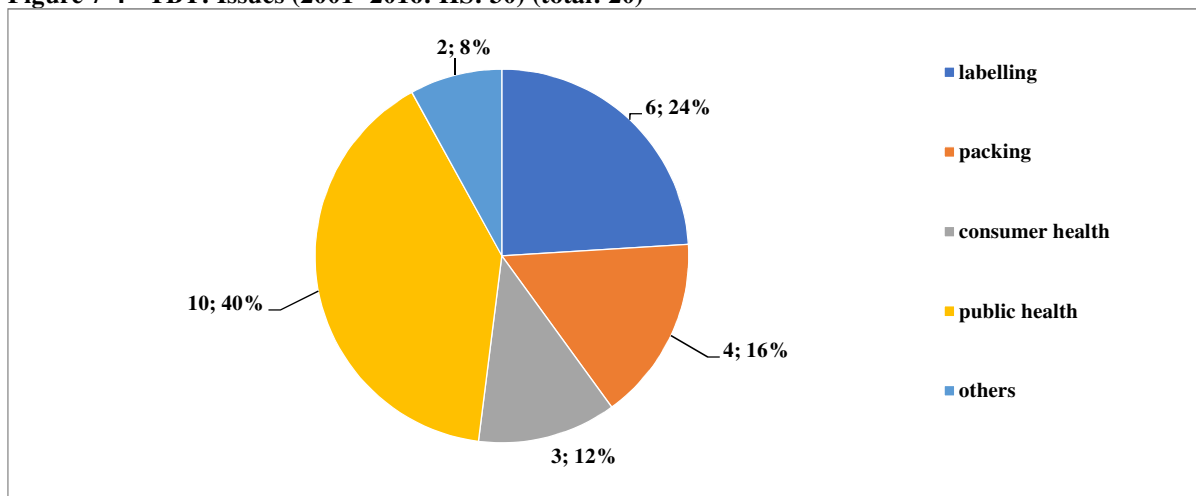
Figure 7-3 - SPS: Issues (2001- 2016: HS: 30) (total: 23)



Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The most frequent issue in the notifications to the TBT Committee is the protection of the environment. Other important topics are consumer protection, labels with nutritional information and human health. No international standardization organization is explicitly mentioned in the notifications.

Figure 7-4 - TBT: Issues (2001- 2016: HS: 30) (total: 20)



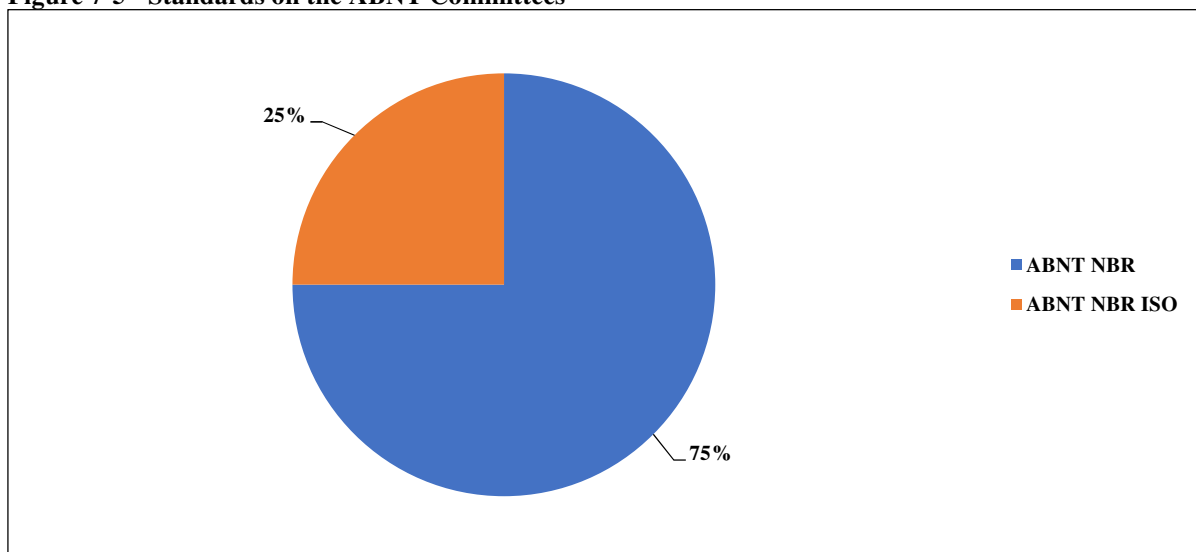
Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

7.1.3. Mapping Technical Standards

Brazil adopts some standards concerning pharmaceutical products. ABNT is liable for the creation of Brazilian Standards. Prepared by its Committees, there are only 4 standards related to medicines or pharmaceutical products at ABNT (see [Annex VII](#)). The standards can be found in the waste from health services committee, medical-hospital committee and safety in articles for babies and children committee. The following table shows the ABNT standards.

The only ABNT standard which follows ISO is the ABNT NBR ISO 14708-4:2016, located in the Medical-Hospital Committee representing 25 per cent of all the standards found in the present analysis. The other 75 per cent of the standards follows the ABNT NBR, manufactured by the own ABNT. The following graphic illustrates the percentage of each type of standard.

Figure 7-5 - Standards on the ABNT Committees



Source: ABNT. Prepared by CCGI-EESP/FGV.

7.1.4. Mandatory conformity assessment procedures

The Brazilian Health Surveillance Agency (ANVISA) is linked to the Ministry of Health and it is responsible for approving products and services subject to sanitary surveillance for both industry and commerce. The RDC 60/2014 provides the criteria for grant renewal of registration of drugs with active principles Synthetic and semi-synthetic, classified as new, generic and similar, and gives other measures⁵³.

The **company registration** is the first stage to have access to ANVISA services. In this context, companies that provide products or services that may be regulated, supervised or sanitary inspected by ANVISA and/or by the State and Municipal Visas must register with ANVISA.

For this the company should access the www.anvisa.gov.br <Regulated Sector <Company Registration <Registration System <Access the System. Fill out and click on "Register New Company".

In addition to allowing the registration of the company, the System of Registration of Companies also requests the registration of users linked to the company, who will be responsible for access to other ANVISA systems. These users can be registered in the following profiles: legal responsible, technical responsible, legal representative and security manager.

Next, the Authorization of Operation of the Company (*Autorização de Funcionamento da Empresa - AFE*) is the act of competence of ANVISA that allows the operation of companies or establishments, by complying with the technical and administrative requirements contained in the RDC No. 16/2014.

The AFE is required of companies that carry out activities of storage, distribution, packaging, shipping, export, extraction, manufacture, fractionation, import, production, purification,

⁵³ BRASIL. Ministério da Saúde Agência Nacional de Vigilância Sanitária Diretoria Colegiada Resolução-RDC nº 60, de 10 de outubro de 2014. Available at: <http://www.poderesau.de.com.br/novosite/images/publicacoes_13.10.2014-III.pdf>. Accessed on: May 15th, 2017.

repackaging, synthesis, transformation and transportation of medicines and pharmaceutical products for human use, products for health, cosmetics, personal hygiene products, perfumes, sanitizers and filling of medicinal gases.

The interested company through the Petitioning System must make the AFE request. In addition, the **Certificate of Good Manufacturing Practices** (*Certificado de Boas Práticas de Fabricação* - CBPF), the document issued by ANVISA certifying that the establishment complies with Good Manufacturing Practices is also required. CBPF is issued per plant, covering the production lines, pharmaceutical forms and special classes of drug products for which the company has been inspected.

The **authorization** is granted exclusively by the health department of the state or local government to authorize establishments carrying out any business activities subject to sanitary surveillance to operate. It must be issued to each establishment separately (an independent, specific authorization). If the establishment aims to manufacture, industrialize or import products subject to sanitary laws, it must operate under the assistance and responsibility of a technician (this is the why companies must keep in their business a sufficient number of technically responsible professionals with proper skills, so that all different activities are covered).

Then comes the **drug registration**, which is the act by means of which ANVISA authorizes the commercialization of the product, through evaluation of the legal-administrative and technical-scientific compliance related to the efficacy, safety and quality of the products. The registration, or market approval, issued by ANVISA is the effective authorization for the manufacturing and marketing of a drug in Brazil.

The application for drug registration must be individualized by pharmaceutical form. If the drug is imported and labeled in Brazil, both CBPFs issued by the manufacturer and the local labeling site must be submitted.

The activity of drug registration is the responsibility of the Board of Authorization and Registration Sanitary (*Diretoria de Autorização e Registro Sanitários* - Diare) of Anvisa. Moreover, within Diare, it is the responsibility of the General Management of Medicines and Biological Products (*Gerência-Geral de Medicamentos e Produtos Biológicos* - GGMed) to coordinate activities and propose the granting or rejection of registration, renewal and post-registration of medicines, among other matters.

7.2. Pharmaceuticals (Argentina)

7.2.1. Overview

Pharmaceutical products are among the most important goods of the chemical industry, as it has to ensure the highest possible level of public health and patient confidence in safe, effective and high-quality health.

Also, pharmaceuticals are the 8th most exported and imported global product. In pharmaceuticals import export business, six types of products are included and come under following HS code – 3004, 3002, 3006, 3005, 3003 and 3001. The product under HS code 3004 (Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses)

are the most exported and imported pharmaceutical products. Besides, Packaged Medicaments are the 399th most complex product according to the Product Complexity Index (PCI).⁵⁴

In Argentina, the pharmaceutical industry is strongly dependent on import of basic chemicals. More complex pharmaceutical products are usually imported by the country.

7.2.2. Mapping Technical Regulation

In Argentina, in 1964, through the enactment of Law No. 16.463, the National Institute for the Regulation of Drugs was created, later the National Institute of Pharmacology and Bromatology (*Instituto Nacional de Farmacología y Bromatología* - INFyB), and later the National Institute of Drugs (*Instituto Nacional de Medicamentos* - INAME).

And in 1992, the National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* - ANMAT) was created by Decree No. 1.490/92, incorporating the INAME into its structure.

The main objectives of the ANMAT are the registration, inspection, control and monitoring of medicines, food and medical technology material whose purpose is to guarantee the population the efficacy, safety and quality of the products.

The INAME is a National Control Laboratory for quality control testing of medicines. Samples are collected by government inspectors for undertaking post-marketing surveillance testing.

Having a nationwide jurisdiction, ANMAT was created to fulfill the process of registration, authorization, standardization, vigilance and monitoring of the products used in the human medicine, food and cosmetic fields. Granted with an economic and financial autarky, in the technical and scientific field it is under the authority of the Ministry of Health.

Likewise, the National System of Pharmacovigilance was created in 1993 by the Ministry of Health and Social Action, through the Resolution No. 706/93. Its functions are collecting, assessing and organizing the information on adverse reactions to drugs after authorization and commercialization. For the functioning of this entity, a Central Enforcer was established in ANMAT headquarters, and Peripheral Enforcers, institutions with relevant experience such as hospitals or university departments, were added later.

Peripheral Enforcers are private and public institutions, of recognized academic or clinic experience. Some of them are the provincial health ministries, professional societies, public and private hospitals, universities and social security organizations.

With the objective of strengthening ANMAT's institutional capacity, as well as fostering coordination with other health authorities, Memoranda of Cooperation and Confidentiality Agreements have been signed with international organizations and strategic foreign regulatory authorities to facilitate regulatory decision-making, such as:

- ANVISA and ANMAT Technical and scientific cooperation in Health Technology Assessment (2005)

⁵⁴ The PCI is the measure of the relative knowledge intensity of a product by considering the knowledge intensity of its exporters (see https://atlas.media.mit.edu/en/rankings/product/hs07/?year_range=2011-2015)

- ANVISA and ANMAT Exchange of inspection reports (2006)
- ANVISA and ANMAT Cooperation in pharmacopoeia (2007)
- ANVISA and ANMAT Joint work on reference substances (2009)
- ANVISA and ANMAT - Joint work on reference substances (2009)

And here you will find ANMAT latest regulations published in the Argentine Official Gazette: http://www.anmat.gov.ar/boletin_anmat/BOindex.asp. Also, under the scope of the National Ministry of Health, the Superintendence of Health Services (*Superintendencia de Servicios de Salud* - SSS) has monitoring, control and enforcement capacities over insurers of the National Health Insurance System.

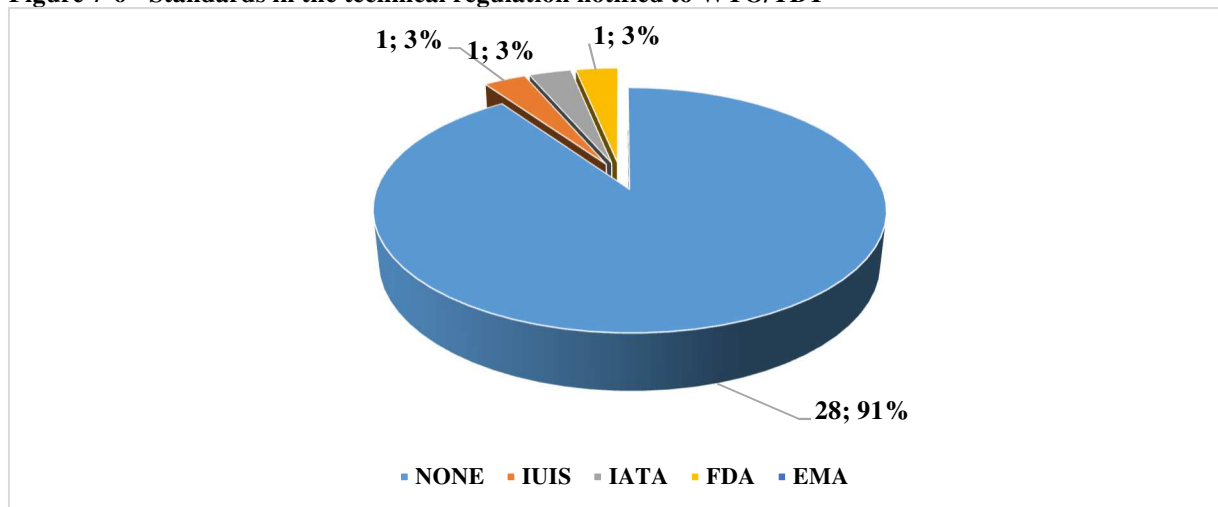
And the Secretariat for Programming Drug Abuse Prevention and the Fight against Drug Trafficking (*Secretaría de Programación para la Prevención de la Drogadicción y la Lucha contra el Narcotráfico* - SEDRONAR), is the national agency acting on behalf of the Executive Branch that controls all operations with certain chemical substances capable of being used in the illicit manufacture of narcotic drugs and psychotropic substances.

In Argentina, legal provisions require registration and marketing authorization for all pharmaceutical products on the market. The list of registered pharmaceutical products is publicly available regularly by ANMAT. The main pharmaceutical products regulation in Argentina is the Law 16.463/64, supplemented by Decrees 9.763/64.

Law 16.463 and Decree 9.763/64 regulate all matters related to the import, export, manufacturing, fractionation, commercialization or storage in Argentine jurisdiction or intended to interprovincial commerce, of drugs, chemical products, reagents, dosage forms, medicines, diagnostic elements, and any other product to be used and applied to human medicine, as well as the physical or legal persons participating in such activities.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the pharmaceutical sector.

Figure 7-6 - Standards in the technical regulation notified to WTO/TBT



Source: WTO. Elaborated by CCGI-EESP/FGV.

So although all standards produced by IRAM which are voluntary, technical regulations notified to WTO/TBT seem to not follow them or any other international standards.

7.2.3. Mapping Technical Standards

In Argentina, considering that the standards are voluntary, the buyer and seller share responsibility in determining what product standard is applicable. For the pharmaceutical sector, all the standards identified in IRAM catalogue are homegrown standards. (see [Annex VII](#), for the full list).

7.2.4. Mandatory conformity assessment procedures

Entities that engage in certification for regulated products must be accredited by the Argentine Accreditation Organization (*Organismo Argentino de Acreditación*, OAA) and recognized by the Argentine Government. Testing laboratories must similarly be accredited and recognized.

The OAA is a non-profit Civil Entity, created within the framework of the National System of Standards, Quality and Certification, to develop the functions established in accordance with the provisions of Decree No. 1474 of the National Executive of August 23, 1994, Resolution No. 90 of the Ministry of Economy and Public Works and Services of September 26, 1995, Resolution No. 330 of the Ministry of Industry, Commerce and Mining of May 19, 1999, Decree No. 73 of the National Executive Power of January 13, 2003, the Statute of the Organization and the principles described in its Policy Manual.

The OAA in the status of sole accreditation body is responsible for: testing laboratories; calibration laboratories; clinical laboratories; fitness test providers.

(OECD), OAA is responsible for:

- Monitor Good Laboratory Practices applicable to non-clinical studies in Pesticides and Biocides and industrial chemical products for registration or marketing authorization purposes under the Mutual Data Acceptance Agreement (MAD).
- All other monitoring of the compliance of Good Laboratory Practices (GLP) that is required.

8. Cosmetics

8.1. Cosmetics (Brazil)

8.1.1. Overview

The cosmetics industry in Brazil is economically very important. Brazil is a major consumer and producer of this type of product. The technical regulation of this sector is almost entirely harmonized within Mercosur.

Cosmetics items are enclosed on Chapters 33 and 34 of the Harmonized System. From 1996 to 2015, the liquid superavit in the sector increased an average of 11,4% (deflated) per year in the last two decades, reaching US\$ 13,0 billion in 2015 (ABIHPEC, 2016). According to Euromonitor, Brazil is the fourth biggest consumer of PHPC products in the world (Euromonitor, 2016).

8.1.2. Mapping Technical Regulation

Law 6.360/76 regulates the PHPC sector. Apart from the law and two decrees that regulate it, there are several ANVISA resolutions and ordinances, INMETRO resolutions and MERCOSUR resolutions (see [Annex 3](#)).

The law regulates the parameters for sanitary surveillance to medicine and the requirements for the products to be sold in the Brazilian market. Article 3 of Law 6.360/76 presents the concepts of perfumery, cosmetics and hygiene products, raw materials, labelling, packaging, batch or lot of a product and establishes their registry number and product quality control.

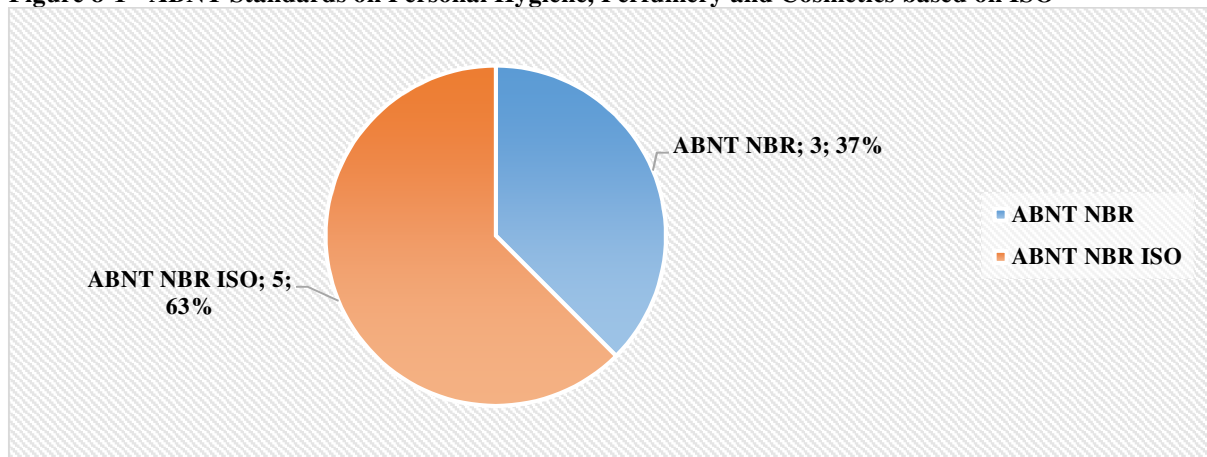
As PHPC are intended to be used externally or through topic application, these products do not need to go through the same drugs and medicine quality procedures, restrictions and surveillance requirements. Regardless of this fact, PHPC products must all be authorized and registered by National Sanitary Surveillance Agency (ANVISA). Article 26 determines which products can be registered as PHPC, while article 27 determines that PHPC must only be composed of innocuous substances, as determined and allowed by ANVISA.

Currently Law 6.360/76 is regulated by Decree 8.077/13. The Decree regulates the conditions for the operation of companies subject to sanitary licensing, and the registration, control and monitoring, within the scope of health surveillance, of all the products referred to in Law n°. 6.360, including PHPC products. It determines the registry, control and monitoring requirements at ANVISA and stipulates that for products that will not harm or risk harming human health, the registry can be simplified and pre-regulated by the agency.

8.1.3. Mapping Technical Standards

There are a few standards on cosmetics and similar products issued by ABNT. Moreover, ABNT has based its standards for detection of microorganisms on ISO standards.

Figure 8-1 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics based on ISO



Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

8.1.4. Mandatory conformity assessment procedures

The registration by ANVISA creates a presumption that the product is adequate to be commercialized domestically. The product has to meet the criteria set forth in laws and the specific rules established by health surveillance authorities. Such rules aim to minimize potential risks associated with the product. The Resolution ANVISA, RDC n. 07/2015 establishes technical requirements for the regularization of toiletries, cosmetics and perfumes.

The registration shall comply with the following steps: i) registry of the user or the company registration, ii) petition or identification of the code of subject related to the petition, iii) taxes including a payment bill (GRU) for the payment of the supervision fee of sanitary surveillance (TFVS) related to the subject chosen, iv) the protocol with all the documentation required by the sanitary authority.

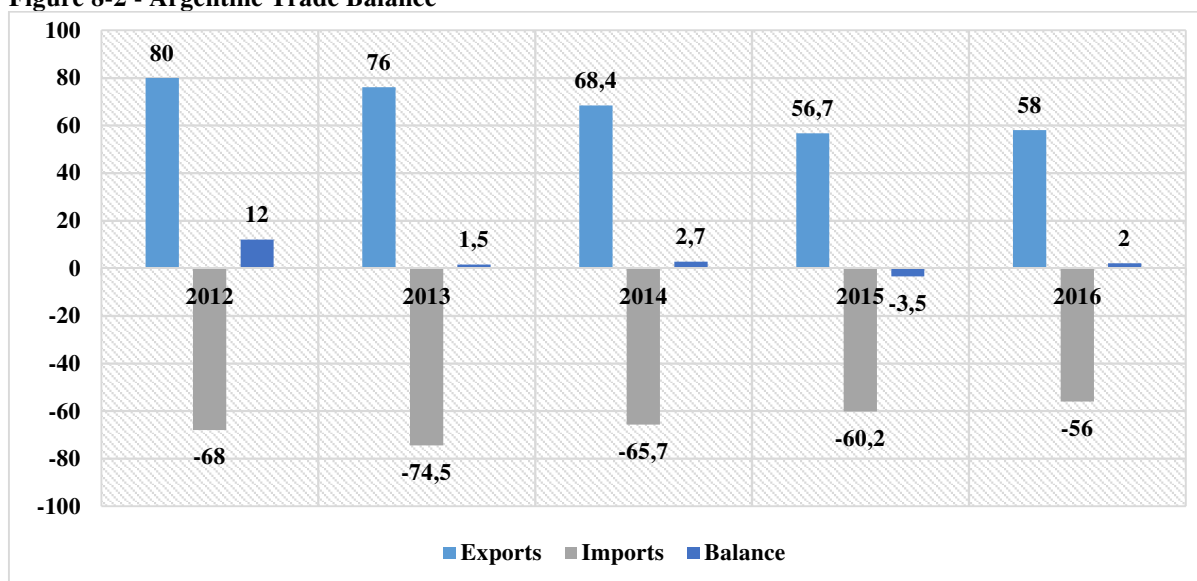
ANVISA shall publish the results in Brazil's Official Gazette (DOU), which serves as proof to the applicant of the given registry. After that, the product has clearance to be commercialized throughout the country for five years, when it expires. This procedure is receiving some criticism because, allegedly, it can have an impact on shipping costs as well as a time-consuming activity because of several deadlines set forth in order to register a given PHPC good.

8.2. Cosmetics (Argentina)

8.2.1. Overview

The foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of electrical materials and equipment.

Figure 8-2 - Argentine Trade Balance

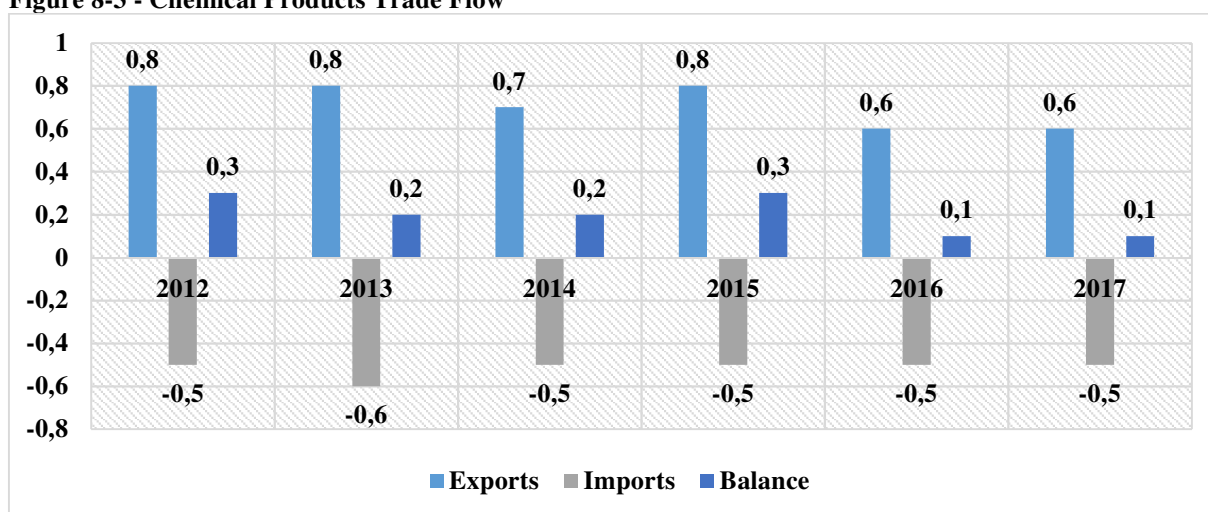


Source: INDEC. Elaborated by CGTI-EESP/FGV.

The analysis of the history of Argentinean industrialization can provide a useful explanation for the main characteristics of the sector of chemical products in Argentina. Although important, the chemicals sector presents structural problems stemming from the incomplete industrialization of the country. Thus, the basic chemical goods industry is underdeveloped and dependent in Argentina. The downstream sectors, therefore, are heavily dependent on imports of basic chemicals, since these are inputs for the production of medicines, cosmetics and other fine chemical by-products.

As the basic chemicals sector weighs heavily on the trade balance, this deficiency of the Argentine chemical industry generates constant deficits in the country's external accounts, as verified in the general figures of the international flow of chemical goods in Argentina.

Figure 8-3 - Chemical Products Trade Flow



Source: INDEC. Elaborated by CGTI-EESP/FGV.

In the last five years, Argentina has had deficits in the trade balance regarding chemicals. While exports declined progressively in this period, imports alternated between periods of increase and decrease. The outcome of this dynamic was a constant trade deficit in the sector.

Analyzing the subsector of cosmetics, the trade balance reveals a surplus on the last five years. The exports fell from 2015 to 2016 and remained stable in 2017. The imports, on the same sense, experienced a steady fall from 2015 to 2017. These variations, thus, led to a fall on the balance of the subsector.

Figure 8-4 - Cosmetics Trade Flow



Source: INDEC. Elaborated by CGTI-EESP/FGV.

8.2.2. Mapping Technical Regulations

The main Argentine regulator cosmetic sector is the National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* - ANMAT) was created by Decree No. 1.490/92, incorporating the INAME into its structure.

The main objectives of the ANMAT are the registration, inspection, control and monitoring of medicines, food and medical technology material whose purpose is to guarantee the population the efficacy, safety and quality of the products.

The INAME is a National Control Laboratory for quality control testing of medicines. Samples are collected by government inspectors for undertaking post-marketing surveillance testing.

Having a nationwide jurisdiction, ANMAT was created to fulfill the process of registration, authorization, standardization, vigilance and monitoring of the products used in the human medicine, food and cosmetic fields. Granted with an economic and financial autarky, in the technical and scientific field it is under the authority of the Ministry of Health.

In Argentina, each province has its own health authority that works on a par with ANMAT and is competent to pass legislation.

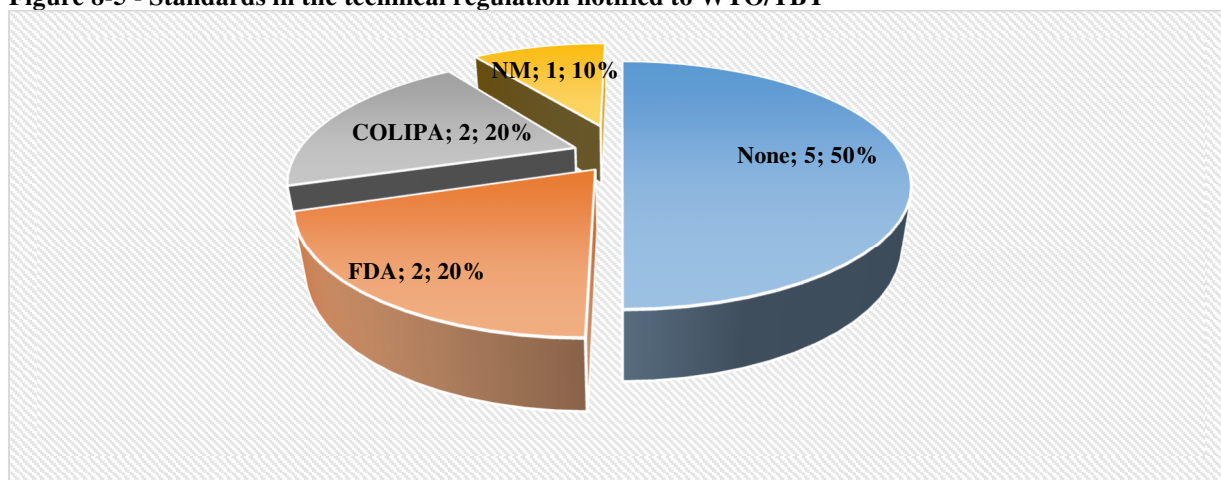
In this framework, ANMAT's principal areas of responsibility include:

- Registration of medicines, medical technology, food and cosmetic product before their manufacturing, import, distribution and commercialization.

- Authorization, control, supervision and inspection of the manufacturing, production, fractioning, packaging, distribution, commercialization, import and export of medicines, medical technology, food and cosmetic products.
- Control, supervision, inspection and authorization of all clinical trials performed in Argentina.
- Authorization, control, supervision and inspection of manufacturing and commercialization of household cleaning products.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT Committee on the cosmetic sector.

Figure 8-5 - Standards in the technical regulation notified to WTO/TBT



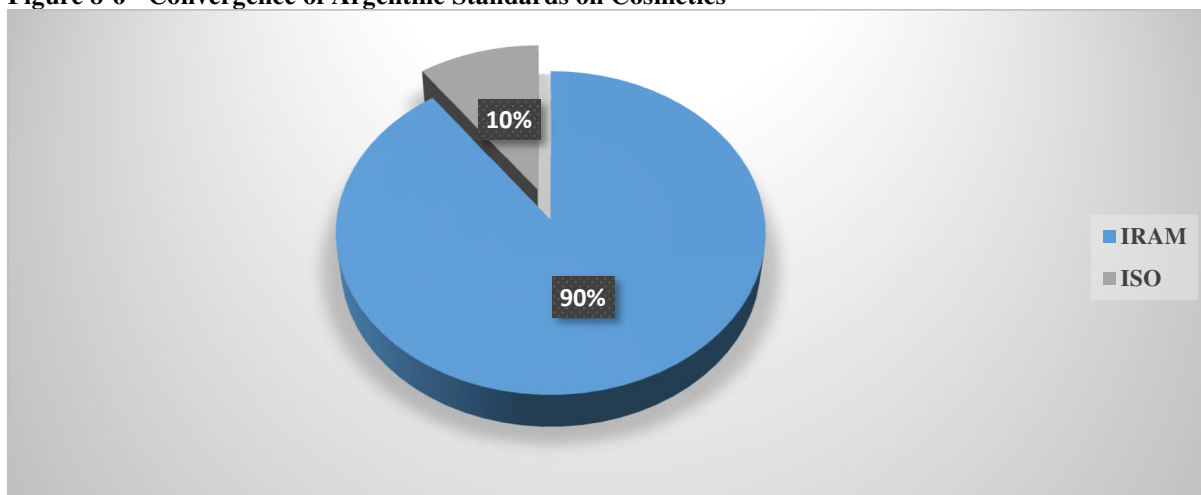
Source: WTO. Elaborated by CGTI-EESP/FGV .

So although all standards produced by IRAM which are voluntary, technical regulations notified to WTO/TBT Committee do not seem to follow them or any other international standards.

8.2.3. Mapping Technical Standards

The main standardization body in Argentina is IRAM, a non-profit institution that brings together specialists in standardization from various sectors of the country's economy. IRAM is a body that represents Argentina within the scope of the International Standardization Organization (ISO), Pan-American Commission of Standards (*Comisión Panamericana de Normas Técnicas*, COPANT) and the Mercosur Association of Standardization (*Asociación Mercosur de Normalización*, AMN).

Figure 8-6 - Convergence of Argentine Standards on Cosmetics



Source: IRAM. Elaborated by CGTI-EESP/FGV.

Most of the IRAM standards on cosmetics can be considered homegrown standards. Of the ten standards identified, only one is derived from an ISO standard, which makes up 10% of the total standards on the subject. It should be noted, however, that IRAM is an important participant in the international standardization bodies, which indicates a coherence between the Argentine standardization policy and international standardization practices.

8.2.4. Mandatory conformity assessment procedures

Like most chemicals, cosmetic conformity assessment procedures are more related to the registration process of these products. The registration of this type of product is necessary for its commercialization in the Argentine market. The registration is usually by public agency and has a predefined term of duration.

For example, Disposition 2723/97 provides firstly the obligation of the previous registry on ANMAT by the firms of cosmetic products. The corresponding authorization of importation is also required. In order to fulfill this need, the form “Authorization for the importation of medicines, cosmetics, reagents of diagnosis of use in vitro and/or disposable material, apparatus and equipment of medical and dental use”. When necessary, ANMAT can require the aggregation of the documents of origin to the authorization of importation.

More details on registry and other mandatory procedures can be seen in Annex 3 of this document.

9. Processed food

9.1. Processed food (Brazil)

9.1.1. Overview

According to data from the Eurostat website⁵⁵, the three largest industrial activities in terms of value added in the G20 were food and beverages, chemicals and vehicles, which, according to Eurostat, Brazil, like Australia, revealed that the ‘food and beverage’ industries represent around one fifth of the manufacturing sector.

Eurostat data also indicate that between 2010 and 2015, for the EU-28’s the highest growth rate for food, beverages and tobacco exports was recorded, an increase of 49.5% over the previous period. In the same period, imports of these same products also increased sharply, 33.8%, according to the same source.⁵⁶

According to records from the European Commission website⁵⁷, the food and beverage industry is the largest industrial sector in the EU in terms of employment and value added (in the last 10 years, EU food and drink exports have doubled, reaching of 90 billion euros (which contributed to a positive balance of almost 30 billion euros).

Its representativeness in the global export market, however, still according to the European Commission, has declined in the last ten years, to the detriment, above all, of Brazil and China.⁵⁸

According to the Brazilian Food Processors’ Association (ABIA), in 2016, the Brazilian food processing industry generated a nominal revenue of R\$ 614.3 billion, increasing 9.3% compared to 2015. Brazil relies on a well-developed food processing industry, with around 45,000 food companies established throughout the country. In addition to domestic enterprises there are major European multinational companies such as Nestle, Unilever, Bunge, Danone, Heineken operating in Brazil.

9.1.2. Mapping Technical Regulation

Food regulations issued at the Brazilian federal level are contained in various types of legal documents (Laws, Decrees, Executive Orders, Directives, Circulars, Resolutions) and to become official, or in order to be implemented, must be published in Brazil’s *Diário Oficial*.

In this report the following hierarchy of Brazilian federal norms was taken into account: 1st, Federal Constitution (Magna Carta); 2^o, Laws and Decrees-Law established by the Federal Legislative Power (National Congress); 3rd, Decrees, regulations of laws from the President of the Republic; and 4th, Resolutions and Normative Instructions from Regulatory Agencies and Ordinances by federal executive bodies, normative and administrative acts as a complement to higher hierarchical level norms.

In terms of sanitary surveillance in Brazil, 1950 was the historical landmark, and still in force, when was enacted Law No. 1283 establishing the obligation of prior inspection of all products

⁵⁵ [http://ec.europa.eu/eurostat/statistics-explained/index.php?title=The_EU_in_the_world - industry, trade and services&oldid=170829](http://ec.europa.eu/eurostat/statistics-explained/index.php?title=The_EU_in_the_world_-_industry,_trade_and_services&oldid=170829)

⁵⁶ http://ec.europa.eu/eurostat/statistics-explained/index.php/International_trade_in_goods

⁵⁷ <http://ec.europa.eu/growth/sectors/food>

⁵⁸ https://ec.europa.eu/growth/sectors/food/processed-agricultural-products/trade-overview_en

of animal origin, from an industrial and sanitary point of view. Despite of its 67 years, the Law No. 1283 was modified only once, by Law No. 7889, in 1989.

In turn, Decree No. 9013/2017 (known as New RIISPOA), that has the objective of establishing the set of regulations concerning the development of the industry and trade in products of animal origin, in accordance with the provisions of Law No. 1283/1950, includes the implementation of new technologies, standardization of technical and administrative procedures and harmonization with international legislation. It is compatible with the Brazilian Consumer Protection Code and the decree establishing the Unified Agricultural Health Care System (SUASA).

Another precursor regulation in Brazil was Decree-Law No. 986/1969, which establishes basic food technical regulation, including dispositions related to the labeling and use of additives.

In 1973, The National System of Metrology, Standardization and Industrial Quality was established by Law No. 5966 with the purpose of formulating and executing the national policy of metrology, industrial standardization and quality certification of industrial products.

Another important fact was the creation in 1999 of Anvisa (by Law No. 9782), which enforces most of the regulations regarding processed food products, and it has similar functions in regulating food as does the Food and Drug Administration (FDA) in the United States.

In Brazil, Anvisa is fundamental to guarantee the control and the inspection of products and services that involve risk to public health.

Therefore, Anvisa, SDA and Inmetro form, undisputedly, the sanitary and technical regulation tripod in Brazil in the food and beverage sector.

Besides, it should be remembered that Law No. 8171/1991 was the first Brazilian regulation on agricultural policy.

In 2006, Law No. 11346, known as the Organic Law on Food and Nutrition Security (LOSAN), set up the National System of Food and Nutrition Security (SISAN) and established definitions, principles, guidelines and objectives of the System. Through SISAN, public power with the participation of organized civil society must formulate and implement policies, plans, programs and actions with a view to ensure the human right to adequate food.

It is relevant to mention yet the Law No. 11105/2005 concerning the safety regulations and inspection mechanisms for activities that involve Genetically Modified Organisms (GMOs) and their by-products, establishes the National Biosafety Council (CNBS), re-structures the National Biosafety Technical Commission (CTNBio), defines the National Biosafety Policy. This Law provides safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, import, export, storage, research, marketing, environmental release and discharge of GMOs and their by-products, guided by the objective of attaining scientific development in the biosafety and biotechnology areas, the protection of human, animal and plant health and life.

9.1.3. Mapping Technical Standards

Within ABNT, there are several committees that develop technical standards on food. Some of these standards are the reproduction, in Portuguese, of ISO standards. In the food macro-sector,

the following committees stand out: ABNT / CB-012 - Brazilian Committee of Agriculture and Livestock; ABNT / CB-013 - Brazilian Beverage Committee; ABNT / CB-030 - Brazilian Committee on Food Technology; ABNT / CB-052 - Brazilian Coffee Committee; ABNT / CB-056 - Brazilian Meat and Milk Committee; ABNT / CEE-072 - Special Study Commission on Tobacco and Tobacco Products; ABNT / CEE-087 - Commission for the Special Study on Beekeeping; ABNT / CEE-095 - Commission for the Special Study of Greenhouses and Agricultural Nurseries; ABNT / CEE-104 - Special Committee on Food Safety; ABNT / CEE-143 - Commission for the Special Study on Non Genetically Modified Grains; ABNT / CEE-156 - Special Sugar Cane Study Commission; ABNT / CEE-157 - Special Committee on Food Microbiology; ABNT / CEE-160 - Special French Bread Study Committee; ABNT / CEE-171 - Special Study Commission on Agrochemicals and Allied Products; ABNT / CEE-174 - Special Study Commission on Sensory Analysis; ABNT / CEE-176 - Special Study Commission for *Carbaúba* Wax; ABNT / CEE-182 - Special Study Committee on Soil Fertilizers and Corrective; ABNT / CEE-192 - Special Aquaculture Study Commission; ABNT / CEE-211 - Special Study Commission on Nutritional Supplements and Foods for Special Purposes; ABNT / CEE-213 - Special Study Committee on Sugarcane Bagasse; ABNT / CEE-214 - Special Poultry Study Commission; ABNT / CEE-227 - Commission of Special Study on Meliponiculture; ABNT / CEE-228 - Special Committee on Animal Welfare.

9.1.4. Mandatory conformity assessment procedures

ANVISA is the public agency responsible for register any food product before its commercialization in the Brazilian market. The registration number issued by ANVISA has to be on the label of the product.

ANVISA does not provide business operation permit (*Autorização de Funcionamento de Empresas* - AFE) for food. For settlement of food establishments, it is necessary to obtain license or health permit at the local health surveillance organization. According to Decree-Law n. 986/1969, the establishments where foodstuffs are manufactured, prepared, processed, packaged, transported, sold or deposited must receive a license from the competent health authority, municipal, state or Federal District, upon the issuance of the respective sanitary permit.

The Good Manufacturing Practices (GMPs) include a set of measures that ensure the quality of processed food. Current Brazilian food good manufacturing practices (GMPs) are in Ordinance SVS/MS nº 326/1997 (based on the Codex Alimentarius). It describes the methods, equipment, facilities, and controls for producing processed food. GMPs also serve as a basis for ANVISA inspections. It is important to highlight that there are also other specific rules on GMPs.

The certification system is also a relevant issue addressed by the Codex Alimentarius. Certification is a procedure by which official certification bodies, or officially recognized certification bodies, ensure, in writing, or equivalently, that foods or food control systems are in conformity with established requirements. There are also alternative measures for certification, which include inspection system and the requirements for an exporting country be equivalent to the importing country; trade partners may also decide for a bilateral or multilateral agreement such as of a mutual recognition nature.

ANVISA can grant or cancel the Certificate of Good Manufacturing Practices (Certificado de Boas Práticas de Fabricação - CBPF) of a company as per Federal Law n. 9,782/1999, albeit such subject requires further regulation for its full implementation. However, ANVISA has

already ruled that palm heart (palmito) industries established in other countries shall have a CBPF to export to Brazil.

Although law No. 9782/1999 establishes that the ANVISA can grant and cancel the Certificate of Good Manufacturing Practices (Certificado de Boas Práticas de Fabricação - CBPF), this subject is not yet regulated, except for the industries of palm heart (palmito) installed abroad, which must possess the CBPF to export to Brazil.

Imported products subject to health surveillance for trade, industry or direct consumption should have ANVISA's consent to be imported. The sanitary authority verifies whether foodstuff products are in conformity with ANVISA regulations, which includes, when applicable, obligation of notification, registration, exemption from registration, or any other form of control established in the law.

According to ANVISA, there are two categories of food products: (i) products with compulsory registration; and (ii) products exempt from registration. Importers, like domestic producers, of food products under the compulsory list must register their products and pay fees, which vary according to the size of the company. Importers or producers of food products exempted from registration have also to request their product's exemption from registration by presenting the required documents by law.

ANVISA can also grant the Product Registration, which recognizes that a foodstuff product is in conformity with sanitary legislation in force. It is a control done prior to marketing. Resolution ANVISA RDC n. 23/2000 establishes the basic procedures for the registration and exemption of registration.

The activity of food registration is the responsibility of the Board of Authorization and Sanitary Registration (Diretoria de Autorização e Registro Sanitários - Diare) of ANVISA. Moreover, within Diare, the General Management for Food Products (*Gerência-Geral de Alimentos* - GGALI) manages the regulation, registration, inspection and clearance of food products.

The following categories of foods have compulsory registration, as set forth in annex II of the RDC No. 27/2010:

- Novel foods and novel ingredients
- Foods with claims of functional properties and/or health
- Infant foods
- Food for enteral nutrition
- Packaging with new technologies (recycled)
- Bioactive substances and probiotics isolated with claims of functional properties and/or health

The categories of foodstuffs that are exempt from the register prior to commercialization, but must deliver the Manufacturing Startup Notice (*Comunicado de Início de Fabricação*) are listed in annex I to the RDC No. 27/2010.

The manufacturer or importer of the foodstuffs exempt from registration will fill out the form of Manufacturing Startup Notice according to RDC No. 23/2000.

Lastly, there are foodstuffs that are exempt from the register and exempt from the Manufacturing Startup Notice, for example, bakery, pastry, pastry, confectionery,

confectionery, rotisserie and ice cream products, when exclusively destined for direct sale to the consumer, carried out at the counter of the producer itself.

The manufacturer or importer is the responsible for the quality and safety of registered products at Anvisa.

Besides Anvisa, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the regulatory authority to enforce federal laws regarding the registration and labeling of beer, distilled spirits, wine, soft drinks and juices (except beverages for athletes, water, energy drinks).

The major regulation for alcoholic and beverage products, both domestic and imported, is Decree No. 6871/2009, which provides for the control, inspection, standardization, classification, establishment registration and product registration of beverages.

In the case of grape beverages, establishments, producers or bottlers of wine and beverages derived from grapes, must be registered at MAPA, according to Law No. 7678/1988 and its subsequent amendments.

The DIPOA communicates that from 18/01/2017 the registration of animal origin products will start to be conducted in a PGA, Agriculture and Cattle Raising Management Platform, system in module PGA/SIGSIF. This change will cover all the registrations of animal origin products, whether of a registered (SIF), listed (ER) or foreign (EE) establishment in compliance with the provisions of Decree No. 30.691/1952, amended by Decree No. 8.681/2016.

The new electronic system designed by the MAPA can only be used to register new labels. MAPA also is responsible for the regulatory inspection and registration of all planting seeds and seeding (including biotech seeds), as well as for agricultural products such as grains, fruits and vegetables.

9.2.Processed food (Argentina)

9.2.1. Overview

Argentina is the world's leading exporter of soy oil and soy meal, the third largest soybean exporter, and a top exporter of corn.

The food and beverage industry is one of the main activities contributing to the Argentine economy, accounting for about 30 percent of Argentina's total exports. Some of its main trends are as follows: i) significant investments in technology updates; ii) local production capacity being fully used, which requires additional investments to supply the growing food demand; iii) "Health and Nutrition" considered a strong concept in the food and beverage business; and iv) Greater interaction between the local industry and universities, fostering innovations.

Together food, beverage and agriculture products account for half of exports. Motor vehicles account for 12% of exports. Machinery is the largest import item, accounting for 30% of all imports, followed by transportation goods (17%) and chemical products (16%).

Brazil is Argentina's main trading partner, accounting for 18% of all exports and 21% of all imports. China and the European Union are also important trading partners. By contrast,

Argentina trades relatively little with other Latin American countries, beyond Brazil. And barriers to entrepreneurship are high and regulatory procedures are complex (OECD Economic Surveys: Argentina 2017).

8.2.2. Mapping Technical Regulation and Authorities

The Argentine Food Code (*Código Alimentario Argentino* – CAA)⁵⁹ was created by Law 18284/1969 and regulated by Decree 2126/1971. The Code regulates locally produced and imported food products. The main Government of Argentina of CAA is to protect public health and the good faith in commercial transactions of foodstuffs within the national territory of Argentina.

The CAA incorporates rules agreed upon within the Southern Cone Common Market (Mercosur) framework, which in turn are influenced by standards from: 1) Codex Alimentarius, 2) the European Food Safety Authority (EFSA), and 3) the U.S. Food and Drug Administration (FDA).

The CAA is constantly being updated by joint resolutions from the Ministry of Health and the Ministry of Agroindustry. View latest CAA Modifications in http://www.conal.gob.ar/CAA_ultimas_modificaciones.php

In Addition, Decree 815/1999 sets the basis for the creation of the National Food Inspection System (*Sistema Nacional de Control de los Alimentos* – SNCA). The SNCA guarantees the enforcement of CAA. Also, Decree 815/1999 established the creation of the National Food Commission (*Comisión Nacional de Alimentos* - CONAL), which is an advisory body that provides support and monitoring to SNCA. The members of SNCA and CONAL belong to the Ministry of Health and the Ministry of Agroindustry.

There are four major government agencies that have the authority to enforce CAA regulation in Argentina:

Within the Ministry of Agroindustry:

SENASA (*Servicio Nacional de Sanidad y Calidad Agroalimentaria*) - National Service of Agri-Food Health and Quality is responsible for executing the government's policy on animal and plant health and for ensuring compliance with the CAA for those food products that are under its exclusive competence listed in Annex I and II of Decree 815/1999 (including fresh, chilled, frozen, and thermo-processed products and by-products of animal, plant and seafood origin). It is also responsible for the control of imports and exports of products, by-products and derivatives of animal and vegetable origin, agri-food products, pharmaceuticals, agrochemicals and fertilizers.

INV (*Instituto Nacional de Vitivinicultura*) - National Wine Institute, which exerts control over wine and wine products during their production, manufacturing, and marketing stages.

Within the Ministry of Health:

⁵⁹http://www.alimentosargentinos.gob.ar/HomeAlimentos/Legislacion%20Alimentaria/codigo_alimentario_argentino.php

ANMAT (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*) - The National Administration of Drugs, Foods and Medical Devices is an agency decentralized from the National Public Administration that was created by decree 1490/92. It cooperates in the protection of human health by assuring the quality of the products it regulates: drugs, foodstuff, medicinal products, diagnosis reagents, cosmetic products, dietary supplements and household cleaning products.

INAL (*Instituto Nacional de Alimentos*) - National Food Institute, which is an agency under the ANMAT. It regulates consumer-ready food products, health supplements, and both alcoholic and non-alcoholic beverages, with the exception of wine. (Sometimes, SENASA and INAL have overlapping responsibilities).

The Argentine regulation on food covers three dimensions:

a) **Packaging and Container Regulations.** Overall, Argentina does not officially have any special packaging or container size requirements or preferences, with the exception of certain products such as salt. It is a marketing issue that the consumer determines what type or size of package/container. Although during the past few years the Government of the City of Buenos Aires has been working on creating awareness among the population on the importance of protecting the environment and getting involved in recycling waste, there are no official municipal waste disposal laws or product recycling regulations that affect imported food products in particular.

b) **Food Additives Regulations.** Argentina uses a positive list of food additives. Article 2 of Decree 2092/1991 states the following: "... all foods, condiments, beverages, or their raw material and food additives which are manufactured, fractioned, preserved, transported, sold, or exposed, must comply with CAA requirements. When one of those is imported, CAA requirements will be applied. The Government of Argentina also considers products from countries which have food controls comparable to those of Argentina, or when they use Codex Alimentarius (FAO/OMS) standards, to be in compliance with Argentina standards."

All additives used must be included in the Mercosur positive list of food additives. If the additive in question does not appear on that list, a presentation requesting its registration for use must be submitted to CONAL. This list varies by product and can be obtained from an importer.

Also SENASA Resolution 256/2003 establishes the Maximum Residue Levels (MRLs) for products that are traded in the country. The mechanism to set them is as follows: a chemical company that applies for a pesticide to be released in the Argentine market must carry out a two-year study in three different agro-ecological areas of Argentina. The sampling method to be used in these cases must be one that is approved by FAO. Argentina uses the Acceptable Daily Intake suggested by *Codex Alimentarius* for the Latin American Region, as a reference. The required listed number is generally lower than the one suggested by Codex but higher than the one suggested by the EU. If SENASA is doubtful about the MRL established by the research, they use the Codex number.

c) **Agricultural Biotechnology.** Argentina continues to be the third largest producer of biotech crops, after the United States and Brazil, producing 14 percent of the world's total biotech crops.

Almost all soybean area is planted with biotech seed varieties, while 95 percent of corn area and 100 percent of cotton area are biotech varieties.

Argentina is one of the first countries with a regulatory framework with specific working regulation for products derived from Innovative Biotechnology or New Breeding Techniques (NBTs). This regulation is the outcome of a three-year debate which took into account the state of the art in NBTs and parallel discussions overseas. It is a product-by-product consideration of the genetic modifications in light of the concept of “novel combination of genetic material.”

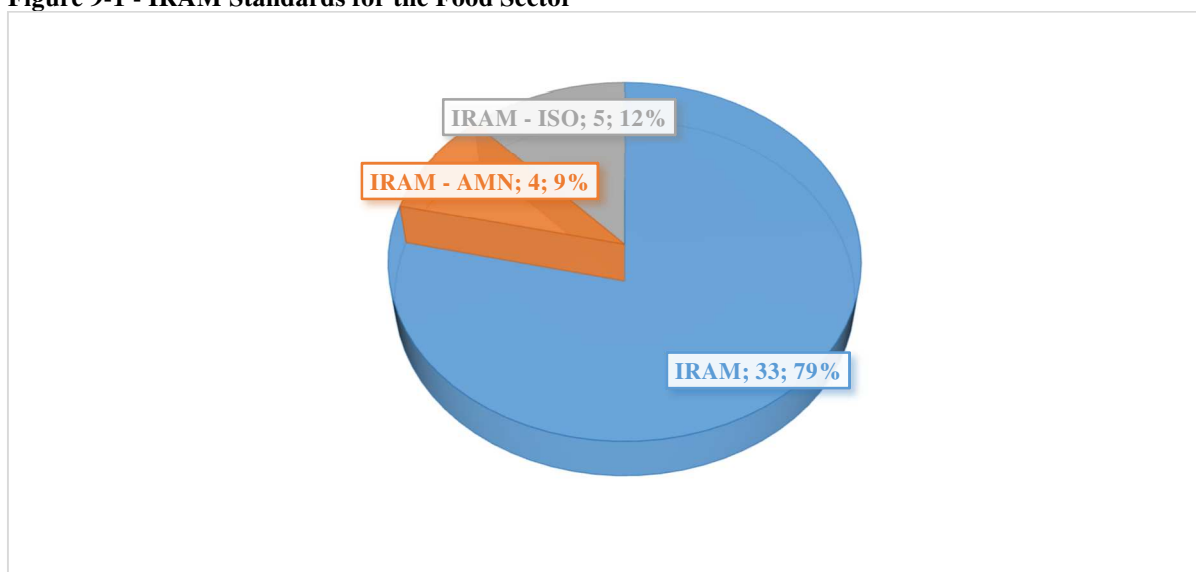
9.2.2. Mapping Technical Standards

A 1994 decree created the legal framework (Decree 1474/94) for standards-related activities in Argentina. There are two private sector organizations that work under the National System for Standards, Quality and Certification (IRAM and OAA).

The Argentine Standards Institute (*Instituto Argentino de Normalización* - **IRAM**) is the official national standards body for Argentina, created in 1935, it is the main developer of national voluntary standards in Argentina. Reliance on international standards as a basis for developing national standards continues to be a strong trend in Argentina. While many IRAM standards are compatible with U.S. standards and many others are patterned after requirements of various European countries.

IRAM has some standards for manufactured food sector. Such sector, however, is not relevant for the standardization work of IRAM.

Figure 9-1 - IRAM Standards for the Food Sector



Source: IRAM. Elaborated by: CCGI-EESP/FGV

9.2.3. Mandatory conformity assessment procedures

On January 28, 2016, the Secretariat of Commerce in Argentina's Ministry of Production published Official Resolution 6/2016 to revoke the Label Supervision System that was established on October 14, 2015 by Official Resolution 420/2015. The Label Supervision System required label approval by the Office of Commercial Fairness, in addition to the initial approval by ANMAT (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*), and was generally viewed as a potential obstacle to imports.

Approval of labels for food, beverage, cosmetic, and personal care products, and household cleaning products will now only be done by ANMAT, which is the government technical agency that has historically been in charge of label approval.

For food and beverage products, INAL (*Instituto Nacional de Alimentos*, within ANMAT) is responsible for the approval of labels.

An import authorization is required to import products through SENASA (fresh, chilled, frozen, and thermo-processed products and by-products of animal and seafood origin) and by-products of animal origin into Argentina. The permit is obtained from SENASA and should be requested by an importer who has already been registered at SENASA, and who has registered the facility for export to Argentina.

This authorization includes the registration numbers of the importer and product. After the permit is granted and within five (5) days prior to arrival of the product at the Argentine port of entry, the importer must advise SENASA of the arrival of the shipment. During the following fifteen (15) days, the importation must be completed. Only with a strong justification can this time period be extended.

To import into Argentina, products or by-products of vegetable origin as well as other articles regulated by phytosanitary risk, it is mandatory to have a Phytosanitary Import Authorization (*Autorización Fitosanitaria de Importación - AFIDI*), prior to any commercial transaction.

Those products that do not have phytosanitary requirements established through the AFIDI, must be submitted to the process of Pest Risk Analysis (see http://www.senasa.gob.ar/cadena-vegetal/aromaticas/comercio/importacion/requisitos-generales/fitosanitarios/previo-al-ingreso/analisis-de-riesgo-de-plagas?_ga=2.220070492.478498366.1511795460-772802131.1511795460)

Products imported through SENASA (products of plant origin), in order to obtain a phytosanitary Certificate required for all plant products entering into Argentina (which must be signed by an Animal and Plant Health Inspection Service/APHIS *official* inspector), the exporter will need to submit the AFIDI certificate to APHIS.

The AFIDI will explain in detail all the necessary requirements needed before the product can be exported. Upon arrival in Argentina, SENASA will hold the product at the port of entry for inspection and to verify that it meets all the requirements stated in the AFIDI. SENASA will then issue an import certificate for Customs to release the product (The SENASA import manual is available at: http://www.senasa.gob.ar/sites/default/files/ARBOL_SENASA/VEGETAL/AROMATICAS/PROD_PRIMARIA/manual_del_usuario_importador_v6_24_11_2015.pdf)

For products imported through INAL (processed foods, alcoholic and non-alcoholic beverages, except wine), the importer must register as an importer and register the product through the INAL, in other words, product and importer registration is required prior to importing a product into Argentina. If the product has no problems, its registration should be ready in less than thirty (30) days. The requirements to register imported processed foods are listed below:

- New importers must register as an importer by applying for a National Register of Establishment (*Registro Nacional de Establecimientos - RNE*) which is valid for five years. And in order to register the product, the importer along with his RNE, must apply for a National Register of Food Product number (*Registro Nacional de Productos Alimenticios - RNPA*).
- Once the RNPA has been issued and the product is in the port, the importer needs to obtain a Certificate of Free Circulation (*Certificado de Libre Circulación*) at INAL. Once the importer has an RNPA for a given product, he does not need to apply for a new one every time that he imports that same product. However, he must request a Certificate of Free Circulation for each shipment.
- For products imported through INV (wine only), the importer must have evidence of prior Tax Identification Registration with AFIP (in which the importer will obtain a *Código Único de Identificación Tributaria* - CUIT, or unique tax identification number) before registering with the INV. If approved, the INV will issue a Certificate of Inscription as Importer of Wine Products (*Certificado de Inscripción como Importador de Productos Vitivinícolas*) along with a registration number that may be requested by authorities in subsequent importations.

10. Plastic and plastic materials

10.1. Plastic (Brazil)

10.1.1. Overview

Economic data reveal that plastic initiated and continues a silent revolution in Brazil. Estimations of Abiplast, based on data from IBGE, indicate that additional R\$ 1 million of production on the transformative sector increases other R\$ 1 million on the production of the supplier sector and increase R\$ 2 million on the total production of the country and R\$ 1,3 million to the GDP (Abiplast, 2017, p. 59). In 2017, the industry of plastic transformed products registers an average annual production of 5,8 million of tons of artifacts, which is enough volume to supply a pulverized chain formed by 11459 companies and 313062 workers (Abiplast, 2017, p. 59-60).

10.1.2. Mapping Technical Regulation

The Brazilian Association of Plastic Industry (Abiplast) is the main national institution on the sector and comprises Sectoral Chambers of Producers of Plastic Transformed Products. The main goal of each chamber is to stimulate the growth of the sector of plastic transformation through the cooperation of companies that belong to the same market niche, through the analysis and debate of themes of common interest. The main strategies adopted are the following: (i) understand the needs and filters of each niche of the sector of transformation of plastic material, (ii) debate forms to develop the industrial sector of transformation of plastic material, considering the specificities of each segment and (iii) create projects, aiming to attend the needs of these segments. The table below lists the sectoral chambers.

Table 10.1 - Sectoral Chambers of Abiplast

SECTORAL CHAMBERS
Sectoral Chamber of the Producers of Industrial Buckets
Sectoral Chamber of the Producers of Pre-forms of PET
Sectoral Chamber of the Producers of Blown Industrial Containers
Sectoral Chamber of the Producers of Automotive Components
Sectoral Chamber of Transformers by Rotomoulding
Sectoral Chamber of the Producers of Domestic Utilities
Sectoral Chamber of the Producers of Plastic Covers
Sectoral Chamber of the Producers of Mono and Bioriented Films – smooth technical coil (PP, PE, PET)
Chamber of Producers of Plastic Pallets
National Chamber of Recyclers of Plastic Material

Source: ABIPLAST. Elaborated by CCGI-FGV/EESP

The main recent initiatives of Abiplast on the plastic sector are the following: the applicative and website “Recycling of Plastics”, the National Label of Recycled Plastics (SENAPLAS), the primer Qualification on Identification and Separation of Plastic Materials, the primer of recyclability of post-consumption plastic materials and the database of plastic residues.

Abiplast also adopted a code of conduct with relevant norms that regulate the plastic sector. Principles as integrity, honesty and transparency must guide each collaborator on its commercial activities. All the associates, suppliers and partners must be treated in conformity with the values of the association and according to the applicable laws and regulations.

The collaborators and associates responsible for any form of registry are responsible to guarantee that the information is precise, opportune, complete, clear and understandable. This rule is applied to any type of technical, commercial and financial registry. The financial registries must follow internal and legal procedures. It will not be admitted that a collaborator creates or participate on the creation of registries that contain intentionally wrongful information, aiming to incur someone in error or hide an improper activity.

When investigations are done by legitimate authorities, all collaborators must cooperate. Every visit of a public official relative to an investigation or inquiry must be received and coordinated by the responsible legal officer and by the responsible officer of the area involved on the investigation. The oversights of governmental authorities, on any sphere, must always be presented on the format of a craft. The answers to these crafts must be done formally, on a written form, with the due analysis of the responsible department and presented through protocol to the requiring body. Every administrative process must be forwarded to the responsible officer to adopt the due measures.

The code of conduct recognizes that the suppliers are fundamental parties on the activities of the association and play a relevant role on the satisfaction of the client. These relations must be ethical and mutually beneficial. The suppliers must be evaluated by objective criteria and without any discrimination. Any kind of favoring is prohibited. The objective of the association is to work with the best suppliers with the highest standards of integrity. Abiplast suppliers must divide and share the same ethical standards on anti-corruption, human rights, labor laws and sustainability issues. The suppliers must know the express conducts foreseen on the code and, through a term of accept, must declare their adequacy to Abiplast standards of conduct.

The code of conduct provides a chapter on anti-corruption policy. Abiplast prohibits any offer, promise, authorization or payment in money or any good of value to public officers or their familiars, directly or indirectly, through partners, aiming to obtain an improper advantage.

Considering issues of conflicts of interest, all the collaborators, associates, preposterous and third parties must remain in conformity with the code of conduct to avoid situations of conflicts of interests. The contracting of partners and suppliers must be based, exclusively, on objective competences, aiming at the best contracting for Abiplast. Every situation of potential conflict of interest must be reported to the immediate manager or to the responsible officer for the compliance.

Abiplast will investigate any violation to its policy of conflicts of interest and, when verified the non-information of a conflict of interest, sanctions will be applied. In the case of application of a sanction, the responsible person will be previously consulted.

The code of conduct also foresees a manual for sectoral chambers. This manual aims to establish the rules and the basic conducts of the meetings of the sectoral chambers. The principles of the sectoral chamber are the freedom of initiative, freedom of competition, the right to expression and the principle of free association. The rules are binding on collaborators, associates, preposterous and third parties.

The bodies of each sectoral chamber are the secretariat, the coordination and the vice-coordination. The sectoral chamber is composed mandatorily by one coordinator and one secretary. The coordinator will be elected by at least 80% of the participants of the sectoral chamber. The secretary will be mandatorily elected by Abiplast. The function of coordinator

will last for two years, being possible the reelection to the function. When there is no coordinator or in the absence on the function without an election on the term of 60 days, it is reserved to Abiplast the right to nominate a representative for the coordination that will also occupy the function of secretary.

The rights and obligations of the coordinator and of the vice-coordinator (if exists) are the following: approve the schedule and propose themes, conduct the meeting, represent the chamber when required by Abiplast, approve the minute and sign the term of conflict of interests. The rights and obligations of the coordinator cannot be transferred or derogated. The rights and obligations of the secretary are the following: organize and prepare the agenda of the meeting, prepare the day order, prepare and send the convocations and prepare the minute of the meeting.

The chambers can have the advice of an advisor through a unanimous approval of the participants present on the sectoral chamber. The conditions of the contract and the charges/fees with the contracting of the advisor will be decided by the participants of the chamber. The advisor will be an auxiliary on the coordination of the proposition of themes and on the execution of themes deliberated during the meetings of the chambers with the due technical and institutional support of Abiplast. It is up to the coordinator with the consent of the other participants of the chamber to allow that the meetings of the group be conducted by an advisor.

10.1.3. Mapping Technical Standards

There are several ABNT committees dealing with plastics and their products. The three main committees are as follows: ABNT / ONS-051 - Packaging and Packaging Sectoral Standardization Body; ABNT / CEE-101 - Special Study Commission on Plastic Pipes for Agricultural Irrigation and Drainage; ABNT / CEE-105 - Special Study Committee on Thermoformed Disposable Plastic Cups. These committees adopt technical standards produced by international standards bodies, such as ISO and IEC.

10.1.4. Mandatory conformity assessment procedures

Some products made of plastic has mandatory conformity assessment procedures. There is no such procedures for plastic products used as raw material. ABNT or ISO standards are the norms used to in the mandatory procedures.

10.2. Plastic (Argentina)

10.2.1. Overview

The international trade of plastic products reveals a significant imbalance in Argentina. The country depends greatly on imports of these products. Exports of plastic products on the last three years were always below 1 billion dollars, which may signal the reduced competitiveness of the sector in the Argentine industry. As observed in Brazil, the sector of plastic is regulated mainly on environmental aspects.

10.2.2. Mapping Technical Regulation

The Argentine regulations of the plastic sector are of federal and provincial nature. Most of these regulations do not contain rules for raw plastics (raw material). Such regulation on plastics

has special nature, because it covers specific products or specific aspects of plastic products. The Argentine regulation covers mainly aspects concerning the protection of the environment and the consumer. Bearing in mind that plastic products are used in practically all economic sectors (e.g. in food packaging, in automotive accessories, in toys and household articles), the Argentine regulatory authorities, in line with the international initiatives, focused mainly on the correct disposal of plastic products, as well as in the environmentally sustainable forms of use of these products.

Argentine regulations on the plastics sector deal with the following themes: safety requisites for school goods, the use of bags of polyethylene and other conventional plastic material, the sale of plastic bags that are not degradable, oxi biodegradable or hidro degradable, the production, trade and use of plastic bags, packaging and recipients that are non-pollutant and degradable and the dumping on the sea of all plastic materials.

Therefore, the regulation of plastics does not intend to determine how the product will be produced or what the general characteristics of the raw plastic should be. The regulation focuses mainly on the final products of plastic, whether they are accessories to the main article consumed or the product itself consumed. Often this regulation refers to technical standards produced in Argentina or other standardization bodies.

For example, Resolution 680/2015 of the Trade Secretariat (*Secretaria de Comercio*) establishes safety requisites for school goods that must be traded on the country. Plastic packaging of continuous use must comply with requisites of resistance to fall, small parts, cutting edge, sharp point, articles of polymeric material and of rubber, including the ones reinforced with textile components and articles with plasticizer. When the packaging has painting and/or coating, this class of packaging must also comply with the requisites of painted articles – coating. The plastic cannot also exceed the limits indicated on table I of standard IRAM NM 300-3:2003 determined according to what is foreseen on chapters 7, 8 and 9 of the aforementioned standard.

Provincial Law 9696/2009 prohibits on the territory of the province of Cordoba the use of bags of polyethylene and any other conventional plastic material, used and delivered by supermarkets, auto services, warehouses and commercial establishments in general for the transport of goods. The owners of the establishments must act in order to replace the aforementioned materials, replacing them by containers of degradable and/or biodegradable material that are compatible with the reduction of environmental impact.

The Secretariat of the Environment or the body that on the future replaces it will apply the law. The application authority must create a program of substitution of plastic bags by degradable and/or biodegradable recipients that will contemplate (i) the diffusion, information, awareness and capacitation on the theme, (ii) the coordination with municipalities, communes and national bodies recognized on the issue, (iii) the determination of the authorized manufacturing technology, (iv) the creation of a registry of manufacturers, distributors and importers, (v) the creation of identification methods of authorized containers and (vi) the determination of criteria of degradability and biodegradability. The authority must also create a program of recycling of degradable and/or biodegradable materials, aiming to reduce the ones that are not used and to recover and reuse them.

The regime of sanctions determined by the application authority comprises the warning, fines, confiscation of the product that is not in conformity with the law and the temporary or definitive closing of the establishment. The guidelines for the gradation of sanctions according to the

magnitude of the violation of the law, the economic condition of the violator and the recidivist character will be fixed on regulations.

Law 2455/2008 of the province of La Pampa prohibits the sale of plastic bags that are not degradable, oxi biodegradable, biodegradable or hidro degradable for transport of goods bought by its clients on the markets and/or industries of the province of La Pampa. The sale of the same bags that are applied for residues is also prohibited. On all cases, the materials used must be innocuous to food. The main objectives of the provincial program are the following: programmed elimination on the territory of the province of bags of polyethylene that are not produced with degradable, oxi biodegradable, biodegradable or hidro biodegradable materials; the practice of diffusion campaigns through brochures, different means of mass communication, nongovernmental organizations and intermediate institutions about the protection of the environment directed to the population; the practice of information campaigns on public and private schools about the implementation of the law and about the protection of the environment and the information to all stakeholders about the implementation of the law.

The shops must deliver to their clients bags of degradable, oxi-biodegradable, biodegradable or hidro-degradable endorsed by the corresponding national and international norms. The following goods are exempted from the prohibition: elaborated or pre elaborated recipients that contain food or wet input that for safety and conservation reasons cannot be replaced by materials that are degradable, oxi-biodegradable, biodegradable or hidro-degradable.

The application authority will be the Subsecretariat of Industry and Trade dependent of the Production Ministry that will enforce the controls in coordination with bodies of comptroller of the municipal shops and industry. A regulation will establish the regime of sanctions and the value of fines as well as a system of prizes to shops and industries that comply with the rules of the law. The application authority will concede technical assistance to allow the owners of shops and industries to internalize the different existing options on the market and to reconvert the affected sectors by the law. The authority must also have a registry of the violating stores aiming to control and follow the established program.

Law 7806/2007 of the province of Mendoza creates the program to foster the production, trade and use of plastic bags, packaging and recipients that are non-pollutant and degradable. The program will comprise the following components: (i) studies and statistical analysis about volume of consumption of plastic bags, packaging and recipients and their impact; market potential for the non-pollutant and degradable plastic material and possible tax incentives for trade and its finance impact, (ii) survey of all varieties of non-pollutant plastic materials that are on the market, (iii) actions of the Executive power with universities, research bodies and private sectors, (iv) technical advice for the industry, research areas and environmental action on the private and public sectors, (v) general information to the society about viability, environmental and economic impact, advantages, costs and other technical issues related to the use of degradable plastic, (vi) actions to clarify the public and (vii) the interaction between professionals of different technical areas and the public.

The execution of the program must foresee the implementation of actions aimed at the participation in activities on primary and secondary schools, events of recreation and leisure in parks and centers of recreation in a cultural, sportive and artistic manners; training about the program with different professional activities through advice, seminars, practical exercises, exhibition of videos, publication and distribution of pertinent explaining brochures and creation

of jobs and sustainable economic activities, mainly in cooperatives of production of non-pollutant bags and recipients as a consequence of the program.

The executive power will regulate the application of the program on all its steps and technical specifications. The Ministry of Environment and Public Services of the province of Mendoza will be the application authority and must foresee on its annual budget the necessary expenses to implement the program.

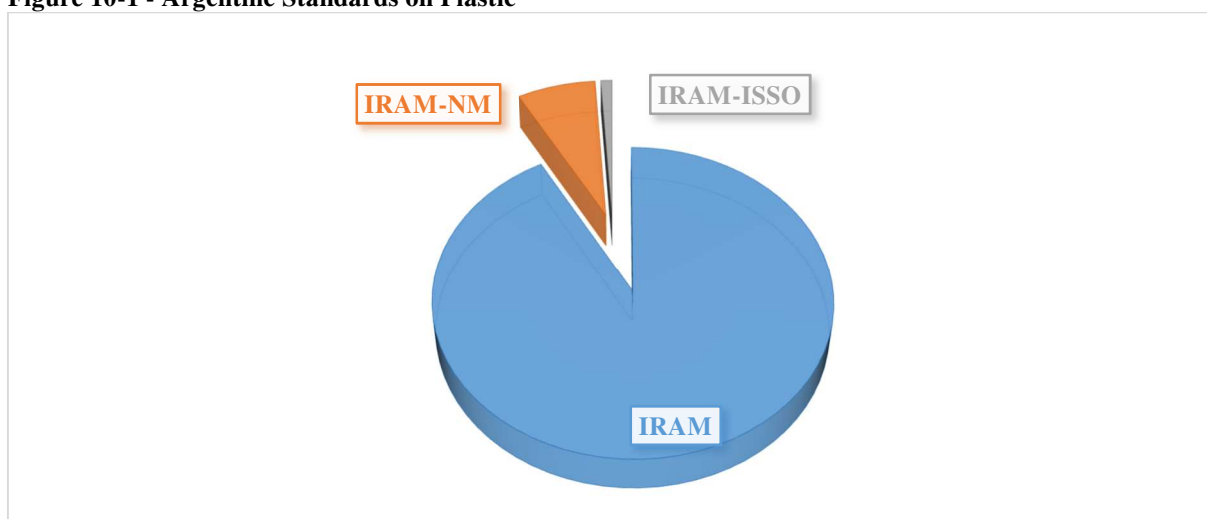
Law 24089/92 approved the international convention to prevent pollution by boats of 1973 and its protocols I and II and annexes. The convention prohibits the dumping on the sea of all plastic materials, which includes the fishing nets of synthetic fibers and plastic bags for rubbish.

10.2.3. Mapping Technical Standards

The Argentine standards on the plastics sector are described on the table below. The vast majority of the standards were created by IRAM and do not follow regional or international standards. In the list with a hundred standards on plastic 6% of the standards are in conformity with ISO standards. Only one standard follows a regional NM standard.

In Argentina, most of the voluntary technical standards in the plastics sector are produced domestically by the Argentine Institute of Standardization and Certification (*Instituto Argentino de Normalización y Certificación*, IRAM).

Figure 10-1 - Argentine Standards on Plastic



Source: IRAM. Elaborated by CCGI-FGV/EESP.

Only a small part of these standards are adoptions of international or regional technical standards. ISO and Mercosur standards represents the universe of non-domestic standards adopted by IRAM.

10.2.4. Mandatory conformity assessment procedures

Some products made of plastic has mandatory conformity assessment procedures. There is no such procedures for plastic products used as raw material. IRAM or ISO standards are the norms used to in the mandatory procedures.

11. Specific trade issues caused by regulatory systems on Brazil and Argentina

In this report, the research analyses the non-tariff difficulties to international trade of Brazil and Argentina, especially (but not limited to) the bilateral trade. The report also identified the more problematic topics concerning the regulatory framework of Brazil and Argentina, suggesting possible solutions for the problems identified in selected sectors. The methodology applied is based on different sources of information subjected to a crosschecking verification. The purpose was to gather evidences on the more important difficulties to international trade of Brazil and Argentina. At the end, the study aims to comprehend not only particular problems of trade, the types of restriction imposed to the commerce and the level of difficult to eliminate them, but also the level of convergence between these two countries' regulatory frameworks.

The first approach to the theme of trade difficulties between Brazil and Argentina was based on the annually reports produced by United States Trade Representative (USTR) and the European Commission, complemented by the information provided the Trade Policy Review of Brazil and Argentina. Although there are other reports on barriers to international trade, the ones herein examined are more completed and encompassing. And despite the issues analyzed in such reports do not apply fully for the case of bilateral trade between Brazil and Argentina, they provide important hints on problematic structures of foreign trade of the two countries. In other words, such reports contain a detailed analysis of the regulation applied to external trade, and the conclusions, in some circumstances, can be used to scrutinize the general problems on barriers to trade.

The second source of information of possible difficulties for the trade between Brazil and Argentina are the specific trade concerns (STCs) raised against Argentina and Brazil in Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) Committees. STCs are instruments used to rise formal concerns against potentially non-legal measures adopted by the members. The history of concerns raised against both countries provides a useful tool for describing specific regulatory problems, which affects directly the bilateral trade.

The third source of information on trade difficulties is the interviews performed with stakeholders from the sectors selected, including companies, associations, standardization bodies and government representatives. Such interviews provide useful information to identify and to fully comprehend the regulatory difficulties of each sector. Only through information provided by actors directly involved in international trade, regulation, standardization and conformity assessment procedures we could check current difficulties involving international trade.

In this study, the concept of difficulties to trade has a broad meaning, encompassing any kinds of regulatory measures that restrict international trade practices. Thus, by definition, tariff measures, quotas and other forms of quantitative restrictions on trade are not included in the report. Moreover, the report focuses only trade in goods, because of specificities not applied to other sectors, such as trade in services, capital flow and intellectual property. In other words, the report centers only on technical barriers to trade and sanitary and phytosanitary measures that interfere in trade flows.

The legal framework that allows the identification of regulatory barriers to international trade imposed by each country are the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade Agreement (TBT), both inserted in the multilateral trade system

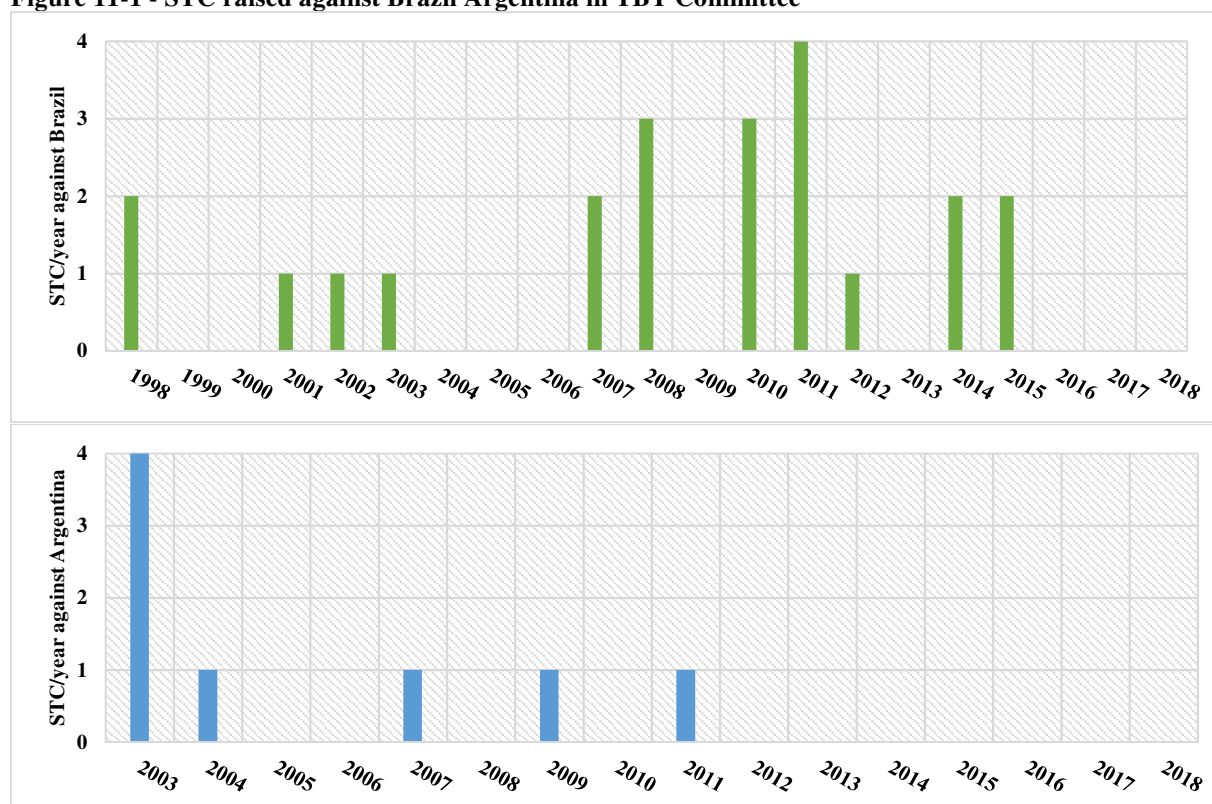
centered on the World Trade Organization (WTO). SPS aims to protect human, animal and plant life or health and is applied to all sanitary or phytosanitary measures with direct or indirect effects on international trade. TBT aims to fulfil legitimate objectives of national security and of deceptive practices prevention and is applied to technical regulations, standards and conformity assessment procedures.

The use of technical regulation and sanitary and phytosanitary measures are admitted by multilateral rules, including the art. XX of General Agreement on Tariffs and Trade (GATT). However, as set forth in TBT and SPS Agreements, the use of such rules cannot unnecessarily affect the trade flow. The measures cannot be a disguised form of protectionism. If the country complies with some agreements' provisions and if its activities is based on international standards, there is a presumption it is in conformity with multilateral rules.

11.1. Specific Trade Concerns

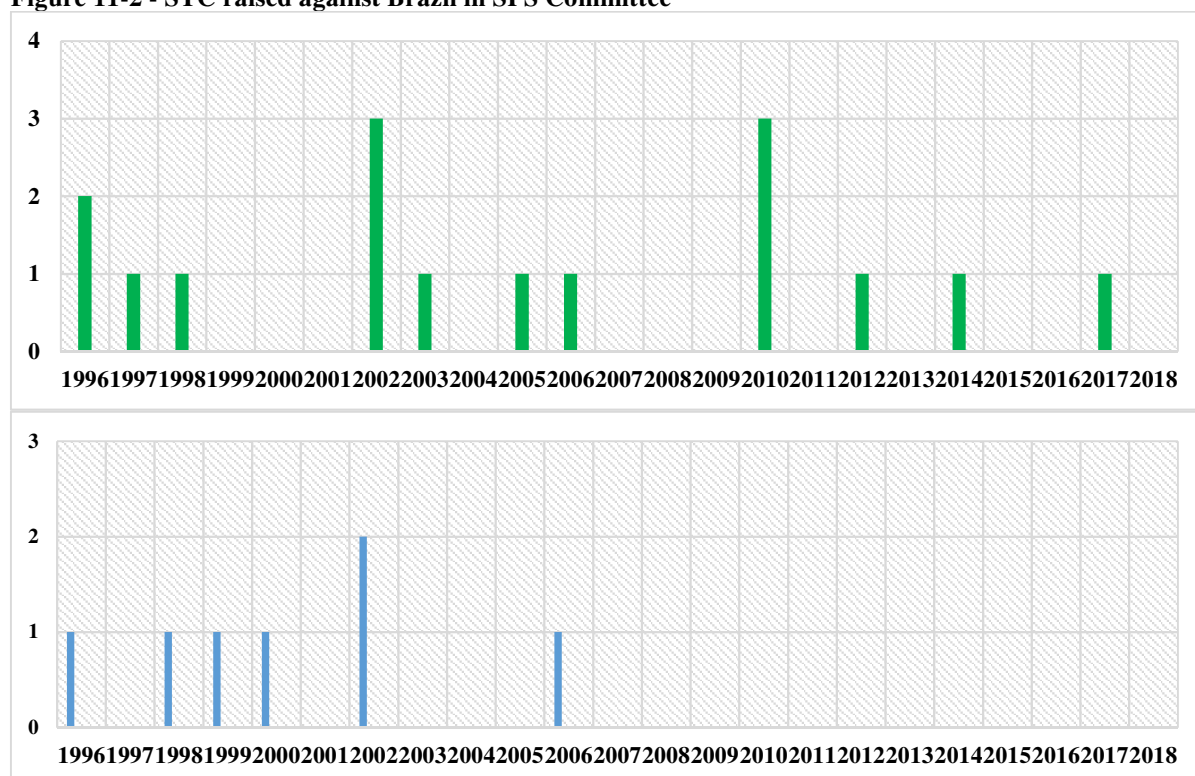
Below the graphs represent the specific trade concerns raised against Brazil and Argentina by all WTO partners. They offer indications of barriers imposed by the two Mercosur members to third countries.

Figure 11-1 - STC raised against Brazil Argentina in TBT Committee



Source: WTO. Elaborated by CCGI/EESP-FGV.

Figure 11-2 - STC raised against Brazil in SPS Committee



Source: WTO. Elaborated by CCGI/EESP-FGV.

In case of Brazil and Argentina, it must be stressed also the regional framework on trade, which constitutes two free trade areas partially overlapped. Both Common Market of South (Mercosur) and Latin American Association of Integration (ALADI) create a free trade region and customs union in which barriers to trade, including non-tariff barriers, have to be gradually eliminated.

The difficulties identified are limited to the sectors analyzed during the research project on regulatory coherence and on regulatory convergence initially between Brazil, European Union and United States and later expanded to Argentina⁶⁰. As mentioned in previous reports, the sectors analyzed are the following: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

⁶⁰ See the website of Center for Global Trade and Investment: <https://ccgi.fgv.br/>

Bearing in mind that the sectors have different characteristics, they have therefore diverse types of difficulties. Some of them are connected with rules on registry and performance of products, others result from discriminatory conformity assessments requirements applied to imported products. For some sectors, the researchers identified no specific barrier or difficulty.

It is also important to highlight the nature of the difficulties. Some problems may be simply a conjuncture and restricted to a specific aspect of the product. This is the case, for example, of the existence of distinct levels of contaminants to ensure the safety of a food product. Other problems may be more serious as they concern the structural aspects of a regulatory system or a set of regulations or technical standards.

The expected results from this analysis is not only the identification of barriers, but also to rank them according to the level of effects to trade. The effect, in turn, will be verified independently of the amount of trade affected, concentrating only on the difficulty of overcoming the barrier. In this way, the greater the difficulty of overcoming the barrier, the greater the level of obstruction. Some barriers will be described in details in order to exemplify how they impose obstacles to trade. Such methodology is useful to policy makers design public policies and adopt mandatory measures, because, by previously knowing the level of the barrier difficulty, simple problems can be prioritized and solved rapidly in first place.

The case of vehicles is emblematic when applying such methodology. The accomplishment of a full regulatory convergence between Brazil and Argentina faces different challenges depending on the dimension of the vehicle regulated. For safety parts of vehicles, the regulation in Brazil and Argentina are very similar, because both follow basic safety requirements demanded internationally. So in this specific case, the regulatory convergence is not a hard task. However, the environmental regulation dimension, especially concerning the greenhouse gas emissions, requires a greater convergence effort since these regulations have fundamental discrepancies.

Thus, based on this context and methodology this report is structured as follows: first main technical barriers to trade as well as sanitary and phytosanitary measures from Brazil are identified, followed by the same possible barriers from Argentina. At the end an effort to detect bilateral challenges and regulatory convergence was also pursued. It is important to note that the identification of convergence efforts is as relevant as the clear perception of trade barriers.

Table 11.1 - Comparative table: difficulties in trade relations by Brazil and Argentina

BRAZIL	ARGENTINA
OVERVIEW OF BARRIERS AND DIFFICULTIES TO TRADE	
MACHINERY SECTOR AND ELECTRICAL APPLIANCES	
<i>Norma Regulamentadora</i> (NR) n. 12, of the Ministry of Labor and Employment, is considered by many importers as an important regulatory difficulty in the machinery and equipment sector in Brazil. NR 12 was designed to regulate labor aspects related to the use of various machines, in a factory and non-factory environment. However, because of the extent of its scope, the NR 12 interferes with the importation of machinery, many of which have differences in safety mechanisms. Several regulations apply international technical standards such as those from ISO and IEC, but Brazil's MTE NR 12 that establishes rules for workers' safety is a hybrid regulation based on Brazilian, international and foreign standards.	On the machinery sector, the main issue is that the Ministry of Labor and Employment (MTE – <i>Ministério do Trabalho e Emprego</i>) constitutes the regulating body of machinery and equipment, which can generate the same problems observed in Brazil with NR 12. However, as the MTE is not a consenting body on foreign trade, it cannot act on customs clearance. Another barrier is present on restrictions imposed on the importation of certain used goods for consumption, such as parts and components that are not used in the manufacture of other products (USTR, 2017, p. 27). The conformity assessment and safety certificate requirements for electrical products constitute a technical barrier to trade. Since 2013, Argentina has maintained conformity assessment requirements that obligate foreign manufacturers and importers to obtain safety certifications

BRAZIL	ARGENTINA
<i>Nota Técnica MTE n. 48/2016</i> is an important source of interpretation of NR 12, and it adds some specifications of NR. It determines: a) the exclusion of the expression “fail-safe” of NR12; b) the inclusion of the concept of state of art; c) and the correlation between the category of safety and levels of performance. The last point is relevant due to the possibility of a non NR12 conformity of that new machines, produced in Europe according to international standards ISO or IEC, or harmonized EN type C standards. Regarding the principle of fail-safe, it used to be applied to specify failures to which a product or a system must be resistant to. However, considering that NR 12 establishes general principles of mandatory compliance and due to the possible conflict between NR 12 and standards in force or in phase of creation/translation, the principle of fail-safe was removed from the norm. The concept of state of art, mentioned in <i>Nota Técnica MTE n. 48/2016</i>, has no precise definition, but it includes technical and economic aspects in a way that technical solutions adopted must apply the most efficient technical means available. The machine producers have to be attentive to technical progress applying the most efficient technical solutions that are adequate to each machine. In cases in which it is not possible to fully satisfy the essential requisites of safety and health on the current state of art, the producer of the machine must comply to the highest extension the objectives foreseen on the essential requisites of safety and health. The NR 12 is in permanent update, which does not result in permanent modernization. The Thematic Tripartite National Commission of the NR 12 (CNTT) was created to regulate it, always considering national characteristics. Evidences of the application of the state of art are the application of international standards and the application of EN harmonized norm of type “c” on specific cases.	from Argentine certification bodies for all imported and electronic products before they can be traded in Argentina (USTR, 2017, p. 21). The restrictive elements present on the conformity assessment procedures are the repetitive testing requirements applicable only to foreign manufacturers, the imposition of significant delays, increase of costs and the imposition on importers of low voltage electrical equipment of safety certificates from the Argentine Gas Institute (IAPG, according to initials in Spanish) for their imports (USTR, 2017, p. 21). Recent infra-legal norms can contribute to reduce the costs and burdens present on the conformity assessment procedures. The approval of dispositions E 578/2016 to E 586/2016 that authorize the recognition of international certification results for specific electronic products has the potential to reduce the testing requirements for these goods. The sectoral research on electrical products revealed that another barrier is present on the standards applied in the sector. Most of the standards used in the electrical sector are homegrown standards, mainly those standards produced by Argentine Institute for Standardization and Certification (IRAM). The international standards such as the IEC and those produced by some Committee of the Mercosur Standardization Association (AMN) correspond to a little more than 20% of the IRAM standards, which may indicate a low degree of the sector internationalization. On the regional sphere, the same profile is repeated as there is a reasonable number of technical standards adopted by AMN, although these are not always adopted by the Argentine standardization body. Another peculiar fact is the relevant number of adopted norms that create technical regulations for specific products and specified tariffs. The protectionist effect of those regulations, however, remains uncertain.
VEHICLES	
In the Brazilian automotive sector, some specific problems and barriers can be identified. In addition to the high tariffs and sectoral stimulus programs directed at companies operating in Brazil, some important technical obstacles should be mentioned, such as the requirement for certification for parts and environmental and safety requirements for the approval of vehicles. The participation of INMETRO in the regulation and determination of mandatory certification for auto parts for the aftermarket is considered to be especially important, as well as the performance of CONTRAN and IBAMA in homologation procedures for the whole vehicle, a necessary condition for the car to be able to travel through the Brazilian roads.	On vehicles, the requirement of compliance of strict active and passive safety regulations imposes an excessive burden on traders and can constitute a barrier. Domestic producers, for example, must present certificates of compliance with specific IRAM standards. Argentina also presents test methods and cycles different from the Brazilian ones. In Brazil, the method follows an American norm. In Argentina, the European method is applied, which leads to variations of fuel, cycle and limit. Argentina will change from Euro 5 method to Euro 6 method. Each method corresponds to a specific level of emissions from light passenger and commercial vehicles. Different measures need to be adopted by Argentina and the first steps are present on the action on the accreditation of laboratories, the action on the committee of the automotive industry of Mercosur subgroup of work 3. These measures aim to identify coherence of positions on the sectoral fora. On vehicles, a barrier is present on the new gaseous pollutant emissions certification of January 15, 2018. Its scope of application comprises light automotive vehicles belonging to categories M1 and N1. This certification must incorporate the certified values of CO₂ emission and fuel consumption for the use of the approved fuel type according to rules without an international nature. The certification procedure is specified on IRAM-AITA 10274 standard, the ECE R. 101 regulation and on the European Directive 715/2007.
MEDICAL DEVICES	
In the Brazilian medical devices sector the main trade restrictive barrier reported is the complex regulatory system	

BRAZIL	ARGENTINA
coordinated by Brazilian Health Regulatory Agency (Anvisa), which is responsible for the registration of these products in concordance with its classification. Products are classified in: i) Lower risk Class I and II devices that follow the <i>Cadastro</i> registration route and require a simplified application; and ii) higher risk Class III and IV devices that follow the <i>Registro</i> registration process. For some products ANVISA also requires a Brazil Good Manufacturing Practice (BGMP) certification. Some measures have been adopted to mitigate the complexity the regulation of the sector. Inside the regulatory system, the Medical Device Single Audit Program (MDSAP) was implemented aiming to allow that producers of health products contract a third party auditing body to do a unique auditing that will encompass the relevant requisites of participating regulatory authorities. The report produced after the auditing will be accepted by different regulators to deal with different requisites of the management systems of quality and good manufacturing practices. The conformity assessment costs will, thus, be reduced. Those submitted to a MDSAP auditing can also accelerate the process of obtaining an ANVISA good manufacturing practice certificate, that is a pre-requisite for trade authorization (BSI, 2018). The ANVISA international partners for MDSAP are the following: Therapeutic Goods Administration (TGA) of Australia; Health Canada of Canada; U.S. Food and Drug Administration of the USA and the Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan. The RE 2347/15 recognized the MDSAP and established that the auditing bodies that comply with the requirements established on the scope of the program will be recognized by ANVISA through the publication of an individual normative act. ANVISA will use the results of the program, including the reports, to constitute an important conformity assessment procedure before and after sale, providing key information that are expected to support the technical evaluation of the regulations on these issues (BSI, 2018). The RDC n. 185/2001 was subsequently altered by the RDC n° 207/2006 and the RDC n° 40/2015. However, there was no modification concerning the class and the types of products. The RDC n° 207/2006 provided on the following aspects: i) the legal condition of the distributor of a medical product; ii) the procedures for registry; iii) the conformity to information; iv) and the information of medical devices labels and instructions. The distributor of medical product that requires the registry of the product manufactured in Brazil is not equated to a importer regarding presentation of documents for registry, alteration, revalidation or cancelling of registry. The medical product submitted to clinical research are exempted of registry in case of compliance with legal norms of the competent sanitary authority. Additionally, the necessary information for the correct and safe use of the medical product must be on the product or on the label of its individual packaging or on the label of its commercial packaging. A barrier may be present on the information on these labels as, despite the existence of general principles for environmental labels on an ISO norm, it is still significant the use of environmental standards that are not recognized internationally. The RDC n° 40/2015 altered the producers or the importers' obligations. They are no longer obliged to register their	

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products on a given agency if the registration is not a requirement. The absence of the obligation to register products without a legitimate and transparent criterion can lead to a discriminatory treatment of products and, thus, constitute a regulatory barrier. Thus, although the regulation of the sector, especially that imposed by ANISA, is complex, it is evident that Brazil has been struggling to conform to international standards. In addition, international convergence schemes, such as the MDSAP, allow for continued convergence in the industry, including in relation to conformity assessment.	
PHARMACEUTICAL PRODUCTS	
ANVISA established the relevant regulations for the pharmaceutical sector to public protect health standards through the sanitary control of the production and consumption of products and services subject to health surveillance. This includes the certification of good practices, the registration of pharmaceutical products and the establishment of medicine prices. The registration of a drug in Brazil faces a complex and time-consuming process. The steps are: the registration of the company in ANVISA's Petitioning System; the authorization of operation of the company (the authorization will only be granted to companies with a commercial representation or subsidiary registered under the Brazilian Law); the Certificate of Good Manufacturing Practices (<i>Certificado de Boas Práticas de Fabricação</i> - CBPF); and, finally, the drug registration. The deadlines for the final decision in drug registration processes are different for the priority category (120 days) and for the ordinary category (365 days) and it only starts to be valid with the publication in the Brazilian Federal Gazette (<i>Diário Oficial da União</i> – DOU). Thus, one possible barrier is the amount of time required by the registration process because the drug can only be marketed after all this registration process. The RDC n. 81/2008 is particularly important regarding regulation on pharmaceuticals, and it can create some difficulties for exporters. The RDC n. 81/2008 provides a <i>Technical Regulation to Imported Goods and Products for Sanitary Surveillance</i>, mainly for pharmaceutical products, adopting definitions, categories of imports, registration of the import license, among others. The RDC n. 81/2008 stipulates that only an authorized firm can import pharmaceutical products. The RDC n. 81/2008 also determines characteristics and basic information of the imported medicine, prescribes the use of the Portuguese language in the documents with technical information about the products⁶¹. These determinations may create difficulties for the foreign company that wishes to sell in the Brazilian pharmaceutical market. Finally, it was reported that one important problem is related to the chronogram of inspection that is not updated on the website⁶² (the last update was in August/2016). Therefore,	On the pharmaceutical sector, products face a range of burdensome and costly registration, licensing and certification procedures which creates difficulties to the exportation of these products. This barrier is present even when a medicine analyzed by another regulatory agency is consumed due to the confidence on the regulatory agency of another country. Besides, the majority of technical regulation notified to TBT committee has no standards indicated, which means that international standards are not supporting them. One example of barrier present on the pharmaceutical sector are measures that affect market access for pharmaceutical products. Concerns were raised about the Argentine system applied for the entry of pharmaceuticals in the country, specifically with regard to the classification of countries and the resulting application of conformity assessment procedures (WTO, 2008, p. 3). The issue could be dealt within the pertinent Mercosur bilateral group, but no initiatives on this sense have been taken up to now. On the last TBT Committee meeting in which this concern was debated, the representative of Colombia informed that, despite the dialogue between Argentine and Colombian authorities, the necessary authorization to allow Colombian companies to export medical products into the Argentine market had not been given (WTO, 2009, p. 56). The representative of Argentina, on the other hand, informed that intensive consultations had taken place between the different federal government agencies, including ANMAT, on how to address the issue (WTO, 2009, p. 56). After consultations, it was agreed that necessary administrative procedures would be initiated to address the concern appropriately (WTO, 2009, p. 56). On the pharmaceutical sector, a barrier is present on the Argentine guidelines for good pharmacovigilance practices that are not wholly in conformity with internationally accepted standards. The guidelines provide a quality system and standard operative procedures for activities of pharmacovigilance. This system presents control mechanisms in order to guarantee its correct functioning and efficiency as the authority of the pharmacovigilance worker to change the pharmacovigilance system in order to guarantee the compliance of the guidelines and the

⁶¹ The use of Portuguese language was not a spontaneous decision by ANVISA. It was determined by judicial decision, after the request of federal prosecutors.

⁶²BASIL. *Cronograma de Inspeção*. ANVISA. Available at: <<http://portal.anvisa.gov.br/documents/33864/2871295/Cronograma+de+Inspe%C3%A7%C3%B5es+de+Medicamentos+-+Janeiro+a+Agosto+de+2016.pdf/ecb178c9-6c5e-497b-93b5-d8245780adbc>>. Accessed on: June 12th, 2017.

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companies cannot have the control of the date scheduled for their inspection to happen. The point of the inspection is to obtain a certificate of good practices. The international certificate issued by ANVISA depends on the inspection procedure performed in several stages, including the analysis of the basic documentation of the inspection request, establishment of an inspection schedule, formation of inspection teams, international travel logistic planning and hosting for members of the team of inspectors. It should be noted that ANVISA only informs and deals with the applicant regularly established in the national territory⁶³. Some of the problems identified do not actually consist of regulatory barriers to trade. They are the simple result of the slow and sometimes bureaucratic functioning of the public administration, which often does not have enough employees to carry out the necessary inspection procedures for the liberalization of certain products.	regulatory measures that can be the result of a pharmacovigilance inspection, namely advise, re-inspection, warning, restrictions due to security reasons and other pertinent measures. Another barrier is present on the content of a specific document of the sector, the periodic informs of safety updates. There are documents in which all the pharmacovigilance data of a medicine gathered on a specific period are presented. This data can be later compared to international standards of the sector. The main goal of these informs is to allow that pharmaceutical laboratories that can be either governmental or accredited participate on the collection of data and notifications, evaluate the safety information gathered and present it on a standardized form to the regulatory authority that registered the medicine. The offer of the national and international experience by these laboratories about the safety of a medicine allows: • the communication of new relevant information about safety from adequate sources, • the presentation on a concise manner of the situation of the registry and trade authority on different countries, whenever applicable, and any important change related to safety and • the periodical facilitation of the opportunity to reevaluate the relation benefit/risk and to decide the modification of security and therapeutic information of the medicinal specialty.
COSMETICS SECTOR	
Labeling requirements, such as the obligation to list all ingredients in Portuguese, are unusual by international standards and have been pointed out by Brazilian and foreign manufacturers as a trade barrier, which led to court challenges against ANVISA. Documentation requirements for the import of cosmetics is also considered a trade barrier. ANVISA has to approve the product registration for the imported cosmetics. The registration process at ANVISA normally lasts on average 490 days for regularization of registered products and more than 730 days for new products, according to ANVISA. The same observation made for pharmaceutical products is valid for the cosmetic sector. Some of the problems identified do not actually consist of regulatory barriers to trade. They are the simple result of the slow and sometimes bureaucratic functioning of the public administration, which often does not have enough employees to carry out the necessary inspection procedures for the liberalization of certain products.	
FOOD AND AGRICULTURE SECTOR	
The Food Industry Sector is regulated by several public bodies and there is not a centralized authority responsible for coordinating and collecting all legislation applied to the food industry products. Despite of that, ANVISA seems to have a relevant role in regulating this sector because of all health issues associated to food industry products. Furthermore, the Brazilian food and beverage regulatory framework is frequently modified. Many resolutions are published in short periods of time. The most recent regulations in force in this area are often publicly available.	On the processed food sector, the then existing European Communities had submitted comments with regard to Argentine notifications on olive oil and on labelling of pre-packaged food. Argentina, on the provision of answers to the comments, explained that consultations had been taking place and that authorities were ready to continue the exchange of views, to receive further comments and to provide responses to them (WTO, 2003, p. 8). The notification of pre-packaged food involved a more complex issue as an Argentine measure was not being questioned, but a Mercosur one. This Mercosur regulation was later

⁶³ See the portal for registration and authorization for companies <http://portal.anvisa.gov.br/registros-e-autorizacoes/empresas/cbpf/inspecao-para> -certification. More details on technical requirements and inspection formalities are set on Resolution RDC n. 39/2013. Finally, ANVISA publishes each year its agenda of international inspections (<http://portal.anvisa.gov.br/inspecoes-internacionais>), which indicates the beginning, the end and the country of the inspection.

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It is important to provide some context to the ANVISA work. Since the agency has started its work only about 20 years ago while its counterparts in developed economies are more prepared. For that reason, the agency is still working to adequate the Brazilian regulation for food industry products with relevant international sanitary standards, especially those of the Codex Alimentarius. The analysis of this sector, when discussed with Brazilian producers and importers, shows some other relevant points: - Burdensome regulation on allergenic ingredients labelling in foodstuff products - ANVISA has adopted a new regulation on allergenic labelling in foodstuff products on July 2015 (enforcement date July 2016). This new requirement is mandatory for foodstuff, beverages, additives and ingredients used in food processing. Its main purpose is to inform consumers about the presence or traces of foods that are commonly associated with food allergies. The initiative was approved after a large popular mobilization of parents who face difficulties in identifying which foods their children can or cannot consume. Either way, this means additional costs to the product. - Technical Regulation on food additives and technology authorized on wine - A regulation (Resolution RDC n. 123/2016) with respect to food additives and technology authorized to use in wine has been published on the website of ANVISA and it entered into force in November 2017. In addition to that, there are other laws and MAPA regulations affecting the production and sales of wine and grape products, two of which were raised as a Specific Trade Concern at the WTO CTBT (See TBT 613/675 and TBT 719). These regulations may not be in conformity with any international and even MERCOSUR standards. - Backlog of market access applications (undue delays by Brazil) - The backlog of evaluations of the inspection and certification systems by the relevant services of the Ministry of Agriculture, Livestock and Food Supply of Brazil remains a serious obstacle to trade. - Slow approval of labels of products of animal origin - To be able to export products of animal origin to Brazil (e.g. meat, dairy and fishery products), establishments must apply for the registration of each label in the Ministry of Agriculture, Livestock and Food Supply (MAPA). New developments have been announced by MAPA regarding the electronic registration of labels, which should speed up the approval of labels.	surpassed by the Resolution 26/03, which took into account the comments made by the European Communities (WTO, 2003, p. 14). Affidavits of Foreign Sales (<i>Declaraciones Juradas de Ventas al Exterior</i> – DJVE) imposed by Argentina since 2015 constitute another technical barrier on the sector. Exporters of grains, oilseeds and their derivatives are required to obtain affidavits and to register the exportation with the Office of Coordination and Evaluation of Subsidies to Domestic Consumption (UCESCI) (USTR, 2017, p. 28). Approved DJVEs are valid for 180 days, except DJVEs for wheat, which are valid for 45 days (USTR, 2017, p. 28). On September 26, 2016, the Ministry of Agroindustry, together with the Ministry of Production and the Ministry of Treasury and Public Finances, issued Joint Resolution 1-E, extending the DJVE requirement for the 2016-2017 agricultural year (USTR, 2017, p. 28). On the processed food sector, Argentina creates some obstacles for the following products: live cattle, beef and beef products, pork and poultry. Most of these obstacles affect imports originating in the US, however, they can pose problems that can be extended to other trading partners. Analyzing the first subsector, Argentina imposed restrictions on imports of all U.S. live cattle, beef and beef products since 2002 due to concerns with bovine spongiform encephalopathy (BSE) (USTR, 2017, p. 21). In 2015, Argentina changed its trade position through resolution 238/15, in which Argentina recognized the OIE's classification of the United States as a country with negligible BSE risk (USTR, 2017, p. 21-22). A historic evolution allows a clearer understanding of the issue. Similar restrictions were imposed on the European Union since 1999. The issue of import restrictions on bovine semen and embryos due to BSE was solved with the lift of the restrictions in 2005. Different countries of the Eastern Europe also drew attention to the notifications of emergency measures banning imports of certain animal products from countries that were BSE-free and not included in the OIE list of countries with reported cases of BSE (WTO, 2001, p. 4). The affected countries were ready to provide Argentina and other Members imposing restrictions with the necessary documentation warranting their status as being BSE-free (WTO, 2001, p. 4-5)⁶⁴. Bulgaria later reinforced in the same year the STC was presented that would keep monitoring the situation. Canada was another country that questioned Argentine measures, which allegedly copied the EC geographical BSE risk categorization scheme (GBR), was not in conformity with an international standard and did not conduct a risk assessment. In its last manifestation of will, the representative of Argentina declared that significant progress had been reached on the issue and he was confident that a resolution could be achieved. On the following year, Canada informed the Secretariat that a solution had been found to the issue. An analysis beyond the STCs raised by Argentina can provide a more objective scenario of the subsector. The OIE members' official BSE risk status map reveals that United States, different European Union countries, Eastern Europe countries, including Bulgaria and Canada present a negligible BSE risk.

⁶⁴ Even if Brazil and Argentina are considered BSE-free, this situation can be changed quickly. The list of countries declared BSE-free is dynamic. At present, Brazil and Argentina are recognized as having a negligible BSE risk by the OIE. The updated list with country categories is available at: <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/en-bse-carte/>

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	Besides the issue of the BSE, Argentina was questioned by the European Communities for restrictions placed on its own beef exports, which led to a reduction in the amount of beef it exported under the Hilton Quota. This trade disruption could lead to a weakening of the SPS controls necessary to ensure that beef exports met the SPS requirements of the European Communities (WTO, 2006, p. 8). The European Communities sought guarantees of compliance of its sanitary requirements, especially in terms of traceability in circumstances of substantial reduction of export quantities. On the pork subsector, Argentina currently does not allow imports of US pork (USTR, 2017, p. 22). Despite United States' proposals to review sanitary certificates to debate concerns previously raised by Argentina, SENASA pointed that only imports of US pork from herds that have tested negative for <i>Trichinellosis</i> and without Porcine Reproductive and Respiratory Syndrome (PRRS) would be imported (USTR, 2017, p. 22). In the past, the European Union had questioned Argentina's temporary prohibition of fresh pork and pork products. The representative of the then European Communities indicated that the region had taken measures to regionalize the three EC member States which had restrictions in this regard, in particular some parts of Germany, the South of Netherlands and parts of Spain, but, in all of these regions the situation was under control (WTO, 1998, p. 9). By introducing a restriction applying across the board to all these countries, Argentina had not abided by Article 6 of the SPS Agreement - Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence - nor the OIE guidelines (WTO, 1998, p. 9). On the poultry subsector, the imports of fresh, frozen and chilled poultry from the United States were prohibited after worries with Avian Influenza. Argentina also has not recognized the US sanitary inspection system as equivalent to the Argentine system (USTR, 2017, p. 22). More recently, Argentina has indicated it would accept cooked poultry products from the United States, but there is no agreement yet on the terms of the necessary sanitary certificate as Argentina has maintained that the US poultry inspection system is not equivalent to the Argentine system (USTR, 2017, p. 22). On the bilateral trade between Brazil and Argentina, three relevant products identified in which barriers are present are red shrimp, citric fruits and olive oil. The issues involving these products will be explained below. On March 2013, Brazil and Argentina reached an agreement in which that country compromised to limit its exports of red shrimp to five tons per year. With the agreement, enabled Argentine companies were authorized to export to Brazil. The Brazilian government complied with the agreement reached on March 2013 when removing technical barriers to importations of red shrimp from Argentina. Importations are, however, currently suspended due to judicial determination. Considering citric fruits, Argentina complains that the Brazilian market on the sector remains closed to its products. According to information provided by MAPA, there is, in Brazil, legislation that restricts the movement of citric fruits on the country, aiming to avoid the risk of dissemination of citrus canker. The allowance of importation of lemons from Argentina would have potentially negative impacts on Brazilian producers as Argentina is one of the greatest exporters of lemon on the world. Regarding the entrance of Argentine orange, the immediate opening of the Brazilian

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	market is also seen as potentially negative to the Brazilian producers. Finally, analyzing olive oil, Argentina claims that great part of olive oil exported to Brazil goes through reclassification through the verification of the percentage of the substance campesterol. After the reclassification, Argentine olive oil could compete with the European product highly subsidized. In this sense, the limit of 4% for the substance campesterol, object of the reclassification, aims to assure the degree of purity and quality of olive oil consumed on the country, as it is very common the adulteration of this product with the use of other vegetable oil or of low quality olive oil.

11.2. Bilateral challenges and regulatory convergence

Concerning only Brazil and Argentina, it is possible to exam the level of convergence of their regulatory and standardization policies. This exam can help these countries to prioritize sectors and better design strategies to enhance their international trade flow. To do so, the degree of difficulties in terms of technical regulation and supporting standards were analyzed and classified. Whether sectoral regulations are harmonized according to the Mercosur system and the supporting standards applied by each country are similar, a high degree of convergence was inferred.

It was assumed that the smaller the number of barriers in a specific sector bilateral trade, the greater the degree of convergence. Also, it was considered harmonized the regulations subject to publication and internalization at the Common Market Group Resolutions, but in cases of non-regulatory harmonization the criterion to identify possible regulatory convergence was to compare the similarities of supporting technical standards existent in each national regulation.

The sector covered are the same ones: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

Each one of this sectors were classified according to the following rules:

- 1) **FULLY CONVERGED:** when no mandatory impediment to trade between Brazil and Argentina was identified;
- 2) **PARTIALLY CONVERGENT:** where the regulation of the sector is in part harmonized in Mercosur and/or the supporting standards applied in both countries' technical regulation are similar;

3) DIVERGENT: for the situation where no trade in a specific sector is allowed.

Starting with the broader regulatory framework, only the cosmetic sector could be considered fully harmonized. The other sectors were considered partially harmonized since only some sectoral norms and/or parts of the sector were identified at the Common Market Group Resolutions.

Table 11.2 - Level of convergence of regulation

SECTOR	REGULATION
Electrical and electronic appliances and machinery	Partially harmonized in Mercosur. The Mercosur regulation covers only a small part of electrical products.
Vehicles and auto-parts	The sector is not formally included in Mercosur, but there are a few norms on traffic and safety so the regulation can be considered partially harmonized.
Cosmetics	Fully harmonized in Mercosur.
Machinery and mechanical equipment	Partially harmonized in Mercosur.
Medical devices	Partially harmonized in Mercosur.
Processed food	Partially harmonized in Mercosur.
Pharmaceutical products	Partially harmonized in Mercosur.
Plastics and plastic products	Lack of regulation. The regulation in two countries is limited to sustainable use of plastic, which is also regulated by Mercosur regulation so it is considered partially harmonized.

Regarding standards, it was observed a lack of mutual strategies between Brazil and Argentina. In some sectors Argentina is more internationalized than Brazil, but regarding medical devices the situation is contrary, Brazil is more internationalized than Argentina. In others, both countries are equally not internationally standardized, although the cosmetic and pharmaceutical sectors are regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards. There are also cases, such as in the vehicles and plastic sectors, equally not internationally standardized. Only the processed food can be similar although Argentina does not indicate Codex as supporting standard.

Table 11.3 - Level of convergence of standards

SECTOR	ARGENTINE STANDARDIZATION	BRAZILIAN STANDARDIZATION	SIMILARITIES
Electrical and electronic appliances and machinery	High degree of internationalization, and regional production based on ISO and IEC.	Low degree of internationalization and production of few regional regulations on the sector. Most of them are national standards (ABNT NBR adapted from IEC).	Argentine standard choices are more internationalized. Brazilian national standards adaptation can indicate protectionism.
Vehicles and auto-parts	Lack of regional standards creates a difficult environment for convergence although some NM regional standards were identified.	Low degree of internationalization, absence of a common regime in Mercosur, common technical regulation on safety and environment regarding the sector, creation of standards by AMN.	Equally not internationally standardized.

Cosmetics	There is no relevant voluntary standard on cosmetics in Argentina.	Few standards, but mainly based on ISO and few regional resolutions adopted by ANVISA.	Equally not internationally standardized. However, the sector is regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards.
Machinery and mechanical equipment	High degree of internationalization, and regional production based on ISO and IEC.	Majority of national standards, but increasing application of international standards and development of regional standards usually in conformity with the work of ISO	Argentine standard choices are more internationalized. Brazilian national standards adaptation can indicate protectionism.
Medical devices	Lack of regional standards creates a difficult environment for convergence although some NM regional standards were identified.	High degree of internationalization and few regional regulations on the sector	Brazilian standard choices are more internationalized. Argentine national standards adaptation can indicate protectionism.
Processed food	Only few regional standards were identified. Codex standards were not chosen in most cases.	Regulations based on Codex standards and regional recommendations aiming to harmonize foodstuff products regulations	Can be similar although Argentina does not indicate Codex as supporting standard.
Pharmaceutical products	There is no relevant voluntary standards.	Low degree of internationalization and few regional regulations on the sector.	Equally not internationally standardized. However, the sector is regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards.
Plastics and plastic products	No standards were identified.	No data on standards and few regional regulations on the sector	Equally not internationally standardized.

In summary, sectors level of convergence can be observed by comparing each sector.

Table 11.4 - Level of convergence of regulation and standards

SECTOR	REGULATION	STANDARDS INTERNATIONALIZATION SIMILARITIES	CONVERGENCE
Electrical and electronic appliances and machinery	Partially Harmonized	Not similar.	No
Vehicles and auto-parts	Partially Harmonized	Similar: not internationalization	Low
Cosmetics	Highly Harmonized	Similar: not internationalization	High
Machinery and mechanical equipment	Partially Harmonized	Not similar.	No
Medical devices	Partially Harmonized	Not similar.	No
Processed food	Partially Harmonized	Similar	Low
Pharmaceutical products	Partially Harmonized	Similar: not internationalization	Low
Plastics and plastic products	Partially Harmonized	Similar: not internationalization	Low

The only sector that appear to present better degree of convergence is the cosmetic sector that has the technical regulation completely harmonized in Mercosur, by means of the Resolution created by Common Market Group, which approves the projects from Working Subgroups of Mercosur. Plastic sector, pharmaceutical, processed food and vehicles (for vehicles, see Annex) are considered poorly convergent because even though both countries are not adopting international standards, but the technical regulations have been partially harmonized. Specifically for the plastics sector, it is possible to notice the absence of compulsory rules, which avoids the existence of contradictions and regulatory inconsistencies, indicating that regulation is not a relevant impediment to trade. Machinery, electrical products and medical devices are considered not convergent and the most complicated sectors to think on regulatory and standardization common policies.

Further studies are needed to evaluate the conformity assessment procedures applied by each country and also to deeply investigate each sector to comprehend whether there is part of the sectors presenting specific difficulties, which could lead to better strategic movements towards convergence.

12. Conclusions: A synthesis of main results

In order to present the main data collected on each sector for both countries, a synthesis is proposed according to the structure of this project. The main categories explored on each selected sector are the following: authorities, regulation and standards. The paragraphs below explain the main elements identified on each category.

The supporting standards to be described on the synthesis tables are those mentioned in the technical regulations notified to the TBT Committee and to the SPS Committee of the WTO. The standards can be either national, regional, international or sectoral with global reach. Focal points are the bodies responsible to notify regulations to WTO committees. In Brazil, INMETRO is the focal point responsible to provide information in the case of technical measures and MAPA and ANVISA have the same responsibility in the case of sanitary and phytosanitary measures. In Argentina the focal point is constituted by experts from ministries. Several other regulations can also issue regulations and standards and shall notify the WTO on a regular basis. In Brazil and Argentina, ABNT and IRAM creates standards in a participatory and consensual manner in conformity with international standards.

This mapping allows conclusions based on the degree of utilization verified (as percentages of the total number of standards identified) and on the information obtained from sectoral reports. Standards can be the basis to the formulation and implementation of rules for the solution or the prevention of problems with the cooperation of the all concerned. The standardization process addresses the conditions for a product to meet determined purposes.

For each selected sector the research obtained the following results:

12.1. Vehicles

The vehicle sector in Brazil is basically regulated by public authorities, which take the form of ministerial organs of the direct administration and autarchies, constituents of the indirect administration. Examples of these authorities are the Brazilian National Environmental Council (CONAMA), the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), the Brazilian National Traffic Council (CONTRAN) and the Brazilian National Institute of Metrology, Quality and Technology (INMETRO).

The regulation is limited to ordinary laws and ordinances mainly on car safety and pollution issues. In terms of standardization, ABNT creates standards for the sector and promotes private and international standards in the area. Considering notified standards, around 60% per cent of them were created by ABNT and the remaining ones are either international, American or European.

In Argentina the automotive sector is regulated mainly by public entities, namely the Ministry of Production, the Ministry of the Environment and Sustainable Development and the Ministry of Transport. In certain specific situations, the power of regulation is delegated to private sector entities. The sector is regulated by different normative sources as ordinary laws and resolutions and encompasses different types of standards. A great variety of standards was notified to the TBT Committee and these standards can be national (e.g. IRAM-AITA standards), regional (e.g. European directives) and international (e.g. ISO standards).

12.2. Machinery

In Brazil, the main regulatory authority is the Ministry of Labor, which regulates aspects concerning the safety of the machine and the safety of machine operator. Ordinary laws and ordinances are the legal instruments used to regulate the sector and aim to guarantee worker safety, machine safety and consumer safety. The standards notified are national as ABNT standards or international as IEC and ISO standards. Often, domestic and international standards are combined in an atypical way, causing compliance problems, especially for foreign companies. The main objectives of the notified standards are safety, environmental protection, conformity assessment and metrology and other less relevant topics.

The machinery sector in Argentina is regulated by different authorities, which encompass, public actors, ministries as the Ministry of Production, two autarchies, the National Institute of Industrial Technology (INTI) and the National Entity Regulator of Gas (ENARGAS), and one non-governmental actor. Ordinary laws are the main source of the regulation for the sector. The supporting standards of regulation notified to WTO are either national (IRAM standards), regional (CEN standards) or international (ISO and IEC standards).

12.3. Electrical products

In Brazil, the electrical products sector is regulated by ministerial and autarchic authorities, namely the Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), Ministry of Labor and Employment (MTE), Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, the Energy Efficiency Indicators Management Committee (CGIEE), the National Institute of Metrology, Quality and Technology (INMETRO) and the National Agency of Telecommunication (ANATEL).

Brazilian regulations include ordinary laws, treaties with the status of ordinary law and different infra-legal norms as ordinances, and resolutions. The supporting standards used in the regulation and notified to the TBT Committee are mainly homegrown ABNT standards, but also include American ASTM standards and international ISO and IEC standards.

In Argentina, the sector is regulated by public entities as the Ministry of Production and private entities with regulatory powers, as a result of legal provision as the Argentine Electrotechnical Association (AEA). The sector is regulated by one ordinary law with general provisions about electrical facilities and infra-legal norms, which use different types of supporting standards. The standards can have different natures: national (IRAM standards), regional (Mercosur standards) and international (ISO and IEC standards).

12.4. Medical Devices

In Brazil, concerning medical devices, public actors as ANVISA and INMETRO perform their functions together with private actors. The technical regulation on medical devices is constituted by ordinary laws, INMETRO ordinances, ANVISA resolutions and normative instructions. The supporting standards notified to the TBT Committee are still in force. The last ones are either national ABNT standards or international ISO or IEC standards. The main objectives of these standards are the following: metrology, human health and safety issues.

The medical devices sector in Argentina is regulated by public entities as the State Secretariat of Public Health through ordinary laws and few infra-legal norms. The stock of sectoral

standards notified to the TBT Committee is constituted mainly by IRAM homegrown standards and international ISO standards. A data worth mentioning is the high percentage of notified technical regulations that do not mention standards.

12.5. Cosmetics

The most important institution in the sector is ANVISA that conducts the registry, control and monitoring of cosmetics. ANVISA also performs a simplified registration procedure for cosmetic products that do not produce any harm or create any risk to human health. The sector is regulated by one ordinary law and different infra-legal norms, such as ordinances and resolutions. Public actors from direct and indirect administration enact such rules, which are compulsory for all the entities in Brazilian territory.

The standards of this sector were notified to the TBT Committee and to the SPS Committee. The standards notified to the TBT Committee are either national, American or international. The majority of standards notified to the SPS Committee do not make reference to international standards and are followed by WOH standards, IPPC standards and Codex standards.

Argentine cosmetics sector has as its features a reduced number of authorities centered on ANMAT, a regulation through infra-legal norms as resolutions and provisions and specific standards. This sector's standards are notified to the TBT Committee and to the SPS Committee. Half of the technical regulations notified to the TBT Committee do not mention standards and the other half comprises regional NM standards, FDA standards and COLIPA standards (standards produced by a European Cosmetic Association).

12.6. Pharmaceuticals

On the Brazilian side, the main authorities are not limited to public actors as the Ministry of Health, but also reach a non-governmental actor, the ABNT and private actors as the Brazilian Association of Chemical Industry (ABIQUIM) and the Brazilian Association of Fine Chemical Industry (ABIFINA). The regulation is mainly through federal laws and infra-legal norms and the main supporting standards deal with technical and sanitary and phytosanitary issues. The standards notified to the TBT Committee and to the SPS Committee refer to ISO and IEC standards and mention the Codex, the IPPC and the OIE.

The pharmaceuticals sector in Argentina has the following features: strong presence of public actors as ANMAT that incorporates on its structure the National Institute of Drugs (INAME) and regulation through ordinary laws and infra-legal norms. The public actors regulate medicines, food, medical technology and industrial property. Ordinary laws and resolutions are the main form of regulation.

IRAM figures out as the most relevant non-governmental actor, producing national standards for the sector. The majority of standards do not copy other standards and are not based on them. Analyzing the technical regulations notified to the TBT Committee, the great majority of them do not make reference to any standards and the remaining ones make reference to IUIS standards, IATA standards, FDA standards and EMA standards. Considering the technical regulations notified to the SPS, the situation is not different. The majority of the technical regulations do not follow standards, and some of them follow OIE standards and IPPC standards.

12.7. Food and beverage

The Brazilian food and beverage industry sector comprises mainly public actors, especially the Brazilian Health Regulatory Agency and the Ministry of Health, authorities related to the guarantee of public health and health surveillance. The Brazilian sectoral report reveals that the most relevant regulations are federal laws and decrees, but the annexes to the report reveals the huge number of ordinances, regulatory instructions and resolutions. Half of the sectoral standards notified to the TBT Committee is Codex standards and the other half comprises national standards as the ABNT NBR standards or international standards as the ISO and IEC standards.

Data collected about the food and beverage industry in Argentina reveals that the main authorities are public actors as government agencies within the Ministry of Agroindustry and the Ministry of Health, the main regulation is a specific ordinary law, the Argentine Food Code, and that the majority of standards is national. The Argentine Food Code is an ordinary law that incorporates rules agreed upon within Mercosur and is constantly updated by joint resolutions. A specific decree also regulates imported food and beverage products.

An overview of the sectoral standards reveals that, besides the great number of national standards, there are also standards produced by AMN and ISO. The standards in the technical regulations are notified to the TBT Committee and to the SPS Committee. On the first institution, a diversity of standards is notified. These can be, for example, either national IRAM standards, regional NM standards, European standards, American FDA standards or international ISO and IEC standards. On the second institution, more than a quarter of technical regulations notified do not mention standards. The remaining standards in the technical regulation notified are either IPPC standards, Codex standards, OIE standards or IFCS standards.

The tables below provide a description and a comparison of the categories above mentioned on the 7 sectors analyzed on this research, namely: vehicles, machinery, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry. The tables also summarize the main results of the research.

12.8. General results by sectors: authorities, regulations and standards and their supporting standards

Table 12.1 – Vehicles

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Production, Ministry of the Environment and Sustainable Development, Ministry of Transport	Public actors: Brazilian National Environmental Council (<i>Conselho Nacional do Meio Ambiente</i> – CONAMA), Brazilian National Traffic Council (<i>Conselho Nacional de Trânsito</i> – CONTRAN). Non-governmental actors: Brazilian Association on Technical Standards (<i>Associação Brasileira de Normas Técnicas</i> – ABNT). Autarchies: Brazilian Institute of the Environment and Renewable Resources (<i>Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis</i> – IBAMA), Brazilian National Institute of Metrology, Quality and Technology (<i>Instituto Nacional de Metrologia e Qualidade</i> – INMETRO).
PRODUCTS	Vehicles, auto parts, safety system, direction devices, emissions devices, speed devices, fuel tanks	Vehicles, auto parts, fuel tanks, braking system, safety system, light devices, vision devices, direction devices, emissions devices, speed devices
REGULATION	4 ordinary laws 2 decrees 18 resolutions 4 provisions	4 ordinary laws 1 decree 1 resolution 4 ordinances
STANDARDS	Notification to TBT Committee Total: 430 (29% UNECE; 20% European directive; 15% IRAM-AITA; 10% NM; 6% FMVSS; 5% Others; 4% IRAM; 3% ISO; 2% EURO III; 2% None; 1% EURO IV; 1% NAG; 1% SAE; 1% EURO V	Notification to TBT Committee Total: 66 (52% ABNT NBR ISO; 8% NBR ISO 5% ABNT NBR ISO/IEC; 5% ABNT NBR NM; 5% ABNT NBR NM ISSO; 5% ASTM; 5% INMETRO GPCR; 3% ECE; 3% FMVSS; 3% ISSO; 1% ABNT ISO/IEC; 1% ABNT NBR ISSO; 1% ALAPA; 1% DIN; 1% ISO-TS; 1% NIE-DINQP

Table 12.2 - Machinery Sector

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Production, National Institute of Industrial Technology (<i>Instituto Nacional de Tecnología Industrial</i> – INTI) Autarchies: National Entity Regulator of Gas (<i>Ente Nacional Regulador del Gas</i> – ENARGAS) and National Entity Regulator of Electricity (<i>Ente Nacional Regulador de la Electricidad</i> – ENRE)	Public actors: Ministry of Mines and Energy (Ministério de Minas e Energia – MME) Non-governmental actors: Brazilian Association of Technical Norms (<i>Associação Brasileira de Normas Técnicas</i> – ABNT) Autarchy: INMETRO
PRODUCTS	Agricultural machinery – tractors, combine harvesters, automotive agricultural implements, seeders and sprayers – and mechanical equipment on public works.	Heating equipment, centrifugal equipment, refrigerator and domestic machines, machines for liquefied petroleum gases (LPGs) and sound equipment
REGULATION	6 ordinary laws 2 resolutions	3 ordinary laws 1 treaty 6 ordinances 22 INMETRO ordinances 1 INMETRO ministerial act 1 IBAMA ordinance

		3 CONTRAN resolutions 22 technical standards 2 technical notes
STANDARDS	Notification to TBT Committee Total: 86 (22%: ASTM; 16%: IRAM 16%: None; 10%: ISO; 7%: IEC 6% IRAM-IAP; 5% EN; 2% AR; 2% CNC; 2% UNE EN; 1% AERNO; 1% ANSI; 1% CEN; 1% IRAM-DEF; 1% IRAM-IAPG; 1% IRAM-ISO; 1% NAG; 1% ORSNA; 1% SAE	Notification to TBT Committee Total: 32 (66% ABNT NBR; 13% General rules; 3% ABNT NBR ISO; 3% ABNT NBR ISO/IEC; 3% ABNT NBR NM ISO 3% IEC; 3% ISO; 3% ISO/IEC; 3% NBR ISO)

Table 12.3 - Electrical products

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Production, Ministry of Energy and Mining, National Institute of Industrial Technology (<i>Instituto Nacional de Tecnología Industrial – INTI</i>) Autarchies: National Entity Regulator of Gas (<i>Ente Nacional Regulador del Gas – ENARGAS</i>) and National Entity Regulator of Electricity (<i>Ente Nacional Regulador de la Electricidad – ENRE</i>)	Public actors: Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, Energy Efficiency Indicators Management Committee (CGIEE), Ministry of Labor and Employment (MTE) Autarchies: National Agency of Telecommunication (ANATEL) and INMETRO. Non-governmental actors: Brazilian Association of Technical Norms (<i>Associação Brasileira de Normas Técnicas – ABNT</i>)
PRODUCTS	Electric cable and conductors; engines and propellers; lighters.	Compact fluorescent lamps with integrated reactor; light emitting diodes; discharge lamps and fluorescent lamps; electric motors and generators, specific for three-phase electric engines of induction; electrical cables and flexible cords electrical; optic fiber cables; power cables with PVC extruded solid isolation; radio-communication systems; restricted radiation radio communications equipment; light-emitting diodes; transmission apparatus for radio or television; wires, cables and electric flexible cords
REGULATION	1 ordinary law 2 decrees 46 AEA resolutions	3 ordinary laws 2 decrees 2 CONFEA resolutions 28 regulatory standards (<i>normas regulamentadoras – NRs</i>) 7 ILO conventions 86 ILO technical conventions 26 ordinances 5 ANATEL ordinances notified 21 INMETRO ordinances 23 INMETRO ordinances (annex 1) 1 MME ordinance 6 ordinances 22 INMETRO ordinances 1 INMETRO ministerial act 1 IBAMA ordinance 3 CONTRAN resolutions 22 technical standards 2 technical notes

STANDARDS	Notifications to TBT Committee Total: 181 (60%: IRAM; 12%: IRAM NM; 11%: NM; 7%: ISO; 3%: IEC; 2%: None; 2%: AR; 1%: IRAM-IAS; 1%: NAG; 1%: DIN	Notifications to TBT Committee Total: 124 (62%: ABNT NBR; 10%: IEC; 5%: ISO; 4%: General rules; 4%: ABNT NBR-IEC; 4%: ABNT NBR NM; 2%: UL; 1%: ASTM ABNT-ISO-IEC; 2%: CISPR; 2%: ABNT NBR-ISO; 1%: ISO-IEC; 1%: CIE; 1%: ABNT NM-IEC

Table 12.4 - Medical Devices

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (<i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica – ANMAT</i>), Secretariat of Health Policy and Sanitary Regulation, Provincial Registry of Medical Equipment in Use and of Lenders, State Secretariat of Public Health, General Customs Direction, Ministry of Social Assistance and Public Health, Coordinating Unity of Evaluation and Execution of Health Technologies, Medical Argentine Association, Secretariat of Policies, Regulation and Institutes, National Coordinating Unity of Evaluation of Sanitary Technologies	Public actors: Ministry of Industry, Trade and Services (MDIC) and Brazil Ministry of Health (MS) Autarchies: ANVISA and INMETRO Non-governmental actors: Brazilian Association of Technical Norms (<i>Associação Brasileira de Normas Técnicas – ABNT</i>) Private actors: Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment (ABIMO) and Brazilian Association of the High-Technology Industry for Health (ABIMED)
PRODUCTS	Gas facilities, implantable medical products, spectacles, measuring instruments and apparatus and speed measurement devices	Thermometers, in vitro diagnostics, needles
REGULATION	2 ordinary laws 1 Ministry of Health resolution 1 resolution 1 decree law 1 ANMAT disposition	3 ordinary laws 13 INMETRO ordinances 2 inter-ministerial ordinances 1 Ministry of Justice ordinance 1 decree 2 ANVISA normative instructions 1 MS normative instruction 17 ANVISA resolutions 1 Mercosur GMC resolution
STANDARDS	Notifications to TBT Committee Total: 12 (59% None; 17% ISO 8% IRAM; 8% OIML; 8% NAG)	Notifications to TBT Committee Total: 13 (29% ISO; 24% ABNT NBR 23% General rules; 18% IEC; 6% ABNT NBR ISO)

Table 12.5 – Cosmetics

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (<i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica – ANMAT</i>), National Institute of Medicines (<i>Instituto Nacional de Medicamentos – INAME</i>)	Public actor: Ministry of Industry, Foreign Trade and Services (<i>Ministério da Indústria, Comércio Exterior e Serviços – MDIC</i>) Autarchies: National Agency of Sanitary Surveillance (<i>Agência Nacional de Vigilância Sanitária – ANVISA</i>) and Brazilian National Institute of Metrology, Quality and Technology (<i>Instituto Nacional de Metrologia e Qualidade – INMETRO</i>) Non-governmental actor: Brazilian Association of Technical Norms (<i>Associação Brasileira de Normas Técnicas – ABNT</i>)

		Private actors: Brazilian Association of the Cosmetic, Toiletry and Fragrance Industry (<i>Associação Brasileira da Indústria de Higiene Pessoal, Perfumaria e Cosméticos</i> – ABIHPEC), Brazilian Association of Chemical Industry (<i>Associação Brasileira da Indústria Química</i> – ABIQUIM), National Confederation of the Industry (<i>Confederação Nacional da Indústria</i> – CNI) and Federation of the Industries of the State of São Paulo (<i>Federação das Indústrias do Estado de São Paulo</i> , FIESP)
PRODUCTS	Personal hygiene products, cosmetics, perfumes, plant products, products of animal origin	Personal hygiene products, cosmetics, perfumes, drugs, products of animal origin
REGULATION	4 resolutions 19 provisions	1 ordinary law 2 decrees 14 ANVISA resolutions and ordinances 9 INMETRO resolutions 48 Mercosur resolutions
STANDARDS	Notifications to TBT Committee Total: 10 (50% None; 20% FDA 20% COLIPA; 10% ISO; 10% NM) Notifications to SPS Committee Total: 7 (57% None; 29% No deviations; 14% OIE)	Notifications to TBT Committee Total: 43 (32% ABNT NBR ASTM; 19% General rules; 16% ABNT NBR; 9% None; 7% ASTM; 5% ABNT NBR ISO 5% ISO/IEC; 2% ABNT NBR ISO IEC 2% ISO/TS Notifications to SPS Committee Total: 39 (59% None; 26% WOH; 10% IPPC; 5% Codex)

Table 12.6 - Pharmaceuticals

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (<i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica</i> – ANMAT) and National Institute of Industrial Property (<i>Instituto Nacional de Propiedad Intelectual</i> – INPI) Non-governmental actor: Argentine Institute for Standardization and Certification (<i>Instituto Argentino de Normalización y Certificación</i> – IRAM)	Public actors: Ministry of Health, Ministry of Industry, Trade and Services (MDIC), Institute for Industrial Property (<i>Instituto Nacional de Propriedade Industrial</i> – INPI) Autarchies: ANVISA and INMETRO Non-governmental actor: Brazilian Association of Technical Norms (<i>Associação Brasileira de Normas Técnicas</i> – ABNT) Private actors: National Confederation of the Industry (<i>Confederação Nacional da Indústria</i> – CNI), Federation of the Industries of the State of São Paulo (<i>Federação das Indústrias do Estado de São Paulo</i>, FIESP), Brazilian Association of Chemical Industry (<i>Associação Brasileira da Indústria Química</i> – ABIQUIM) and Brazilian Association of the Industries of Fine Chemistry, Biotechnology and its Specialties (<i>Associação Brasileira das Indústrias de Química Fina, Biotecnologia e Suas Especialidades</i> – ABIFINA)

PRODUCTS	Mixed or non-mixed products for therapeutic or prophylactic ends, blood and bandages and analogous articles	Mixed or non-mixed products for therapeutic or prophylactic ends, blood, vaccines and glands
REGULATION	2 ordinary laws 7 decrees 2 joint resolutions 1 resolution 1 AFIP resolution 1 ANA resolution 1 ANMAT resolution 1 Ministry of Production resolution 16 ANMAT provisions 1 ministry regulation	4 federal laws 2 ordinances 36 resolutions
STANDARDS	Notifications to TBT Committee Total: 40 (82% None; 6% EMA; 6% IUIS; 3% FDA; 3% IATA) Notifications to SPS Committee Total: 14 (50% None; 29% No deviations; 14% OIE; 7% IPPC)	Notifications to TBT Committee Total: 43 (32% ABNT NBR ASTM; 19% General rules; 16% ABNT NBR; 7% ASTM; 5% ABNT NBR ISSO; 5% ABNT NBR ISO/IEC; 5% ISO/IEC; 2% ISO/TS) Notifications to SPS Committee Total: 39 (59% None; 26% WOH 10% IPPC; 5% Codex)

Table 12.7 - Food and beverage industry

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Agroindustry, Ministry of Health National Service of Agri-Food Health and Quality (<i>Servicio Nacional de Sanidad y Calidad Agroalimentaria</i> - SENASA), National Wine Institute (<i>Instituto Nacional de Vitivinicultura</i> - INV), National Administration of Drugs, Foods and Medical Devices (<i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica</i> - ANMAT) and National Food Institute (<i>Instituto Nacional de Alimentos</i> - INAL)	Public actors: Ministry of Agriculture, Livestock and Food Supply (<i>Ministério da Agricultura, Pecuária e Abastecimento</i> - MAPA), Ministry of Health (<i>Ministério da Saúde</i> - MS), Brazilian Institute of Environment and Renewable Natural Resources and Brazilian Institute of Environment and Renewable Natural Resources (<i>Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis</i> - IBAMA). Autarchies: ANVISA and INMETRO.
PRODUCTS	Soy, food based on soy, corn, alcoholic beverages and wine.	Animal origin products, fresh fruit and vegetables, alcoholic and nonalcoholic beverages, juices, grains, seeds, and animal feed (including pet food) and processed food products.
REGULATION	The Argentine Food Code (CAA) created by Law 18284/1969 and regulated by Decree 2126/1971 regulates locally produced and imported food products. The CAA is constantly being updated by joint resolutions. View latest CAA Modifications in http://www.conal.gob.ar/CAA_ultimas_modificaciones.php In particular, for food and beverage products, Decree 2092/1991 (supplemented by Decree 1812/1992) regulates all imported food and beverage products.	MAPA and ANVISA's regulations may be consulted on-line. On MAPA's website (www.agricultura.gov.br) the search tool SISLEGIS makes available the current regulations. A similar search tool called VISALEGIS can be found at ANVISA's website (www.anvisa.gov.br).
STANDARDS	Notifications to TBT Committee Total: 100 (23% ISO; 13% NM; 12% FDA; 7% Codex; 7% IRAM; 5% European Directive;	Notifications to TBT Committee Total: 24 (50% Codex; 17% FIL; 13% ABNT NBR; 8% ISO; 4% ABNT NBR ISSO; 4% IEC; 4% EPA SW)

4% IEC; 4% ICMSF; 4% APHA; 3% OIV; 2%
ASTM; 2% FSIS)

Notifications to SPS Committee
Total: 194 (27% None; 27% No deviations;
19% IPPC; 16% Codex; 10% OIE; 1% IFCS)

Some evidences can be drawn from these tables:

- The degree of internationalization or sector globalization of the supporting standards used by Brazil and Argentina in their regulations and standards are relatively small.
- As a complement, the degree of grow-made or domestically-made standards are significant.
- A comparison of the supporting standards used by Brazil and Argentina shows that they came from different sources, each sector utilizing independently either the US or the EU models.
- The consequences of this strategy are the following: Brazil and Argentina create regulatory barriers against each other; the process of convergence is hampered; exports to third countries are made more difficult and costs of adaptation to external demands increase.

12.9. Conclusions and proposals

Regulatory convergence is, at the present time, one of the most relevant issues to explain positive results in international trade. After years focused on tariff-barrier at the borders, trade analysis is reviewing barriers created by regulatory measures. On one hand, countries can determine the characteristics and degrees of confidence for consumer protection of goods and services. On the other hand, technical barriers can be considered a quite efficient barrier to trade.

Despite the efforts for the negotiation of the TBT and SPS Agreements in the WTO, technical, sanitary, phytosanitary and environment measures are being used as a new wave of protection or even protectionism under the pressure of domestic producers, consumers concern on quality, climate change, pollution, emissions, quality of water and air, labor and animal welfare. The WTO agreements on TBT and SPS, negotiated in 90's, need an urgent review to take care of all these new concerns.

In relation to trade integration and preferential agreements, after the first phase of tariff elimination, regulatory convergence is the most important goal to achieve economic integration. Tariffs are easy to erase; regulatory convergence among partners is much more complex to achieve.

Concerning TBT and SPS measures, three different aspects should be examined: regulations (mandatory), standards (voluntary) and conformity assessment (certification).

However, the core issue to exam on convergence aspect is related to the "origin or model" of the supporting standards used to establish national regulations, national standards and conformity measures. They can be developed based in three main strategies: i) to use international standards created by international organizations such as ISO, IEC, ITU (industrial goods), or CODEX, OIE and IPCC (agriculture and food) as recommended by the WTO; ii) to follow some of the more globalized standards such as the American or European or someday the Chinese ones, considered more as the main "standard makers" of the world; iii) to develop

its own domestic standards to create barriers to third countries; iv) to develop a technology and impose its own standards to the world. The main question to answer is what is the goal of each country: to close its market, to export or to participate in value global platforms.

The standardization policy of Brazil and Argentina have similarities and differences. Today, the process of regulatory convergence initiated by Mercosur in the 90's reaches an impasse and is stalled. To break this impasse, governments, agencies and enterprises need to rethink the whole system or to accept its failure. A first step is to focus in two of its main members: Brazil and Argentina. In a second step to integrate the other members of Mercosur.

Point 1: Regulations

In Brazil, the main aspects of technical regulation are established by regulatory agencies. In the state reform introduced in the 90's, ministries are in charge mainly of sectoral policies. Regulatory agencies were created with technical autonomy and independent budget to regulate their respective areas of competence. This is not the case for autos (which have important regulation issued by DENATRAN, CONTRAN and Ministry of Environment) and machinery (Ministry of Labor), where the role of Ministries is still in force.

For agriculture there is no specific agency. The Ministry of Agriculture has the central role as policy determination, regulation and supervision. Today this old model is facing many challenges to take care of all three functions in a satisfactory way.

Among the agencies, INMETRO is central to core aspects related to mandatory regulation on TBT. As a public autarchy constituted in an old legal model, it performs its role as an executive agency. It acts in coordination with other public bodies when related to specific industrial goods. INMETRO is also responsible for the metrology and the accreditation procedures, which authorizes private bodies to develop certification, testing, calibration procedures. A question to ask is why in the process of the reform, INMETRO lost its role as the regulatory body for automobiles and machinery. Other important agencies are ANVISA for food and medicines and ANATEL for telecommunication goods.

In Argentina, the regulatory structure is different. Policies and regulations are subordinated to political bodies, driven directly by political authorities. The main role in the area of technical regulation is performed by the Ministry of Production. There are no independent agencies. Some important governmental bodies should be highlighted: INTI in the area of metrology, SENASA and ANMAT for sanitary, quality of food and medicines.

This difference of approach could explain part of the conflicting relationship between the formulation of policies and orientation for officials in charge of convergence negotiations by the two countries, mainly related to the activities of MERCOSUR SGT 3, 8 and 11. The small achievements of these groups show that the process of negotiation must be changed and adapted to face the real challenges of integration.

In relation to transparency, a concept considered as a pillar of good practices, both countries have problems. To make a research on regulations, standards and conformity assessment is a complex and discouraging task. The updating processes offered by both countries are less frequent than the necessary. Notifications to the WTO are non-uniform. Brazil notifies all technical regulations including drafts. Argentina only notifies some approved regulations, imposing further research to find all necessary regulations.

Point 2: Standards

Concerning the development of standards, Brazil has a centralized body in ABNT, a private organization, that coordinates more than a hundred committees covering different sectors. ABNT participates as the representative of Brazil in international initiatives in the area of standardization

In Argentina this role is played by IRAM, also a private body, which is responsible for the development of national standards. This activity is more decentralized than in Brazil, since many standards are published directly by the standardizing bodies of industry associations, for example, AITA, IAS in the sectors of steel and electric goods.

Transparency is also a major problem. Both countries offer some difficulties to access information in an understandable and organized way. Public information to clarify the issues are unavailable and costs involved to search more detailed information are significant.

Point 3: Conformity assessment

In Brazil, INMETRO, as a public agency is also responsible for the accreditation policy. This body participates in international initiatives in the area of accreditation and laboratory cooperation.

In Argentina, this task is performed by OAA, also a private body, that is responsible for the domestic accreditation system and international initiatives.

The conformity assessment system, especially the accreditation procedures for certification bodies, is similar in both countries. Brazil and Argentina have a large number of products that require compulsory certification, but this list is quite variable and usually regulated by non-statutory laws.

In the accreditation area, the fact that Brazil has a public body is in charge of accreditation and Argentina has private one presents a complex problem to solve. The dialogue is more complex.

The most pressing problem to solve among the two countries is the double certification imposition. Certification activities of each country are not accepted in the other country. This represent costs and the duplication of activities.

Point 4: Use of international standards

With regard to the internationalization of the regulatory system through the use of international standards made by ISO, IEC and ITU, each countries presents a very low average, with a clear preference for the use of domestic standards.

With regard to globalized sectoral standards produced by the main “standards-makers” of the world, Brazil and Argentina have a low level of utilization of this standards as their supporting standards. Both countries opted for the strategy of developing national standards. This preference is a consequence of the industrial policy adopted by Latin-American in the 60’s on import substitution. Many times, sectoral standards were captures by particular interests of

national or multinational enterprises, with the consequence of closing the market for imports and new technologies, but also to exports.

However, at the present time, this strategy is fading away and has increasing costs. It hinders the insertion of products in the international market and the participation in global platforms. Most important – it even creates obstacles to bilateral trade.

This research revealed that for all sectors studied, the degree of internationalized or global sectoral standards are low and around only 40%.

Point 5: Regulatory convergence

Mercosur has more than 20 years of age. However, progress in trade integration was achieved only in the tariff related areas of agriculture and industrial goods. In the area of regulatory convergence, despite of the creation of sub-groups on technical barriers, agriculture and health, the results presented are very discouraging. Initiatives for the creation of common regulation are fading away, and despite pressure to reduce the time process, the number of positive results are only for a few products.

Efforts to produce regional regulations and technical regulations, including regulatory convergence efforts within Mercosur in different committees have been insufficient to guaranty the free movement of goods between members and, above all, to ensure exports from the region to other markets in the world.

AMN – Mercosur Association of Norms, a private standardizing initiative, has an important role to play. However, the results presented, when compared to other international initiatives, are discouraging. After three decades of integration, only around a thousand common standards are initiated. But half of the proposed regional standards were finished, and still worst, from them, only half internalized and integrated in regional and domestic norms.

Some suggestions

Mercosur is facing a dilemma – to deepen integration by regulatory convergence or to accept failure and transform Mercosur in a simple free trade area, where only tariffs and rules of origin matters.

The lead of the process must be with Brazil and Argentina. Both countries have some task to analyse and implement:

- . To realize a deep study of the real costs of the non-integration of Mercosur – “the costs of non-Mercosur”. This kind of study was fundamental to convince Europeans in the 70’s to accept the initiative of the “Internal Market” and the implementation of the “new approach” on standardization, fundamental to the creation of the European standardization organizations, auto-certification and market supervision with strong legal supervision.

- . Concerning regulations, the mandate of Mercosur to harmonize technical regulation should be revisited and re-interpreted. The experience of the European Union should be analysed with new eyes. After more than 20 years from its creation, and trying, without success, to harmonize its standards, the EU in the 70’s restarts the process with the new approach and then the global approach.

Brazil and Argentina should negotiate a new “Bilateral new approach”, with a strong political initiative from the central governments to impose a strict mandate to their regulatory agencies and bodies to negotiate a “bilateral common approach” to sectoral regulations. It is easier for an expert and government official to stick to their technical position than to really construct a common approach. Their positions are too comfortable to be maintained. They have to assume their new role – Brazil and Argentina must go further on regulatory convergence. A possible way out is to choose some less sensitive sector to start the exercise: automotive (already in its way), electrical, machinery, textile, plastic, food, cosmetics, among others.

. Concerning standards, a new strategy should be supported to convince both private sectors to leave national standards and go to internationalized ones, allowing their industries to move to accept international or globalized standards. The consequence is clear: if a standard is an international or global standard it must be accepted by the other country and by third countries. Again, some less sensitive sector could be chosen to start the exercise: automotive (already in its way), electrical, machinery, textile, plastic, food, cosmetics, among others.

. This can be a good incentive to both countries to think about the necessity of a structural regulatory reform. To Argentina, to explore its governance structure and make a reform toward the creation of regulatory agencies more independent of the central government. This is already of the recommendations proposed by OECD to other countries in acceding process. For Brazil, to modernize its agencies structure, because the present model is already old and no more functional. Agencies were included in the bargaining of political parties and lost their main independence and expertise. They have a huge stock of obsolete regulations, they introduce regulations for political reasons without any study on costs and benefits and risk analysis.

To start the process, a basic concept must be politically accepted and implemented. The experience came from the Europeans, in the 70’s, at the time of the Cassis de Dijon decision between Frenchs and Germans on a disputable content of alcohol of liquors.

The mantra between Brazil and Argentina must be: if a product does not kill an Argentinian it will not kill a Brazilian and vice versa!

Brazil and Argentina have to face reality and go further or to face failure and lose space in the international arena.

13. References

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14. Appendices

14.1. Appendix 1 - Electrical Appliances

Table 14.1 - Regulation on Electrical Appliances (Brazil)

Name	Theme
Decree 4508/02	Electric motors
Law 10295/01	Electric energy consumption bands and goals, water usage and gas consumption
ILO convention 119/94	Machinery protection
Resolution 336/89 of Federal Council of Engineering and Agronomy (CONFEA)	Regulates the engineering profession
Ordinance SIT 3214/78	Establishes the regulatory norms
Law 6496/77	Creates the Technical Liability Annotation
Resolution 218/73	Regulates the engineering profession
Law 5194/66	Regulates the engineering profession
Decree 5452/43	Consolidation of the labor laws
Ordinance 104/13	Distribution transformers
Ordinance 1008/10	Fuorescent compact lamps
Ordinance 1007/10	Incandescent lamps
Ordinance 959/10	Electromagnetic reactors for lamps
Ordinance 371/09	Basic compulsory standards for all electronic products that do not fall under Inmetro's PBEs
Ordinance 298/08	Water heaters
Ordinance 364/07	Air conditioning
Ordinance 363/07	Gas ovens and stoves
Ordinance 362/07	Refrigerators and freezers
Ordinance 132/06	Fluorescent compact lamps
INMETRO ordinance 54/16	Certification of electrical equipment under health surveillance scheme
INMETRO ordinance 144/15	Certification of LED lamps with integrated device based
INMETRO ordinance 563/14	Supplier's declaration of televisions
INMETRO ordinance 8/13	Digital certificate standard equipment ICP – Brazil
INMETRO ordinance 640/12	Certification of wires, cables and flexible electrical cords
INMETRO ordinance 446/12	Certification of commercial electric ovens
INMETRO ordinance 497/11	Certification of microwave ovens
INMETRO ordinance 480/11	Certification of electronic point recorder
INMETRO ordinance 335/11	Approves Mercosur technical regulation on essential safety requirements for low-voltage electrical products
INMETRO ordinance 4/11	Supplier's declaration of systems and equipment for photovoltaics (module, charge controller, inverter and battery)
INMETRO ordinance 489/10	Supplier's declaration of compact fluorescent lamps with integrated ballast to base
INMETRO ordinance 488/10	Supplier's declaration of electric motors three-phase induction squirrel-cage rotor
INMETRO ordinance 483/10	Supplier's declaration of sodium vapor lamps high pressure
INMETRO ordinance 454/10	Supplier's declaration of electromagnetic ballasts for lamps and sodium vapor lamps to metal vapour (hydrogen Halides)
INMETRO ordinance 267/09	Certification of AC powered electronic ballasts for tubular fluorescent lamps, circular and compact retilineas
INMETRO ordinance 179/10	Electrical equipment for explosive atmospheres under conditions of flammable gases and vapors and combustible dusts
INMETRO ordinance 283/08	Supplier's declaration of household lamps-incandescent Line
INMETRO ordinance 234/08	Certification of switches for household and similar fixed electrical installations
INMETRO ordinance 348/07	Certification of circuit breakers
INMETRO ordinance 324/07	Certification of plugs and sockets adapters
INMETRO ordinance 262/07	Certification of single-phase voltage stabilizers, with alternating voltage output with nominal voltage of up to 250 V for powers up to 3 kVA/3kW
INMETRO ordinance 261/07	Supplier's declaration of hot rolled steel bars for assembling electric power transmission towers
INMETRO ordinance 85/06	Certification of plugs and Sockets for domestic and similar use
INMETRO ordinance 190/04	Supplier's declaration of carbon steel tubes or micro-ligados steel tube, with or without stitching for assembling electric power transmission towers
INMETRO ordinance 20/02	Certification of ballasts for tubular fluorescent lamps
NR-28	Supervision and penalties
NR-26	Safety signs determining colors used in workplaces to identify safety equipment
NR-14	Safety in ovens and stoves
NR-12	Labor safety
NR-10	Safety in electric installations and services
NR-9	Programs on environmental risk prevention

Source: INMETRO and MTE. Prepared by CCGI-EESP/FGV.

Table 14.2 - Standards on Electric and Electronic Appliances (Brazil)

ABNT NBR 10505:2017 Electrical insulating liquids-determination of corrosive sulfur
ABNT NBR 13506:2017 Fiber optics-determination of optical sensitivity the camber
ABNT NBR 14199:2017 Stationary lead-acid accumulator ventilated — Essays
ABNT NBR IEC 61439-1:2016 Errata 1:2017 Sets and low voltage command Part 1: General requirements
ABNT NBR IEC 60529:2017 Degrees of protection provided by enclosures (IP Code)
ABNT NBR IEC 60270:2017 Techniques of high-voltage electrical testing-measurement of partial discharges
ABNT NBR 14198:2017 Stationary lead-acid accumulator ventilated-Terminology
ABNT NBR 14197:2017 Stationary lead-acid accumulator ventilated — specification
ABNT NBR IEC 60309-2:2017 Plugs and Sockets for industrial use Part 2: dimensional interchangeability requirements for PIN and contact tubular accessories
ABNT NBR IEC 61000-4-5:2017 Electromagnetic compatibility (EMC) Part 4-5: testing and measurement techniques – surge immunity test
ABNT NBR 5356-8:2017 Power transformers Part 8: application guide
ABNT NBR IEC 61892-7:2017 Marine fixed and mobile units-electrical installations Part 7: hazardous areas
ABNT NBR IEC 61439-2:2016 Sets and low voltage command Part 2: Sets and power command
ABNT NBR IEC 61439-1:2016 corrected version: 2017 Sets and low voltage command Part 1: General requirements
ABNT NBR 16487:2016 Vented lead-acid battery stationary-Maintenance
ABNT IEC/TS 60079-40:2016 Explosive atmospheres Part 40: requirements for process sealing between flammable fluids and electrical system
ABNT NBR 5123:2016 Errata 1:2016 Interchangeable fotocontrol relay and socket for lighting-specification and testing
ABNT NBR IEC 60079-28:2016 Explosive atmospheres Part 28: protection of equipment and transmission systems using optical radiation
ABNT NBR 16264:2016 Residential structured cabling
ABNT NBR 15701:2016 Errata 1:2016 Conduletes screw-type and metal for electrical conduit systems
ABNT NBR IEC 60079-14:2016 Explosive atmospheres Part 14: design, selection and installation of electrical installations
ABNT NBR 5356-9:2016 Power transformers Part 9: Receipt, storage, installation and maintenance of power transformers and reactors immersed in an insulating liquid
ABNT NBR IEC 60695-2-11:2016 Errata 1:2016 Tests relating to risk of fire
Part 2-11: incandescent wire test — test method of flammability for finished products (GWEPT)
ABNT NBR IEC 60079-2:2016 Explosive atmospheres Part 2: equipment protection by pressurized enclosure "p"
ABNT NBR 16527:2016 Grounding for distribution systems
ABNT NBR 16521:2016 Industrial cabling
ABNT NBR 9512:2016 Electric wires and cables-artificial Weathering under condensation of water, temperature and ultraviolet B radiation from fluorescent lamps
ABNT NBR 9885:2016 Power cables with aerial cover — artificial Weathering under electrical tension — test method
ABNT NBR IEC 61892-1:2016 Marine fixed and mobile units-electrical installations Part 1: General requirements and conditions
ABNT NBR 5356-11:2016 Errata 1:2016 Power transformers Last 11: dry-type Transformers-specification
ABNT NBR 15701:2016 corrected version: 2016 Conduletes screw-type and metal for electrical conduit systems
ABNT NBR 10502:2016 Phone cord CCE-APL-ASF polyethylene or polypropylene insulated, protected by a cover APL-specification
ABNT NBR 11788:2016 Aluminum connectors for air services of electrical conductors in power systems
ABNT NBR IEC 60079-19:2016 Explosive atmospheres Part 19: repair, overhaul and equipment recovery
ABNT NBR 14401:2016 Amendment set for optical cables-specification
ABNT NBR 14416:2016 Amendment set for optical cables (air and underground)-temperature variation-test method
ABNT NBR IEC 60079-26:2016 Explosive atmospheres Part 26: equipment with equipment protection level (EPL) Ga
ABNT NBR IEC 60079-5:2016 Explosive atmospheres Part 5: equipment protection by immersion in sand "q"
ABNT NBR 14408:2015 Amendment 1:2016 Amendment set for air and underground optical cables — Vibration test method
ABNT NBR 14408:2016 Amendment set for air and underground optical cables — Vibration test method
ABNT NBR 25415:2016 Methods of measurement and reference levels for exposure to electric and magnetic fields in the frequency of 50 Hz and 60 Hz
ABNT NBR IEC 60079-18:2016 Explosive atmospheres Part 18: equipment protection by encapsulation "m"
ABNT NBR 11789:2016 Cables with extruded thermoplastic polyethylene insulation for descent of antenna-requirements and test methods
ABNT NBR IEC 60079-1:2016 Explosive atmospheres Part 1: equipment protection by flameproof enclosure "d"
ABNT NBR IEC 60079-10-2:2016 Explosive atmospheres Part 10-2: classification of areas – explosive dust Atmospheres
ABNT NBR 10488:2016 Telephone cable with tinned conductors, insulated with thermoplastic and cover protected core APL — specification
ABNT NBR 10501:2016 Shielded telephone cable for internal networks — specification
ABNT NBR 7286:2015 Errata 1:2016 Power cables with extruded insulation etilenopropileno rubber (EPR, HEPR or EPR 105) to 1 kV voltages the 35 kV — performance requirements
ABNT NBR IEC 60079-0:2013 Errata 2:2016 Explosive atmospheres Part 0: equipment – General requirements
ABNT NBR 5356-11:2016 corrected version: 2016 Power transformers Part 11: dry-type Transformers-specification
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ABNT NBR 14014:2016 Instant water heaters and electric taps — determination of the maximum increment of temperature
ABNT NBR 14015:2016 Instant water heaters and electric taps — determination of electric energy consumption
ABNT NBR 14409:2016 Underground seam set for optical cables-compression-test method
ABNT NBR 14410:2016 Set of underground optical cables amendment-current drain capacity-test method
ABNT NBR 14411:2016 Set of underground optical cables-seam resistance to chemical attack-test method
ABNT NBR 14412:2016 Amendment set to aerial optical cables and underground-traction-test method
ABNT NBR 14414:2016 Set air splicing optical cables-accelerated Weathering-test method
ABNT NBR 14415:2016 Amendment set for optical cables (air and underground)-variation of the attenuation after fiber case accommodation-test method
ABNT NBR 16458:2016 Interlocking coils for power systems in alternating current (AC)
ABNT NBR IEC 62722-2-1:2016 Luminaire performance Part 2-1: particular requirements for LED fixtures

ABNT NBR IEC 60695-2-11:2016 corrected version: 2016 Tests relating to risk of fire
Part 2-11: incandescent wire test — test method of flammability for finished products (GWEPT)

ABNT NBR 11635:2016 Mineral oils of high flash point for electrical equipment

ABNT NBR 9655:2016 WM power cables, GM and GM-CT equipment, mobile connections with insulation etilenopropilene rubber (EPR) for voltages up to 750 V — specification

ABNT NBR 5123:2016 corrected version: 2016 Interchangeable fotocontrol relay and socket for lighting — specification and tests

ABNT NBR 16426:2016 Non-compound type pillar insulators for voltages above 1 000 V – dimensions and characteristics

ABNT NBR 15123:2016 Insulators for overhead lines with a nominal voltage above 1 000 V-Strings and orchestration of insulators for a.c. systems

ABNT NBR 7285:2016 Power cables with extruded thermosetting polyethylene insulation (XLPE) for 0.6/1 kV voltage-without cover-performance requirements

ABNT NBR 7290:2016 Control cables with extruded insulation of XLPE, EPR or HEPR for voltages up to 1 kV-performance requirements

ABNT NBR 16432:2016 Mineral insulating oil — determination of chlorinated products

ABNT NBR 6007:2016 Electrodes and connecting pins of graphite for electric arc furnaces — requirements

ABNT NBR 17094-2:2016 Rotating electrical machines Part 2: single-phase induction motors — requirements

ABNT NBR 17094-4:2016 Rotating electrical machines Part 4: single-phase induction motors — Test Methods

ABNT NBR 8159:2013 Amendment 1:2016 Electrotechnical fittings for overhead electrical distribution — Standardization

ABNT NBR 8159:2016 Electrotechnical fittings for overhead electrical distribution — Standardization

ABNT NBR IEC 60357:2016 Tungsten halogen lights (except bulbs for automotive vehicles) — performance specifications

ABNT NBR 12160:2016 Sulfur hexafluoride to electrical equipment — verification of properties

ABNT NBR IEC 61434:2016 Secondary cells and batteries containing alkaline or other non-electrolyte acid — Guide to the designation of current in standards of secondary batteries alkaline cells

ABNT NBR 12090:2016 Electric showers — determination of the leakage current-test method

ABNT NBR 5356-5:2015 Power transformers Part 5: ability to withstand short circuits

ABNT NBR IEC/CISPR 15:2014 Errata 1:2015 Limits and methods of measurement of radio disturbances characteristics of electrical lighting and similar

ABNT NBR 12087:2015 Electric showers-determination of electrical power-test method

ABNT NBR 12088:2015 Electric showers-determination of minimum operating pressure and maximum temperature increase-test method

ABNT NBR 12089:2015 Electric showers-determination of electric energy consumption test method

ABNT NBR 12483:2015 Electric showers-General requirements

ABNT NBR 14011:2015 Instant water heaters and electric taps-General requirements

ABNT NBR 14013:2015 Instant water heaters and electric taps-determination of electrical power-test methods

ABNT NBR 14016:2015 Instant water heaters and electric taps-determination of leakage current-test method

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ABNT NBR 16431:2015 Electric equipment-determination of compatibility of materials with insulation vegetable oil

ABNT NBR IEC 60695-2-10:2015 Essays concerning fire risks Part 2-10: incandescent wire test/warm-stereo and common test method

ABNT NBR 15422:2015 Vegetable oil insulation for electrical equipment

ABNT IEC GUIDE 115:2015 Application of measurement uncertainty in conformity assessment activities in the electrical sector

ABNT NBR 16446:2015 Synthetic insulating liquids based on aromatic hydrocarbons for electrical equipment

ABNT NBR IEC 60670-24:2015 Boxes and enclosures for electrical appliances for fixed electrical installations for household and similar use Part 24: specific requirements for wrappers for protection devices and other electric devices that dissipate power

ABNT NBR 16442:2015 Non-halogenated and control cables with low smoke for voltages up to 1 kV-performance requirements

ABNT NBR 14203:2015 Alkaline nickel-cadmium accumulator stationary vented-Terminology

ABNT NBR 16429:2015 Fiber optic connectors for mounting on field-specification

ABNT NBR 14305:2015 Ballast and ignitor for metal vapor lamp (halides)-requirements and tests

ABNT NBR 13248:2014 Errata 1:2015 Power cables and insulated conductors without coverage, and not with low smoke, for voltages up to 1 kV-performance requirements

ABNT NBR IEC 60432-2:2015 Incandescent lamps — safety Specifications Part 2: halogen lamps for domestic and similar general lighting

ABNT NBR 16415:2015 Paths and spaces for structured cabling

ABNT NBR 16412:2015 Mineral insulating oil-determination of disulfide dibenzil by gas chromatography

ABNT NBR 16404:2015 Lead-acid battery-stationary vented installation and Assembly Requirements

ABNT NBR 14405:2015 Amendment set for optical cables (air and underground)-Bending-test method

ABNT NBR 14406:2015 Amendment set for optical cables (air and underground)-twist-test method

ABNT NBR 14407:2015 Amendment set for optical cables (air and underground)-Pressure-test method

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Power cables with extruded insulation Ethylpropylene rubber (EPR, HEPR or EPR 105) to 1 kV voltages the 35 kV — performance requirements

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ABNT NBR 5419-2:2015 On lightning protection Part 2: risk management

ABNT NBR 5419-3:2015 On lightning protection Part 3: physical damage to structures and dangers to life

ABNT NBR 5419-4:2015 On lightning protection Part 4: electrical and Electronic Systems in structure

ABNT NBR 14403:2015 Set of underground optical cables amendment — immersion in water — test method

ABNT NBR 14404:2015 Set of underground optical cables amendment — — Impact test method

ABNT NBR 5435:2015 Bushings for liquid-immersed transformer insulation-rated voltage 15 kV, kV, and kV-36.2 24.2 Specifications

ABNT NBR 16367-1:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 1: air dryer

ABNT NBR 16367-3:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 3: oil temperature indicators and rewinding

ABNT NBR 16367-4:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 4: digital Monitor temperature of oil and winding

ABNT NBR 16367-6:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 6: valves for transformers

ABNT NBR 16367-7:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 7: relay type gas detector Buchholz

ABNT NBR 16367-2:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 2: pressure relief Device

ABNT NBR 16367-5:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 5: oil level indicator

ABNT NBR 14074:2015 Lightning cables optical fibers (OPGW) for transmission overhead lines-requirements and test methods

ABNT NBR 16361:2015 Interpretation of dissolved gas analysis (AGD) in mineral insulating oil of electrical equipment in factory testing

ABNT NBR 16362:2015 Copper cables with aluminum core, naked, for electrical purposes — specification

ABNT NBR IEC 60079-33:2015 Explosive atmospheres Part 33: equipment protection by special protection "s"

ABNT NBR IEC 60947-6-1:2015 Maneuver and control devices of low voltage Part 6-1: multiple function Equipment – transfer switching equipment

ABNT NBR IEC 62660-2:2015 Lithium-ion secondary cells for propulsion of electric road vehicles Part 2: reliability testing and abuse

ABNT NBR 14633:2013 Amendment 1:2015 Flexible cords and cables with extruded insulation of polyethylene Chlorosulfonate (CSP) for voltages up to 500 V — performance requirements

ABNT NBR 14633:2015 Flexible cords and cables with extruded insulation of polyethylene Chlorosulfonate (CSP) for voltages up to 500 V — performance requirements

ABNT NBR 6856:2015 Current transformer-specification and testing

ABNT NBR 16345:2015 Bakery machines-electric ovens of ballast-Method for performance measure

ABNT NBR 6234:2015 Mineral insulating oil-determination of interfacial tension of oil-water by the method of the ring-test method

ABNT NBR IEC 62262:2015 Degrees of protection provided by enclosures of electrical equipment against external mechanical impacts (IK code)

ABNT NBR 16343:2015 Bakery machines-electric ovens to convection-Method for performance measure

ABNT NBR 16344:2015 Bakery machines-electric ovens combined-Method for performance measure

ABNT NBR IEC 60670-23:2015 Boxes and enclosures for electrical appliances for fixed electrical installations for household and similar use

Part 23: particular requirements for boxes and enclosures of floor

ABNT NBR IEC 61000-4-4:2015 Electromagnetic compatibility (EMC) Part 4-4: testing and measurement techniques-test of immunity to electrical fast transient/saves

ABNT NBR 7302:2015 Electrical conductors of stress-strain in aluminum aluminum conductors-test method

ABNT NBR 8664:2015 Signs for identification of airline transmission of electrical energy-Requirements

ABNT NBR IEC 60309-1:2015 Plugs and Sockets for industrial use Part 1: General requirements

ABNT NBR IEC 61892-6:2014 Marine fixed and mobile units-electrical installations Part 6: installation

ABNT IEC/TS 60815-3:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 3: polymeric Insulators for a.c. systems

ABNT IEC/TS 60815-1:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 1: definitions, principles and general information

ABNT NBR 15643:2014 Polymeric insulators for indoor and outdoor use with a nominal voltage above 1 000 V – project Trials

ABNT NBR 16327-1:2014 Polymeric insulator for pin-type cable networks covered fixed at voltages above spacers, 1 000 V Part 1: definition, test methods and acceptance criteria

ABNT NBR 16327-2:2014 Polymeric insulator for pin-type cable networks covered fixed at voltages above spacers, 1 000 V Part 2: dimensions and characteristics

ABNT IEC/TS 60815-2:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 2: porcelain and glass Insulators for a.c. systems

ABNT NBR 10301:2014 Electric wires and cables-fire resistance

ABNT NBR 16326:2014 Polymeric insulators for high voltage, for external and internal use-squeezing and erosion test, by squeezing wheel and method for testing of 5 000 h

ABNT NBR 16323:2014 Guidelines for producing, testing and diagnosis of compound insulators with respect to brittle fracture of core material

ABNT NBR IEC 60079-29-4:2014 Explosive atmospheres Part 29-4: gas detectors – performance requirements of open path detectors for flammable gases

ABNT NBR ISO/IEC 80079-34:2014 Explosive atmospheres Part 34: application of quality systems for the manufacture of equipment

ABNT NBR 7272:2014 Aluminium electrical conductor-breakage and dimensional feature

ABNT NBR 9311:2014 Electrical cables isolated-classification and designation

ABNT NBR 9326:2014 Connectors for power cables-testing of thermal cycles and short circuits

ABNT NBR 5405:2014 Solid insulating materials-determination of dielectric strength under industrial frequency voltage

ABNT NBR 9152:2014 Wires and cables for telecommunications-thermal Shock test method

ABNT NBR IEC 60079-17:2014 Explosive atmospheres Part 17: inspection and maintenance of electrical installations

ABNT NBR IEC 60669-2-1:2014 Switches for household and similar fixed electrical installations Part 2-1: particular requirements-electronic Switches

ABNT NBR 5032:2014 Insulators for overhead lines with voltages above 1 000 V – porcelain or glass Insulators for a.c. systems

ABNT NBR 5034:2014 Bushings for alternating voltages above 1 kV

ABNT NBR 5175:2014 Numbers of the functions of the devices of maneuver, control and power systems-protection Coding

ABNT NBR IEC 60079-31:2014 Explosive atmospheres Part 31: equipment protection against ignition of dust wrappers "t"

ABNT NBR IEC/CISPR 24:2014 Information technology equipment-immunity characteristics-limits and methods of measurement

ABNT NBR 6248:2014 Brown insulator — dimensions, characteristics and test procedures

ABNT NBR 6249:2014 Pulley type insulator made of porcelain or glass — dimensions, characteristics and test procedures

ABNT NBR IEC 60947-5-1:2014 Maneuver and control devices of low voltage Part 5-1: circuit devices and switching elements-electromechanical devices for control circuit

ABNT NBR IEC 60947-5-5:2014 Maneuver and control devices of low voltage

Part 5-5: circuit devices and switching elements-electrical emergency stop Devices with mechanical locking

ABNT NBR IEC 62660-1:2014 Lithium-ion secondary cells for propulsion of electric road vehicles Part 1: performance test

ABNT NBR 5356-6:2012 Errata 1:2014 Power transformers Part 6: Reactors

ABNT NBR 13248:2014 corrected version: 2015 Power cables and insulated conductors without coverage, and not with low smoke, for voltages up to 1 kV-performance requirements

ABNT NBR IEC 60079-0:2013 Errata 1:2014 Explosive atmospheres Part 0: equipment – General requirements
 ABNT NBR 16305:2014 Electrical instant water heating fixed — safety and performance Requirements
 ABNT NBR 10296:2014 Electric insulating material — evaluation of squeezing and erosion resistance under harsh environmental conditions
 ABNT NBR IEC/CISPR 15:2014 corrected version: 2015 Limits and methods of measurement of radio disturbances characteristics of electrical lighting and similar
 ABNT NBR IEC 60079-20-1:2011 Errata 2:2014 Explosive atmospheres Part 20-1: characteristics of substances for classification of gases and vapours-Test Methods and data
 ABNT NBR IEC 61058-2-1:2014 Switches for appliances Part 2-1: particular requirements for switches for flexible cables
 ABNT NBR 5356-3:2007 Errata 2:2014 Power transformers Part 3: insulation Levels, dielectric tests and external air spacing
 ABNT NBR 5440:2014 Errata 1:2014 Overhead distribution transformers-requirements
 ABNT NBR 5440:2014 corrected version: 2014 Overhead distribution transformers-requirements
 ABNT NBR 9147:2014 Wires and cables for telecommunications — Fluidity — test method
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ABNT NBR 14039:2003 Amendment 1:2005 Electrical installations of medium voltage switchgear 1.0 kV to 36.2 kV

ABNT NBR 14039:2005 Electrical installations of medium voltage switchgear 1.0 kV to 36.2 kV

ABNT NBR 15214:2005 corrected version: 2006 Electric power distribution network-infrastructure sharing with telecommunications networks

ABNT NBR 8371:2005 Askarel transformers and capacitors-characteristics and risks

ABNT NBR IEC 60050-161:2005 International Electrotechnical Vocabulary Chapter 161: Electromagnetic Compatibility

ABNT NBR 15204:2005 Semiconductor converter-uninterrupted power supply system with AC output (UPS)-security and performance

ABNT NBR 9115:2005 Phone cord FI insulated with polyvinyl chloride (PVC)-specification

ABNT NBR 9886:2005 Internal CCI-telephone cable Specification

ABNT NBR NM 60335-2-3:2005 Safety of household and similar appliances Part 2: particular requirements for electric irons, ironing (IEC 60335-2-3:1993 MOD)

ABNT NBR NM IEC 60332-1:2005 Methods of tests on electric cables under fire conditions Part 1: test on a single insulated conductor or cable upright

ABNT NBR NM IEC 60332-3-10:2005 Test methods for electric cables under fire conditions Part 3-10: test for vertical flame spread of vertically bundles cables-test equipment

ABNT NBR NM IEC 60332-3-21:2005 Test methods for electric cables under fire conditions Part 3-21: test for vertical flame spread in conductors or cables into bundles mounted vertically-category A F/R

ABNT NBR NM IEC 60332-3-22:2005 Test methods for electric cables under fire conditions Part 3-22: test for vertical flame spread in conductors or cables into bundles mounted vertically-category A

ABNT NBR NM IEC 60332-3-23:2005 Test methods for electric cables under fire conditions Part 3-23: test for vertical flame spread in conductors or cables into bundles mounted vertically-category B

ABNT NBR NM IEC 60332-3-24:2005 Test methods for electric cables under fire conditions Part 3-24: test for vertical flame spread in conductors or cables into bundles mounted vertically-category C

ABNT NBR NM IEC 60332-3-25:2005 Test methods for electric cables under fire conditions Part 3-25: test for vertical flame spread in conductors or cables into bundles mounted vertically-category D

ABNT NBR NM IEC 60811-3-1:2005 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 3: methods specific to PVC compounds-Chapter 1: pressure test at high temperature-tests for resistance to cracking

ABNT NBR NM IEC 60811-3-2:2005 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 3: methods specific to PVC compounds Chapter 2: loss of mass test-thermal stability test

ABNT NBR NM IEC 60811-4-1:2005 Common test methods for insulating and sheathing materials of electric cables-coverage Part 4: methods specific to polyethylene and polypropylene compounds-Chapter 1: resistance to environmental stress cracking per share-winding test after thermal ageing in air-measurement of index of fluidity-determination of carbon black and/or mineral loading in polyethylene

ABNT NBR IEC 60156:2004 Insulating liquids-determination of dielectric strength at industrial frequency-test method

ABNT NBR IEC 60998-1:2004 Connecting devices for low-voltage circuits for household and similar Part 1: General requirements

ABNT NBR NM 60335-2-45:2004 corrected version: 2013 Safety of household and similar appliances Part 2: particular requirements for mobile heating tools and similar appliances (IEC 60335-2-45:1996, MOD)

ABNT NBR 15149:2004 Subduct polyethylene systems for telecommunications-verification of tensile strength of corrugated subdutos

ABNT NBR IEC 61058-1:2004 Switches for appliances Part 1: General requirements

ABNT NBR NM 60669-1:2004 Switches for household and similar fixed electrical installation Part 1: General requirements (IEC 60669-1:2000, MOD)

ABNT NBR 5410:2004 corrected version: 2008 Low-voltage electrical installations

ABNT NBR IEC 60439-2:2004 Sets and low-voltage control Part 2: particular requirements for prefabricated electrical lines (armoured bus systems)

ABNT NBR 15110:2004 Optical cable with dielectric and metal protection for core application buried

ABNT NBR 15121:2004 For high-voltage insulator-radio interference measurement test

ABNT NBR 15124:2004 Porcelain or glass insulator for voltages above 1 000 V-perforation test under boost

ABNT NBR NM 60898:2004 Circuit-breakers for overcurrent protection for household and similar installations (IEC 60898:1995, MOD)

ABNT NBR 14566:2004 Dielectric optical cable for underground application in air and duct espinado

ABNT NBR 15108:2004 Optical cable with dielectric and metal protection for core application in pipeline lines

ABNT NBR NM IEC 60335-2-8:2004 Safety of household and similar appliances Part 2: particular requirements for electric shavers, hair clippers and similar appliances

ABNT NBR 14702:2001 Amendment 1:2004 Flexible coaxial cables with 75 Ω impedance-specification

ABNT NBR 14702:2004 Flexible coaxial cables with 75 Ω impedance to broadband networks-specification

ABNT NBR 14770:2001 Amendment 1:2004 Coaxial cables 75 Ω impedance hard for broadband networks-specifications

ABNT NBR 14770:2004 Coaxial cables 75 Ω impedance hard for broadband networks-specifications

ABNT NBR IEC 60439-3:2004 Sets and low-voltage control Part 3: particular requirements for installation of low voltage accessories intended for the installation in places accessible to people not qualified for your use-distribution boards

ABNT NBR 10511:2004 Residual mechanical strength test for string insulator units of ceramic or glass after mechanical damage of the dielectric

ABNT NBR NM 274:2001 1:2004 Errata Insulated flexible cables with silicone rubber bounce and Multipole-polar with cover, heat resistant, for rated voltages up to and including 450/750 V

ABNT NBR 15014:2003 Semiconductor converter-uninterrupted power supply system, with AC output (UPS)-Terminology

ABNT NBR 15001:2003 Appliance appliance fixed instant water heating-Determination of energy efficiency

ABNT NBR IEC 60269-3-1:2003 Devices-low-voltage fuses Part 3-1: supplementary requirements for fuses for use devices by unskilled persons (fuses mainly use devices and similar domestic)-sections I to IV

ABNT NBR NM IEC 60811-1-4:2003 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 1: methods for general application-Chapter 4: Tests at low temperatures

ABNT NBR NM IEC 60811-2-1:2003 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 2: methods specific to elastomeric materials-chapter 1: trials of ozone resistance, hot set and mineral oil immersion

ABNT NBR 14977:2003 Fiber optics-determination of optical loss in amendment by backscatter

ABNT NBR 14532:2000 Amendment 1:2003 Household and similar appliances-Safety-particular requirements for ceiling fans

ABNT NBR IEC 60439-1:2003 Sets and low-voltage control Part 1: type test assemblies with fully tested (TTA) and partially type assemblies with test tested (PTTA)

ABNT NBR 13937:1997 Errata 1:2002 Enameled copper wire of circular cross-section, based on modified polyester, covered with poliamida-thermal Class 200° C-specification

ABNT NBR 14897:2002 Cables and flexible cords insulated with polyvinyl chloride (PVC), for special applications in appliances, devices connectors cords in tensions up to 500 V

ABNT NBR 14898:2002 Insulated flexible cables with etilenopropileno rubber (EPR), for special applications in appliances, devices connectors cords in tensions up to 500 V

ABNT NBR NM IEC 60335-2-10:2002 Safety of household and similar appliances Part 2-10: particular requirements for floor treatment machines and wet rubbing washing

ABNT NBR NM 247-1:2002 corrected version: 2011 Insulated cables with policloreto chloride (PVC) for rated voltages up to 450/750 V
Part 1: General requirements (IEC 60227-1, MOD)

ABNT NBR NM 247-2:2002 corrected version: 2011
Insulated cables with polyvinyl chloride (PVC) for nominal voltage up to 450/750 V, including Part 2: methods of test (IEC 60227-2, MOD)

ABNT NBR NM IEC 60983:2002 Miniature lamps

ABNT NBR 5383-1:2002 Rotating electrical machines Part 1: three-phase induction motors-Essays

ABNT NBR NM 247-3:2002 corrected version: 2002 Insulated cables with polyvinyl chloride (PVC) for rated voltages up to and including 450/750 V
Part 3: isolated Conductors (without cover) for fixed wiring (IEC 60227-3, MOD)

ABNT NBR NM IEC 60335-2-13:2002 Safety of household and similar appliances Part 2-13: particular requirements for deep fryers, frying pans and similar appliances

ABNT NBR NM IEC 60335-2-2:2002 Safety of household and similar appliances Part 2-2: particular requirements for vacuum cleaners and water suction cleaning

ABNT NBR NM IEC 60335-2-23:2002 Safety of household and similar appliances Part 2-23: particular requirements for appliances for skin or hair care

ABNT NBR NM IEC 60335-2-9:2002 Safety of household and similar appliances Part 2-9: particular requirements for tostadores, "grills", roasters and similar appliances

ABNT NBR NM 274:2001 Insulated flexible cables with silicone rubber bounce and Multipole-polar with cover, heat resistant, for rated voltages up to and including 450/750 V

ABNT NBR 13511:2001 Optical fibers and cables-chemical attack to test optical fiber dyed-test method

ABNT NBR 13519:2001 Optical fibers and cables-test of thermal cycles in optical fiber dyed-test method

ABNT NBR 9888:2001 Telephonic cable insulated with thermoplastic and geleado cover protected core APL-specification

ABNT NBR 9889:2001 Phone cord CIP-APL, insulated with thermoplastic, covers protected core APL and self-sustained by strand of steel-specification

ABNT NBR NM IEC 60811-1-1:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 1: measurement of thickness and external dimensions-Tests for determining the mechanical properties

ABNT NBR NM IEC 60811-1-2:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 2: thermal ageing methods

ABNT NBR NM IEC 60811-1-3:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 3: methods for determining the density-water absorption tests-shrinkage Test

ABNT NBR 14684:2001 Subduct polyethylene systems for telecommunications-determination of density of plastics by displacement

ABNT NBR 14685:2001 Subduct polyethylene systems for telecommunications-determination of carbon black

ABNT NBR 14686:2001 Subduct polyethylene systems for telecommunications-verification of dispersion of pigments

ABNT NBR 14687:2001 Subduct polyethylene systems for telecommunications-rsistence check to crushing

ABNT NBR 14688:2001 Subduct polyethylene systems for telecommunications-determination of dimensional stability

ABNT NBR 14689:2001 Subduct of polietileno systems for telecommunications-verification of resistance to impact

ABNT NBR 14690:2001 Subduct polyethylene systems for telecommunications-verification of internal hydrostatic pressure resistance

ABNT NBR 14691:2001 Subduct polyethylene systems for telecommunications-determination of dimensions

ABNT NBR 14692:2001 Subduct polyethylene systems for telecommunications-determination of oxidation induced time

ABNT NBR 14693:2001 Subduct polyethylene systems for telecommunications-rsistance to compression check

ABNT NBR 14694:2001 Subduct polyethylene systems for telecommunications-verification of resistance to artificial weathering

ABNT NBR 14695:2001 Subdutos polyethylene systems for telecommunications-resistance check the curvature

ABNT NBR 14704:2001 External phone cord binado FEB-specification

ABNT NBR 14706:2001 Optical cables, wires and telephone cables-determination of ultraviolet absorption coefficient-test method

ABNT NBR 9116:2001 External phone cord FE, insulated with polyvinyl (PVC), polyethylene (PE) or copolymer-specification

ABNT NBR 9123:2001 FDG insulated phone cord with polyvinyl chloride (PVC)-specification

ABNT NBR 6814:1985 Errata 1:2001 Electric wires and cables-electrical resistance test

ABNT NBR 6939:2000 Coordination of isolation-Procedure

ABNT NBR 11880:2000 Telephonic cable insulated with thermoplastic expanded, core filled with jelly and protected-specification

ABNT NBR 14602:2000 Optical fiber dispersion single mode type taken off-specification

ABNT NBR 14603:2000 Sampling and factory inspection of optical fibers-Procedure

ABNT NBR 14604:2000 Optical fiber dispersion-shifted single mode type and non-null-specification

ABNT NBR 14607:2000 Telephonic cable insulated with thermoplastic expanded and protected by cover core APL-specification

ABNT NBR 14613:2000 Telephone-wire tensile strength and elongation under tension the wire FEB-dielectric test method

ABNT NBR 13489:2000 Fiber optics-determination of bandwidth-test method

ABNT NBR 13490:2000 Fiber optics-determination of numerical aperture-test method

ABNT NBR 13491:2000 Fiber optics-determination of optical attenuation-test method

ABNT NBR 13492:2000 Fiber optics-determination of cutoff wavelength-test method

ABNT NBR 13493:2000 Fiber optics-determination of modal field diameter-test method

ABNT NBR 13502:2000 Fiber Optics-Optical attenuation uniformity check-test method

ABNT NBR 13503:2000 Fiber optics-mechanical constant-voltage test test method

ABNT NBR 13504:2000 Fiber optics-determination of chromatic dispersion-test method

ABNT NBR 13520:2000 Óptical fibre-determination of optical attenuation variation-test method

ABNT NBR 14584:2000 Optical cable with metal protection for underground facilities-verification of susceptibility to damage caused by atmospheric discharge-test method

ABNT NBR 14585:2000 Optical cables-determination of strength of DPE cable duct removal-test method

ABNT NBR 14587-1:2000 Fiber optics-measurement of polarization mode dispersion Part 1: spectral Scan-test method

ABNT NBR 14587-2:2000 Fiber optics-measurement of polarization mode dispersion Part 2: Method interferométrico-test method

ABNT NBR 14588:2000 Fiber optics-Determination of bending-test method

ABNT NBR 14589:2000 Optical cable with metal protection for underground installations-determination of current drain capacity-test method

ABNT NBR 14591:2000 Fiber optics-thermal cycle-test method

ABNT NBR 14538:2000 Fluorescent lamp with integrated ballast to base for general lighting – safety requirements

ABNT NBR 14539:2000 Fluorescent lamp with integrated ballast for general lighting based-performance requirements
 ABNT NBR 13500:1999 Fiber optics-geometrical parameters Determination of coating-test method
 ABNT NBR 13505:1999 Fiber optics-determination of length-test method
 ABNT NBR 14422:1999 Fiber optics-determination of geometric parameters of optical fiber-test method
 ABNT NBR 9124:1999 corrected version: 2000 Telephonic cable insulated with thermoplastic and cover protected core APL-specification
 ABNT NBR 9154:1999 Sampling and factory inspection of wires and telephone cables-Procedure
 ABNT NBR IEC 60598-2-19:1999 Light fixtures Part 2: particular requirements-Chapter 19: light fixtures to air-conditioning systems (safety requirements)
 ABNT NBR 9124:1999 Errata 1:2000 Telephonic cable insulated with thermoplastic and cover protected core APL-specification
 ABNT NBR 5314:1999 Plastic spools for winding wire-packing Specification
 ABNT NBR 9142:1999 Wires and telephone cables-test of resistance to cracking-test method
 ABNT NBR 9143:1999 Wires and telephone cables-contraction tests-test method
 ABNT NBR 9144:1999 Wires and telephone cables-check the electrical continuity and contact-test method
 ABNT NBR 9134:1998 Optical cables and test phone grip tape APL-test method
 ABNT NBR 9136:1998 Optical cables and telephone penetration test of moisture test method
 ABNT NBR 9137:1998 Optical cables and pressurization test phone-test method
 ABNT NBR 9138:1998 Telephone cables-capacitive unbalance test-test method
 ABNT NBR 9140:1998 Optical cables and wires and telephone cables-color comparison test-test method
 ABNT NBR 9141:1998 Optical cables and wires and telephone cables-testing of traction and stretching to break-test method
 ABNT NBR 9148:1998 Optical cables and wires and telephone cables-accelerated aging test-test method
 ABNT NBR 9149:1998 Telephone cables-flow Testing of the filling compound-test method
 ABNT NBR 14201:1998 Alkaline nickel-cadmium accumulator stationary-specification
 ABNT NBR 14202:1998 Alkaline nickel-cadmium accumulator stationary-Essays
 ABNT NBR 1428:1998 Insulator-cylinder of glass or porcelain-units and columns-Standardization of dimensions and characteristics
 ABNT NBR 6524:1997 Amendment 1:1998 Wire and cables of copper hard and a little stiff with or without protective cover for aerial installations
 ABNT NBR 6524:1998 Wire and cables of copper hard and a little stiff with or without protective cover for aerial installations
 ABNT NBR 6882:1998 Insulator-porcelain pedestal-support units and columns-Standardization of dimensions and characteristics
 ABNT NBR 6983:1998 Copper wire of rectangular or square section, enamelled or not, covered with one or two whorls of fiberglass-polyester, thermal class 155° C specification
 ABNT NBR 10510:1998 Insulator-porcelain Rod-Standardization of dimensions and characteristics
 ABNT NBR 7110:1998 PIN insulator made of porcelain or glass-Standardization of dimensions and characteristics
 ABNT NBR 13910-3:1998 Errata 1:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars
 Part 3: procedures for determining and verifying declared noise emission values
 ABNT NBR 14159:1998 Optical cable with cold cover protected core APL-specification
 ABNT NBR 14161:1998 Emergency-dielectric optical cable Specification
 ABNT NBR 13910-2-2:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars
 Part 2: particular requirements for hair dryers
 ABNT NBR 13910-2-3:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars
 Part 2: particular requirements for blenders
 ABNT NBR 13910-3:1998 corrected version: 1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars
 Part 3: procedure for determining and verifying declared noise emission values
 ABNT NBR 14104:1998 Sampling and inspection in the factory of cables and optical cords-Procedure
 ABNT NBR 5282:1998 Shunt power capacitors for nominal voltage above 1 000 V
 ABNT NBR 8603:1998 Internal fuses for power capacitors-performance requirements and tests
 ABNT NBR 8763:1998 Series capacitors for power systems
 ABNT NBR 7095:1981 Errata 1:1998 Electrotechnical fittings for transmission lines and substations, high voltage and extra high voltage
 ABNT NBR IEC 60061-1:1998 Bases of lamps, lamps, as well as feedbacks for the control of interchangeability and safety
 Part 1: lamp Bases
 ABNT NBR 14075:1998 Cord-determination of optical fiber optic doformação for optical cord pull
 ABNT NBR 14076:1998 Optical cables-Determination of the wavelength of single mode fiber wired-test method
 ABNT NBR 5429:1977 Errata 2:1998 Sampling plans and procedures for inspection by variables
 ABNT NBR 7312:1998 Rolls of wires and electrical cables-dimensional features
 ABNT NBR 13975:1997 Fiber optics-determination of strength of coating-extraction method
 ABNT NBR 14012:1997 Instant water heaters and electric taps-verification of resistance to wear or marking removal-test method
 ABNT NBR IEC 60809:1997 Filament lamps for automotive vehicles-dimensional, electrical and luminous Requirements
 ABNT NBR 13974:1997 Optical cables-determination of air-resistance test method
 ABNT NBR 13976:1997
 Optical cables-Immersion test method
 ABNT NBR 13977:1997 Optical cables-Determination of the oxidative induction time (OIT)-test method
 ABNT NBR 13978:1997 Optical cables-cable Pull-test method
 ABNT NBR 13989:1997 Optical cable underground – determination of performance when subjected to the test of coefficient of static friction-test method
 ABNT NBR 13990:1997 Optical cable underground – determination of performance when subjected to vibration-test method
 ABNT NBR IEC 61167:1997 Metallic vapor lamps (halides)
 ABNT NBR 13942:1997 Enamelled aluminum wire of circular cross-section based on modified Polyester-180° C thermal Class-specification
 ABNT NBR 8661:1997 Cables with extruded insulation plan format of polyvinyl chloride (PVC) for voltage up to 750V-specification
 ABNT NBR 8762:1997 Extra-flexible cables for electric arc-welding machines and other applications-specification
 ABNT NBR 9511:1997 Electric cables-minimum bending Radii for installation and minimum diameter reel cores for packaging
 ABNT NBR 13910-1:1997 Test guidelines for the determination of acoustic noise of aircraft appliances and similars
 Part 1: General requirements

ABNT NBR 13910-2-1:1997 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 2: particular requirements for refrigerators, freezers, combined and similar

ABNT NBR 5416:1997 Application of loads in power transformers-Procedure

ABNT NBR IEC 60081:1997 Tubular fluorescent lamps for general lighting

ABNT NBR 5111:1997 Bare copper wires, of circular cross-section, for electrical purposes

ABNT NBR 5368:1997 Soft tinned copper wire for electrical purposes-specification

ABNT NBR IEC 60662:1997 Sodium vapor lamps high pressure

ABNT NBR 5349:1997 Naked soft copper cables for electrical purposes-specification

ABNT NBR IEC 60901:1997 Basic fluorescent lamps-Performance Requirements

ABNT NBR IEC 60360:1996 Standard method for determining the temperature increase of the lamp base

ABNT NBR 5125:1996 Ballast for mercury vapor lamp high pressure

ABNT NBR 5170:1996 Ballast for mercury vapor lamp high pressure-Tests

ABNT NBR 13570:1996 Electrical installations in crowds-specific requirements

ABNT NBR 13571:1996 Copper steel grounding rod and accessories-specification

ABNT NBR 13486:1995 Fiber optics-Terminology

ABNT NBR 13508:1995 Optical cables-bend test

ABNT NBR 13509:1995 Optical cables-impact test

ABNT NBR 8377:1995 Active power meter-specification

ABNT NBR 8378:1995 Active power meter-test method

ABNT NBR 13418:1995 Fire resistant cables for security installations-specification

ABNT NBR 6245:1995 Electric wires and cables-determination of oxygen content

ABNT NBR 13223:1994 Telephone cables-cable pull-test test method

ABNT NBR 5462:1994 Reliability and maintainability with

ABNT NBR 7288:1994 Power cables with extruded solid insulation of polyvinyl chloride (PVC) or polyethylene (PE) for 1 kV voltages the 6 kV

ABNT NBR 9375:1994 Power cables with solid insulation extrututada etilenopropileno rubber (EPR), for mobile equipment links to 3 kV voltages the 25 kV-specification

ABNT NBR 13018:1993 Rope to work on energized installation-Transmission-specification

ABNT NBR 12694:1992 Specifying colors according to the Munsell notation system-specification

ABNT NBR 12479:1992 Shunt power capacitors, for nominal voltage above 1000 V-electrical characteristics and constructive-Standardization

ABNT NBR 5460:1992 Electrical power systems

ABNT NBR 11855:1991 Insulating platform to work on energized distribution networks-specification

ABNT NBR 11857:1991 Shielded cable for provisional jampe for aerial energized up to 15 kV-specification

ABNT NBR 11858:1991 Device for washing equipment energized distribution network-specification

ABNT NBR 12132:1991 Telephone cables-compression test-test method

ABNT NBR 12133:1991 Electrical insulating liquids – Determination of the dielectric loss factor and relative permittivity (dielectric constant)-test method

ABNT NBR 12134:1991 Mineral insulating oil-determination of 2.6-di-tertiary butyl para--test method

ABNT NBR 12135:1991 Mineral insulating oil inhibited-determination of oxidation stability-test method

ABNT NBR 12139:1991 Electric wires and cables-test for determining the toxicity index of gases developed during combustion of polymeric materials-test method

ABNT NBR 5461:1991 Lighting

ABNT NBR 11835:1991 Accessories plug-in power cables insulated for 15 kV voltages the 35 kV-specification

ABNT NBR 11809:1991 Voltage regulators-specification

ABNT NBR 11633:1990 Electric wires and cables-test for determination of degree of acidity of gases developed during combustion of components-test method

ABNT NBR 12454:1990 Maximum voltage power transformers up to 36, 2kV and power of 225 kVA up to 3750 kVA-Standardization

ABNT NBR 12460:1990 Nominal voltage 15 kV bushings, 24.2 kV and 36.2 kV power transformers and reactors-Standardization

ABNT NBR 7036:1990 Receipt, installation and maintenance of power distribution transformers, immersed in insulating liquids

ABNT NBR 5370:1990

Copper connectors for conductors in electrical power systems

ABNT NBR 11300:1990 Electric wires and cables-determination of density of smoke emitted in burning conditions-test method

ABNT NBR 6869:1989 Electrical insulating liquids – determination of the dielectric strength (electrodes)

ABNT NBR 5779:1989 Mineral insulating oils-qualitative determination of chlorides and sulfates, inorganic

ABNT NBR 10860:1989 Three-pole keys for distribution networks-laden Operation-specification

ABNT NBR 7277:1988 Transformers and reactors-determining the noise level

ABNT NBR 5438:1987 Bushing for transformers-1.3 kV nominal voltage, 2000, 3150, the 5000-dimensions

ABNT NBR 5471:1986 Electrical conductors

ABNT NBR 5474:1986 Electric connector

ABNT NBR 5474:1980 Amendment 1:1986 Electrotechnics and electronics-electrical connectors

ABNT NBR 6814:1985 Amendment 1:1986 Electric wires and cables-electrical resistance test

ABNT NBR 6814:1986 corrected version: 2001 Electric wires and cables-electrical resistance test

ABNT NBR 9029:1985 Use of relays for Busbar protection in power system-Procedure

ABNT NBR 5422:1985 Airline project of electric power transmission

ABNT NBR 5437:1984 Bushing for conservative oil transformers-1.3 kV nominal voltage-160, 400, 800 A-Dimensions

ABNT NBR 8449:1984 Design of lightning conductor cables for overhead lines of electric-power transmission Procedure

ABNT NBR 5052:1984 Synchronous machine-Essays

ABNT NBR 5310:1982 Plastic materials for electrical purposes-determination of water absorption

ABNT NBR 7303:1982 Aluminum electrical conductors-fluency in aluminium conductors

ABNT NBR 7095:1981 corrected version: 1998 Electrotechnical fittings for transmission lines and substations, high voltage and extra high voltage

ABNT NBR 6811:1981 Electric wire and cable-grip test and continuity in tinned copper wires

ABNT NBR 6813:1981 Electric wires and cables-insulation resistance Test

ABNT NBR 5079:1975 Amendment 1:1976 Enameled copper wire of circular cross-section weldable polyurethane base covered with nylon, thermal class 130° C

Source: ABNT. Elaborated by CCGI-EESP/FGV.

Table 14.3 - Regulation Electrical Products (Argentina)

NAME	THEME
LAW 19587/72	Hygiene and safety at work
DECREE 351/79	Amends law 19587
DECREE 911/96	Amends law 19587
RESOLUTION 197/04	Provides models of conformity assessment
RESOLUTION 171/16	Defines technical expressions and prescribes the certification of low voltage electrical products
REGULATION AEA 90364-7-701	Bathrooms and places with baths, showers and other objects with water emitting taps
REGULATION AEA 90364-7-771	Regulation for the execution of electrical facilities on property – homes, offices and premises
REGULATION AEA 90364-0	Regulation for the execution of electric facilities on property – guide of application
REGULATION AEA 90364-1	Regulation for the execution of electric facilities on property – reach, object and fundamental principles
REGULATION AEA 90364-2	Regulation for the execution of electric facilities on property – definitions
REGULATION AEA 90364-3	Regulation for the execution of electric facilities on property – determination of general features of the facilities
REGULATION AEA 90364-4	Regulation for the execution of electric facilities on property – protections to preserve safety
REGULATION AEA 90364-5	Regulation for the execution of electric facilities on property – election and installation of electric materials
REGULATION AEA 90364-6	Regulation for the execution of electric facilities on property – verification of electric facilities (initial and periodicals) and its maintenance
REGULATION AEA 90706	Guide to the management of maintenance of facilities
REGULATION AEA 90364-7-712	Photovoltaic panels
REGULATION AEA 90364-7-710	Regulation for the execution of electric facilities on property – places for medical uses and external rooms
REGULATION AEA 90364-7-718	Regulation for the execution of electric facilities on property – places of public competition
REGULATION AEA 90364-7-770	Unifamiliar homes (until 63 A – classifications BA2 and BD1)
REGULATION AEA 90364-7-779 IRAM 36066	Particular rules for facilities on special places – section 779: modules of concentrated installation of minimum electrification
REGULATION AEA 90364-7-780	Regulation for the execution of electric facilities on property part 7: particular rules for facilities in special places section 780: electric facilities of automatization of buildings
REGULATION AEA 90790	Protection against electric atmospheric discharges on charge stations of liquid and gas fuel
REGULATION AEA 90865-1 IRAM 60865-1	Short circuit currents – calculation of the effects. Part 1 – definitions and methods of calculation
REGULATION AEA 90890-1	Method for the verification by calculation of the increase of temperature on boards BT. Part 1: natural ventilation
REGULATION AEA 90909-0	Short circuit currents on triphasic systems of alternative current – normative document. Calculation of currents
REGULATION AEA 90909-1	Short circuit currents on triphasic systems of alternative current – technical inform. Factors for the calculation
REGULATION AEA 91140	Protection against electric shocks. Common aspects to facilities and its components, materials and equipment
REGULATION AEA 90079-10-1	Explosive atmospheres. Part 10 – classification of áreas – sec. 1 – explosive gas atmospheres
REGULATION AEA 90079-10-2	Explosive atmospheres. Part 10 – classification of areas – sec. 2 – dust explosive atmosphere
REGULATION AEA 90079-14. AEA 90079-17	Explosive atmospheres. Part 14, project, selection and building of electric facilities. Explosive atmospheres. Part 17, inspection and maintenance of electric facilities.
REGULATION AEA 90364-8	Regulation for the execution of electric facilities on property – part 8 energetic efficiency on electric facilities of low tension. Section 1 – general requirements of energetic efficiency.
REGULATION AEA 91340-1	Regulation about electrostatic technical inform part 1 electrostatic phenomena – principles and measurements
REGULATION AEA 92305-1 IRAM 2184-1	Protection against thunders. Evaluation of risk.
REGULATION AEA 92305-3 IRAM 2184-3	Protection against thunders. Physical damage to structure and human risk.
REGULATION AEA 92305-4 IRAM 2184-4	Protection against thunders. Electric and electronic systems in structures.
REGULATION AEA 92305-11 IRAM 2184-11	Protection against thunders. Guide for the election of the systems of protection against thunders (SPCR).
REGULATION AEA 92559-1	Smart electric networks. Part 1 guide of concepts, benefits and challenges for its implementation
REGULATION AEA 92606	Regulation for the protection against the electric arc. Calculation of representative magnitudes of thermal effects and its protection
REGULATION AEA 95101	Regulation for external electric lines in general – underground facilities of energy and of telecommunications
REGULATION AEA 95150	Regulation for the execution of electric facilities of submission and measurement in low tension

REGULATION AEA 95201		Regulation of external air lines of low tension
REGULATION AEA 95301		Regulation of external air lines of medium and high tension
REGULATION AEA 95401		Regulation about transformation centers and submission in medium tension
REGULATION AEA 95402		Regulation for transformative stations
REGULATION AEA 95702		Regulation for the execution of works with tension in electric facilities higher than 1 kV
REGULATION AEA 95703		Regulation for the execution of electric facilities of public lighting
REGULATION AEA 95704		Regulation for the signaling of electrical facilities on public track. Includes the application guide
REGULATION AEA 95705		Regulation for the execution of works with tension on electrical facilities of low tension
MERCOSUR RESOLUTION 18/98	GMC	Working plan of the safety commission of electrical products of SGT n° 3 “technical regulations”
MERCOSUR RESOLUTION 42/01	GMC	Windows of energized functioning
MERCOSUR RESOLUTION 4/09	GMC	Cables and electrical conductors of low tension
MERCOSUR RESOLUTION 4/10	GMC	Light switchers for fixed electrical facilities

Source: Argentina. Elaborated by CGTI-EESP/FGV.

Table 14.4 - Standards of Electrical Appliances (Argentina)

NUMBER	TITLE
IRAM - 2004	Electrical copper conductors hard, for air power and put lines to land.
IRAM - 2011	Annealed copper wires. For electrical conductors.
IRAM - 2012	Method of verification of the mechanical characteristics of the insulation of conductors (rubber or substitutes).
IRAM-2021-2	Electric heaters for environments. Performance requirements.
IRAM - 2026	Electrical insulating materials. New insulating mineral oils for transformers and equipment of maneuver.
IRAM - 2028	Insulating mass of bituminous nature for wiring boxes.
IRAM - 2031	Method of verification of the finish of the fibrous cap of electrical conductors. Insulated with rubber or substitutes.
IRAM - 2034	Starters and regulators rheostats for electric motors.
IRAM - 2042	Electric thermostats.
IRAM - 2052	Plugs for electrical heating appliances. Bipolar, non-effective ground and nominal voltage of 220 V.
IRAM-2053-1	Identification of electrical terminals and terminals. General rules for marking with alpha-numeric notation.
IRAM-2053-2	Electrical conductors. Insulated and bare. Identification by numbers or colors.
IRAM - 2061	Distilled water to electric storage batteries.
IRAM - 2064	Connectors of electric heating appliances. Bipolar grounded for home use and effective nominal voltage of 220 V.
IRAM - 2065	Plugs for electrical heating appliances. Bipolar, with effective ground and nominal voltage of 220 V socket.
IRAM - 2076	Electrical connectors. General requirements.
IRAM - 2081	Multipliers series and shunts for indicators electrical instruments.
IRAM - 2082	Humidity Chamber grade B. For testing of materials and electrical appliances.
IRAM - 2089	Humidity Chamber grade A. For testing of materials and electrical appliances.
IRAM - 2090	Lead and alloys of lead for pods and electrical cables.
IRAM - 2093	Small power electric motor. Test methods.
IRAM - 2094	Single-phase asynchronous electric motors.
IRAM - 2101	AC voltage dielectric test equipment.
IRAM-2103-1	Solid Electric insulating materials. Determination of the dielectric. Trials at industrial frequencies.
IRAM-2103-2	Solid electric materials. Determination of the dielectric. Additional requirements for testing to DC voltage.
IRAM-2103-3	Solid Electric insulating materials. Dielectric tests. Additional requirements for impulse tests.
IRAM - 2105	Transformers for transport and distribution of electrical energy. Levels of insulation and dielectric tests.
IRAM-2107-1	Solid Electric insulating materials. Methods of test of cross resistance and the surface.
IRAM - 2109	Small power electric motor. Three-phase induction.
IRAM - 2114	Solid Electric insulating materials. Determinations of the permittivity (dielectric constant) and dissipation factor. Frequency industrial, audio and radio frequency, including VHF.
IRAM - 2117	Lead oxides for electric accumulators and lead to their obtaining.
IRAM-2118-2	Electric fans and their speed controllers. Performance requirements.
IRAM - 2119	Stationary electric accumulators. Lead-acid, type planted.
IRAM - 2125	Polyphase Induction Motors. General test methods.
IRAM - 2126	Small power electric motor. Dimensions.
IRAM - 2129	Small power electric motor. Universal and direct current.
IRAM-2141-3	Electric washing machine. Part 3 - Energy efficiency labelling.
IRAM - 2144	Registrars electric instruments.
IRAM - 2162	Indicators electric instruments, Board. Dimensions.
IRAM-2178-1	Cables insulated with dielectric solid extruded for rated voltages from 1 kV (Um = 1,2 kV) up to 33 kV (Um = 36 kV). Part 1 - Wire power, control, signalling and command for nominal voltages from 0.6/1 kV (Um = 1,2 kV).
IRAM-2178-2	Cables insulated with dielectric solid extruded for rated voltages from 1 kV (Um = 1,2 kV) up to 33 kV (Um = 36 kV). Part 2 - For nominal voltages of 3.3 kV power Cables (3.6 kV) up to 33 kV (36 kV).
IRAM - 2182	Diesel electric generators. Fundamental requirements.
IRAM-2184-4	The lightning protection. Part 4 - Electrical and electronic systems in structures.
IRAM - 2189	Ingots of aluminium for the manufacture of electrical conductors. Chemical composition.
IRAM - 2192	Electric induction motors. Main measures and ratings.
IRAM - 2195	Switchboards, control and command under metal roof. Dielectric tests.
IRAM - 2200	Switchboards, control and command under metal roof.
IRAM - 2212	Aluminum alloy conductors. For overhead power lines.
IRAM - 2217	Thermoplastic materials of synthetic rubber for coating of electrical cables with metallic sheath.
IRAM - 2219	Single embedding box for single-phase electric meters.
IRAM - 2239	Electrical extension cords for household and similar, shutters and no blinds.

IRAM-2281-1	Grounding of electrical systems. General considerations. Code of practice.
IRAM-2281-2	Grounding of electrical systems. Guide for measurement of magnitudes of grounding (resistance, resistivity, and gradients).
IRAM-2281-3	Grounding of electrical systems. Installations with nominal value less than or equal to 1 kV. Part 3 - Code of practice.
IRAM-2281-4	Grounding of electrical systems. Installations with rated voltages of 1 kV. Part 4 - Code of practice.
IRAM-2281-8	Grounding of electrical systems. Part 8 - Grounding brackets and appliances for use electric in public with nominal value lower or equal to 1 kV. Code of practice.
IRAM - 2292	Safety of electrical and electronic equipment for domestic and similar use. Inspection and reception.
IRAM - 2296	Hollow insulators used in electrical equipment. Test methods.
IRAM-2307-1	Composed of poly (vinyl chloride) (PVC) for insulations and sheaths of electric cables.
IRAM - 2339	Solid Electric insulating materials. Method for the determination of levels of resistance and test of electrical routing in wet conditions.
IRAM - 2340	Electrical insulating liquids. Measurement of the relative permittivity and dielectric dissipation (tg range) in AC power factor and resistivity in direct current.
IRAM - 2341	Electrical insulating liquids. Determination of dielectric frequency. Test method.
IRAM-2359-1	Electric panels. Permanent current copper bars. Design.
IRAM-2359-2	Electric panels. Bars of aluminium for steady flow. Design.
IRAM - 2368	Connectors of electric heating appliances. Bipolar without grounded, for home use and rated voltage 220 V effective.
IRAM - 2370	Electrical and electronic equipment. Rating for your protection against electrical shock.
IRAM - 2376	Solid Electric insulating materials. Method for the determination of flammability by exposure to a source of ignition. (IEC 60707:1981, MOD)
IRAM-2378-1	Trials relating to the risks of fire in electrical appliances. Test method with filament and application guide.
IRAM-2378-2	Trials relating to the risks of fire in electrical appliances. Needle burner test method.
IRAM-2378-3	Trials relating to the risks of fire in electrical appliances. Poor contact with filaments heating test method.
IRAM - 2392	Appliances, portable tools and similar electrical appliances. Limits and methods of measurement of radio interference characteristics.
IRAM - 694	Bars and rods of aluminum alloy for electrical conductors.
IRAM - 698	Aluminium wire non-alloy for electrical conductors.
IRAM - 702	Of copper rod for electrical conductors.
IRAM-AADL J 2024	Photoelectric switches for exterior lighting. Definitions, General conditions and requirements.
IRAM-AADL J 2025	Photoelectric switches for exterior lighting. Test methods.
IRAM-AITA 1-F15-1	Incandescent (filament) lamps for motor vehicles. Part 1: Dimensional, electrical and luminous requirements.
IRAM-IAPG-IEC 79-11	Electrical materials for explosive gaseous atmospheres. Security intrinsic 'I'.
IRAM-IAPG-IEC 79-12	Electrical materials for explosive gaseous atmospheres. Classification of mixtures of gases or vapors of flammable substances with air, according to the maximum experimental safety interstitium and the minimum ignition current.
IRAM-IAPG-IEC 79-13	Electrical materials for explosive gaseous atmospheres. Construction and use of rooms or buildings protected by pressurization.
IRAM-IAPG-IEC 79-14	Electrical materials for explosive gaseous atmospheres. Electrical installations in hazardous areas (except mine).
IRAM-IAPG-IEC 79-15	Electrical materials for explosive gaseous atmospheres. Electrical materials with 'n' protection mode.
IRAM-IAPG-IEC 79-16	Electrical materials for explosive gaseous atmospheres. Artificial ventilation for the protection of rooms of analyzers.
IRAM-IAPG-IEC 79-17	Electrical materials for explosive gaseous atmospheres. Recommendations for inspection and maintenance of electrical installations in hazardous areas (does not apply to mines).
IRAM-IAPG-IEC 79-18	Electrical materials for explosive gaseous atmospheres. Encapsulation "m".
IRAM-IAPG-IEC 79-19	Electrical materials for explosive gaseous atmospheres. Repair and overhaul of equipment used in potentially explosive atmospheres (excluding mines and explosives).
IRAM-IAPG-IEC 79-2	Electrical materials for explosive gaseous atmospheres. Electrical materials with protection 'p' mode.
IRAM-IAPG-IEC 79-20	Electrical materials for explosive gaseous atmospheres. Data of gases and vapors related to the use of electrical materials.
IRAM-IAPG-IEC 79-3	Electrical materials for explosive gaseous atmospheres. Exploder for intrinsically safe circuits.
IRAM-IAPG-IEC 79-4	Electrical materials for explosive gaseous atmospheres. Test method for the determination of the ignition temperature.
IRAM-IAPG-IEC 79-5	Electrical materials for explosive gaseous atmospheres. Powder filling 'q'.
IRAM-IAPG-IEC 79-6	Electrical materials for explosive gaseous atmospheres. Oil immersion 'o'.
IRAM-IEC 1241-1-1	Electrical materials for use in the presence of combustible dust. Part 1: Electrical materials protected by wraps. Section 1: Specifications for materials.
IRAM-IEC 1241-1-2	Electrical materials for use in the presence of combustible dust. Part 1: Electrical materials protected by wraps. Section 2: Selection, installation and maintenance.
IRAM-IEC 1241-2-1	Electrical materials for use in the presence of combustible dusts. Part 2: Methods of test. Section 1: Methods for determining the minimum ignition temperature of dust.
IRAM-IEC 1241-2-2	Electrical materials for use in the presence of combustible dust. Part 2: Methods of test. Section 2: Method for the determination of the electrical resistivity of dust layers.

IRAM-IEC 1241-2-3	Electrical materials for use in the presence of combustible dusts. Part 2: Methods of test. Section 3: Method for the determination of the minimum energy of ignition of dust/air mixtures.
IRAM-IEC 1241-3	Electrical materials for use in the presence of combustible dusts. Part 3: Classification of areas where are or may be present combustible dusts.
IRAM-NM 300-6	Safety of toys. Part 6: Safety of electrical toys.
IRAM-NM 326	Non-destructive testing. Mounting piezoelectric acoustic emission, contact sensors. Procedure.

Source: IRAM. Elaborated by CGTI-EESP/FGV.

14.2. Appendix 2 - Vehicle

Table 14.5 - Regulation on Vehicles (Brazil)

NAME	THEME
LAW 13111/15	Obligation of the sellers of automotive vehicles to inform the buyer the value of the taxes applied on the sale and the regular situation of the vehicle
LAW 12977/14	Dismantling of land vehicles
LAW 9503/97	Brazilian traffic code
LAW 8723/93	Regulates the license for the use of the vehicle or motor configuration
ORDINANCE 315/12	Child restraints
INMETRO ORDINANCE 547	CO2 emissions – fuel control
INMETRO ORDINANCE 330/12	LPG tanks
INMETRO ORDINANCE 301/11	Certification of products (autoparts) by laboratory accredited by INMETRO
INMETRO ORDINANCE 139/11	Diesel smoke
INMETRO ORDINANCE 205/08	New tires destined to commercial, light commercial and towed vehicles
INMETRO ORDINANCE 165/08	New tires destined to passenger cars, including those of mixed use and towed
INMETRO ORDINANCE 8/11	CNG tanks
INMETRO ORDINANCE 30/04	Braking and brake linings
CONAMA RESOLUTION 433/11	Emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 415/09	Emissions and emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 403/08	Emissions and emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 315/02	Emissions, diesel smoke, emissions (Euro IV and V) of heavy duty vehicles and CO2 emissions – fuel consumption
CONAMA RESOLUTION 282/01	Replacement of catalytic converters
CONAMA RESOLUTION 272/00	Emission levels for vehicles
CONAMA RESOLUTION 252/99	Emission levels for vehicles
CONAMA RESOLUTION 226/97	Diesel smoke and CO2 emissions – fuel consumption
CONAMA RESOLUTION 17/95	Permissible sound level
CONAMA RESOLUTION 16/95	Diesel smoke and CO2 emissions – fuel consumption
CONAMA RESOLUTION 15/95	CO2 emissions – fuel consumption
CONAMA RESOLUTION 18/86	Brazilian Program for the Control of Pollution by Motor Vehicles (PROCONVE)
CONTRAN RESOLUTION 644/16	Buses and coaches
CONTRAN RESOLUTION 630/16	Braking and strength of superstructure
CONTRAN RESOLUTION 629/16	Buses and coaches and strength of superstructure
CONTRAN RESOLUTION 595/16	Fuel tanks
CONTRAN RESOLUTION 593/16	Rear protective devices
CONTRAN RESOLUTION 559/15	Anti-theft and immobiliser
CONTRAN RESOLUTION 548/15	Headlamps (R2 and HS1)
CONTRAN RESOLUTION 519/15	Braking
CONTRAN RESOLUTION 485/14	Anti-theft and immobiliser
CONTRAN RESOLUTION 445/13	Buses and coaches and strength of superstructure
CONTRAN RESOLUTION 330/09	Anti-theft and immobiliser
CONTRAN RESOLUTION 316/09	Seat strength, seat belt anchorages, seat belts and restraint systems
CONTRAN RESOLUTION 254/07	Safety glazing
CONTRAN RESOLUTION 245/07	Anti-theft and immobilizer
CONTRAN RESOLUTION 234/07	Couplings and close-coupling device
CONTRAN RESOLUTION 227/07	Headlamps (H1, H2, H3, H4, HB3, HB4, H7 and/or H8, H9, HIR 1, HIR2 and/or H11, R2, HS1, sealed beam, asymmetrical passing beam, halogen sealed beam, filament lamps for use in approved lamp units and headlamps with gas-discharge light sources, gas-discharge light sources for use in approved gas-discharge lamp units), adaptative front-lighting systems, front fog lamps, rear fog lamps, reversing lamps, parking lamps
CONTRAN RESOLUTION 226/07	Indirect vision devices and retro reflectors
CONTRAN RESOLUTION 225/07	Direction indicators and identification of controls, tell-tales and indicators
CONTRAN RESOLUTION 221/07	Fuel tanks and frontal impact
CONTRAN RESOLUTION 220/07	Seat strength, head restraints and head restraints (combined with seats)
CONTRAN RESOLUTION 197/06	Couplings and close-coupling device
CONTRAN RESOLUTION 48/98	Seat belt anchorages
CONTRAN RESOLUTION 44/98	Head restraints (combined with seats)
CONTRAN RESOLUTION 37/98	Audible warning
CONTRAN RESOLUTION 35/98	Audible warning
CONTRAN RESOLUTION 686/87	Anti-theft, immobilizer and vehicle alarm system
CONTRAN RESOLUTION 675/86	Flammability
CONTRAN RESOLUTION 486/74	Fuel tanks
CONTRAN RESOLUTION 463/73	Fuel tanks, door latches and hinges, behavior of steering device under impact, seat strength and seat strength for buses and coaches

CONTRAN RESOLUTION 448/71	Vehicle alarm systems
SECEX ORDINANCE 23/11	Regulates the import of used cars
DENATRAN ORDINANCE 190/09	Local homologation and labelling
IBAMA ORDINANCE 86/96	Pollutant emission levels and noise levels for imported vehicles
MERCOSUR GMC RESOLUTION 31/94	Fuel tanks

Source: INMETRO, CONAMA, CONTRAN. Prepared by CCGI-EESP/FGV.

Table 14.6 - Standards on Vehicles (Brazil)

Standard
ABNT NBR 14375:2017 Road vehicles-Clutch system-Scale for hybridity vehicle assessment
ABNT NBR 14828:2017 Road vehicles-Safety procedures for maintenance on vehicles equipped with an air bag
ABNT NBR 14753:2017 Automotive Road Vehicles-Injection Valve-Inspection and Diagnosis in Otto Cycle Engines
ABNT NBR 15905:2017 Spark-ignition internal combustion engines-Monolithic aluminum alloy piston
ABNT NBR 13705:2016 Road vehicles-Concentrated additives is endothermic engine cooling, types A, B and C-Requirements and test methods
ABNT NBR 15598:2016 Light motor vehicles-Determination of unburned ethanol contained in the exhaust gas by gas chromatography-Test method
ABNT NBR 16567:2016 Light electric hybrid road vehicles-Measurement of exhaust emission and fuel and energy consumption-Test methods
ABNT NBR ISO 28741:2016 Automotive Road Vehicles-Spark Plugs and Their Head Seats-Basic Features and Dimensions
ABNT NBR ISO 6621-3:2009 Errata 1:2016 Internal combustion engines-Piston rings Part 3: Material specifications
ABNT NBR 16564:2016 Internal combustion engines-Elastomer rings for sealing cylinder liners mounted on the engine block-Specifications and test methods
ABNT NBR ISO 11451-1:2016 Road vehicles-Vehicle test methods for electrical disturbances caused by narrow-band electromagnetic energy emitted Part 1: General Principles and Terminology
ABNT NBR ISO 11565:2016 Road vehicles-Spark plugs-Requirements and test methods
ABNT NBR 16529:2016 Motorcycles and similar vehicles-Evaporative emission measurement
ABNT NBR 14261:2016 Road vehicles-Cooling solutions for endothermic engines, types A, B and C-Requirements and test methods
ABNT NBR 11410:2016 Road implements-Automatic coupling and spherical coupling for trucks and trailers-Requirements
ABNT NBR 14752:2016 Automotive Road Vehicles-Electric Fuel Pump-Inspection and Diagnosis (Otto Cycle)
ABNT NBR 12026:2016 Lightweight road vehicles – Determination of the emission of aldehydes and ketones contained in the exhaust gas by liquid chromatography-DNPH Method
ABNT NBR 15940:2016 Lead-acid batteries for use in four or more-wheel motor vehicles-Specification and test methods
ABNT NBR 16532:2016 Road vehicles-Ignition cables-Maintenance, inspection and exchange (Otto cycle)
ABNT NBR 11927:2016 Determination of adhesion between vulcanized elastomers and metals
ABNT NBR ISO 6621-4:2016 Internal combustion engines-Piston rings Part 4: General Specifications
ABNT NBR ISO 6310:2016 Road vehicles-Brake linings-Compressive deformation test methods
ABNT NBR 14843:2016 Road vehicles-Fuel pressure regulator-Test method
ABNT NBR 15917:2016 Road Attachments-Pneumatic suspension for mechanical suspension of truck-tractor and towed vehicles applied in dangerous goods vehicles-Requirements
ABNT NBR 16427:2016 Chains, crowns and pinions of motorcycles, scooters, mopeds, tricycles and quadricycles-Dimensions and test methods
ABNT NBR 16481:2016 Radiators for cooling internal combustion engines by liquid-Test method of mechanical strength and durability for vehicles of categories M1 and N1
ABNT NBR 14096:2016 Fire-fighting vehicles-Requirements for performance, manufacturing and test methods
ABNT NBR 7540:2016 Control the direction of the energy absorber-test method for determination of characteristics
ABNT NBR 7540:2016 Control of the direction of the energy absorber-Test method for determination of characteristics
ABNT NBR 12858:2016 Gaseous and gaseous mixtures used in vehicle emission laboratory-Determination of concentration, minimum purity and contaminants
ABNT NBR 16449:2016 Road implements-Mechanical coupling between four-axle tractor-trailer and semi-trailer-Interchangeability
ABNT NBR 7335:2016 Road vehicles-Impact test instrumentation
ABNT NBR 15646:2016 Accessibility-Vehicle lift and vehicular access ramp for accessibility of persons with disabilities or reduced mobility, on passenger vehicles of categories M1, M2 and M3-Requirements
ABNT NBR 10966-6:2013 Amendment 1:2015 Road vehicles-Brake system
Part 6: Test requirements for vehicles of categories M, N and the equipped with anti-locking system
ABNT NBR 10966-6:2015 Road vehicles-Brake system
Part 6: Test requirements for vehicles of categories M, N and the equipped with anti-locking system
ABNT NBR 15934:2015 Compression-ignition internal combustion engines (Diesel)-Monolithic aluminum alloy piston
ABNT NBR 7471:2015 Road vehicles-Helmets and visors for drivers and passengers of motorcycles and similar vehicles-Performance requirements and test methods
ABNT NBR 7812:2015 Copper tubes, seamless, for conducting application fluids on road vehicles, tractors and the like
ABNT NBR 10966-1:2013 Amendment 1:2015 Road vehicles-Brake system
Part 1: Uniform provisions concerning braking approval for vehicles of categories M, N and the
ABNT NBR 10966-1:2015 Road vehicles-Brake system
Part 1: Uniform provisions concerning braking approval for vehicles of categories M, N and the
ABNT NBR 10966-2:2013 Amendment 1:2015 Road vehicles-Brake system
Part 2: Braking and performance tests for vehicles of categories M, N and the
ABNT NBR 10966-2:2015 Road vehicles-Brake system Part 2: Braking and performance tests for vehicles of categories M, N
ABNT NBR 14599:2014 Errata 1:2015 Road implements-Safety requirements for solid waste collectors/compactors

ABNT NBR 9491:2015 Safety glasses for road vehicles-Requirements
ABNT NBR 9493:2015 Safety Glasses-Determination of impact resistance with phantom
ABNT NBR 9494:2015 Safety glass-Determination of impact resistance with ball
ABNT NBR 9497:2015 Safety glass-Determination of secondary image separation
ABNT NBR 9498:2015 Safety Glasses-Abrasion Test Method
ABNT NBR 9499:2015Safety Glasses-High Temperature Resistance Test
ABNT NBR 9501:2015Safety Glasses-Radiation Testing
ABNT NBR 9502:2015 Safety Glasses-Resistance to humidity test
ABNT NBR 9504:2015Safety Glasses-Determination of Optical Distortion
ABNT NBR 9503:2015 Safety glasses-determination of light transmittance
ABNT NBR 6606:2015 Motor road vehicles-Determination of range of manual controls
ABNT ISO/TR 8713:2015 Road vehicles propelled electricity-Vocabulary
ABNT NBR 9995:2015 Exhaust gas of diesel engines-determination of opacity in dynamometer cycle
ABNT NBR 6091:2015 Motor road vehicles – Anchorages of safety belts, ISOFIX anchorage system and ISOFIX top tether anchorage of — Location and tensile strength
ABNT NBR 14148:2015 Side guard for trucks and towed
ABNT NBR 6068:2015 Road vehicles-masses and dimensions of adults
ABNT NBR 7318:2015 Vulcanized elastomer for use in motor vehicles – determination of hardness
ABNT NBR 16402:2015
Road vehicles-automotive exhaust system requirements for the replacement market for category M and N vehicles with Otto cycle engine
ABNT NBR 6016:2015 Exhaust gas of Diesel engine-evaluation of soot content with the Ringelmann scale
ABNT NBR 6144:2015 Connectors for auto radios antennas-dimensions
ABNT NBR ISO 7637-1:2015 Motor road vehicles-electrical Disturbances by conduction and coupling
Part 1: definitions and general considerations
ABNT NBR 16369:2015 Motorcycles and similar vehicles – Determination of hydrocarbons, carbon monoxide, nitrogen oxides and carbon dioxide in exhaust gas
ABNT NBR 16331:2014 Errata 1:2015 Traffic safety-plastic barrier pipe
ABNT NBR IEC 62660-2:2015 Lithium-ion secondary cells for propulsion of electric road vehicles
Part 2: reliability testing and abuse
ABNT NBR 15725:2015 Adhesives-structural bonding system in automotive glass replacement-requirements and test methods
ABNT NBR ISO 6622-2:2015 Internal combustion engines-piston rings Part 2: rectangular piston rings made of steel
ABNT NBR 16330:2014 Traffic safety — easels and barriers to road signaling types I, II and III
ABNT NBR 16331:2014 corrected version: 2015 Traffic safety-plastic barrier pipe
ABNT NBR 16320:2014 Motor road vehicles-steering indicator Flashlight-specification
ABNT NBR 16321:2014 Motor road vehicles — astern Lantern — specification
ABNT NBR 7337:2014 Motor road vehicles-safety-belt requirements and tests
ABNT NBR ISO 6621-5:2014 Internal combustion engines-piston rings Part 5: quality requirements
ABNT NBR 9078:2014 Motor road vehicles-main with normal bulb Headlight-specification
ABNT NBR 9183:2014 Road vehicles-automotive Headlamp with halogen H4 main light bulb-specification
ABNT NBR 9293:2014 Motor road vehicles-main with halogen incandescent lamp Headlight (H1-H2-H3)-specification
ABNT NBR 9296:2014 Motor road vehicles-bounding, Lantern and brake position-specification
ABNT NBR 14599:2014 corrected version: 2015
Road equipment-safety requirements for collectors-solid waste compactors
ABNT NBR IEC 62660-1:2014 Lithium-ion secondary cells for propulsion of electric road vehicles
Part 1: performance test
ABNT NBR 6743:2014 Road equipment-trucks, tractors and buses-trucks-adaptation for installation of vehicular auxiliary axis
ABNT NBR 10312:2014 Errata 1:2014 Automotive light road vehicles-determination of resistance to displacement by rolling track-free deceleration and dynamometer simulation
ABNT NBR 10312:2014 corrected version: 2014 Automotive light road vehicles — determination of resistance to displacement by rolling track-free deceleration and dynamometer simulation
ABNT NBR ISO 17268:2014 Connection devices for refueling vehicles with gaseous hydrogen
ABNT NBR ISO 3795:2014 Road vehicles, tractors and agricultural and forestry machinery — determining the combustion behavior of interior materials
ABNT NBR 15830:2014 Motor road vehicles — suspension damper — classification, terminology and identification
ABNT NBR 13308:2014 Motor road vehicles — suspension damper — verification of performance and durability — test method
ABNT IEC/TR 60783:2014 Wiring and connectors of electric road vehicles
ABNT NBR 9492:2014 Safety glasses — breaking Test — security against shrapnel
ABNT NBR ISO 18669-1:2014 Internal combustion engines--piston pins Part 1: general specifications
ABNT NBR ISO 6623:2014 Internal combustion engines--piston rings--Rings scrapers made of cast iron
ABNT NBR ISO 6626-2:2014 Internal combustion engines--piston rings
Part 2: oil control rings with coil spring and reduced height, made of cast iron
ABNT NBR 10966-3:2013 Motor road vehicles — brake System
Part 3: measurement procedures of response time in vehicles equipped with pneumatic brake systems of categories M, N and O
ABNT NBR 10966-4:2013 Road vehicles-automotive brake System
Part 4: provisions relating to energy sources and energy storage devices (energy tanks) for vehicles of categories M, N and O
ABNT NBR 10966-5:2013 otor road vehicles — brake System
Part 5: specifications for specific conditions for spring braking systems hoarder (spring brake) for vehicles of categories M, N and O
ABNT NBR 10966-7:2013 Motor road vehicles — brake System
Part 7: distribution of braking among the axles and requirements of compatibility between tractors and trailed vehicles of categories M, N and O
ABNT NBR 16231:2013 Uniform provisions concerning the filament lamps for use in lighting systems and/or signalling systems of self-propelled road vehicles and their towed

ABNT NBR IEC 62196-2:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed plugs — electric vehicle conductive Charging
Part 2: dimensional Requirements of compatibility and interchangeability for AC accessories with pins and tubular contacts
ABNT NBR 16218:2013 Impact resistant safety glasses for road vehicles ballistic armor — Visual and optical Aspects — requirements and test methods
ABNT NBR 15914:2013 Lead-acid battery for use in motor vehicles of four or more wheels — requirements and symbology
ABNT NBR 16204-1:2013 Motor road vehicles — occupant protection — side-impact tests
Part 1: General
ABNT NBR 16204-2:2013 Motor road vehicles — occupant protection — side-impact tests
Part 2: procedure and performance requirements in side impact test with speed of impact barrier with an angle of 63° to the longitudinal axis of the vehicle
ABNT NBR 16204-3:2013 Motor road vehicles — occupant protection — side-impact tests
Part 3: procedure and performance requirements in side impact test with the impact barrier perpendicular to the longitudinal axis of the vehicle
ABNT NBR 15300-1:2013 Motor road vehicles — occupant protection — frontal impact tests
Part 1: performance requirements
ABNT NBR 15283:2013 Motor road vehicles — strength of the seats, their anchorages and head restraint
ABNT NBR IEC 61851-1:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed Plugs — conductive Charging for electric vehicles Part 1: General requirements
ABNT NBR 16187:2013 Road motor vehicles — procedure for the determination of the H points and R
ABNT NBR 14652:2013
Road equipment-Collector waste carrier — health services construction and inspection requirements
ABNT NBR IEC 61851-1:2013 Conductive charging system for electric vehicles Part 1: General requirements
ABNT NBR IEC 61851-21:2013 Conductive charging system for electric vehicles
Part 21: electric vehicle Requirements for conductive connection to an a.c/d.c. supply
ABNT NBR IEC 61851-22:2013 Conductive charging system for electric vehicles Part 22: AC recharging station for electric vehicles
ABNT NBR 16176:2013 Air-cooled cylinder shirts (finned) for internal combustion engines mounted on the engine block
ABNT NBR 16171:2013 Motor road vehicles — Horns — procedures and test requirements for vehicles categories L
ABNT NBR 6750:2013 Errata 1:2013 Wheels for cars — verification of the durability and resistance
ABNT NBR 13909:2013 Wheels and rims road and agricultural vehicles — terminology
ABNT NBR 6608:2013 Wheels and rims road vehicles — Dimensions and IDs
ABNT NBR 6750:2013 corrected version: 2013 Wheels for cars — verification of the durability and resistance
ABNT NBR 6752:2013 For aluminum alloy wheel for light commercial cars and SUVs — performance verification tests
ABNT NBR 15861:2013 Road equipment — vehicular Equipment used — identification number
ABNT NBR 14681:2013 Road equipment — light Trailers — security Chains
ABNT NBR 16141:2013 Road equipment — locking System and Tipper lifting — requirements
ABNT NBR 16142:2013 Road equipment — stairway to road tank vehicle
ABNT NBR 15875-2:2011 Amendment 1:2013 Motor road vehicles — energized Triggers Part 2: technical requirements in accordance with European Union Directive 74/60/EEC
ABNT NBR 15875-2:2013 Motor road vehicles-powered Triggers Part 2: technical requirements in accordance with the EU Directive 74/60/EEC
ABNT NBR 15875-4:2011 Amendment 1:2013 Road motor vehicles
Actuators energized Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR 15875-4:2013 Motor road vehicles-powered Triggers
Part 4: technical requirements according to ECE R-21 of the United Nations
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ABNT NBR 14040-5:1998 corrected version: 1999 Vehicle safety inspection-light and heavy vehicles Part 5: lighting
ABNT NBR 14040-6:1998 Vehicle safety inspection-light and heavy vehicles Part 6: Brakes
ABNT NBR 14040-7:1998 Vehicle safety inspection-light and heavy vehicles Part 7: Direction
ABNT NBR 14040-8:1998 corrected version: 1999 Vehicle safety inspection-light and heavy vehicles Part 8: axles and suspension
ABNT NBR 14040-9:1998 Vehicle safety inspection-light and heavy vehicles Part 9: tyres and wheels
ABNT NBR ISO 1585:1996 Road vehicles-engine test Code-net Power effective
ABNT NBR 10452:1996 Transport of livestock-Procedure
ABNT NBR 6948:1996 Rubber gasket for hydraulic brakes-precipitation verification after soaking in liquid for brake
ABNT NBR 7317:1996 Rubber gaskets for hydraulic brakes-verification of change after immersion in brake fluid

ABNT NBR 13539:1995 Infrared Analyzer of carbon monoxide (CO), hydrocarbons (HC) and carbon dioxide (CO ₂) contained in the exhaust gas of automotive light road vehicles
ABNT NBR 13540:1995 Infrared Analyzer of carbon monoxide (CO), hydrocarbons (HC) and carbon dioxide (CO ₂) contained in the exhaust gas of automotive light road vehicles-Tests
ABNT NBR 13477:1995 Flexible hoses for hydraulic brakes for road vehicles
ABNT NBR 13478:1995 Flexible hoses for hydraulic brakes for road vehicles-Tests
ABNT NBR 7321:1995 Hydraulic oil filter-determination of pressure drop characteristics of flow
ABNT NBR 13367:1995 Rubber gaskets for hydraulic brakes master cylinders-determination of structural strength-test method
ABNT NBR 6143:1995 Disc brake pad-determination of friction and wear through the test bench Krauss
ABNT NBR 6050:1995 Clutch
ABNT NBR 13102:1994 Reflective surfaces applied to motor road vehicles-measurement of specular gloss-test method
ABNT NBR 13123:1994 Reflective surfaces applied to motor road vehicles-specification
ABNT NBR 8359:1994 Locks and hinges of the side doors of motor road vehicles – Determination of the characteristics-test method
ABNT NBR 8358:1994 Locks and hinges of the side doors of motor road vehicles-specification
ABNT NBR 12898:1993 Report of traffic accident (RAT)-Procedure
ABNT NBR 6052:1993 Flange of the fuel level sensor, gasket and fuel tank flange-mounting shapes and basic dimensions
ABNT NBR 13042:1993 Manufacture of vehicle-alarm Procedure
ABNT NBR 12897:1993 Use of the opacimeter for medication of the soot content of Diesel engine-light absorption method-Procedure
ABNT NBR 12895:1993 Check the performance of the service brakes linings for road vehicles, in test bench inertial type (for brake dynamometer)-Procedure
ABNT NBR 5541:1993 Brake trim-verify the characteristics of friction and wear
ABNT NBR 7329:1993 Hydraulic oil filter-Determination of the integrity of the filter element
ABNT NBR 12813:1993 Extraction of samples of hydraulic fluid from one system into operation, particulate contamination analysis-Procedure
ABNT NBR 12685:1992 Lighting Lantern rear license plate of motor road vehicles-specification
ABNT NBR 6609:1992 Friction levels of friction materials for brake linings
ABNT NBR 12146:1992 Feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the tightness and performance-test method
ABNT NBR 12149:1992 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 12153:1992 Fuel feeder for feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 12515:1992 Graphic symbols for systems and components of hydraulic and pneumatic brakes-Symbolism
ABNT NBR 12530:1992 Symbols of the dimensions of road vehicles, cargo and special automotive mixed Symbols
ABNT NBR 12556:1992 External and internal dimensions of road vehicles, cargo and special automotive mixed Terminology
ABNT NBR 12557:1992 Road vehicles-automotive controls, indicators and optical instruments or acoustic-Terminology
ABNT NBR 12562:1992 Long range auxiliary Lighthouse-specification
ABNT NBR 11893:1991 Feed components of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11894:1991 Fuel filter for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11895:1991 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11896:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11897:1991 Fuel feeder for feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 12147:1991 Fuel filter for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklift trucks-inspection of tightness test method
ABNT NBR 12148:1991 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklift trucks-inspection of tightness test method
ABNT NBR 12150:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas oil, for exclusive use in forklifts-verification of the tightness of the valve body-test method
ABNT NBR 12151:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 11866:1991 Rubber sealing ring for cylinders of the disk brakes-specification
ABNT NBR 11868:1991 Round wire of carbon steel, drawn for the manufacture of wheels-specification
ABNT NBR 12101:1991 Rubber sealing ring for cylinders of the disk brakes-Determination of characteristics-test method
ABNT NBR 5534:1991 Description of the requirements for the location and identification of controls lighting cars and vans
ABNT NBR 6602:1991 Clutch-evaluation on capacity of ramp work stream
ABNT NBR 5520:1991 Brake linings-determination of hardness "Gogan" of friction materials
ABNT NBR 12013:1990 Automotive light road vehicles-measurement of the concentration of carbon monoxide in the exhaust gas, idling (field test)-test method
ABNT NBR 11407:1990 Vulcanized elastomer-determination of changes of the physical properties, the effect of liquid-immersion test method
ABNT NBR 11800:1990 Retrorrefletores for road vehicles-test method
ABNT NBR 5531:1990 Road vehicles-shooting
ABNT NBR 6056:1990 Positioning of the locus of the driver's eyes in relation to road vehicle
ABNT NBR 6060:1990 Locus of the driver's eyes in self-propelled road vehicles-dimensions
ABNT NBR 11408:1990
Road vehicles-determination of burning velocity of the inner-coating materials test method
ABNT NBR 11472:1990 Plastic fuel tank for self-propelled road vehicles-specification

ABNT NBR 11954:1990 Determination of the coefficient of friction between the windshield and the cleaning of the pick blade-test method
ABNT NBR 6047:1990 Automotive-Engine road vehicles
ABNT NBR 11216:1990 Identification of connections of pneumatic brake systems, engines of road vehicles-Procedure
ABNT NBR 7026:1990 Exhaust gas emitted by Diesel engine-measuring soot with Sampler for filter element
ABNT NBR 10965:1989 Warning triangle-specification
ABNT NBR 5521:1989 Windshield wiper of cars and vans-verification of durability
ABNT NBR 10853:1989 Indicators of temperature and electric meters fuel-level Specification
ABNT NBR 9712:1989 Heat transfer limitation of the brake drum for tire-specification
ABNT NBR 9500:1986 Errata 1:1989 Project minimum requirements for road vehicle door-container-Procedure
ABNT NBR 10962:1989 Brake trim-verification of resistance of glue between the friction surfaces and work due to corrosion-test method
ABNT NBR 10753:1988 Brake trim-evaluation of characteristics of friction material in test bench inertial type (dynamometer) for brakes of cars and vans of mixed use-test method
ABNT NBR 5533:1988 Motor road vehicles bodywork and chassis frame
ABNT NBR 5108:1987 Terminals with electrical connections by screw clamps for insulated cables-dimensions and tolerances
ABNT NBR 6058:1987 Use of two-dimensional device for positioning of occupants in road vehicles
ABNT NBR 5556:1986 Symbols for identification of controls, indicators and pilot lights of road vehicles and road machines, automotive, industrial and agricultural tractors
ABNT NBR 5505:1984 Friction material to the brake lining of road vehicles, industrial and similar verification of stability, expansion and growth
ABNT NBR 8360:1984 Vulcanized elastomer-accelerated aging in ozone Chamber-static test-test method
ABNT NBR 8833:1983 Determination of the conformity of vehicles with the established standards for leakage-issuance Procedure
ABNT NBR 7014:1981 Horns for motor road vehicles
ABNT NBR 7023:1981 Direction-self-propelled road vehicles
ABNT NBR 6018:1980 Low voltage terminals for ignition coil
ABNT NBR 5929:1978 Alternative vehicular internal combustion engines to ethanol
ABNT NBR 5552:1977 Rubber gaskets for hydraulic brakes
ABNT NBR 5922:1977 Steel tubes for fuel injection in diesel engines for use in vehicles, tractors and similar
ABNT NBR 5443:1977 Double-wall steel tubes for fluid conduction

Source: ABNT. Prepared by CCGI-EESP/FGV.

Table 14.7 - Vehicles Regulation (Argentina)

NAME	THEME
LAW 24449	Regulates traffic in Argentina
DECREE 779/95	Regulates law 24449
RESOLUTION 247/05	Attributes to the National Institute of Industrial Technology the competence to verify the compliance with legal requirements for the management of the requests for granting the License for Model Configuration (LCM).
RESOLUTION 97/14	Approves the requirements and procedure for registration to the National Registry of Autoparts Testing Laboratories
INTI DIRECTING COUNCIL RESOLUTION 10/14	Approves the procedure for recognition of testing/measurement laboratories for the automotive and auto parts industry to incorporate to the "Network of Laboratories for the Automotive Industry" (RELIAU)
LAW 26363	Creates the National Road Safety Agency
PROVISION 166/10	Implements in all zero kilometer vehicles the double airbag, the anti-lock braking system and the headrest for all seats adjacent to the doors (side)
PROVISION 494/10	Implements the central headrest, visual and acoustic warning device for the driver's safety belt and automatic lighting
PROVISION 272/11	Implements the frontal and rear impact test and the child restraint system
DISPOSITION 408/10	Establishes terms for the implementation of the automatic low-beam lighting system on motor vehicles that would be incorporated into the Argentine automotive park
RESOLUTION 91/01	Regulates the replacement market for auto parts for automotive vehicles
DECREE 13/15	Appoints the Secretariat of Environmental Control and Monitoring as the competent authority in the contamination control
RESOLUTION 1464/15	Implements the limits and procedures of emissions certification

Source: Ministerio de Producción. Prepared by CCGI-EESP/FGV.

Table 14.8 - Vehicles Standards (Argentina)

NAME	TITLE
IRAM-AITA 8-A1	Road vehicles. Wheels for trucks, buses, and towed vehicles. Requirements and test methods.
IRAM - 10271	Commercial road vehicles. Mechanical coupling devices. Wear limits.
IRAM - 12542	Tempered glass, safety, road transport vehicles. Methods of determination of defects.
IRAM - 12536	Flat and curved, safety, tempered, glass for land transport vehicles. Test method for determining the resistance to impact.
IRAM - 12554	Safety glass, tempered, flat and curved, for terrestrial transport vehicles. Fragmentation test method.
IRAM - 12546	Safety glass tempered for terrestrial transport vehicles.
IRAM - 12564	Land transport vehicle safety glasses. Method for the determination of the light transmission.
IRAM - 12571	Lamellar safety glass for land transport vehicles. Test method for impact resistance.
IRAM - 12570	Lamellar safety glass for land transport vehicles. Test method for moisture resistance.
IRAM - 8407	Industrial vehicles. Symbols for the tell-tales, indicators and controls.

IRAM - 8411	Industrial vehicles. Safety requirements for their construction and operation.
IRAM - 8410	Industrial vehicles. The braking performance.
IRAM - 8406	Industrial vehicles. Definitions and terminology.
IRAM - 8401	Industrial vehicles. Front forklift. Counterbalanced.
IRAM - 16030	Vehicles of medical transport and its equipment. Ground ambulances. Requirements.
IRAM-AITA 13-J7	Road vehicles. Symbols for controls, indicators and witnesses.
IRAM-AITA 1-N10B1	Road vehicles. Wiper system. Part 1 - Requirements and test methods.
IRAM-NM-ISO 3842	Road vehicles. Hitch plate. Interchangeability.
IRAM - 10251	Road vehicles. Bolt the hitch plate. Strength tests.
IRAM-NM-ISO 4086	Road vehicles. 90 fifth wheel hitch PIN. Interchangeability.
IRAM-AITA 11-B3	Road vehicles. Address ends, axial joints and joints from suspension. Requirements and test methods.
IRAM-AITA 21069-1	Road vehicles. Test of brake systems of vehicles with total maximum authorized mass greater 3,5 t using roller brake testers. Part 1 - Air brake systems.
ISO	
IRAM-AITA 10274-1	Road vehicles. Energy efficiency. Part 1 - Measurement of emissions of CO2 and fuel economy.
IRAM-AITA 6-G2	Road vehicles. Diaphragms for air brake chambers. Requirements and test methods.
IRAM-AITA 10275	Road vehicles. Names and categories.
IRAM-AITA 6-C2	Road vehicles. Sets lining brake, disc or drum, replacement, for motor vehicles and their trailers. Requirements and test methods.
IRAM-AITA 6-E4	Road vehicles. Hydraulic master cylinder for brake and clutch. Requirements and test methods.
IRAM-AITA 11-A2	Road vehicles. Boxes of steering rack and pinion. Part 2: Methods of test.
IRAM-AITA 11-A1	Road vehicles. Boxes of steering rack and pinion. Part 1: Requirements.
IRAM-AITA 6-G3-2	Road vehicles. Vacuum pumps (depressants) to over-run. Part 2: Methods of test.
IRAM-AITA 6-G3-1	Road vehicles. Vacuum pumps (depressants) to over-run. Part 1: Requirements.
IRAM-AITA 4-D2	Road vehicles. Conventional telescopic hydraulic dampers. Requirements and test methods.
IRAM-AITA 4-D3	Road vehicles. Structural dampers (McPherson). Requirements and test methods.
IRAM - 10269	Commercial road vehicles. Location of electrical and pneumatic connections between tractor vehicles and towed.
IRAM - 10268	Commercial road vehicles. Hose coiled for the connection of the pneumatic between tractor vehicle and trailer brake system. Requirements and test methods.
IRAM - 10262	Commercial road vehicles. Hitch plate. Requirements and test methods.
IRAM - 10272	Commercial road vehicles. The hitch plate backing plate. Requirements and test methods.
IRAM - 10252	Commercial road vehicles. Drawbar eye. Requirements and test methods.
IRAM - 10253	Commercial road vehicles. 50 mm of drawbar eye. Requirements and interchangeability.
IRAM-AITA 10261	Commercial road vehicles. Tow hook. Requirements.
IRAM - 10258	Commercial road vehicles. Axes. Requirements and test methods.
IRAM-AITA 10260	Commercial road vehicles. Rear (bumper) protection devices. Requirements and test methods.
IRAM - 10259	Commercial road vehicles. Mechanical coupling devices. Marking.
IRAM-AITA 10276	Commercial road vehicles. Lateral protection devices. Requirements.
IRAM - 10255	Commercial road vehicles. Coupling devices and rigid eyelets. Strength tests.
IRAM - 10256	Commercial road vehicles. Mechanical device for coupling articulated traction bars. Strength tests.
IRAM - 10263	Commercial road vehicles. Vertical bracket Assembly of semi-trailers. Requirements and test methods.
IRAM - 10265	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 7-pin type connector 24 (supplementary) S for vehicles with a rated voltage of 24 V.-requirements and test methods.
IRAM - 10264	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 7-pin type connector 24 N (normal) for vehicles with a rated voltage of 24 V.-requirements and test methods.
IRAM - 10266	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 15-pin connector for vehicles with nominal voltage of 24 V.-requirements and test methods.
IRAM - 10267	Commercial road vehicles. Brake pneumatic between tractor vehicle and trailer connectors. Requirements and test methods.
IRAM - 10257	Commercial road vehicles. Mechanical coupling between towing device vehicle's coupling in the rear and with drawbar trailers. Interchangeability.
IRAM - 10254	Commercial road vehicles. Drawbar coupling. Interchangeability.
IRAM-NM-ISO 337	Road vehicles. 50 fifth wheel coupling pin. Mounting and interchangeability characteristics and basic measures.
IRAM-NM-ISO 8717	Commercial road vehicles. Hitch plate. Strength tests.
IRAM-AITA 1-N10B3	Motor vehicles. Systems wipers for automobiles and light trucks. Test methods.
IRAM-AITA 1-N10B2	Motor vehicles. Systems wipers for automobiles and light trucks. Inspection and reception.
IRAM-AITA 1-N1	Motor vehicles. System washer, for cars and trucks.
IRAM-AITA 6-H2	Motor vehicles. Liquids for hydraulic brake and clutch systems. Test methods.
IRAM-AITA 6-H10	Motor vehicles. Liquids for hydraulic brake and clutch systems. Inspection and reception.
IRAM-AITA 6-H5	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 5.1.
IRAM-AITA 6-H4	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 4.
IRAM-AITA 6-H3	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 3.
IRAM-AITA 6-A2-1	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Requirements.
IRAM-AITA 6-A2-3	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Test methods.
IRAM-AITA 6-A2-2	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Merchandise inspection and reception.
IRAM-AITA 6-E4-2	Motor vehicles. Master cylinder for hydraulic brakes. Inspection and reception.
IRAM-AITA 1-K15-2	Motor vehicles. Anchorages for safety belts. Part 2: on vehicles without anchor factory.
IRAM-AITA 1-K15-1	Motor vehicles. Anchorages for safety belts. Part 1: on vehicles with factory Rke anchors.
IRAM-AITA 4-D2-2	Motor vehicles. Telescopic shock absorbers. Inspection and reception.
IRAM-AITA 0-B3	Motor vehicles, trailers and semiacoplados. Definition of dimensions.
IRAM-AITA 0-B1	Commercial motor vehicles, trailers and semiacoplados. General definitions.
IRAM-AITA 3680 - 1	On Board of motor vehicles (SRI) child restraint systems. Part 1 - Definitions and classification.

IRAM-AITA 3680 - 3	Child restraint (SRI) on Board of motor vehicle systems. Part 3 - LATCH System. Requirements and test methods.
IRAM-AITA 3680 - 2	Child restraint (SRI) on Board of motor vehicle systems. Part 2 - ISOFIX system and universal, semi-universal, restricted and specific categories. Requirements and test methods.
IRAM - 3927	Safety in lifting equipment. Hydraulic articulated jib cranes mounted on vehicles or on surface. Constructive characteristics, operation, inspection, testing and maintenance.
IRAM - 3926	Safety in lifting equipment. Lifting and rotating aerial devices mounted on vehicles (gidroelevators), to position personal.
IRAM - 11076	Wheels for commercial vehicles. Measures.
IRAM - 10051	Ramps for the entry and exit of persons with reduced mobility to vehicles for the transport of passengers with a capacity of more than nine seats.
IRAM - 10052	Platform lifts for the entry and exit of people in wheelchairs to vehicles for the transport of passengers with a capacity of more than nine seats.
IRAM-2008-2	Rotating electrical machines. Methods of test for the determination of losses and performance, excluding machines for electric traction vehicles.
IRAM - 2185	Rotating electrical machines of traction. To be used in the railways, vehicles and four-wheel-drive systems.
IRAM-FA L 7010	Railway material. Coil springs suspension for vehicles.
IRAM-FA L 7019	Material ferroviario. Bars for the manufacture of springs for suspension for vehicles.
IRAM-AITA 1-F15-2	Incandescent (filament) lamps for motor vehicles. Part 2: Performance requirements and test conditions.
IRAM-AITA 1-F15-1	Incandescent (filament) lamps for motor vehicles. Part 1: Dimensional, electrical and luminous requirements.
IRAM-FA L 2055	Incandescent electric lamps for railway vehicles.
IRAM-FA L 7025	Wheels for railway vehicles.
IRAM - 4260	Instruments for measuring the speed of motor vehicles.
IRAM - 3895	Protective clothing for racing drivers. Protection against heat and fire. Performance requirements and test methods.
IRAM-IAPG TO 6863	Natural gas. Compressed natural gas (CNG) used as a fuel for motor vehicles. Quality parameters.
IRAM-FA L 7007	Central screw Coupler. For towed vehicles.
IRAM-FA L 7020	Axes for towed vehicles.
IRAM-FA L 12578	Double glazed sealed for railway vehicles with air conditioning.
IRAM-3641-1	Seat belts for use in motor vehicles. Requirements and test methods.
IRAM-3641-2	Seat belts for use in motor vehicles. Inspection and reception.
IRAM-IAS U 500 255	Hot vehicle rolled high strength steel sheets.
IRAM-AITA 0-B2	Loads in commercial motor vehicles, trailers and semiacoplados. General definitions.
IRAM-AITA 9-C	Acoustic. Measurement of noise emitted by vehicles in acceleration. Engineering method.
IRAM-AITA 9-C1	Acoustic. Measurement of noise emitted by motor vehicles in use, detained. Verification method.

14.3. Appendix 3 – Cosmetics

Table 14.9 - Regulation on cosmetics (Brazil)

NAME	THEME
DECREE 8077/13	Regulates law 6360/76
LAW 6360/76	Basic rules for personal hygiene, perfumery and cosmetics products
ANVISA ORDINANCE 131/16	Labeling for SUS
ANVISA ORDINANCE 83/16	Internalization of Mercosur regulation
ANVISA ORDINANCE 69/16	Internalization of Mercosur regulation
ANVISA ORDINANCE 15/15	Internalization of Mercosur regulation
ANVISA ORDINANCE 7/15	Internalization of Mercosur regulation
ANVISA ORDINANCE 48/13	Internalization of Mercosur regulation
ANVISA ORDINANCE 19/13	Internalization of Mercosur regulation
ANVISA ORDINANCE 15/13	Internalization of Mercosur regulation
ANVISA ORDINANCE 44/12	Internalization of Mercosur regulation
ANVISA ORDINANCE 30/12	Internalization of Mercosur regulation
ANVISA ORDINANCE 29/12	Internalization of Mercosur regulation
ANVISA ORDINANCE 3/12	Internalization of Mercosur regulation
ANVISA ORDINANCE 54/11	Time extension
ANVISA ORDINANCE 38/11	Internalization of Mercosur regulation
ANVISA ORDINANCE 36/09	Formaldehyde
ANVISA ORDINANCE 92/08	Deregulation (Degrees 1 and 2)
ANVISA ORDINANCE 176/06	Internalization of Mercosur regulation
ANVISA ORDINANCE 172/06	Time extension
ANVISA ORDINANCE 78/06	Time extension
ANVISA ORDINANCE 332/05	Cosmetic vigilance system
ANVISA ORDINANCE 108/05	Time extension
ANVISA ORDINANCE 13/03	Toothbrushes
ANVISA ORDINANCE 254/02	Inclusion of www.anvisa.gov.br website
ANVISA ORDINANCE 79/00	Definition of PHPC
ANVISA ORDINANCE 74/00	Training program on good governance for auditors and inspectors
ANVISA ORDINANCE 10/99	Pacifiers and other items
ANVISA RESOLUTION 481/99	Microbiological control of PHPC
ANVISA ORDINANCE 296/98	Adoption of Mercosur classification system

ANVISA ORDINANCE 295/98	Toothbrushes
ANVISA ORDINANCE 97/96	Evaluation Regulation of Social Responsibility Management System
INMETRO ORDINANCE 228/05	Rules for toys under the Brazilian System for Conformity Assessment (SBAC)
INMETRO ORDINANCE 108/05	Revises the technical metrological regulation establishing the minimum conditions thermometers used in the determination of the temperature of petroleum have to meet as much as their liquid derivatives
INMETRO ORDINANCE 197/02	Creates a Technical Metrological Regulation that establishes the conditions portable and non-portable ethylometers for evidentiary purposes have to meet
INMETRO ORDINANCE 146/01	Pre-measured cosmetics and toilet products
INMETRO ORDINANCE 105/01	Provisions for PHPC goods in the following states: solid, semi-solid, gel, solid and liquid form; and which are physically characterized by lack of fluidity
INMETRO ORDINANCE 69/01	Establishes requirements for the liquid-flow glass thermometers, internal scale and total immersion type EIL and EIC
INMETRO ORDINANCE 100/00	Establishes criteria for commercialization, indication of the net content and methodology of verification of the liquid content of soap and bar soap
INMETRO ORDINANCE 126/99	Establishes the conditions the packaging of soap and bar soap products commercialized in the domestic market have to meet
INMETRO ORDINANCE 87/99	Classification of personal hygiene products, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 7/05	Compulsory Labelling General for Personal Care Products, Cosmetics and Perfumes
MERCOSUR GMC RESOLUTION 36/04	Specific technical requirements for toiletries, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 26/04	Specific labelling for personal care products, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 36/99	Requirements for the registration of Mercosur and extra-zone cosmetic products and for business entities registration holders and importers
MERCOSUR GMC RESOLUTION 24/95	Definition of cosmetic products
MERCOSUR GMC RESOLUTION 110/94	

Source: ANVISA, INMETRO, MERCOSUR. Prepared by CCGI-EESP/ FGV (May 2017).

Table 14.10 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics (Brazil)

STANDARD	THEME
ABNT NBR 16483:2016	Beauty salon — people skills who work in beauty salons
ABNT NBR 16383:2015	Beauty salon-requirements of good practice in the provision of services
ABNT NBR 16283:2015	Beauty salon-Terminology
ABNT NBR ISO 21149:2008	Cosmetics-microbiology-detection and Count of aerobic mesophilic bacteria
ABNT NBR ISO 21150:2008	Cosmetics-microbiology-detection of Escherichia coli
ABNT NBR ISO 22717:2008	Cosmetics-microbiology-detection of Pseudomonas aeruginosa
ABNT NBR ISO 22718:2008	Cosmetics-microbiology-detection of Staphylococcus aureus
ABNT NBR ISO 21148:2008	Cosmetics-microbiology-general instructions for microbiological research

Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

Table 14.11 - Regulation on cosmetics, hygienic products and perfumery (Argentina)

NAME	THEME
ANMAT RESOLUTION 2016/93	Regulates cosmetics and hygiene goods subject to the intervention of ANMAT
ANMAT DISPOSITION 2723/97	Approves the Unique Form of authorization for the importation of medicine, cosmetic products and hygienic products, reactive of diagnosis of use "in vitro" and/or disposable material, apparatus and equipment of medical and dental use
ANMAT DISPOSITION 1109/99	Conditions techniques for the qualifications that are required and eligibility requirements of such applications, in relation to the production or importation of cosmetic products for personal hygiene and perfume
ANMAT DISPOSITION 1402/08	Pharmaceuticals, personal hygiene, cosmetics and perfumes approving procedures
ANMAT DISPOSITION 1107/09	Rule that one must adjust companies producing, importing, exporting and packing of products of personal hygiene, cosmetics and Perfumes
ANMAT DISPOSITION 11276/16	Prohibit the use, marketing, import and export of the substance pure gamma butyrolactone (GBL) for the reasons set out in recital of the present
ANMAT DISPOSITION 13831/16	Banned products using antibacterial registered in ANMAT. Products of personal hygiene, cosmetics and perfumes are these national and imported, the substances listed in annex I, which is part of this provision
ANMAT DISPOSITION 13832/15	All physical and/or legal person performing import, export, production, manufacture, fractionation, marketing and/or deposit, within national jurisdiction or destined for interprovincial trade, of substances listed in the annex of the this provision, as well as also for medicinal or pharmaceutical specialties containing them, must register with the DVSSCE of the INAME to obtain a special certification for the management of these substances
ANMAT DISPOSITION 7529/13	Established that the substances formaldehyde and paraformaldehyde only may be used in personal hygiene products, cosmetics and perfumes under the conditions and detailed use restrictions
ANMAT DISPOSITION 7230/12	Grant term for companies that manufacture and importing of personal hygiene products, cosmetics and perfumes to proceed with adjustments for the fulfilment of the provision ANMAT No. 957/2012
ANMAT DISPOSITION 6544/12	It establishes the list of substances for limited use observed at the national level for personal hygiene products, cosmetics and perfumes

ANMAT RESOLUTION 327/12	Establishment requirements of registration and authorization for the marketing of repellents for human use in the national territory
ANMAT DISPOSITION 959/12 (WITH THE MODIFICATIONS OF THE DISPOSITION 5812/12)	Adopting the electronic management system with digital signature for the application for automatic admission of products of personal hygiene, cosmetics and perfumes of annex I, categorized according the ANMAT No. 345/06 available
ANMAT DISPOSITION 685/09	Establish that admission of personal hygiene products, cosmetics and perfumes of grade I must be requested and processed exclusively in electronic form, prior to the marketing of them
ANMAT DISPOSITION 374/06	Measures taken on labeling to follow personal hygiene products, cosmetics and perfumes. Glossary of definitions
ANMAT DISPOSITION 5572/05	Prohibit the use use of lead acetate in cosmetic products from the entry into force of this provision. Prohibit the marketing of cosmetic products containing in its formulation lead acetate, as of January 31, 2006. Companies producing and/or importing must withdraw from the market the existing containers according to the date indicated in the preceding article and proceed to their destruction
ANMAT DISPOSITION 6830/01	The Disposition set forth that will be considered cosmetic products those protective solar which meet the definition established by article 2 ° (former M.S. & A.S.) resolution No. 155/98
ANMAT DISPOSITION 1112/99	Limitations that apply to the use of certain raw materials that can be used in Personal hygiene, cosmetics and perfume products are making national or imported
ANMAT DISPOSITION 1108/99	Technical standards for the products of personal hygiene, cosmetics and Perfumes-automatic admission
MSYAS FORMER RESOLUTION 155/98	Update of regulations related to the personal hygiene cosmetic products and Perfumes, and activities inherent to them
MERCOSUR GMC RESOLUTION 62/2014	Mercosur technical regulation about the list of substances that cannot be utilized on products of personal hygiene, cosmetics and perfumes.
MERCOSUR GMC RESOLUTION 16/2012	Mercosur technical regulation about the list of color substances allowed to products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 24/2011	Mercosur technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on conditions and with the restrictions established
MERCOSUR GMC RESOLUTION 19/2011	Mercosur technical regulation of good practices of production for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 8/2011	Mercosur technical regulation about sun protectors on cosmetics
MERCOSUR GMC RESOLUTION 7/2011	Mercosur technical regulation about the list of substances of conservative action allowed for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 48/2010	List of substances of cosmetic use
MERCOSUR GMC RESOLUTION 46/2010	Mercosur technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on the conditions and with the restrictions established
MERCOSUR GMC RESOLUTION 38/2009	List of color substances allowed for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 51/2008	Criteria and mechanism for the update of Mercosur lists of substances in products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 49/2008	Criteria for the subscription of simplification agreements of procedures of sanitary control of products of personal hygiene, cosmetics and perfumes grade 1 produced in Mercosur
MERCOSUR GMC RESOLUTION 26/2006	Contracting of outsourcing for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 25/2005	Update of the resolution GMC n° 71/00 – Mercosur technical regulation “List of ultraviolet filters allowed for personal hygiene products, cosmetics and perfumes”
MERCOSUR GMC RESOLUTION 19/2005	Program of cosmetic vigilance, on the area of personal hygiene products, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 7/2005	Mercosur technical regulation “Classification of products of personal hygiene, cosmetics and perfumes”
MERCOSUR GMC RESOLUTION 5/2005	Mercosur technical regulation “Authorization of functioning / habilitation of companies of products of personal hygiene, cosmetics and perfumes, its modifications and eliminations/cancellations”
MERCOSUR GMC RESOLUTION 36/2004	Mercosur technical regulation about general compulsory labelling for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 26/2004	Specific technical requisites for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 48/2002	Mercosur technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on the conditions and with the established restrictions
MERCOSUR GMC RESOLUTION 26/2002	Mercosur technical regulation about sun protectors in cosmetics
MERCOSUR GMC RESOLUTION 71/2000	Update of res. GMC n° 8/99 – Mercosur technical regulation “List of ultraviolet filters, allowed to personal hygiene products, cosmetics and perfumes”
MERCOSUR GMC RESOLUTION 50/2000	Mercosur technical regulation for the quantitative indication of cosmetics
MERCOSUR GMC RESOLUTION 49/2000	Mercosur technical regulation about the control of liquid content for the quantitative indication of cosmetic and hygienic products and traded in nominal amounts from 5g/ml to 20g/ml
MERCOSUR GMC RESOLUTION 47/1999	Program of training of inspectors on good practices of production and control for the industry of hygiene products, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 36/1999	Technical regulation about specific labelling for products of personal hygiene, cosmetics and perfumes

MERCOSUR GMC RESOLUTION 8/1999	Update of res. GMC n° 25/95 "List of ultraviolet filters, allowed for products of personal hygiene, cosmetics and perfumes"
MERCOSUR GMC RESOLUTION 51/1998	Parameters of microbiological control for products of personal hygiene, cosmetics and perfumes
MERCOSUR GMC RESOLUTION 41/1996	Name for ingredients utilized in products of personal hygiene, cosmetics and perfumes of Mercosur origin and extra zone for use on registry between State parties
MERCOSUR GMC RESOLUTION 28/1995	List of substances that cannot be utilized on the formulation of cosmetic products
MERCOSUR GMC RESOLUTION 27/1995	List of conservative agents allowed for use in hygiene products, perfumes and cosmetics
MERCOSUR GMC RESOLUTION 25/1995	List of ultraviolet filters, allowed for use on hygiene products, perfumes and cosmetics
MERCOSUR GMC RESOLUTION 24/1995	Requisites for the registry of Mercosur and extra zone cosmetic products and for habilitation of representing companies that detain the registry on the receiving State party and importers
MERCOSUR GMC RESOLUTION 110/1994	Definition of cosmetic products

Source: ANMAT. Elaborated by CCGI-EESP/FGV

Table 14.12 - Standards on Cosmetic (Argentina)

NAME	TITLE	STATE
IRAM-ISO 21148	Cosmetics. Microbiology. General instructions for microbiological examination.	In force.
IRAM - 25536	Products for personal hygiene, cosmetics and perfumes. Test method for microbiological control.	In force.
IRAM-37022-1	Cosmetics. Good practices of manufacture of cosmetic products. Directives for the design, construction specifications, operating conditions and maintenance of manufacturing areas.	In force.
IRAM-37022-2	Cosmetics. Good practices of manufacture of cosmetic products. Directives relating to the adequacy, clothing and hygiene of personnel from the area of manufacturing.	In force.
IRAM-37022-3	Cosmetics. Good practices of manufacture of cosmetic products. Directives for the design, maintenance and cleaning of the area of manufacturing equipment.	In force.
IRAM-37022-4	Cosmetics. Good practices of manufacture of cosmetic products. Guidelines for the documentation and registration of manufacturing activities.	In force.
IRAM-37022-5	Cosmetics. Good practices of manufacture of cosmetic products. Guidelines for the areas of storage and forwarding.	In force.
IRAM-37022-6	Cosmetics. Good practices of manufacture of cosmetic products. Directives to elaborate.	In force.
IRAM-37022-7	Cosmetics. Good practices of manufacture of cosmetic products. Filling, packaging and packaging directives.	In force.
IRAM - 37028	Cosmetics. Guide to application of methods for the study of the stability.	In force.

Source: IRAM. Elaborated by CCGI-EESP/FGV.

14.4. Appendix 4 – Machinery and Mechanical Equipment

Table 14.13 - Regulation on Machinery and mechanical Equipment (Brazil)

NAME	THEME
LAW 123/06	Exceptions to NR 12 for small and micro enterprises (SMEs)
ILO CONVENTION 119	Protection of machinery
LAW 6514/77	Safe work environment for workers in the machinery sector
DECREE 5452/43	Consolidation of the labor laws
ORDINANCE 509/16	In case of a conflict between the items of annexes and the items of general parts of the norm, the requisites in the annex prevail
ORDINANCE 211/15	Manual of machinery and mechanical appliances produced or imported since the validity of the norm
ORDINANCE 857/15	Exemption of compliance with technical safety requirements foreseen in NR 12
ORDINANCE 1893/13	Changes NR 12
ORDINANCE 23/11	Import of used machinery and used parts of machinery
ORDINANCE 197/10	Creates the National Thematic Tripartite Commission – CNTT of NR 12 with the objective of accompanying the implementation of the new NR 12 regulation
INMETRO ORDINANCE 577/15	Refrigerators, freezers and other refrigerating or freezing equipment
INMETRO ORDINANCE 165/15	Vehicle platform list
INMETRO ORDINANCE 164/15	Vehicle platform lift. Other lifting, handling, loading; unloading machinery elevators
INMETRO ORDINANCE 547/14	Catalytic converter body
INMETRO ORDINANCE 472/14	Parts and accessories of the motor vehicles of headings 87.01 to 87.05
INMETRO ORDINANCE 406/14	Taps, cocks, valves and similar appliances for pipes
INMETRO ORDINANCE 343/14	Powders fire extinguishers / Mechanical appliances for projecting/dispersing
INMETRO ORDINANCE 255/14	Steam or other vapor generating boilers
INMETRO ORDINANCE 123/14	Parts and accessories of vehicles of headings 87.11 to 87.13
INMETRO ORDINANCE 50/14	Silencers (mufflers) and exhaust pipes
INMETRO ORDINANCE 45/14	Parts and accessories for motor cycles
INMETRO ORDINANCE 18/14	Child devices
INMETRO ORDINANCE 442/13	Child devices
INMETRO ORDINANCE 410/13	Air conditioning machines comprising a motor-driven fan and elements for changing the temperature and humidity, incl. those machines in which the humidity cannot be separately regulated; parts thereof
INMETRO ORDINANCE 642/12	Vehicle platform

INMETRO ORDINANCE 588/12	Vehicle platform
INMETRO ORDINANCE 301/12	Systems and equipment for water heating using solar energy
INMETRO ORDINANCE 182/12	Instantaneous/storage gas water heaters
INMETRO MINISTERIAL ACT 7/12	Systems and equipment for water heating using solar energy
INMETRO ORDINANCE 486/10	Fire extinguishers and parts of fire extinguishers, spray guns and sprayers
INMETRO ORDINANCE 18/04	Parts; accessories for adp machines; units
INMETRO ORDINANCE 261/02	Non-automatic weighing instruments
INMETRO ORDINANCE 171/02	High pressure cylinders for methane gas storage
IBAMA ORDINANCE 6/15	Vehicles, tractors; mechanical appliances for agricultural machinery, etc.
CONTRAN RESOLUTION 641/16	Vehicles (Electronic stability control - ESC)
CONTRAN RESOLUTION 593/16	Bumpers and parts, for motor vehicles
CONTRAN RESOLUTION 567/15	Vehicles (stability control system)
NR 36	Safety and health on work in slaughter companies and processing of meat and meat products
NR 34	Conditions and work environment in the industry of construction, repair and ship dismantling
NR 33	Safety and health on work in confined spaces
NR 32	Safety and health on work in health services
NR 31	Safety and health on work in agriculture, livestock, forestry, forest exploration and aquaculture
NR 30	Safety and health on waterway work
NR 29	Safety and health on port work
NR 28	Oversight and penalties
NR 23	Protection against fires
NR 22	Safety and occupational health in mining
NR 20	Safety and health in the work with flammable and combustible
NR 19	Explosives
NR 18	Conditions and working environment in the construction industry
NR 17	Ergonomics
NR 13	Boilers and pressure vessels
NR 12	Safety at work in machines and equipment
NR 11	Transportation, movement, storage and handling of materials
NR 5	Internal commission of prevention of accidents – CIPA
NR 4	Specialized services in safety and work medicine engineering
NR 3	Embargo or ban
NR 2	Previous inspection
NR 1	General provisions
TECHNICAL NOTE DSST/SIT 179/16	Application of national standards (ABNT), international technical standards (ISO and IEC) and harmonized European standards
TECHNICAL NOTE 48/16	Alters NR 12

Source: INMETRO e MTE. Prepared by CCGI-EESP/FGV.

Table 14.14 - Mechanical Machinery Standards (Brazil)

STANDARDS
ABNT NBR 16579:2017 Hydraulic presses-Safety requirements
ABNT NBR ISO 7500-1:2016 Metallic materials – Calibration and verification of static uniaxial testing machines Part 1: tensile/compression test-calibration and verification of measurement system of the force
ABNT NBR 16557:2016 Bakery machines-Mass rolling machines-Safety and hygiene requirements
ABNT NBR 15456:2016 Storage of flammable and combustible liquids – Construction and testing of line voltages
ABNT NBR 6412:2016 Ed 3:2016 Hydraulic turbines — Approval of models
ABNT NBR 6412:2016 Amendment 1:2016 Hydraulic turbines-Reception of models
ABNT NBR 16357:2016 Seamless steel cylinder, for the manufacture of portable fire extinguishers and on wheels with load up to 10 kg of CO2 — Requirements and test methods
ABNT NBR 13865:2016 Bakery machines — Rods with roller length greater than or equal to 400 mm — Safety and hygiene requirements
ABNT NBR 16542:2016 Bakery machines — Flour mills — Safety and hygiene requirements
ABNT NBR 16543:2016 Bakery machines — Sliceries — Safety and hygiene requirements
ABNT NBR 15734:2016 Bakery machinery — Dough mixers — Safety and hygiene requirements
ABNT NBR 16535-1:2016 Roller bearings-Accessories Part 1: mounting bushings and plugs of disassembly for bearings of tapered bore
ABNT NBR 16535-2:2016 Roller bearings-Accessories Part 2: dimensions of fastening nuts and locking devices
ABNT NBR 14250:2016 Pressure regulators for gas cylinders used in welding, cutting and allied processes-requirements and test methods
ABNT NBR 11327:2016 Requirements for use of pulleys with motor operator
ABNT NBR 16496:2016 Measurement of water and gas-metering service provider for residential and commercial buildings-Requirements
ABNT NBR 10147:2016 Escalators and crawlers — Inspection and acceptance testing, periodic and routine
ABNT NBR 11093:2016 hort stem for broaching-Specifications
ABNT NBR 16455:2016 Pressure vessels-methodology for non-intrusive inspection
ABNT NBR ISO 15241:2016 Roller bearings — Symbols for physical quantities
ABNT NBR 15406:2016 V belts for agricultural machinery-Requirements

ABNT NBR ISO 5167-3:2016 Fluid flow measurement by differential pressure devices inserted into the penstocks of circular cross-section Part 3: nozzles and Venturi nozzles
ABNT NBR 13536:2016 Safety of machinery — Plastic and rubber injection molding machine
ABNT NBR 8854:2016 Surface defects in screws — Procedure
ABNT NBR 10976:2016 Locking washers with external nail — Dimensions
ABNT NBR 9581:2016 Hydraulic turbines and turbine pumps accumulation — verification of the cavitation erosion
ABNT NBR 11326:2016 Lifting equipment and cargo handling-hook-forged rod set-dimensions
ABNT NBR 16463-1:2016 Cranes Part 1: requirements for the preparation of instruction manuals
ABNT NBR 16463-2:2016 Cranes Part 2: Identification
ABNT NBR ISO 8528-7:2014 Errata 1:2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR 16579:2017 Hydraulic presses-safety requirements
ABNT NBR ISO 7500-1:2016 Metallic materials – calibration and verification of static uniaxial testing machines Part 1: tensile/compression test-calibration and verification of measurement system of the force
ABNT NBR 16557:2016 Bakery machines-mass rolling machines-safety and hygiene requirements
ABNT NBR 15456:2016 Storage of flammable and combustible liquids – Construction and testing of line voltages
ABNT NBR 6412:2016 Ed 3:2016 Hydraulic turbines — approval of models
ABNT NBR 6412:2016 Amendment 1:2016 Hydraulic turbines-reception of models
ABNT NBR 16357:2016 Seamless steel cylinder, for the manufacture of portable fire extinguishers and on wheels with load up to 10 kg of CO ₂ — requirements and test methods
ABNT NBR 13865:2016 Bakery machines — Rods with roller length greater than or equal to 400 mm — safety and hygiene requirements
ABNT NBR 16542:2016 Bakery machines — flour mills — safety and hygiene requirements
ABNT NBR 16543:2016 Bakery machines — Slicing — safety and hygiene requirements
ABNT NBR 15734:2016 Bakery machinery — dough mixers — safety and hygiene requirements
ABNT NBR 16535-1:2016 Roller bearings-accessories Part 1: mounting Bushings and plugs of disassembly for bearings of tapered bore
ABNT NBR 16535-2:2016 Roller bearings-accessories Part 2: dimensions of fastening nuts and locking devices
ABNT NBR 14250:2016 Pressure regulators for gas cylinders used in welding, cutting and Allied processes-requirements and test methods
ABNT NBR 11327:2016 Requirements for use of pulleys with motor operator
ABNT NBR 16496:2016 Measurement of water and gas-metering service provider for residential and commercial buildings-Requirements
ABNT NBR 10147:2016 Escalators and crawlers — inspection and acceptance testing, periodic and routine
ABNT NBR 11093:2016 Short stem with 7:24 cone for broaching-specifications
ABNT NBR 16455:2016 Pressure vessels-methodology for non-intrusive inspection
ABNT NBR ISO 15241:2016 Roller bearings — symbols for physical quantities
ABNT NBR 15406:2016 V belts for agricultural machinery-Requirements
ABNT NBR ISO 5167-3:2016 Fluid flow measurement by differential pressure devices inserted into the penstocks of circular cross-section Part 3: nozzles and Venturi nozzles
ABNT NBR 13536:2016 Safety of machinery — plastic and rubber injection molding machine
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ABNT NBR 16463-1:2016 Cranes Part 1: requirements for the preparation of instruction manuals
ABNT NBR 16463-2:2016 Cranes Part 2: Identification
ABNT NBR ISO 8528-7:2014 Errata 1:2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR 16127:2015 Plain bearings-thin-walled Bearings with or without flange-Tolerance, design features and test methods (ISO 3548-1:2014, MOD)
ABNT NBR ISO 6892-1:2013 Errata 1:2015 Metallic materials — Tensile Testing Part 1: Method of test at ambient temperature
ABNT NBR ISO 9809-1:2014 Errata 1:2015 Gas cylinders-seamless steel cylinders, gases-design, construction and tests Part 1: Quenched and tempered steel cylinders with tensile strength less than 1 100 MPa
ABNT NBR 16348:2015 Conveyor belts with tarpaulins, textile products in bulk-dimensions, specifications and markings
ABNT NBR 16017:2015 Plain bearings-multilayer Materials for thin-walled plain bearings
ABNT NBR 16128:2015 Plain bearings-Aluminum alloys for solid bearings
ABNT NBR 6110:2015 Continuous conveyors — Belt conveyors — Widths and lengths of conveyor belts
ABNT NBR 14610:2015 Temperature indicator with sensor-Calibration by comparison
ABNT NBR ISO 8528-1:2014 Alternating current generators, driven by reciprocating internal combustion engines Part 1: application, features and performance
ABNT NBR ISO 8528-10:2014 Alternating current generators driven by reciprocating internal combustion engines Part 10: measurement of environmental noise by the surrounding surface
ABNT NBR ISO 8528-12:2014 Alternating current generators driven by reciprocating internal combustion engines Part 12: power source for safety services
ABNT NBR ISO 8528-2:2014 Alternating current generators driven by reciprocating internal combustion engines Part 2: engines

ABNT NBR ISO 8528-3:2014 Alternating current generators driven by reciprocating internal combustion engines Part 3: generators for generating sets
ABNT NBR ISO 8528-4:2014 Alternating current generators driven by reciprocating internal combustion engines Part 4: switching and control equipment
ABNT NBR ISO 8528-5:2014 Alternating current generators driven by reciprocating internal combustion engines Part 5: generators
ABNT NBR ISO 8528-6:2014 Alternating current generators driven by reciprocating internal combustion engines Part 6: test methods
ABNT NBR ISO 8528-7:2014 corrected version: 2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR ISO 8528-8:2014 Alternating current generators driven by reciprocating internal combustion engines Part 8: requirements and testing for low power generating groups
ABNT NBR ISO 8528-9:2014 Alternating current generators driven by reciprocating internal combustion engines Part 9: measurement and evaluation of mechanical vibration
ABNT NBR 16329:2014 Stationary mixers — Safety requirements
ABNT NBR 5891:2014 Rounding decimal numbering rules
ABNT NBR 16324:2014 Chain hoists with manual override — Requirements and test methods
ABNT NBR ISO 4649:2014 Rubber, vulcanized or thermoplastic-Determination of abrasion resistance by using a rotating cylindrical drum device
ABNT NBR 16318:2014 Measurement of liquid flow in closed conduits-Volumetric liquid collection method in measuring tank
ABNT NBR 8011:2014 Continuous conveyors-Belt conveyors-Capacity calculation
ABNT NBR 12550:2014 Thermometry-Terminology
ABNT NBR 10124:2014 Instrument for measurement and control-measuring tape-Fiber ribbon requirements
ABNT NBR 6172:2014 Continuous conveyors-Conveyor belts-Drums-Dimensions
ABNT NBR ISO 1119:2014 Geometrical product specifications (GPS) — A series of angles and cones of cone-shape/fusiform
ABNT NBR 15473:2014 Storage of flammable and combustible liquids-Post vehicle dealer (services)-Manufacturing and performance of additional filter for line voltages (metering pump)
ABNT NBR ISO 5941:2014 Compressors, pneumatic tools and machines-Preferred pressures
ABNT NBR 12727:2014 Diaphragm type gas meter, for residential installations-Requirements and test methods
ABNT NBR ISO 10100:2014 Hydraulic fluid systems-Cylinders-Acceptance tests
ABNT NBR 15827:2014 Industrial valves for exploration, production, refining and transport of oil products — Design requirements and testing of prototype
ABNT NBR 16301:2014 Specification and acceptance of heating furnaces, heat treatment and thermochemical processes of metals
ABNT NBR 15538:2014 Water meters — Tests for evaluation of efficiency
ABNT NBR 16133:2012 Errata 1:2014 Bakery machines-Accessories-Baking sheets and pans
ABNT NBR 15015:2014 Storage of flammable and combustible liquids — Floating ball valve
ABNT NBR 15138:2014 Storage of flammable and combustible liquids — Unloading sealed device
ABNT NBR 16275:2014 Continuous conveyors — Belt conveyors cleaning system — Method of obtaining reference value for assessing the efficiency of scrapers
ABNT NBR 15139:2014 Storage of flammable and combustible liquids — Non-return valve installed at suction lines
ABNT NBR ISO 9809-1:2014 corrected version: 2015 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 1: Quenched and tempered steel cylinders with tensile strength less than 1 100 MPa
ABNT NBR ISO 9809-3:2014 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 3: normalized steel cylinders
ABNT NBR ISO 9809-2:2014 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 2: Quenched and tempered steel cylinders with tensile strength greater than or equal to 1 100 MPa
ABNT NBR 8205:2014 Continuous conveyors – Belt conveyors — Calculation of strength and power
ABNT NBR 8163:2014 Continuous conveyors — Belt conveyors – Conveyor belts thickness and your toppings
ABNT NBR ISO 23125:2013 Machine tools — Safety
ABNT NBR 15177:2013 Poly V belts — Requirements
ABNT NBR ISO 12100:2013 Safety of machinery — General principles of design — assessment and reduction of risks
ABNT NBR 8194:2013 Water meters — Standardization
ABNT NBR ISO 9386-1:2013 Motorized lifting platforms for persons with reduced mobility — Safety requirements, dimensions and functional operation Part 1: vertical lift platforms
ABNT NBR ISO 148-1:2013 Metallic materials-Charpy pendulum impact test Part 1: test method
ABNT NBR ISO 148-2:2013 Metallic materials-Charpy pendulum impact test Part 2: verification of testing machines
ABNT NBR ISO 13855:2013 Safety of machinery — Positioning of protective equipment with reference to the approach of human body parts
ABNT NBR 16197:2013 Errata 1:2013 Calculation of rolling paths in elastic solid basis for lifting and handling of loads — Procedure
ABNT NBR 12240:2013 Metallic materials – Calibration of static torque measuring devices
ABNT NBR ISO 6892-2:2013 Metallic materials — Tensile testing Part 2: test method for high temperature
ABNT NBR ISO 9513:2013 Metallic materials – Calibration of strain gage systems used in axially round trials
ABNT NBR 16022:2013 Plain bearings — Thin-walled bearings — Measurement of the height of the back of the sleeve — Application of standard plug
ABNT NBR ISO 3548-3:2013 Plain bearings — Thin-walled bearings with or without flange Part 3: measurement of peripheral length

ABNT NBR 16198:2013 Measurement of fluid flow in closed conduits — Methods using ultrasonic flowmeter for transit time — General guidelines for the selection, installation and use
ABNT NBR 14712:2013 Electric and hydraulic lifts — Freight elevators, lifts and elevators of gurney — Safety requirements for construction and installation
ABNT NBR 16035-5:2013 Boilers and pressure vessels – Minimum requirements for the construction Part 5: pressure vessels not subject to call-European standard
ABNT NBR 15082:2013 Narrow V-belts metric — Requirements
ABNT NBR 16197:2013 corrected version: 2013 Calculation of rolling paths in elastic solid basis for lifting and handling of loads — Procedure
ABNT NBR 14105-1:2013 Errata 1:2013 Pressure gauges Part 1: analog gauges with elastic element sensor manufacturing requirements, grading, testing and use
ABNT NBR 16035-4:2013 Boilers and pressure vessels — Minimum requirements for construction Part 4: according to ASME Code, Section VIII, Division 2
ABNT NBR 16107:2013 Errata 1:2013 Conversion factor of gas volume
ABNT NBR 14153:2013 Safety of machinery — Parts of safety-related control systems — General principles for design
ABNT NBR 16169:2013 Continuous conveyors, belt conveyors — Methodology for dynamic test of fence in rolls of belt conveyors in mud tank
ABNT NBR 16200:2013 Construction elevators for persons and materials with vertically guided cabin-safety requirements for construction and installation
ABNT NBR ISO 6892-1:2013 corrected version: 2015 Metallic materials — Tensile testing Part 1: method of test at ambient temperature
ABNT NBR ISO 463:2013 Geometric specifications of products (GPS) — Dimensional measuring instruments — Metrological characteristics and mechanical comparator clock project
ABNT NBR 14105-1:2013 corrected version: 2013 Pressure gauges Part 1: analog gauges with elastic element sensor manufacturing requirements, grading, testing and use
ABNT NBR ISO 8573-1:2013 Compressed air — Contaminants and purity classes
ABNT NBR 16100:2012 Amendment 1:2013 Retaining rings for holes — Rectangular section — Specification
ABNT NBR 16100:2013 Retaining rings for holes — Rectangular Section — Specification
ABNT NBR 13861:2013 Continuous conveyors — Belt conveyors — Storage, packaging and handling of conveyor belts
ABNT NBR 15070:2013 Double "V" belts (hexagonal) classics — Requirements
ABNT NBR 9711:2013 Industrial hoses — Terminology
ABNT NBR ISO 376:2012 Errata 1:2013 Metallic materials – Calibration of force measuring instruments used for the verification of testing machines uni axially round
ABNT NBR 16147:2013 Lifting equipment and cargo handling — Commissioning — Specification
ABNT NBR 16144:2013 Plain bearings — Thin-walled bearings — Tolerances and design features for the micro-filament of the inner diameter of the sleeve
ABNT NBR 5854:2013 Simple pressure washers with folded edges or straight — Shapes and dimensions
ABNT NBR 13770:2013 Thermocouple-Calibration by comparison with standard instrument
ABNT NBR 16139:2013 Conveyor belts — Procedure for dynamic test for rollers — Test method
ABNT NBR 16133:2012 corrected version: 2014 Bakery machines — Accessories — Baking sheets and pans
ABNT NBR 16035-2:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 2: according to ASME Code, Section I
ABNT NBR 16035-3:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 3: according to ASME Code, Section VIII, Division 1
ABNT NBR 16035-1:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 1: general
ABNT NBR 10123:2012 Measuring and control instrument — Steel tape measuring tape — Requirements
ABNT NBR ISO 7183:2012 Compressed air dryers — Specifications and tests
ABNT NBR 16107:2012 corrected version: 2013 Conversion factor of gas volume
ABNT NBR ISO 19973-1:2012 Pneumatic systems-Determination of confidence in components by means of tests Part 1: general procedures
ABNT NBR ISO 19973-2:2012 Pneumatic systems-Determination of confidence in components by means of tests Part 2: directional control valves
ABNT NBR 10143:2012 Air compressors — Classification
ABNT NBR 10144:2012 Air compressor — Terminology
ABNT NBR 16084:2012 Measurement of fluid flow in closed conduits — Guidance for the selection, installation and use of Coriolis meters (measurement of mass flow rate, density and volumetric)
ABNT NBR 16083:2012 Maintenance of lifts, escalators and crawlers — Requirements for maintenance instructions
ABNT NBR ISO 1217:2012 Positive displacement compressors — Acceptance tests
ABNT NBR ISO 4414:2012 Pneumatic power transmission — General and safety requirements for systems and components
ABNT NBR 15003:2012 V-belts for light duty — Requirements
ABNT NBR 14963:2012 Classical V-belts-Requirements
ABNT NBR 15002:2012 Narrow V-belts-Requirements
ABNT NBR ISO 9386-2:2012 Motorized lifting platforms for persons with reduced mobility — Safety requirements, dimensions and functional operation Part 2: stairway lifts for users seated, standing and wheelchair-bound, moving on an inclined plane

ABNT NBR 8197:2012 Metallic materials – Calibration of force measuring instruments of general use
ABNT NBR ISO 376:2012 corrected version: 2013 Metallic materials – Calibration of force measuring instruments used for the verification of testing machines uni axially round
ABNT NBR 16042:2012 Electric passenger lifts — Safety requirements for the construction and installation of lifts without machine room
ABNT NBR 16043-1:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 1: specifications
ABNT NBR 16043-2:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 2: installation requirements
ABNT NBR 16043-3:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 3: test methods and equipment
ABNT NBR 16020:2011 Electronic measurement of liquids — Flow computers
ABNT NBR ISO 4378-1:2011 Plain bearings -Terms, definitions, classification and symbols Part 1: design, materials and their properties
ABNT NBR ISO 4384-2:2011 Plain bearings-Metal hardness testing of sliding Part 2: solid material
ABNT NBR ISO 10099:2011 Pneumatic systems-Cylinders – Final examination and acceptance criteria
ABNT NBR 15972:2011 Plain bearings — Copper alloys — Copper alloys processed mechanically to flat solid bearings (ISO 4382-2:1991, MOD)
ABNT NBR 15970:2011 Glass liquid thermometer — Calibration
ABNT NBR 15962:2011 Hoses, rubber, for grit blasting — Requirements
ABNT NBR 15959:2011 Rubber hoses for welding, cutting and related processes — Requirements
ABNT NBR 15958:2011 Safety requirements for design of load-lifting equipment
ABNT NBR ISO 12301:2011 Plain bearings-techniques of quality control and inspection of quality characteristics of geometric and material
ABNT NBR ISO 5167-2:2011 Fluid flow measurement for pressure differential devices inserted in circular cross-section penstocks Part 2: orifice plates
ABNT NBR 5866:2011 Pressure washers for screws with cylindrical head-Dimensions
ABNT NBR 5868:2011 Metric trapezoidal screw ISO
ABNT NBR 5876:2011 Threads-Terminology
ABNT NBR 10065:2011 Fasteners of stainless steel and corrosion-resistant steel – Specification
ABNT NBR 6669:2011 Chipboard screws — Requirements
ABNT NBR 5875:2011 Bolts, nuts and fittings – Terminology
ABNT NBR 10081:2010 Calculation of pipe thread gauges where the fence is not made by the doughnut — Procedures
ABNT NBR 10112:2010 Cylindrical head screw with hexagon socket-product grade A – Dimensions
ABNT NBR 10043:2010 Cross-slotted screw-Penetration calibrator, shapes and dimensions
ABNT NBR ISO 4379:2010 Plain bearings — Copper alloy bushings
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ABNT NBR 14271:1999 Errata 1:1999 Fastener-fixing bolt for payload-specification
ABNT NBR 14267:1999 Fasteners-threaded Parts with coatings of hot-dip zinc-specification
ABNT NBR 14268:1999 Fastener-chipboard screws for concrete and masonry-specification
ABNT NBR 14269:1999 Fasteners-Nails of tempered steel for fixing in concrete and masonry-specification
ABNT NBR 14270:1999 Fasteners-plastic expansion Plugs-specification
ABNT NBR 14271:1999 corrected version: 1999 Fastener-fixing bolt for payload-specification
ABNT NBR 14245:1998 Machines for leather and shoes-technical manuals-Structuring of content
ABNT NBR NM 152:1998 Measuring instruments and systems of bias-Levels
ABNT NBR NM 153:1998 Tilt measurement systems-cylindrical tubes with bubbles-dimensions and requirements
ABNT NBR NM 154:1998 Tilt measurement systems-Electronic Systems-types and requirements
ABNT NBR NM 155:1998 Numerical control of machines-nomenclature of coordinate system and movements
ABNT NBR NM ISO 2972:1998 Numerical control of machines-Symbols
ABNT NBR 14191-1:1998 Safety of machinery-reduction of risks to health resulting from hazardous substances emitted by machinery Part 1: principles and specifications for machinery manufacturers
ABNT NBR 14171:1998 Industrial gas oven-safety requirements
ABNT NBR 10126:1987 Errata 2:1998 Dimensioning on technical drawing-Procedure
ABNT NBR 14152:1998 Safety of machinery-two-hand control devices — functional aspects and principles for project
ABNT NBR 14154:1998 Safety of machinery — prevention of unexpected departure
ABNT NBR 14097:1998 Mineral insulation thermocouple
ABNT NBR 12430:1998 Valve-drawer of nodular cast iron
ABNT NBR NM 103:1998 Granite Desempenos
ABNT NBR NM 104:1998 Cast iron Desempenos
ABNT NBR NM 80:1998 Wired ruler
ABNT NBR NM 81:1998 Steel brackets 90°
ABNT NBR NM ISO 1:1997 Standard reference temperature for industrial measurements of length
ABNT NBR NM ISO 3611:1997 Micrometer for external measurements
ABNT NBR 14005:1997 corrected version: 2004 peed meter for cold water, of 15 m ³ /h up to 1 500 m ³ /h nominal flow
ABNT NBR 13996:1997 Blow moulding machines intended for the production of hollow thermoplastic articles-safety requirements for design and construction
ABNT NBR 13970:1997 Safety of machinery-temperatures of accessible surfaces-ergonomics Data to establish temperature limit values for hot surfaces
ABNT NBR 8009:1997 Single-Jet water meter for cold water to 15.0 m ³ /h nominal flow-Terminology
ABNT NBR 13881:1997 Bimetallic thermometers-manufacturing Recommendations and use Terminology, safety and calibration
ABNT NBR 12228:1997 Stationary tank for the storage of highly chilled gas-periodic inspection
ABNT NBR 6409:1997 Geometric tolerances-Tolerances of form, orientation, position, and beat-Generalities, symbols, definitions and directions in drawing
ABNT NBR ISO 8526-1:1997 Modular units for machine tool pallet truck door parts Part 1: pallet-holders with nominal dimension up to 800 mm
ABNT NBR ISO 8526-2:1997 Modular units for machine tools pallet truck door parts Part 2: pallet-holders with nominal dimension greater than 800 mm
ABNT NBR 13780:1997 Thin-walled half bearing with or without flange-Tolerance, design features, test data

ABNT NBR 13757:1996 Injection moulding machines for plastics and elastomers-Terminology
ABNT NBR 13759:1996 Safety of machinery-emergency stop equipment, functional aspects-principles for design
ABNT NBR 13264:1995 Guide columns for door-dies-shapes and dimensions-Standardization
ABNT NBR 13265:1995 Bushing-Guide to columns-shapes and dimensions-Standardization
ABNT NBR 13266:1995 Puller-shape and dimensions-Standardization
ABNT NBR 13267:1995 xtender tools-shapes and dimensions-Standardization
ABNT NBR 13268:1995 Nose-to-tree with Morse cones and metric-shapes and dimensions
ABNT NBR 13269:1995 Tree-nose shapes and dimensions-Standardization
ABNT NBR 13270:1995 losing shape and dimensions-Standardization
ABNT NBR 13271:1995 Clamping screw-shape and dimensions-Standardization
ABNT NBR 13232:1994 Threaded bolts with cross-Rod fixed Forms and dimensions-Standardization
ABNT NBR 13233:1994 hreaded bolts with cross-Rod mobile-shapes and dimensions-Standardization
ABNT NBR 13234:1994 Pressure disk-shapes and dimensions-Standardization
ABNT NBR 13243:1994 Steel cylinders for compressed gases-hydrostatic test the water shirt-test method
ABNT NBR 13225:1994 Measurement of fluid flow in penstocks using orifice plates and nozzles in special settings (with drain holes in pipes with diameters of less than 50 mm, such as input and output devices, and other settings)-specification
ABNT NBR 13196:1994 Pressure gauges for compressed gases used in welding, cutting and Allied processes-specifications
ABNT NBR 13197:1994 Pneumatic systems-Cylinders-acceptance tests
ABNT NBR 13198:1994 neumatic directional control valve five-way-coding system for specification of the re-patterning valve functions
ABNT NBR 13200:1994 Calculation of the volume of gas stored in high pressure cylinder
ABNT NBR 13181:1994 Security router-Procedure
ABNT NBR 13183:1994 nspection and testing of seamless aluminum alloy for gases-Procedure
ABNT NBR 8402:1994 Implementation of character for writing in technical drawing-Procedure
ABNT NBR 11312:1993 Numerical control of machinery-Terminology
ABNT NBR 12952:1993 Inspection of valves, cast steel and forged steel, petrochemical industry-Procedure
ABNT NBR 6178:1993 Industrial laundry
ABNT NBR 12985:1993 External hex plugs, heavy type, with cylindrical thread-dimensions and characteristics-Standardization
ABNT NBR 13004:1993 Self-aligning, concave and conical washers-shapes and dimensions-Standardization
ABNT NBR 13043:1993 Welding-numbers and names Standardization processes
ABNT NBR 12913:1993 Seal faces for threaded ends and her holes-shapes and dimensions-Standardization
ABNT NBR 12955:1993 Countersunk and recesses for screws and nuts-shapes and Dimensions-Standardization
ABNT NBR 12987:1993 Hexagon socket plugs with cylindrical thread-dimensions and characteristics-Standardization
ABNT NBR 12811:1993 Check for pipe thread gauges where the fence is made by thread-Procedure
ABNT NBR 6675:1993 Installation of air conditioners for domestic use (type monobloc or modular)
ABNT NBR 12954:1993 Pins locators-shapes and dimensions-Standardization
ABNT NBR 10277:1993 Mounting clamp for tools with drag-shapes and dimensions-Standardization
ABNT NBR 10278:1993 Mounting clamp for tools with and without drag square-shapes and dimensions-Standardization
ABNT NBR 12746:1993 Pneumatic directional control valve five-way-subplate dimensions without electrical connector-Standardization
ABNT NBR 12689:1992 Flat head screw (countersunk) with Hexagon socket-product Grade A-Dimensions-Standardization
ABNT NBR 12690:1992 Truss head screws with Hexagon socket-level of product sizes and specifications-Standardization
ABNT NBR 9584:1992 Chipboard screws with hex-head sizes and specifications-Standardization
ABNT NBR 12656:1992 Flat washers to the bolts and nuts, metric thread, for general use-products degrees and C-Standardization
ABNT NBR 12660:1992 Beveled flat washers-normal Series-300 class Hardness HV-Product grade A-Standardization
ABNT NBR 12680:1992 Coupling dimensions for fastening elements-coupling measures-Standardization
ABNT NBR 11749:1992 Cylinder valves for compressed gases-specification
ABNT NBR 12158:1992 Woodworking machines-circular saw-radial Tests for verification of accuracy-test method
ABNT NBR 12159:1992 Woodworking machines-circular saw with and without Mobile-table Tests for verification of accuracy-test method
ABNT NBR 12288:1992 Simplified representation of Centre holes in technical drawing-Procedure
ABNT NBR 12510:1992 Flat cylinders valves for medical gases-PIN system of security indicators-Standardization
ABNT NBR 12560:1992 Diaphragm metering pumps-specification
ABNT NBR 12596:1992 Dimensioning of hydraulic balance for small hydropower plants (SHP)-Procedure
ABNT NBR 12602:1992 Pneumatic cylinders with removable mounting rod, series 1100 kPa (10bar)-32 mm piston diameters to 320 mm-mounting Dimensions-Standardization
ABNT NBR 11375:1992 Errata 1:1992 Drum for steel cord-Standardization
ABNT NBR 12157:1991 Woodworking machines-Planing of two, three or four sides-precision verification tests-test method
ABNT NBR 12507:1991 Nose cone tree-centring and fixing flange bayonet systems-accessories-dimensions
ABNT NBR 12555:1991 Heat exchangers-Terminology
ABNT NBR 11701:1991 Threads-types and applications-Classification
ABNT NBR 12502:1991 Guide Bush type quick-change drilling and exchangeable and accessories-dimensions-Standardization
ABNT NBR 12296:1991 Design of penstocks for small hydropower plants (SHP)-Procedure

ABNT NBR 8855:1991 Mechanical properties of fasteners bolts and prisoners-specification
ABNT NBR 11808:1991 Mechanical surface aerator brush type-specification
ABNT NBR 12463:1990 Pressure washers-jagged shapes and dimensions-Standardization
ABNT NBR 12464:1990 Serrated washers-shapes and dimensions-Standardization
ABNT NBR 11403:1990 Flanged Hexagon socket screw-light series-Standardization
ABNT NBR 11404:1990 Flanged Hexagon socket screw-heavy-duty range-Standardization
ABNT NBR 11394:1990 Hexagon nuts low Degrees of product A and B-dimensions-Standardization
ABNT NBR 11396:1990 Hexagon nuts low Castle-Degrees of product A and B-dimensions-Standardization
ABNT NBR 11309:1990 Tracer height meter-specification
ABNT NBR 10126:1987 Errata 1:1990 Dimensioning on technical drawing-Procedure
ABNT NBR 11184:1990 Mechanical vertical surface aerator type high rotation-specification
ABNT NBR 11200:1990 corrected version: 1996 Hex head screw, with full-product A and B grades, with thin thread-dimensions-Standardization
ABNT NBR 11207:1990 Hex head screw, with total thread-Degrees of product A and B-dimensions-Standardization
ABNT NBR 11145:1990 Spring representation in technical drawing-Procedure
ABNT NBR 11311:1990 Verification of accuracy of woodworking machines surfacers-Procedure
ABNT NBR 10982:1990 Electric lifts-operation and signaling devices-Standardization
ABNT NBR 11086:1990 7:24 cone rod for tools and fasteners-dimensions-Standardization
ABNT NBR 11087:1990 Cutter-holder shaft nut-Standardization
ABNT NBR 11203:1990 Grub screw, with Hexagon socket and flat Tip-Product Grade A-Dimensions-Standardization
ABNT NBR 11204:1990 Grub screw, with Hexagon socket and end-product Grade A-Dimensions-Standardization
ABNT NBR 11205:1990 Grub screw, with Hexagon socket and conical Tip-Product Grade A-Dimensions-Standardization
ABNT NBR 11206:1990 Grub screw, with Hexagon socket and hollow point-product Grade A-Dimensions-Standardization
ABNT NBR 11214:1990 Verification of the compatibility of materials of filtering elements with the fluid power hydraulic systems-Procedure
ABNT NBR 11183:1990 Mechanical vertical surface aerator type of low-specification
ABNT NBR 11211:1990 Castle hex nut 1 type, grade A and B products-Standardization
ABNT NBR 10980:1989 Pulley-dimensions and materials-Standardization
ABNT NBR 11375:1989 corrected version: 1992 Drum for steel cord-Standardization
ABNT NBR 10977:1989 Fluid flow meter-Terminology
ABNT NBR 10981:1989 Chain hoists with motor operator-specification
ABNT NBR 10902:1989 Cutter-holder shaft with keyway for longitudinal and transverse cylindrical milling cutter-dimensions-Standardization
ABNT NBR 10903:1989 Security lock hook forged stem nut-dimensions and materials-Standardization
ABNT NBR 10582:1988 Sheet presentation to technical drawing-Procedure
ABNT NBR 10092:1987 Low socket head cap screw with Hexagon socket-dimensions and mechanical characteristics-Standardization
ABNT NBR 10126:1987 corrected version: 1998 Dimensioning on technical drawing-Procedure
ABNT NBR 10133:1987 Large hydraulic valves-Terminology
ABNT NBR 10140:1987 Hydraulic and pneumatic systems-nominal Pressures-Standardization
ABNT NBR 10068:1987 Drawing sheet-layout and dimensions-Standardization
ABNT NBR 10070:1987 Forged Rod hooks for lifting and moving loads-dimensions and mechanical properties-Standardization
ABNT NBR 8400:1984 Errata 3:1987 Calculation of equipment for lifting and moving loads-Procedure
ABNT NBR 9585:1986 Chipboard screws with countersunk head and crack-dimensions-Standardization
ABNT NBR 12231:1986 Periodic inspection of stationary tanks used for packaging and storage of carbon dioxide (CO)-Procedure
ABNT NBR 8896:1985 Graphic symbols for hydraulic and pneumatic systems and components-basic and functional Symbols-Symbolism
ABNT NBR 8897:1985 Graphic symbols for hydraulic and pneumatic components and systems energy transformations-Symbolism
ABNT NBR 8898:1985 Graphic symbols for hydraulic and pneumatic components and systems-distribution and energy regulator-Symbolism
ABNT NBR 8400:1984 corrected version: 1987 Calculation of equipment for lifting and moving loads-Procedure
ABNT NBR 8403:1984 Application of lines in drawings-linetypes-Widths of the lines-Procedure
ABNT NBR 8404:1984 Indication of the State of surfaces in technical drawings-Procedure
ABNT NBR 6406:1980 Calibrators-constructive characteristics, tolerances

Source: ABNT. Elaborated by CCGI-EESP/FGV.

Table 14.15 - Regulation on Machinery (Argentina)

NAME	THEME
LAW 19587	Regulates hygiene and safety at work
LAW 1843/99	Provides rules for the circulation of agricultural machines and the transport of grass roll
RESOLUTION 3542/92	Regulates the registry of machines
LAW 9585/84	Creates the provincial registry of tractors, combine harvesters and automotive agricultural implements
LAW 22254/80	Dissolves the mechanical industries of the State

LAW I – NUMBER 4	Creates the department of rural mechanics
LAW 1884/50	Regulates the use of mechanical equipment on public works
RESOLUTION 595/99	Regulates the intervention of the Argentine Association of Producers of Machines, Accessories and Similar Goods on the assessment of goods

Source: Argentina. Elaborated by CCGI-EESP/FGV.

Table 14.16 - Machinery Standards (Argentina)

NAME	TITLE
IRAM - 1219	Paints for marine use. Paints enamel synthetic bright, motors and machine roomsi - <i>Pinturas para uso marino. Pinturas esmalte sintéticas brillantes, para motores y salas de máquina.</i>
IRAM-2008-2	Rotating electrical machines. Methods of test for the determination of losses and performance, excluding machines for electric traction vehicles. - <i>Máquinas eléctricas rotativas. Métodos de ensayo para la determinación de las pérdidas y del rendimiento, excluyendo las máquinas para vehículos de tracción eléctrica.</i>
IRAM - 2019	Orders and offers of rotating electrical machines and transformers.- <i>Pedidos y ofertas de máquinas eléctricas rotativas y transformadores.</i>
IRAM - 2131	Carbon brushes for electrical machines. Test methods. - <i>Escobillas para máquinas eléctricas. Métodos de ensayo.</i>
IRAM - 2139	Prismatic brushes for electrical machines. - <i>Escobillas prismáticas para máquinas eléctricas.</i>
IRAM - 2145	Welding arc machines. With transformer in air. - <i>Máquinas de soldar a arco. Con transformador en aire.</i>
IRAM - 2150	Synchronous machines. Trials of the dielectric - <i>Máquinas sincrónicas. Ensayos del dieléctrico.</i>
IRAM - 2151	Synchronous machines. Global warming essay. - <i>Máquinas sincrónicas. Ensayo de calentamiento</i>
IRAM - 2152	Synchronous machines. Performance and regulation. - <i>Máquinas sincrónicas. Rendimiento y regulación.</i>
IRAM - 2153	Synchronous machines. Determination of characteristic magnitudes - <i>Máquinas sincrónicas. Determinación de magnitudes características.</i>
IRAM - 2154	Synchronous machines. Method for the determination of the characteristic moments - <i>Máquinas sincrónicas. Método de determinación de los momentos característicos.</i>
IRAM - 2185	Rotating electrical machines of traction. To be used in the railways, vehicles and four-wheel-drive systems - <i>Máquinas eléctricas rotativas de tracción. Para ser utilizadas en ferrocarriles, vehículos y sistemas de tracción.</i>
IRAM - 2223	Rotating electrical machines. Definitions - <i>Máquinas eléctricas rotativas. Definiciones</i>
IRAM - 2244	Electrical machines presses with increased safety - <i>Maquinas eléctricas rotativas con seguridad aumentada.</i>
IRAM - 2259	Rotating electrical machines. Noise limits - <i>Máquinas eléctricas rotativas. Límites de ruido.</i>
IRAM - 2260	Rotating electrical machines. Symbols for the forms of construction and mounting arrangements - <i>Máquinas eléctricas rotativas. Símbolos para las formas de construcción y las disposiciones de montaje.</i>
IRAM - 3027	Strips of cotton for typewriters and calculating machines - <i>Cintas de algodón para máquinas de escribir y máquinas de calcular.</i>
IRAM - 3028	Carbon paper for typewriters - <i>Papel carbónico para máquinas de escribir.</i>
IRAM - 3030	Inks for obliteratoras machines and metal seals. Blue and black colors - <i>Tintas para máquinas obliteratoras y para sellos de metal. Colores azul y negro.</i>
IRAM - 3037	Tape of polyamide for typewriters and calculating machines - <i>Cintas de poliamida para máquinas de escribir y máquinas de calcular.</i>
IRAM - 3574	Machinery safety protections. For plastic and rubber injection moulding machines - <i>Protecciones de seguridad en maquinarias. Máquinas de moldeo por inyección para material plástico y caucho.</i>
IRAM - 3578	Machinery safety protections - <i>Protecciones de seguridad en maquinarias.</i>
IRAM-3681-11	Electric elevators. Part 11 - Safety for the construction and installation of lifts without machine room - <i>Ascensores eléctricos de pasajeros. Parte 11 - Seguridad para la construcción e instalación de ascensores sin sala de máquinas.</i>
IRAM-4119-1	Agricultural and forestry machinery acoustic. Method for the determination of the sound level. Part 1: on the position of the operator - <i>Maquinaria agrícola y forestal, Acústica. Método de determinación del nivel sonoro. Parte 1: En el puesto del operador.</i>
IRAM-4119-2	Agricultural and forestry machinery acoustic. Method for the determination of the sound level. Part 2: Out of the position of the operator - <i>Maquinaria agrícola y forestal, Acústica. Método de determinación del nivel sonoro. Parte 2: Fuera del puesto del operador</i>
IRAM - 5031	Heights of trees of machines shafts - <i>Alturas de ejes de árboles de máquinas .</i>
IRAM - 5041	Machine tools for working metals with release of chips. Nomenclature and reception conditions - <i>Máquinas herramientas para trabajar metales con desprendimiento de virutas. Nomenclatura y condiciones de recepción.</i>
IRAM - 5080	Bits with square shank. For hand-operated machines - <i>Brocas helicoidales con vástago cuadrado. Para máquinas de accionamiento a mano..</i>
IRAM - 5084	Short males for machine or by hand, with whitworth thread thick and thin. Manufacturing in the threaded part tolerances. <i>Machos cortos para máquina o a mano, con rosca whitworth gruesa y fina. Tolerancias de fabricación en la parte roscada.</i>
IRAM - 5087	Short males for machine or hand unified coarse and fine thread. Manufacturing in the threaded part tolerance - <i>Machos cortos para máquina o a mano con rosca unificada gruesa y fina. Tolerancia de fabricación en la parte roscada</i>
IRAM - 5089	Machine tool. Mechanical presses. Safety requirements - <i>Máquinas herramienta. Prensas mecánicas. Requisitos de seguridad.</i>
IRAM - 5091	High speed steel extracorta series cylindrical shank bits. For automatic and semi-automatic machines - <i>Brocas helicoidales de acero rápido con vástago cilíndrico serie extracorta. Para máquinas automáticas y semiautomáticas.</i>
IRAM - 5124	Males die, short. Machine thread and thread by hand. General measures - <i>Machos de roscar, cortos. De roscar a máquina y de roscar a mano. Medidas generales.</i>
IRAM - 5125	T-slots, for machine tools - <i>Ranuras T, para máquinas herramientas.</i>
IRAM - 5130	T screws for machine tools - <i>Tornillos T para máquinas herramientas.</i>
IRAM - 5131	T nuts for machine tools - <i>Tuercas T para máquinas herramientas.</i>
IRAM - 5137	Machine with conical shank reamers - <i>Escariadores de máquina con vástago cónico.</i>
IRAM - 5163	Tweezers and conical pods, for machine tools - <i>Pinzas y vainas cónicas, para máquinas herramientas.</i>
IRAM - 5188	Males die long, thread-tapping machine. General measures - <i>Machos de roscar largos, de roscar a máquina. Medidas generales.</i>

IRAM - 5212	Bolts for tillage machines. ISO metric thread. Enough quality - <i>Bulones para máquinas de labranza. Rosca métrica ISO. Calidad basta..</i>
IRAM - 5256	Axes and buckets slotted for machine tools. Four slots - <i>Ejes y cubos ranurados para máquinas herramientas. Cuatro ranuras.</i>
IRAM - 5257	Axes and buckets slotted for machines tools. Six slots - <i>Ejes y cubos ranurados para máquinas heramientas. Seis ranuras.</i>
IRAM - 5258	Handles for machine tools. Steel - <i>Mangos para máquinas herramientas. De acero.</i>
IRAM - 5259	Rotating handles for machine tools. Steel - <i>Mangos giratorios para máquinas herramientas. De acero.</i>
IRAM - 5265	Levers with taper shank for machine tools - <i>Palancas con mango cónico para máquinas herramientas.</i>
IRAM - 5273	Teaching material. Centrifugal machine - <i>Material de enseñanza. Máquina centrífuga.</i>
IRAM - 5277	School material. Pneumatic vacuum machine - <i>Material escolar. Máquina neumática de vacío.</i>
IRAM - 5294	Machine tool test code - <i>Código de ensayo de máquinas herramienta..</i>
IRAM - 5322	Wood-working machines. Milling machine table single-spindle. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Fresadora de mesa monohusillo. Nomenclatura y verificación geométrica.</i>
IRAM - 5323	Wood-working machines. Myriad of table saw. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Sierra sinfin de mesa. Nomenclatura y verificación geométrica.</i>
IRAM - 5330	TACA fixture for mobile machines. Geometric verification and installation conditions - <i>Taca portapieza para máquinas de columna móvil. Verificación geométrica y condiciones de instalación.</i>
IRAM - 5335	Wood-working machines. Simple circular saw with mobile table or without it. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Sierra circular simple con mesa móvil o sin ella. Nomenclatura y verificación geométrica.</i>
IRAM - 5360	Roller chains. For agricultural and similar machines - <i>Cadenas de rodillos. Para máquinas agrícolas y similares.</i>
IRAM - 5371	Males for threading machine or by hand with ISO metric thread. Manufacturing in the threaded part tolerance - <i>Machos para roscar a máquina o a mano con rosca métrica ISO. Tolerancia de fabricación en la parte roscada..</i>
IRAM - 5388	Wood-working machines. Parallel lathe. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Torno paralelo. Nomenclatura y verificación geométrica..</i>
IRAM - 5389	Wood-working machines. A face with tool Rotary Planer. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Cepilladora de una cara con herramienta rotativa. Nomenclatura y verificación geométrica.</i>
IRAM - 5390	Wood-working machines. Jointer plane of a face with cylindrical blade Arbor. Nomenclature and geometric verification - <i>Máquinas para trabajar madera. Garlopa de una cara con portaherramienta cilíndrico de cuchilla. Nomenclatura y verificación geométrica.</i>
IRAM - 6629	Lubricants for refrigeration equipment - <i>Aceites lubricantes para máquinas frigoríficas..</i>
IRAM - 6630	Lubricants for refrigeration equipment. Method for determination of insoluble matters in diclorodifluorometano - <i>Aceites lubricantes para máquinas frigoríficas. Método de determinación de materias insolubles en diclorodifluorometano..</i>
IRAM-6665-1	Lubricants for refrigeration equipment. Method for the determination of the point of flocculation by the closed tube technique - <i>Aceites lubricantes para máquinas frigoríficas. Método de determinación del punto de floculación mediante la técnica del tubo cerrado..</i>
IRAM-6665-2	Lubricants for refrigeration equipment. Method for the determination of the point of flocculation by the technique of the open tube - <i>Aceites lubricantes para máquinas frigoríficas. Método de determinación del punto de floculación mediante la técnica del tubo abierto.</i>
IRAM - 6670	Oils for refrigeration equipment. Comparative method for the determination of the chemical stability in the presence of dichlorodifluoromethane. The sealed tube technique - <i>Aceites para máquinas frigoríficas. Método comparativo de determinación de la estabilidad química en presencia de diclorodifluorometano. Técnica del tubo sellado.</i>
IRAM - 6731	Containers and packaging. Expedition packs complete and full or empty. Test method for compression and stacking using a compression machine - <i>Envases y embalajes. Embalajes de expedición completos y llenos o vacíos. Método de ensayo de compresión y apilamiento utilizando una máquina de compresión.</i>
IRAM-ATIPCA P 3044	Paper and cardboard. Determination of the direction of the machine - <i>Papel y cartón. Determinación de la dirección de máquina.</i>
IRAM-IAS U 500 108	Tensile testing machines. Methods of verification - <i>Máquinas de ensayo de tracción. Métodos de verificación.</i>
IRAM-IAS U 500 16-2	Steel. By Charpy impact bending test on specimen with notch in V. part 2: verification of testing machines - <i>Acero. Ensayo de flexión por impacto con péndulo Charpy sobre probeta con entalladura en V. Parte 2: Verificación de las máquinas de ensayo.</i>
IRAM-IAS U 500 18	Machines, pendulum type impact bending test. Methods of verification - <i>Máquinas tipo péndulo de ensayo a la flexión por impacto. Métodos de verificación.</i>
IRAM-IAS U 500 184-2	Forgings of steel, on horizontal forging machines. Dimensional tolerances - <i>Piezas de acero, forjadas en máquinas forjadoras horizontales. Tolerancias dimensionales.</i>
IRAM-IAS U 500 79	Vickers and Knoop microhardness testing machines. Verification method - <i>Máquinas de ensayo de microdureza Vickers y Knoop. Método de verificación.</i>
IRAM-IAS U 500 80	Vickers and Knoop microhardness testing machines. Method of calibration block pattern - <i>Máquinas de ensayo de microdureza Vickers y Knoop. Método de calibrado de bloques patrón.</i>
IRAM-IAS-NM-ISO 6506 - 2	Metallic materials - Brinell hardness test. Part 2: Verification and calibration of testing machines. (ISO 6506-2:2005, IDT) - <i>Materiales metálicos - Ensayo de dureza Brinell. Parte 2: Verificación y calibración de máquinas de ensayo. (ISO 6506-2:2005, IDT)</i>
IRAM-IAS-NM-ISO 6507 - 2	Metallic materials. Vickers hardness test. Part 2: Verification and calibration of testing machines. (ISO 6507-2:2005, IDT) - <i>Materiales metálicos. Ensayo de dureza Vickers. Parte 2: Verificación y calibración de las máquinas de ensayo. (ISO 6507-2:2005, IDT)</i>
IRAM-IAS-NM-ISO 6508 - 2	Metallic materials. Rockwell hardness test. Part 2: Verification and calibration of testing machines (scales A, B, C, D, E, F, G, H, K, N, T). (ISO 6508-2:2005, IDT) - <i>Materiales metálicos. Ensayo de dureza Rockwell. Parte 2: Verificación y calibración de máquinas de ensayo (escalas A, B, C, D, E, F, G, H, K, N, T). (ISO 6508-2:2005, IDT)</i>
IRAM-ISO 3308	Machine smoking routine analytics. Definitions and normal conditions - <i>Máquina de fumar analítica de rutina. Definiciones y condiciones normales.</i>
IRAM-ISO 3776 - 1	Tractors and machinery for agriculture. Safety belts. Part 1 - Location of the belt anchorages requirements - <i>Tractores y maquinaria para agricultura. Cinturones de seguridad. Parte 1 - Requisitos de ubicación de los anclajes.</i>

IRAM-ISO 3776 - 2	Tractors and machinery for agriculture. Safety belts. Part 2 - The anchorages strength requirements - <i>Tractores y maquinaria para agricultura. Cinturones de seguridad. Parte 2 - Requisitos de resistencia de los anclajes.</i>
IRAM-ISO 3776 - 3	Tractors and agricultural machinery. Safety belts. Part 3 - Requirements for the assembled sets - <i>Tractores y maquinaria agrícola. Cinturones de seguridad. Parte 3 - Requisitos para los conjuntos ensamblados.</i>
IRAM-ISO 4387	Cigarettes. Determination of total particulate material, and the particulate dry and free of nicotine, using a smoking machine analytical routine - <i>Cigarrillos. Determinación del material particulado total, y del material particulado seco y libre de nicotina, mediante una máquina de fumar analítica de rutina.</i>
IRAM-NM-ISO 2860	Road machinery. Minimum dimensions of access - <i>Maquinaria vial. Dimensiones mínimas de acceso.</i>
IRAM-NM-ISO 3164	Road machinery. Evaluations of protective structures laboratory. Specifications for deflection limit volume - <i>Maquinaria vial. Evaluaciones de laboratorio de estructuras de protección. Especificaciones para el volumen limitador de deflexión.</i>
IRAM-NM-ISO 3449	Machinery for soil movement. The falling-object protection structures. Laboratory tests and performance requirements. (ISO 3449:2005, IDT) - <i>Maquinaria para movimiento de suelos. Estructuras de protección contra la caída de objetos. Ensayos de laboratorio y requisitos de desempeño. (ISO 3449:2005, IDT).</i>
IRAM-NM-ISO 3450	Road machinery. Machine equipped with pneumatic brake systems. Systems, performance and test methods and system requirements - <i>Maquinaria vial. Sistemas de frenos de máquinas equipadas con neumáticos. Sistemas, requisitos del sistema y de desempeño y métodos de ensayo.</i>
IRAM-NM-ISO 3457	Machinery for soil movement. Protections - definitions and requirements. (ISO 3457:2003, IDT) - <i>Maquinaria para movimiento de suelos. Protecciones - Definiciones y requisitos. (ISO 3457:2003, IDT).</i>
IRAM-NM-ISO 5005	Road machinery. Method of determining the center of gravity - <i>Maquinaria vial. Método para determinar el centro de gravedad.</i>
IRAM-NM-ISO 5006	Machinery for soil movement. Field of view of the operator - test method and performance criteria. (ISO 5006:2006, IDT) - <i>Maquinaria para movimiento de suelos. Campo de visión del operador - Método de ensayo y criterios de desempeño. (ISO 5006:2006, IDT).</i>
IRAM-NM-ISO 5010	Machinery for soil movement. Machines with pneumatic tires. Address requirements - <i>Maquinaria para movimiento de suelos. Máquinas con neumáticos. Requisitos de dirección.</i>
IRAM-NM-ISO 5353	Road machinery, tractors and machinery for agriculture and forestry. The seat index point - <i>Maquinaria vial, tractores y maquinaria agrícola y forestal. Punto índice del asiento.</i>
IRAM-NM-ISO 6014	Road machinery. Determination of the scroll speed - <i>Maquinaria vial. Determinación de la velocidad de desplazamiento.</i>
IRAM-NM-ISO 6015	Machinery for soil movement. Hydraulic excavators and backhoe loaders. Methods for the determination of the forces of the tool - <i>Maquinaria para movimiento de suelos. Excavadoras hidráulicas y retrocargadoras. Métodos para la determinación de las fuerzas de la herramienta.</i>
IRAM-NM-ISO 6165	Machinery for soil movement. Basic types. Identification, terms and definitions - <i>Maquinaria para movimiento de suelos. Tipos básicos. Identificación, términos y definiciones.</i>
IRAM-NM-ISO 6483	Road machinery. Dump boxes. Full nominal capacity - <i>Maquinaria vial. Cajas para volquetes. Capacidad nominal colmada.</i>
IRAM-NM-ISO 6484	Road machinery. Autocargadoras scrapers. Nominal capacities filled box - <i>Maquinaria vial. Traíllas autocargadoras. Capacidades nominales colmadas de la caja.</i>
IRAM-NM-ISO 6485	Road machinery. Nominal volumetric capacity of scrapers - <i>Maquinaria vial. Capacidad nominal volumétrica de mototraíllas.</i>
IRAM-NM-ISO 6683	Machinery for soil movement. Seat belts and seat belt anchorages - test and performance requirements - <i>Maquinaria para movimiento de suelos. Cinturones de seguridad y anclajes de cinturones de seguridad - Ensayos y requisitos de desempeño.</i>
IRAM-NM-ISO 6746 - 1	Machinery for soil movement. Definitions of measures and codes. Part 1: Basic machine - <i>Maquinaria para movimiento de suelos. Definiciones de las medidas y códigos. Parte 1: Máquina básica.</i>
IRAM-NM-ISO 6746 - 2	Machinery for soil movement. Definitions of measures and codes. Part 2: Equipment and accessories - <i>Maquinaria para movimiento de suelos. Definiciones de las medidas y códigos. Parte 2: Equipamientos y accesorios.</i>
IRAM-NM-ISO 6747	Road machinery. Bulldozer. Terminology and commercial specifications - <i>Maquinaria vial. Topadora. Terminología y especificaciones comerciales.</i>
IRAM-NM-ISO 7131	Road machinery. Wheel loaders. Terminology and commercial specifications - <i>Maquinaria vial. Cargadoras. Terminología y especificaciones comerciales.</i>
IRAM-NM-ISO 7132	Machinery for soil movement. Dump. Terminology and commercial specifications. (ISO 7132:2003, IDT) - <i>Maquinaria para movimiento de suelos. Volcadores. Terminología y especificaciones comerciales. (ISO 7132:2003, IDT)</i>
IRAM-NM-ISO 7133	Road machinery. Scrapers. Terminology and commercial specifications - <i>Maquinaria vial. Mototraíllas. Terminología y especificaciones comerciales.</i>

Source: IRAM. Elaborated by CCGI-EESP/FGV.

14.5. Appendix 5 - Medical Devices

Table 14.17 - Regulation on Medical Devices (Brazil)

NAME	THEME
DECREE 8077/13	Registry, control and monitoring of the products addressed by Law 6360/76, and the conditions for the operation of companies subject to sanitary licensing, within the scope of health
LAW 9933/99	Competences of Conmetro and Inmetro and establishes the metrological service tax
LAW 8078/90	Consumer protection and other arrangements
LAW 6437/77	Violations to federal sanitary legislation and their respective penalties
LAW 6360/76	Main legal norm controlling the sector
ANVISA RESOLUTION 102/16	Provisions on the procedures for the transfer of registration of products subject to health surveillance, global transfer of responsibility for clinical testing and update of registration data related to the operation and certification of companies as a result of corporate or commercial operations

ANVISA RESOLUTION 40/15	Aims at defining the registration requirements for the sanitary control of medical products exempt from <i>registro</i> registration, as per paragraph 1, of art. 25, of law no. 6.360/1976
ANVISA RESOLUTION 37/15	Standard sentences to be used on the labels of medical devices that contain natural rubber latex
ANVISA RESOLUTION 36/15	Classification of risks, <i>cadastro</i> and <i>registro</i> control systems, and labeling and instructions for use requirements, for <i>in vitro</i> diagnostic products, including their instruments
ANVISA RESOLUTION 15/14	Provisions on the requirements related to the proof of compliance with Good Manufacturing Practices for <i>registro</i> registration of healthcare products
ANVISA RESOLUTION 39/13	Provisions on the administrative procedures for granting Good Manufacturing Practice Certification and Good Distribution and/or Storage Practice Certification
ANVISA RESOLUTION 16/13	Provisions on the requirements of Good Manufacturing Practices, and medical products, and <i>in vitro</i> diagnosis products
ANVISA RESOLUTION 23/12	Provisions on the compulsory execution and notification of field actions by the registration holders for health products in Brazil
ANVISA RESOLUTION 27/11	Provisions on the procedures for the mandatory certification of equipment under the Health Surveillance Policy
ANVISA RESOLUTION 3/10	Chronological criteria for reviews of <i>registro</i> and <i>cadastro</i> applications of medical devices at ANVISA
ANVISA RESOLUTION 67/09	Provisions on technovigilance rules applicable to registration holders for health products in Brazil
ANVISA RESOLUTION 24/09	Scope and application form for the system of registration for the sanitary control of health products
ANVISA RESOLUTION – RE 2605/06	A list of medical products classified as of single use and prohibited to be reprocessed
ANVISA RESOLUTION 13/04	Health surveillance of import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition, demonstration or distribution in fairs or events
ANVISA RESOLUTION 185/01	Approves the technical regulations contained in the annex to this resolution, which deals with registration, alteration, revalidation and cancellation of the registration of medical devices through the National Health Surveillance Agency - ANVISA
ANVISA RESOLUTION 56/01	Minimal requirements with which manufacturers and importers must comply, seeking to unify the criteria for the information requested by the health surveillance authority pertaining to the safety and efficacy of healthcare products
ANVISA RESOLUTION 25/01	Provisions on the import, commercialization and donation of used and refurbished healthcare products
INMETRO ORDINANCE 54/16	Criteria and compliance evaluation procedures for Equipment under Health Surveillance Policy, with emphasis on safety through the mechanism of certification in order to prevent accidents. It approves improvement of the Requirements for the Compliance Evaluation of these devices considering Reference Term of the Brazilian Compliance Evaluation System (SBAC)
INMETRO ORDINANCE 248/15	Inmetro Vocabulary of Compliance Assessment with terms and definitions commonly used by the Compliance Assessment Inmetro Board
INMETRO ORDINANCE 118/15	Improves the General Requirements of Product Certification (RGCP)
INMETRO ORDINANCE 274/14	Regulations for the Use of Brands, Symbols, Marks and Labels of Inmetro
INMETRO ORDINANCE 332/12	Revision of conformity assessment requirements for surgical and non-surgical gloves made of natural rubber, synthetic rubber and a mixture of synthetic rubbers
INMETRO ORDINANCE 162/12	Conformity assessment requirements for breast implants
INMETRO ORDINANCE 503/11	Conformity assessment procedure for single use sterile hypodermic syringe
INMETRO ORDINANCE 502/11	Conformity assessment requirements for single use appliances for transfusion, gravitational infusion and infusion for use with infusion pump
INMETRO ORDINANCE 501/11	Conformity assessment requirements for single use sterile hypodermic needles and single use gum needles
INMETRO ORDINANCE 350/10	Period up to twelve (12) months, from the date this ordinance is published, for products certified according to Inmetro ordinance no. 86 (of April 3, 2006, published on the Federal Official Gazette of April 6, 2006, Section I, page 44) to comply with the requirements approved herein
INMETRO ORDINANCE 230/09	Conformity assessment procedure for Personal Protective Equipment (PPE) – to accessories for filtering facepiece respirators
INMETRO ORDINANCE 96/08	Metrological Technical Regulation of digital electronic sphygmomanometers
INMETRO ORDINANCE 89/06	Metrological Technical Regulation of digital clinical thermometers
ORDINANCE OF MINISTRY OF JUSTICE 487/12	Procedure of calling consumers or recall products and services that are considered harmful or dangerous after their introduction to the consumer market
ORDINANCE OF MINISTRY OF HEALTH AND SECRETARIAT OF SANITARY SURVEILLANCE 453/98	Radiological protection in medical and dental radiodiagnosis
INTERMINISTERIAL ORDINANCE MS/MDIC 206/13	Institutes the Technical Committee of Articulation with the Brazilian Health Surveillance Agency within the scope of Bigger Brazil Plan (CTVSPBM)
INTERMINISTERIAL ORDINANCE MS/MDIC 692/09	Operationalization of the actions Technical Cooperation and Quality Assurance of Medical Devices Safety subject to health surveillance control, as established by the Term of Technical Cooperation signed by the Ministry of Health (MS) and the Ministry of Development, Industry, and International Trade (MDIC)

ANVISA NORMATIVE INSTRUCTION 4/15	Updated list of Technical Standards which shall be adopted to the certification of compliance within the scope of Brazilian Compliance Evaluation System (SBAC), of equipment under health surveillance policy
ANVISA NORMATIVE INSTRUCTION 3/15	Regulates item I of Art. 20 of the RDC 36/15, that describes the classification of risk, the schemes for control of cadastro and registro registrations and the requirements for both labeling and instructions of use for in vitro diagnostic products, including its instruments, and gives other provisions
MS NORMATIVE INSTRUCTION 8/13	Scope of application of the provisions of GMP of medical devices and in-vitro diagnostic products to importers, distributors and storage companies, and makes other considerations
MERCOSUR GMC RESOLUTION 72/98	Essential requirements for safety and efficacy of medical devices

Source: ANVISA and MERCOSUR . Elaborated by CCGI/FGV-EESP.

Table 14.18 - Regulation on Medical (Argentina)

NAME	THEME
LAW 21908/78	Establishes the rights of importation of equipment of medical use
RESOLUTION 30/97	Updates norms that regulate the importation of products considered medical apparel and equipment subject to the intervention of ANMAT
DECREE LAW 2469/58	Establishes conditions for the use of every medical instrument or equipment with diagnosis or therapeutic goals
LAW 14583/13	Regulates medical equipment
ANMAT DISP 2318/02	Provides a definition of medical equipment
RESOLUTION 458/09	Creates the Coordinating Unity of Evaluation and Execution of Health Technologies

Source: ANMAT. Prepared by CCGI-EESP/FGV.

Table 14.19 - Standards on Medical Devices (Argentina)

NAME	TITLE
IRAM - 113060	Exams medical, sterile or non-latex gloves, use only once.
IRAM - 37008	Medical devices. Sterilization by ethylene oxide. Validation and routine control.
IRAM-37019-1	Biomedical devices. Good manufacturing practices. Directives for the design, construction specifications, operating conditions and the maintenance of the production area.
IRAM-37019-2	Biomedical devices. Good manufacturing practices. Directives relating to suitability, responsibility, hygiene and clothing of personnel in the area of development.
IRAM-37019-3	Biomedical devices. Good manufacturing practices. Directives for the design, maintenance and cleaning of the area of development teams.
IRAM-37019-4	Biomedical devices. Good manufacturing practices. Directives to make the documentation and records related to the area of development.
IRAM-37019-5	Biomedical devices. Good manufacturing practices. Guidelines for labeling and packaging.
IRAM-37019-6	Biomedical devices. Good manufacturing practices. Guidelines for quality assurance.
IRAM-37019-7	Biomedical devices. Good manufacturing practices. Guidelines for the laboratory of quality control.
IRAM-37021-1	Biological evaluation of biomedical devices. Part 1: Evaluation and testing.
IRAM-37021-2	Biological evaluation of biomedical devices. Requirements concerning the protection of animals.
IRAM-37021-3	Biological evaluation of biomedical devices. Tests for genotoxicity, carcinogenicity and toxicity on reproduction and development.
IRAM-37021-4	Biological evaluation of medical devices. Part 4 - Selection of interaction with blood tests.
IRAM-37030-1	Synthetic latex gloves to use only once. Part 1 - for sterile medical exams or not.
IRAM - 37105	Sterilization of health care products. Packaging for medical devices with terminal sterilization.
IRAM-4220-1	Electro-medical devices. Part 1: General requirements for safety.
IRAM-4220-1-1	Electro-medical devices. Part 1: General requirements for safety. 1 collateral standard: safety requirements for medical electrical systems.
IRAM-4220-1-2	Electro-medical devices. Part 1 - General requirements for safety. Section 2 - Collateral standard: electromagnetic compatibility. Requirements and tests.
IRAM-4220-1-3	Electro-medical devices. Part 1: General requirements for safety. 3. collateral standard: General requirements for radiation protection in diagnostic x-ray equipment.
IRAM-4220-1-4	Electro-medical devices. Part 1 - General requirements for safety. 4 collateral standard: systems programmable electrical.
IRAM-4220-2-12	Electro-medical devices. Part 2: Particular requirements for the safety of lung ventilators for medical use.
IRAM-4220-2-13	Electro-medical devices. Part 2-13 - Particular requirements for the safety and essential of anesthesia systems performance.
IRAM-4220-2-16	Electro-medical devices. Hemodialysis devices. Particular safety requirements.
IRAM-4220-2-19	Electro-medical devices. Baby incubators. Particular safety requirements.
IRAM-4220-2-2	Electro-medical devices. Part 2-2 - Particular safety requirements of high-frequency Electrosurgical apparatus.
IRAM-4220-2-20	Electro-medical devices. Infant transport incubators. Particular safety requirements.
IRAM-4220-2-24	Electro-medical devices. Part 2-24-Particular req for the safety of infusion pumps and controllers of infusion.
IRAM-4220-2-25	Electro-medical devices. Part 2-25: Particular safety requirements for electrocardiographs.
IRAM-4220-2-49	Electro-medical devices. Part 2-49 - Particular requirements for the safety of multifunction patient monitoring equipment.
IRAM-4220-2-7	Electro-medical devices. Part 2-7: Particular safety requirements for the high-voltage generators of diagnostic x-ray equipment.
IRAM - 60336	Electro-medical devices. Assembly of medical diagnostic x-ray tube. Characteristics of focal points.
IRAM - 62353	Electro-medical devices. Recurrent trials and trials after repairs from the electromedical device.

IRAM-IEC CISPR 11	Industrial, scientific and medical equipment. Characteristics of RF disturbances. Limits and methods of measurements.
IRAM-ISO 11137-1	Sterilization of health care products. Radiation. Part 1 - Requirements for development, validation and control of routine sterilization of medical devices.
IRAM-ISO 13485	Medical devices. The quality management system. Requirements for regulatory purposes.
IRAM-NM-ISO 15198	Clinical analysis laboratories. Medical products for in vitro diagnostic use. Validation by the manufacturer's quality control procedures for the user. (ISO 15198:2004, IDT)

Source: IRAM. Elaborated by CCGI/FGV-EESP.

14.6. Appendix 6 – Food

Table 14.20 - Regulation on Food (Brazil)

NAME	THEME
DECREE 9013/17	Establishes the set of regulations concerning the development of the industry and trade in products of animal origin
LAW 13305/16	Provisions regarding the labeling of foodstuffs containing lactose
DECREE 8772/16	Implements law 13123/15, which regulates access to components of the genetic heritage, protection of and access to associated traditional knowledge, and the sharing of benefits for the conservation and sustainable use of Brazilian biodiversity
DECREE 6871/09	Control, inspection, standardization, classification, establishment registration and product registration of beverages
DECREE 6759/09	Activities of the customs administration, control and taxation of foreign trade, including sanitary, phytosanitary or animal health controls
LAW 11346/06	Establishes the National System of Food and Nutrition Security (SISAN) with a view to ensuring the human right to adequate food
LAW 11265/06	Lays down provisions on food commercialization for breast-feeding babies and early childhood children, as well as pediatric products, forbidding advertising related to food supplements and pacifiers.
DECREE 5839/06	Provisions regarding the organization, attributions and electoral process of the National Health Council (CNS)
DECREE 5741/06	Organizes the Unified Animal and Plant Health Protection System and sets out further measures. The Unified System includes the control of activities related to health, inspection, education and surveillance on animals, plants and their products. This Presidential Decree establishes the rules which must be complied with by the participants of the System and the procedures to carry out official controls to check compliance with Sanitary and Phytosanitary Legislation and quality of agricultural products.
LAW 11105/05	Safety regulations and inspection mechanisms for activities that involve Genetically Modified Organisms (GMOs) and their by-products
LAW 10674/03	Establishes that all labelling for foodstuffs must carry the inscription "contains gluten" or "does not contain gluten", as appropriate
DECREE 4680/03	Consumer protection rules (guaranteed by Law No. 8078/1990) as regards foods and food ingredients intended for human or animal consumption that contain or are produced from Genetically Modified Organisms (GMOs)
DECREE 4062/01	Provisions regarding the terms "cachaça" and "cachaça do Brasil" as geographical indications
LAW 9972/00	Establishes the classification of plant products, by-products and waste of economic value
LAW 9933/99	Establishes the competencies of National Council of Metrology, Standardization and Industrial Quality (Conmetro) and National Institute of Metrology, Quality and Technology (Inmetro), and makes other provisions
LAW 9782/99	Establishes the system of international agriculture and cattle surveillance
LAW 9677/98	Amends the Criminal Code to include in the classification of crimes considered heinous: falsification, corruption or adulteration of foodstuffs
DECREE 2314/97	Simple alcoholic distillate
DECREE 369/97	Supporting inclusion of technology/drafting technical regulation for identity and quality of milk powder
DECREE 352/97	Identity and quality of the Minas fresh cheese
LAW 9294/96	Restrictions on the use and advertising of tobacco products, alcoholic beverages, medicines and agricultural pesticides
DECREE 1812/96	Fluid milk quality in quantity for Industrial use
LAW 8918/94	Establishes provisions related to standardization, classification, registration, production and inspection of beverages and the Intersectoral Beverage Committee.
LAW 8171/91	Provisions on the agricultural policy
LAW 8080/90	Organic law of health
LAW 7967/89	Establishes the value of the fines for violations of health legislation, amends the Law No. 6437/1977, and provides other measures
LAW 7678/88	Registry of grape-based beverages, establishments, producers or bottlers of wine and beverages derived from grapes
LAW 6437/77	Provisions concerning the violations of the federal sanitary legislation, establishes their respective penalties, and makes other provisions
LAW 5966/73	Formulates and implements the national policy of metrology, industrial standardization and quality certification of industrial products
DECREE 72718/73	Lays down the general principles of food irradiation
DECREE-LAW 986/69	Basic food technical regulation
DECREE 63526/68	Creates technical requirements on additives approved by the National Commission on Food Standards
DECREE-LAW 212/67	Provisions concerning the sanitary safety measures in Brazil
DECREE 55871/65	Amends presidential decree no. 50040/1961 as regards the use of certain food additives
DECREE 50040/61	Lays down technical requirements on chemical additives and technology coadjuvants for use in food

DECREE 30691/52	Regulation of Industrial and Sanitary Inspection of Products of Animal Origin (RIISPOA of 1952), to be applied in interstate or international trade
LAW 1283/50	Prior inspection of all products of animal origin
ORDINANCE MS 710/99	Approves the National Food and Nutrition Policy
ORDINANCE SVS/MS 31/98	Approves the technical regulation concerning the addition of essential nutrients to foods
ORDINANCE SVS/MS 29/98	Approves the Technical Regulation on Foods for Special Purposes
ORDINANCE SVS/MS 27/98	Approves the Technical Regulation on Complementary Nutrition Information
ORDINANCE SVS/MS 579/97	Determines that the publication in the Federal Official Gazette of the registration of products related to the food area, is sufficient to prove the granting of registration in the Ministry of Health
ORDINANCE SVS/MS 326/97	Brazilian food good manufacturing practices (GMPs)
ORDINANCE MS 1428/93	General guidelines for the establishment of good manufacturing practices for food industry
ANVISA RESOLUTION 149/17	Authorizes the use of food additives and technology adjuvants in various food categories and gives other provisions
ANVISA RESOLUTION 138/17	Provisions concerning the maximum tolerated limits (LMT) for mycotoxin deoxynivalenol in wheat and wheat products ready for sale to the consumer
ANVISA RESOLUTION 136/17	Requirements for the mandatory declaration of the presence of lactose on food labels
ANVISA RESOLUTION 135/17	Amends Ordinance SVS / MS No. 29/1998, that approves the technical regulation referring to foods for special purposes, to lay down provisions concerning foods for diets with restriction of lactose
ANVISA RESOLUTION 91/16	Establishes criteria and procedures for sanitary control of water intended for human consumption from a water supply system or alternative solution for water supply in ports, airports and border crossings throughout the national territory
ANVISA RESOLUTION 43/15	Establishes rules on the provision of food services at mass events, including minimum requirements for prior assessment and operation of facilities and services related to trade and food handling and definition of responsibilities
ANVISA RESOLUTION 26/15	Provides for the requirements for the mandatory labeling of the main food causing food allergies. The food, ingredients, food additives and technology coadjuvants containing or derived from the food listed should contain the following statement: "Allergic: Contains (common names of food causing food allergies)"
ANVISA RESOLUTION 24/15	Provisions concerning the collection of food and its communication to ANVISA and to consumers
ANVISA RESOLUTION 54/14	Technical regulation on enzymes and enzymatic preparations for use in food production in general
ANVISA RESOLUTION 53/14	List of enzymes, food additives and authorized vehicles in enzyme preparations for use in food production in general
ANVISA RESOLUTION 52/14	Amends resolution RDC No. 216/2004 on the technical regulation of good practices for food services
ANVISA RESOLUTION 14/14	General provisions that contribute to the evaluation of macroscopic and microscopic foreign material as an indicative of risks to human health or failures in the application of Good Practices in the food and drinks supply chain and set their limits of tolerance
ANVISA RESOLUTION 42/13	Maximum residue levels of inorganic contaminants in foods
ANVISA RESOLUTION 8/13	Positive lists of food additives with their respective functions for manufacturing fruit and vegetable products and mocotó jelly
ANVISA RESOLUTION 7/13	Positive list of technology coadjuvants with their respective functions for the manufacture of fruit and vegetable products, including edible mushrooms
ANVISA RESOLUTION 5/13	Approves the use of food additives with their respective functions and maximum limits for alcoholic beverages, except fermented
ANVISA RESOLUTION 3/13	Provisions concerning the modifications in the composition of standardized foods for use of complementary nutritional information
ANVISA RESOLUTION 56/12	Approves the MERCOSUR technical regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment in contact with food
ANVISA RESOLUTION 54/12	Technical regulation on complementary nutritional information
ANVISA RESOLUTION 53/12	Approves the MERCOSUR technical regulation on analytical methodologies, acceptable daily intake and maximum residue limits for veterinary drugs in foods of animal origin
ANVISA RESOLUTION 31/12	Nutritional labeling of non-alcoholic beverages traded in returnable packages
ANVISA RESOLUTION 5052/11	Prohibited the importation, manufacture, distribution and marketing, throughout the national territory, of foods and beverages based on Aloe Vera, because there is no proof of safety of using or registration
ANVISA RESOLUTION 40/11	Approves the use of tannic acid and tannins as processing aid in the function of clarifying/filtering agents for the manufacture of sugar and alcoholic beverages
ANVISA RESOLUTION 2468/10	Ban on the marketing of human milk in States parties
ANVISA RESOLUTION 52/10	Colorants on recipients and plastic equipment intended to be in contact with food
ANVISA RESOLUTION 51/10	Migration and equipments plastic packings aims of getting in contact con foods

ANVISA RESOLUTION 48/10	Conversion factor for calculating energy of erythritol
ANVISA RESOLUTION 46/10	Maximum residue limits for Additives excluded from the list of "Additives authorized for food use according to the GMP"
ANVISA RESOLUTION 45/10	Additives authorized for food use according to Good Manufacturing Practices
ANVISA RESOLUTION 27/10	Products with compulsory registration and products exempt from registration
ANVISA RESOLUTION 24/10	Rules concerning the supply, advertising, information and other related practices linked to the commercial promotion of foodstuffs with high amounts of sugar, saturated fat, trans fat, sodium, and low-nutritional beverages Technical regulation of imported goods for health surveillance purposes
ANVISA RESOLUTION 81/08	Additives and their maximum limits for foodstuffs and snacks
ANVISA RESOLUTION 64/08	Food grade recycled polyethylene terephthalate (PET) packaging intended to come into contact with foodstuffs
ANVISA RESOLUTION 20/08	Positive list of additives for plastic materials used in packaging and equipment in contact with food
ANVISA RESOLUTION 17/08	Prohibits the use of Propylparaben and Propylparaben Sodium in foods
ANVISA RESOLUTION 8/08	Nutrition labelling of packaged foods
ANVISA RESOLUTION 36/07	Technical regulation on packaging, coatings, utensils, lids and metallic equipment in contact with food
ANVISA RESOLUTION 20/07	Attribution of additives and their maximum levels for the food category 6.2: cereals and/or cereals
ANVISA RESOLUTION 5/07	Additive maximum limits for category 13 and food condiments for sauce
ANVISA RESOLUTION 4/07	Additive and its maximum limits for category 3 sweet foods eatables
ANVISA RESOLUTION 3/07	List of botanical species and update criteria
ANVISA RESOLUTION 2/07	Nutritional labeling of packaged foods (Complementation of Resolutions RDC No. 359 and RDC No. 360, of 2003)
ANVISA RESOLUTION 163/06	Technical regulation for products of vegetables, fruit products and edible mushrooms
ANVISA RESOLUTION 272/05	Use of certain additives
ANVISA RESOLUTION 201/05	Good practices procedures for food services in order to ensure the hygienic sanitary conditions of the prepared food
ANVISA RESOLUTION 216/04	Labelling of packaged foods
ANVISA RESOLUTION 123/04	Technical regulation on nutritional labeling of packaged foods, making nutrition labeling compulsory
ANVISA RESOLUTION 360/03	Technical regulation of portions of packaged foods for the purposes of nutrition labeling
ANVISA RESOLUTION 359/03	Program for Analysis of Residues of Veterinary Medicines in Foods of Animal Origin (PAMVet)
ANVISA RESOLUTION 253/03	Food manufacturers using tartrazine dye must state on the labeling in the list of ingredients the name of the tartrazine dye in full
ANVISA RESOLUTION 340/02	Standard operational procedures that contribute to the guarantee of hygienic sanitary conditions necessary for the industrialization of food, complementing the good manufacturing practices
ANVISA RESOLUTION 275/02	Quantitative indication of the net content of pre-measured products
ANVISA RESOLUTION 274/02	Technical regulation on packaged food labeling
ANVISA RESOLUTION 259/02	Synthetic casings of regenerated cellulose film in contact with foodstuffs
ANVISA RESOLUTION 218/02	Regenerated cellulose films aimed at getting in contact with food
ANVISA RESOLUTION 217/02	Packaging and cellulosic equipment in contact with food
ANVISA RESOLUTION 130/02	Technical regulation on recycled cellulosic material for food packaging
ANVISA RESOLUTION 129/02	Technical regulation for the labeling of packaged foods and beverages containing gluten
ANVISA RESOLUTION 40/02	Prepared film makers based on polymers and/or resins for the coating of food
ANVISA RESOLUTION 124/01	Analytical methodologies for the control of packaging and equipment intended to come into contact with food
ANVISA RESOLUTION 123/01	Paraffins in contact with food
ANVISA RESOLUTION 122/01	Adhesives used in the manufacture of packaging and equipment intended to come into contact with food
ANVISA RESOLUTION 91/01	

ANVISA RESOLUTION 34/01	Technical regulation on the use of food additives, establishing their functions and their maximum limits for industrial culinary preparations
ANVISA RESOLUTION 33/01	Technical regulation on the use of food additives, establishing their functions and their maximum limits for soups and broths
ANVISA RESOLUTION 12/01	Technical regulation on microbiological standards for food and identity and quality of the Parmesan cheese, Reggiano and Sbrinz
ANVISA RESOLUTION 5/01	Technical regulation on sampling methods for the control of veterinary drug residues in food of animal origin
ANVISA RESOLUTION 1/01	Technical regulation on the use of additives with a function of flavor enhancers, establishing their maximum limits for foods
ANVISA RESOLUTION 23/00	Basic procedures for the registration and exemption of registration
ANVISA RESOLUTION 22/00	Product's exemption from registration
ANVISA RESOLUTION 383/99	Technical regulation on the use of food additives, establishing their functions and their maximum limits for bakery products and cookies
NATIONAL COUNCIL OF HEALTH RESOLUTION 408/08	Guidelines for the promotion of human nutrition with impact on the reversal of the obesity epidemic and prevention of chronic non-communicable diseases
RE-ANVISA RESOLUTION 386/99	Updating the general harmonized list of additives Mercosur : gelatine
RE-ANVISA RESOLUTION 382/99	Insertion of additives and their limits for category 13: food sauces and condiments; and the subcategory 13.10: Vinegar
MS/ANVS RESOLUTION 105/99	Packaging and polyethylene Fluor equipment in contact with food
CNNPA RESOLUTION 15/93	Potassium bromate
CISA RESOLUTION 10/84	Provisions concerning the Instructions for preservation in the transportation, commercialization and consumption phases of perishable, industrialized or processed foods, packaged
CNNPA RESOLUTION 35/77	Identity and quality standards for fast frozen foods
CNNPA RESOLUTION 17/77	Criteria for authorization of using of additives and technology coadjuvants in foods, and setting the respective limits of addition
INMETRO/MDIC ORDINANCE 391/14	Facilities and equipment in the production of food baskets
INMETRO/MDIC ORDINANCE 298/12	Provisions on foodstuffs that are packaged in unit-dose in blister pack, on the safety of using and precaution of handling accidents
INMETRO/MDIC ORDINANCE 157/02	Approves the Technical Metrological Regulation establishing how to express the liquid content to be used in the pre-measured products
INMETRO ORDINANCE 75/99	Contents of aerosols
CONMETRO RESOLUTION 5 ORDINANCE	Establishes INMETRO activities to implement WTO TBT practices and rules
SDA/MAPA 126/16	Aims to modernize the procedures for equivalence recognition of foreign sanitary inspection systems with regard to export animal products to Brazil
INTERMINISTERIAL ORDINANCE 701/15	Updates the values of Sanitary Surveillance Inspection Fees (TFVS)
ORDINANCE OF MINISTRY OF JUSTICE 2658/03	Creates provisions concerning the use of the transgenic symbol.
ORDINANCE OF MINISTRY OF MINES AND ENERGY 470/99	Establishes that the label to be used in the bottling of mineral and table water must be approved by the National Department of Mineral Production (DNPM), at the request of the interested party, after publication in the Official Gazette of the respective mining concessionaire
ORDINANCE SSC 451/97	Identity and quality of the food casseinatos
ORDINANCE MAA 370/97	Inclusion of the additive Sodium Citrate as a stabilizer in the RTM of identity and quality of U.H.T. Milk (U.A.)
ORDINANCE MAA 185/97	Identity and quality of fresh fish
ORDINANCE MAA 183/96	Maximum levels for pesticide residues
ORDINANCE MAA 146/96	Fluid milk quality in quantity for Industrial use
ORDINANCE 540/97	Almidones modified
ORDINANCE 366/97	Identity and quality of the dough to make Mozzarella cheese
ORDINANCE 365/97	Identity and quality of the cheese Tandil
ORDINANCE 364/97	Identity and quality of the mozzarella
ORDINANCE 363/97	Identity and quality of the Pategras cheese sandwich
ORDINANCE 362/97	Identity and quality of the cheese Tybo
ORDINANCE 361/97	Identity and quality of the cheese Tilsit
ORDINANCE 360/97	Identity and quality of the Dambo cheese
ORDINANCE 359/97	Identity and quality of cheese curd
ORDINANCE 358/97	Identity and quality of the cheese plate

ORDINANCE 357/97	Identity and quality of grated cheese
ORDINANCE 146/96	Tolerance limits for inorganic contaminants
ORDINANCE MAARA 183/96	Tolerance limits for inorganic contaminants
ORDINANCE MAARA 146/96	Identity and quality of milk CTU
ORDINANCE MAARA 646/95	Identity and quality of tomato
ORDINANCE MAARA 553/95	Identity and quality of tomato
ORDINANCE MAARA 529/95	Identity and quality of onion
ORDINANCE SVS/MS 987/98	Disposable packaging of polyethylene terephthalate-pet-for multilayer packaging of carbonated non-alcoholic drinks
ORDINANCE SVS/MS 685/98	General principles for the establishment of maximum levels of chemical contaminants in foods
ORDINANCE SVS/MS 540/97	Transfers of food additives
ORDINANCE SVS/MS 451/97	Identity and quality of the Minas fresh cheese
ORDINANCE SVS/MS 326/97	Sanitary hygienic conditions and good manufacturing practices for policy makers/industrializers food establishments
ORDINANCE SVS/MS 71/96	List of coloring agents allowed
ORDINANCE SVS/MS 26/96	Determination of residual styrene monomer
ORDINANCE SVS/MS 10/95	Pesticide residues in agricultural products <i>in natura</i>
NORMATIVE INSTRUCTION MAPA 17/17	Production, sale and use of seeds and seedlings of forest species or environmental or medicinal interest, native and exotic, in order to guarantee their origin, identity and quality
NORMATIVE INSTRUCTION MAPA 5/17	Establishes the requirements for the equivalence evaluation of the Unified Animal and Plant Health Protection System relating to the physical structure, dependencies and equipment of small agroindustrial establishment of products of animal origin
NORMATIVE INSTRUCTION SDA/MAPA 1/17	Procedures for registration, renewal, modification, audit and cancellation of registration regarding animal products produced by establishments registered on the Federal Inspection Service (Serviço de Inspeção Federal, SIF), and foreign establishments authorized to export to Brazil
NORMATIVE INSTRUCTION SDA/MAPA 57/13	Establishes the criteria and requirements for the accreditation and monitoring of laboratories by the Ministry of Agriculture, Livestock and Supply
NORMATIVE INSTRUCTION SDA/MAPA 66/03	Establishes, within the scope of the Ministry of Agriculture, Livestock and Supply, the System of Registration of Agents of the Productive Chain of Vegetables, its Products, Byproducts and Derivatives for Safety and Quality Certification (SICASQ)
NORMATIVE INSTRUCTION ANVISA 15/17	Procedures for the evaluation of flavoring additives from regional plant species, according to the Resolution RDC No. 2/2007, approving the technical regulation on flavoring additives
INTERMINISTERIAL NORMATIVE INSTRUCTION 1/04	Technical regulation on labeling of foods and food ingredients that contain or are produced from Genetically Modified Organisms (GMOs)
JOINT NORMATIVE INSTRUCTION 9/02	Provisions concerning the packagings intended for the packaging of vegetables “in natura”
NORMATIVE RULING SDA 54/01	Brewery products
NORMATIVE RULING SDA/MAA 15/01	Principles, guidelines, criteria and parameters for the recognition of equivalence of Food control systems between the States parties of Mercosur
NORMATIVE INSTRUCTION MA/SDA 12/01	Analytical methodologies acceptable for daily intake, maximum residue limits for residues and veterinary medicinal products in foodstuffs of animal origin
NORMATIVE INSTRUCTION SDA/MAPA 5/00	Technical regulation for the manufacture of beverages and vinegars, including wines and grape derivatives
NORMATIVE STATEMENT 46/07	Identity and quality of fermented milk
NORMATIVE STATEMENT 45/07	Identity and quality of the blue cheese
MERCOSUR CMC RESOLUTION 20/02	Structure and Criteria for the elaboration of identity and quality of vegetable products "in natura"
MERCOSUR GMC RESOLUTION 50/01	Positive list of additives for plastic materials intended for the production of packaging and equipment in Contact with food

Table 14.21 - Technical Regulation on PAPs (Argentina)

NAME	THEME
LAW 18284/69	Creates the Argentine Food Code

DECREE 2126/71	Regulates the Argentine Food Code
DECREE 2092/91	Regulates all imported food and beverage products both manufactured domestically and imported, except wine
DECREE 1490/92	Creates the National Administration of Drugs, Foods and Medical Devices
DECREE 815/99	Sets the basis for the creation of the National Food Inspection System (SNCA) and creates the National Food Commission (CONAL)
SENASA RESOLUTION 256/03	Establishes the Maximum Residue Levels (MRLs) for products that are traded in the country
RESOLUTION 5/15	Establishes the System for Import Control
DECREE 133/15	Revised export taxes and eliminated or reduced export tariffs on agricultural and industrial products
DECREE 160/15	Revised export taxes and eliminated or reduced export tariffs on agricultural and industrial products
RESOLUTION 3823/15	Establishes the System for Import Control
OFFICIAL RESOLUTION 6/16	Revokes the Label Supervision System

Source: SENASA. Elaborated by CGTI-EESP/FGV.

Table 14.22 - Technical Standards on PAPs (Argentina)

NAME	TITLE
IRAM-1109-B13	Paintings. General test methods. Method for detecting alterations of the smell and taste of food by the painting effect.
IRAM-12901-1	Articles of glass and ceramic glazed in contact with food. Release of lead and cadmium. Method of determination.
IRAM-12901-2	Articles of glass and ceramic glazed in contact with food. Release of lead and cadmium. Permissible limits.
IRAM-12909-1	Ceramic articles for cooking food. Release of lead and cadmium. Part 1: Methods of determination.
IRAM-12909-2	Ceramic articles for cooking food. Release of lead and cadmium. Part 2: Permissible limits.
IRAM - 14100	Food. Best practices in the conservation of the cold chain. Storage, transport and distribution.
IRAM - 14103	Food industry. Guide for the implementation and application of good manufacturing practices.
IRAM - 14107	Food. Guide for the evaluation of suppliers.
IRAM - 14108	Food for animal feed. Good manufacturing practices. Requirements.
IRAM - 14201	Food services. Good manufacturing practices.
IRAM - 14202	Food services. Vocabulary.
IRAM - 14203	Food. (POES) sanitation standard operating procedures. Application guide.
IRAM-14808-2	Natural toxins in foods. Patulin. Rapid determination in juice of apples and cider.
IRAM-14809-2	Natural toxins in foods. Determination of ochratoxins A and B in coffee. In thin layer chromatographic method.
IRAM-14821-1	Natural toxins in foods. Qualitative determination of sulphur in rapeseed oil. Silver benzoate method.
IRAM-14821-2	Natural toxins in foods. Qualitative determination of sulphur in rapeseed oil. 'Currency' or the silver object method.
IRAM - 14824	Natural toxins in foods. Determination of the total content of glucosinolate in rapeseed. Routine method.
IRAM - 14825	Natural toxins in foods. Determination of total Glucosinolates in rapeseed. Reference method by liquid chromatography (HPLC) high resolution.
IRAM - 14903	Microbiology of food and animal feed products. Horizontal method for the detection of Salmonella spp.
IRAM-14915-1	Microbiology of food and animal feed products. Horizontal method for detection and enumeration of Listeria monocytogenes. Part 1 - Method of detection.
IRAM-14915-2	Microbiology of food and animal feed products. Horizontal method for detection and enumeration of Listeria monocytogenes. Part 2 - Counting method.
IRAM-186-1	Sanitary polished. Part 1 - Metallic elements used in the food industry and beverage.
IRAM - 20022	Sensory analysis. General guidelines and methodology for the evaluation of the color of the food.
IRAM - 20301	Food irradiation. Good practices for the process of irradiation of foodstuffs intended for human consumption.
IRAM - 20304	Food irradiation. Guide for selection and use of containers and materials in contact with foods to be irradiated as a whole.
IRAM - 20305	Food irradiation. Requirements for the control of micro-organisms and insects in spices, herbs and vegetable seasonings dried, through the application of ionizing radiation.
IRAM - 20306	Food irradiation. Requirements for the control of sprouting bulbs and tubers through the application of ionizing radiation.
IRAM-2120-4	Apparatus for cooling. Household. Apparatus for storing frozen food and freezer of food (freezers). Characteristics and test methods.
IRAM-2120-5	Domestic-refrigeradores frost-free use refrigeration products, refrigerador-congeladores - storage compartments for frozen food and freezer food cooled by internal forced air circulation. ANCI
IRAM - 23010	Pesticide residues. Classification of food and feed according to their approximate content of fat and water.
IRAM-23026-1	Pesticide residues. Process diagram for the systematic analysis of pesticide residues in non-fatty foods.
IRAM-23026-2	Pesticide residues. Process diagram for the systematic analysis of pesticide residues in fatty foods.
IRAM-23029-1	Organ-phosphorus pesticide residues. Method of determination in non-fatty foods with more than 70% water content.
IRAM-29012-5	Quality of the environment. Quality of water. Sampling. Part 5: Guide on sampling of drinking water and water used for food processing and beverages.
IRAM-AMN ISO TS 22003	The food safety management systems. Requirements for bodies carrying out the audit and certification of food safety management systems. (ISO/TS 22003:2007, IDT)
IRAM-AMN ISO TS 22004	The food safety management systems. Guidance for the implementation of NM ISO 22000:2008 standard. (ISO/TS 22004:2005, IDT)
IRAM-ISO 14470	Food irradiation. Requirements for development, validation and control of routine of the process of irradiation using ionising radiation for the treatment of food.
IRAM-ISO 16654	Microbiology of food for human and animal consumption. Horizontal method for the detection of Escherichia coli O157.

IRAM-ISO TS 22002-1	Prerequisites of food safety programs. Part 1 - Food processing.
IRAM-ISO TS 22002-2	Prerequisites of food safety programs. Part 2 - Catering.
IRAM-ISO TS 22002-4	Prerequisites of food safety programs. Part 4 - Manufacture of food containers.
IRAM-NM 324	The food industry. Good manufacturing practices. Requirements.
IRAM-NM-ISO 22000	The food safety management systems. Requirements for any organization in the food chain. (ISO 22000:2005, IDT)

Source: IRAM. Elaborated by CGTI-EESP/FGV.

14.7. Appendix 7 - Pharmaceuticals

Table 14.23 - Regulation on Pharmaceutical Products (Brazil)

NAME	THEME
LAW 13411/16	Modifies the registration process
LAW 10742/03	Creates the Regulatory Chamber of Medicines Market
LAW 9782/99	Creates ANVISA
LAW 8080/90	Creates the Unified Health System (SUS)
LAW 6360/76	Products subject to the health surveillance
LAW 5991/73	Sanitary control of drugs, medicines, pharmaceutical and correlated inputs
ANVISA RESOLUTION 208/18	Labeling in Brazilian Portuguese within the Brazilian territory
ANVISA RESOLUTION 108/16	Minimum requirements for inspection in establishments which work with controlled products. Incorporates into the national legal order the GMC Resolution Mercosur n. 46/15
ANVISA RESOLUTION 74/16	Importing process of medicines
ANVISA RESOLUTION 67/16	Provides on the requests for authorization of habilitation, renewal of habilitation, modifications after habilitation, outsourcing of tests, suspensions and cancellations of Pharmaceutical Equivalence Centers and other measures.
ANVISA RESOLUTION 65/14	Provides for prior notification of export of ephedrine, pseudoephedrine and special containing them. This Resolution incorporates the GMC Resolution Mercosur n° 30/12 into the national legal system.
ANVISA RESOLUTION 60/14	Criteria for grant renewal of registration of drugs with active principles, synthetic and semi-synthetic, classified as new, generic and similar
ANVISA RESOLUTION 56/14	Certificate of good practices
ANVISA RESOLUTION 16/14	Technical and administrative requirements for the authorization of operation of the company
ANVISA RESOLUTION 15/14	Certificate of good practices
ANVISA RESOLUTION 39/13	Inspection of goods and products under sanitary surveillance and certificate of good practices
ANVISA RESOLUTION 61/12	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 60/12	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 13/11	Provides for the common criteria of the Mercosur for conversion factors for substances controlled nationally by the States Parties that are not objects of international control. This Resolution incorporates the Mercosur Resolution n°. 21/10 into the national legal system.
ANVISA RESOLUTION 12/11	Provides on the Mercosur mechanism of periodicity of the updating of lists and exchange of information on narcotic, psychotropic, precursory and other substances under special control. This Resolution incorporates the MERCOSUR Resolution n° 20/10 into the national legal system.
ANVISA RESOLUTION 23/10	It extends validity of Resolution of the Collegiate Board for purposes of adequacy of the productive sector to the requirements of the norm.
ANVISA RESOLUTION 21/10	Provides the updating of Annex I, Lists of Narcotic Substances, Psychotropic, Precursors and Other under Control Special Issue of Ordinance SVS/MS n° 344 from May 12th, 1998 and makes other provisions.
ANVISA RESOLUTION 71/09	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 47/09	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 12/09	Revoke Art. 1° of RDC n°. 239 from August 28th, 2002
ANVISA RESOLUTION 81/08	Technical regulation on imported goods and products for sanitary surveillance
ANVISA RESOLUTION 63/08	Revoke the provisions applicable to List "C4", to antiretroviral substances and medicinal enacted by RDC N° 103 from August 31st, 2016. New text to art. 34 of the Ordinance SVS/MS N° 344 of May 12th, 1998 providing that the purchase and sale on the internal and external market of the list in this Technical Regulation and its updates. It considers GMC Resolution n° 46/99, which provides for the use of a reimbursement system for the purchase / sale of narcotic drugs and psychotropic substances
ANVISA RESOLUTION 58/08	Provides for the improvement of the control and monitoring of substances psychotropic and other measures.
ANVISA RESOLUTION 25/07	Provides the outsourcing of production steps, analysis of quality control and storage of medicines.
ANVISA RESOLUTION 233/05	Approves the technical regulation of production and quality control for registration, post-registration alteration and revalidation of allergenic extracts and allergenic products.
ANVISA RESOLUTION 217/05	To approve the Extension of Use of the Additive Sulfur Dioxide and its Salts of Calcium, Sodium and Potassium.
ANVISA RESOLUTION 323/03	Approve the technical regulation of registration, modification and revalidation of registration of probiotic medicines, according to the Technical Regulation attached.
ANVISA RESOLUTION 332/02	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUR, according to Resolution - RDC n° 25, of December 9, 1999. Prohibits the importation and sale through the national territory, of the drug

	registered as a similar drug based on CICLOSPORINA of <i>Laboratório Químico Farmacêutico Bêrgamo</i> Ltda., under the name Pharmsporin.
ANVISA RESOLUTION 298/02	Requirements concerning raw material importation, ganglioside-based drugs manufacturing, distribution, trading and prescription as well as drug usage will be subject to the control of the Brazilian Sanitary Surveillance Agency
ANVISA RESOLUTION 214/02	The importer must present the information listed in resolution's annexes and fill in the forms contained in it.
ANVISA RESOLUTION 172/02	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUR, according to Resolution - RDC nº 25, of December 9, 1999. Prohibits the importation and sale, throughout the national territory, of medicines registered as medicines Similar products based on MICOFENOLATO MOFETIL.
ANVISA RESOLUTION 168/02	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 137/03	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 33/01	It is established, considering the importance of making national legislation compatible, harmonized instruments in the Mercosur related to food additives (GMC Resolution 16/00). It creates the "Technical Regulation that approves the use of Food Additives, establishing their functions and their maximum limits for Food Category 12: Soups and Broths.
ANVISA RESOLUTION 92/00	Labeling of medicines and content of the package inserts
ANVISA ORDINANCE 4/08	Certificate of good practices
ANVISA ORDINANCE 344/98	ANVISA's prior consent and authorization to ship to Brazil
NORMATIVE INSTRUCTION 26/09	Manufacturing, quality control, trading and the usage of antimicrobial drugs in animals
MAPA NORMATIVE INSTRUCTION 7/06	Production, evaluation, control and use of poultry vaccines and diluents
MAPA NORMATIVE INSTRUCTION 4/06	Animal Health
MAPA ORDINANCE 23/16	Guidelines on performance of the Ministry of Agriculture, Livestock and Supply (MAPA)
INTER-MINISTERIAL ORDINANCE 701/15	Monetary update on registration and GMP certification fees related to health products in Brazil
ORDINANCE 230/04 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
ORDINANCE 572/02 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
ORDINANCE 510/99 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
RESOLUTION 433/05 OF THE NATIONAL COUNCIL OF PHARMACY	Responsibility to monitor the compliance with sanitary regulations

Source: ANVISA Elaborated by CGTI-EESP/FGV.

Table 14.24 - Pharmaceutical Products Standard (Brazil)

STANDARD	CONTENT
ABNT NBR 16090: 2012	Aluminum tube for pharmaceuticals - Requirements and test methods
ABNT NBR 11819: 2004 ERRATA 1: 2005	Glass bottles for pharmaceutical products - Requirements and test methods
ABNT NBR 11819: 2004 VERSION FIXED: 2005	Glass bottles for pharmaceutical products - Requirements and test methods
ABNT NBR 11280: 2008	Glass ampoules - Requirements and test methods

Table 14.25 - Regulation on Pharmaceutical Products (Argentina)

NAME	THEME
DISPOSITION 828/17	Establishes that the laboratories authorized by the national administration as importers and/or processors of medicinal specialties may request authorization of programs of expanded access (PAE) drugs for groups of patients that required treatments with drugs not yet marketed in the country, as specified in article 2 of this provision
DISPOSITION 6301/15	From 6 months of the entry into force of this provision, medicinal disciplines reached by the ANMAT N provision 3683/11 should be released to the market by its respective register without identification of die holders
DISPOSITION 5039/13	Stating that the information contained in the official list of marketed drugs (LOMAC) and in the drug formulary will be available in the "VADEMECUM national drug" (VNM), which will be published in the institutional Web page: www.anmat.gov.ar
DISPOSITION 2574/13	Gluten-free medications
DISPOSITION 4990/12	Adopted the common name Argentina (DCA) for ingredients pharmaceutical assets (IFA's), used in human medicine contained in annex I of this provision, which is part of the same
LAW 26688/11	Declared of national interest research and public production of medicines, raw materials for the production of medicines, vaccines and healthcare products, understanding them as social goods
DISPOSITION 3686/11	" Minimum requirements to apply for the status of OTC of a medical specialty"
DISPOSITION 2124/11	Crease in the scope of the national administration of medicines, foods and medical technology (A.N.M.A.T.) National Control of drugs and medical products-market program
DISPOSITION 1719/11	Be created within the scope of this national administration of drugs, foods and medical technology, the program for the support to the innovation in medicines and products for health, whose main objective will be the availability of a specific platform for assistance in research and development projects related to processes and products that are innovative character and of interest to public health

DISPOSITION 5576/09	Become the Technical Advisory Committee of chemical substances and medicines, which will act as a pro bono, which shall consist of the scope of this national administration by: the Director of the National Institute of medicine, who will exercise ((the Presidency, a professional representative of each of the following areas: a) direction of Legal Affairs, b) Department of psychotropic and narcotic drugs; (c) Department of Pharmacology; (d) Department of studies and projects; e) Department of registration; (f) Department of pharmaceutical technology); (g) Department of pharmacovigilance; and two professionals by the Directorate of evaluation of drugs
LAW 26492/09	Medicines regulation of medicinal cold chain
DECREE 248/09	Medicines observed and enacted the law No. 26.492
RESOLUTION 1644/08	Created the national registry of drug stores enabled. Conditions of registration
DISPOSITION 4932/08	Approve is the procedure operating for the processing of the requests of authorization of distribution with transit interprovincial and/or between provinces and the city autonomous of Buenos Aires, of lots of products immunobiological, made in laboratories of Public production of medicines, not enrolled in the register of specialties Medicinales
RESOLUTION 609/08	Ministry of health – the national administration of medicines, food and technology medical (ANMAT) through the National Drug Institute supervise and control the medicinal and pharmaceutical specialties whose importation authorized for carry out the Ezeiza delegation of the Directorate GENERAL of customs of income of Administration FEDERAL public
RESOLUTION 582/08	Ministry of health-administration national of medication, food and medical technology through the National Drug Institute supervise and control the medicinal and pharmaceutical specialties whose importation is carried out by the Income Federal Administration public, Dirección General de Ingresos Públicos, Directorate-General for customs, delegation Bahía Blanca
RESOLUTION 627/07 (WITH AMENDMENTS TO THE RESOLUTION 1061/07)	Health publishes approving the "good practices of promotion of drugs for sale low recipe"
RESOLUTION 17/06 MSA	DRUGSTORES. Establishment legal and technical conditions that must comply with the signatures requesting the habilitation as drugstore.
DECREE 987/03	Regulation of the law of promotion the use of medicines by its generic name, law N° 25649
RESOLUTION 145/03	Adopted the Mercosur technical regulation for transport of infectious substances and samples for diagnosis, incorporating the legal regulations national vigente
LAW 25649	Law of generic drugs
DISPOSITION 3554/02	Requirements for registration of pharmaceutical products registered and processed in a State part of Mercosur (State part producer) similar to products registered in the country (part receiving State). Deadline for completion of the process. Time to start the marketing of products
DISPOSITION 2321/02	Apruebase document "mandatory communication between States part of MERCOSUR on the removal of drug from the market" (resolution GMC No. 78/99)
LAW 24766	Privacy Act information and products
DECREE 150/92 (WITH MODIFICATIONS OF THE DECREES 968/92, 1890/92, 177/93, 1528/04 AND RES. CONJ. 452/14 AND 1227/14)	Rules for registration, preparation, fractionation, prescription, dispensing medications
RESOLUTION 147/92 AND JOINT RESOLUTION 342/92 JOINT RESOLUTION 268/92	Regulate the development of activities in pharmacies and marketing of medicines, products of hygiene and toiletries, cosmetics, Perfumes, equipment and devices for medical use, and dental, diagnostic reagents and products for household use with impact on the health of people Regulating Decree No. 150/92 (medical specialties)
RESOLUTION 129/87 (WITH AMENDMENTS TO THE RES. 50/07 OF THE SPRRS)	Modify the conditions of sale of the specifics that contain dextromethorphan, antihistamines, aspirin in Pediatrics and Zipeprol
REGULATORY DECREE 9763/64	Regulates Act No. 16463
LAW 16463	Drugs
DISPOSITION 10564/16	The system of traceability of medicines that need to implement the natural or legal persons involved in the chain of marketing, distribution and dispensing of pharmaceutical products included in the registration of pharmaceutical products (REM) of the national administration in the terms established in the resolution of the Ministry of health no. 435/11, will apply to all those specialties, already registered or which in the future register containing in their composition the ingredients pharmaceutical assets (IFA's) included in annex I, alone or in partnership (unless otherwise stated) and pharmaceutical forms that therein
DISPOSITION 963/15	The system of traceability established, must be implemented for all of the previously listed medicinal specialties, to the first business day of March 2015, for all links in the chain of distribution
DISPOSITION 247/13	Incorporanse to the national system of traceability of medicines, starting on June 15, 2013, all those medical specialties containing in their composition the active pharmaceutical ingredients (IFA's) included in annex I that is an integral part of it, either as monodroga or in association with any one or more other IFA's, in all of its pharmaceutical forms
DISPOSITION 1831/12	System of traceability of medicines that need to implement the natural or legal persons involved in the chain of marketing, distribution and dispensing of pharmaceutical products included in the register of specialties Medicinal

RESOLUTION 435/11	Established that natural or legal persons involved in the chain of marketing, distribution and dispensing of medicinal specialties included in the registration of pharmaceutical products, need to implement a system of traceability that allows ensuring control and follow-up
DISPOSITION 3683/11	Technical requirements and stages of implementation of the system of traceability of medications
RESOLUTION 549/11	Traceability - the insurance agents (resolution No. 594/11 of the Superintendence of health services)
CIRCULAR 4/16	Update data in the VNM
CIRCULAR 7/16	Update of data in the national formulary of drugs
DISPOSITION 7304/14	Set that on the medicinal specialties containing as IFA Amphotericin B liposomal must be the acute toxicity test on the finished product at least in a different batch every six months, according to the test described in annex I forming an integral part of this provision
DISPOSITION 7240/14	Approve the inspection Guide to implement market monitoring of medicines distributed, as annexes I and II form an integral part of this provision
DISPOSITION 7066/13	Establish that companies enabled by the ANMAT to develop and/or air conditioning, own plant or of third parties, and/or importing and/or exporting drugs or active pharmaceutical ingredients, must annually submit the master site file (AMS) , according to the specifications provided for in this provision
DISPOSITION 5569/13	Approval of the "Guide for inspectors on good practices of manufacturing of ingredients pharmaceutical assets", which, as annex I, form an integral part of this provision, as complementary to the annex VI of the ANMAT NO2819/04 available
DISPOSITION 7667/10	Companies that produce and/or import not necessarily sterile products must comply with the microbiological Control in accordance with the limits of acceptability set out by article 20 of the present provision
DISPOSITION 5469/10	Incorporated into the national legal order the resolution N° 15/09 GMC Mercosur "good practices of manufacture of pharmaceuticals and mechanisms of implementation in the scope of the MERCOSUR (repeal of the RES.)" (No 14/96 GMC and 61/00)
DISPOSITION 5363/10	Incorporated into the national legal order the GMCN Mercosur resolution n° 16/09 "common procedures for inspections in establishments pharmacists in States parties (repeal of the RES.)" (N° 23/96 GMC and 34/99) "
DISPOSITION 5743/09	The evaluation of information relating to the methods of control, development, trials pharmacotechnical, stability, operational capacity to develop and/or control included in requests for registration in the register of specialties medicinal, will be made by technical verification of such information, having completed the requirements laid down in the provision no. 2819 A.N.M.A.T. / 2004 or in the future replace it and stated quality specifications in the Argentina Pharmacopoeia, Pharmacopoeia Brazilian and/or other internationally recognized pharmacopoeia
DISPOSITION 5260/08	Establishment requirements that must be completed settlements which develop and/or divide drugs and medications
DISPOSITION 2372/08	Approving the "Guide for inspectors on good practices of manufacture of drugs" and the "classification of deficiencies of compliance of them good practices of manufacture- " "
DISPOSITION 1402/08	Pharmaceuticals, PERSONAL hygiene, cosmetics and PERFUMES approving procedures for the removal of Personal hygiene products and pharmaceutical products, cosmetics and Perfumes
DISPOSITION 3477/05	Ministry of Foreign Affairs, international trade and worship Mercosur /GMC/Res. No 50/95 contracting outsourcing services for pharmaceutical products in the scope of the Mercosur
DISPOSITION 3476/05	Modifications of the authorization of functioning of the companies applicants registration products pharmaceutical of the Member State receiver
DISPOSITION 2123/05	Good practices of production and Control of medicinal/Prod specialties. Pharmacists
DISPOSITION 2819/04 (WITH AMENDMENTS OF THE DISP. 4844/05)	General guidelines of good manufacturing practice for processors, importers / exporters of drugs
DISPOSITION 6826/02	Practices and procedures of manufacturing, control and marketing that is must apply for ensure that them facilities, methods and controls used in the development and sale of products allergens for use in live are appropriate to ensure it efficiency , quality, stability and safety of them
DISPOSITION 3555/02	Requirements to be fulfilled by companies seeking to be recognized as representatives in the country's signature holders of registrations of pharmaceutical products manufactured in another State part of the Mercosur
DISPOSITION 2386/02	Adopted the document "Self-inspection mandatory on good practices of manufacturing and Control" (resolution GMC No. 79/99)
DISPOSITION 2338/02	Approve the document "Contractual relationship between the holder of the registration in the State part producer and its representative at the State party recipient of Mercosur , in the framework of the resolution GMC 23/95" (resolution GMC No 39/97)
DISPOSITION 2313/02	Adopted the document "Re-inspections joint in the scope of Mercosur " (resolution GMC N ° 34/99)
DISPOSITION 2309/02	Approves the document "Good practice for manufacture and Control of medicines who 92", (resolution No. 61/00 GMC)
DISPOSITION 6897/00 (WITH AMENDMENTS OF THE DISP. 3595/04)	Pharmaceutical products - sanitary risk
DISPOSITION 5221/97	Public health adopted the document entitled "Strategy of adaptation on surveillance health"
DISPOSITION 5220/97	Establishes that the training of human resources to inspections to pharmaceutical processing facilities will take place pursuant to the so-called technical paper: "training for inspectors in good manufacturing practices"that, as annex I, form an integral part of the present provision
DISPOSITION 5219/97	Specialties medicinal regime of inspections
DISPOSITION 5218/97	Establishes that pharmacochemistry industry inspections will be carried out in accordance with the so-called technical paper: "System of evaluation of procedures for the inspection of industries APIs" which, as annex I, part Member of the present provision

DECREE 1299/97 (WITH THE ELUCIDATION OF THE RES. EX MSYAS 832/98)	Presidency of the nation – Ministry of health and Social Action-Regulanse critical stages of marketing of medicines. Laboratories. Distribution companies. Pharmacies. Sale to the public. Create database only establishments
DISPOSITION 1930/95	Compliance with BPFyC
DISPOSITION 7038/15	The drugstores must comply with the requirements and conditions established in this provision, for the purposes of commercial transactions of drugs and pharmaceutical products outside the jurisdiction that are enabled) inter-jurisdictional transit)
DISPOSITION 5316/09	Incorporated into the national legal system resolution Mercosur GMC No. 48/08 "Regulation technical MERCOSUR on good practices health of transport of supplies and pharmaceutical products"
DISPOSITION 5307/09	Approving the "Guide for inspectors on good practices for storage, distribution and transportation of drugs" and the "classification of compliance deficiencies of the good practices of storage, distribution and transportation of" Drugs"
DISPOSITION 3475/05	Annex Mercosur /GMC/Res. N° 49/02: regulation technical Mercosur on good practices of distribution of pharmaceutical products
DISPOSITION 105/02	Distributors of drugs - system of registration and Control
DISPOSITION 7439/99	Medicinal enabling specialties of distributors of drugs
RESOLUTION 538/98	Creation of the national register of establishments distributors of pharmaceutical-products
DECREE 1299/97 (WITH THE ELUCIDATION OF THE RES. EX MSYAS 832/98)	Presidency of the nation – Ministry of health and Social Action-Regulanse critical stages of marketing of medicines. Laboratories. Distribution companies. Pharmacies. Sale to the public. Create database only establishments
RESOLUTION 223/96	SPECIALTY medical Actualizanse rules governing the same productive sector, for the purpose of placing in a symmetry plane competitive industries on the international arena and in harmony with the activities carried out in the MERCOSUR
DISPOSITION 4010/17	Approving new forms for application for authorisation and the presentation of results of bioavailability/bioequivalence studies
DISPOSITION 4009/17	Approving the requirements and conditions to be fulfilled the assistance centers to be permitted to carry out studies of phase I pharmacology clinical and/or bioequivalence, appearing as annex I to this provision and which forms an integral part of the same
DISPOSITION 4008/17	Replaced item 2 ° of the ANMAT provision N ° 6677/10 which will be drafted in the following way "article 2 °.establish that once submitted and accepted the documentation which is referenced in the scheme approved by the article 1 of the present Available, the technical areas involved must be dispatched in the term of 60 (sixty) business days. This period may be suspended whenever objections are made and until the person concerned delivery of all documentation and/or complete all observations or clarifications chosen. Once issued the report, within (the 10 ten) business days will be extended the corresponding administrative act."
DISPOSITION 12792/16	Established by this provision the procedure for the application for import of the medication/treatment and materials for access post-research by participants in a clinical pharmacology study authorized by this National Administration
CIRCULAR 3/11	EFC sponsors must submit filed version of informed consent
CIRCULAR 1/11	Sets a field intended for the presentation of clinical research projects
RESOLUTION 1480/11	Approval of the guidelines for research involving humans, which, as annex I, form an integral part of the present resolution, and which aims to guide researchers, sponsors and members of committees of ethics in research and regulatory authorities and health of different jurisdictions in the development and evaluation of research involving humans
CIRCULAR 4/10	Clinical trials in the country. Phase I and/or II.
DISPOSITION 6677/10	" Adopted the regime of good clinical practice clinical pharmacology studies"
DISPOSITION 2247/09	Medical specialties - Approved guide for clinical studies of type 2 Diabetes. Criteria of evaluation of protocols
DISPOSITION 1310/09	Public health incorporated the best practices guide of clinical research in humans, approved by resolution of the Ministry of health no. 1490/07, as part of specific regimes in force in this national administration
RESOLUTION 102/09	Create the registration of clinical trials in human beings
DISPOSITION 6/08 AND ANNEXES – PUBLIC HEALTH	Development of procedures relating to clinical pharmacology trials subject to approval of the national administration of drugs, foods and medical technology (ANMAT)
RESOLUTION 1490/07	Approval of the guide of the good practices of research clinic in humans, which form an integral part of the present resolution as annex I
DISPOSITION 9222-E/17	Labs holders of certificates of pharmaceutical products registered in the register of medicinal specialties (REM) and sold, containing, as monodroga, one of the ingredients pharmaceutical assets (IFA) referred to then must submit protocols to the studies of equivalence vivo within one hundred twenty (120) calendar days as from the entry into force of this provision
DISPOSITION 8870/17	The pharmaceutical products containing the pharmaceutical active ingredients (IFAs), monodroga, as indicated in annex I to the present, and for all its authorized concentrations, will not require bioequivalence studies
DISPOSITION 8262/17	Establish product called LEVOTHYROXINE GLAXOSMITHKLINE / LEVOTHYROXINE sodium, tablets, as reference product for bioequivalence studies of the ingredient pharmaceutically active levothyroxine sodium
DISPOSITION 8259/17	Establish product called T4 MONTPELLIER / LEVOTHYROXINE sodium, tablets SLOTTED, as reference product for bioequivalence studies of the ingredient pharmaceutically active levothyroxine sodium
DISPOSITION 4010/17	Dejanse annexes II, III and IV of the ANMAT provision void No. 5040/06. Approval of the new form for the request for authorization to carry out studies of bioavailability/bioequivalence guidelines and requirements of information and documentation which appears as annex I to this provision and is an integral part of the same

DISPOSITION 12704/16	Adopt the criteria of the average bioequivalence with escalation to the reference product to the IFAs or formulations of high variability intra-subject, for pharmacokinetic parameter maximum concentration (Cmax), provided that such escalation does not have any impact on the safety and efficacy of the product
CIRCULAR 11/16	Compliance with requirement of bioequivalence studies applicable to new applications for registration and applications for registration of pharmaceutical products pending
DISPOSITION 11247/16	Establishment products of reference medicinal specialties that contain active pharmaceutical ingredients subject to bioequivalence studies contained as an annex to this provision
DISPOSITION 6766/16	Requests for Bioexenciones of pharmaceutical active ingredients with bioequivalence requirements shall be carried out according to the "Guide for the application of active pharmaceutical ingredients with bioequivalence requirement Bioexenciones" that annexed it forms an integral part of this provision
CIRCULAR 5/2013	First phase of the timetable for pharmaceutical products containing the following psychoactive drugs such as IFA: CLOZAPINE, HALOPERIDOL, OLANZAPINE, QUETIAPINE and RISPERIDONE
DISPOSITION 4394/13	Approve the rules of good laboratory practice applicable to the Bioanalytical centers for bioavailability/bioequivalence studies, which appears as annex I to this provision and an integral part of it
DISPOSITION 2434/13	Established that the holders of laboratories of pharmaceutical products containing IFAs, for which this national administration requires the completion of bioequivalence studies, requesting the approval of results of studies carried out abroad, they shall comply with the requirements listed in annex I to this provision
DISPOSITION 1918/13	Establishment criteria for the selection of a medical specialty as reference product for Bioequivalence and equivalence In-Vitro studies referred to in annex I to this provision, which forms an integral part of it
CIRCULAR 1/13	Authorization of clinical studies of bioavailability and bioequivalence
DISPOSITION 4788/12	Incorporanse the requirements of preparation of bioequivalence/bioavailability studies, established by provision (ANMAT) No. 3185/99, active pharmaceutical ingredients contained in annex I of this provision, which is part a member of the same
DISPOSITION 4326/12	Adoptanse as criteria of risk health, for the inclusion of ingredients pharmaceutical active in the schedule of requirement of studies of bioequivalence vivo, to them hearing in the annex I of the present provision
DISPOSITION 4133/12	Established that, from the entry into force of this provision, shall only present results of bioequivalence studies that are included within the confidence interval 90% of 0, 80-1, 25, both for concentration Maxima as for the Area under the curve
DISPOSITION 4132/12	Merge, the requirement for demonstration of bioequivalence established in the provision (ANMAT) N ° 3185/99, all concentrations marketed and/or placed on the market of a medical specialty, oral solid dosage form, containing any Ingredients pharmaceutical assets included in the national rules referred to in the seen, and subsequent supplementary provisions of bioequivalence requirement
DISPOSITION 1263/12	Establishment new requirements for the realization of the equivalence or bioequivalence study "in vitro"
DISPOSITION 4351/10	Designanse members of the Commission adviser ad honorem at themes of Bioequivalence and bioavailability
DISPOSITION 3113/10	Incorporanse the requirement of bioequivalence studies / bioavailability, established by the provision (ANMAT) No. 3185/99, topiramate and lamotrigine active pharmaceutical ingredients
DISPOSITION 758/09	Products medicinal criteria of Bioexencion of bioequivalence studies for immediate-release oral solid medications
DISPOSITION 556/09	Medicinal SPECIALTIES available 556/2009 approval of the Guide to apply on changes of scale and subsequent changes to the registry drugs subject to demonstration of bioequivalence
DISPOSITION 7188/07	Acceptanse the results of the "study of bioequivalence in healthy volunteers single dose of two different formulations of Saquinavir Mesilato: PROTEOVIR Saquinavir mesylate Richmond and FORTOVASE (products Roche S.A.Q. e I.)."
DISPOSITION 5643/07	Acceptanse the results of the "study of comparative bioavailability of Indinavir after a single administration of 400 mg"
DISPOSITION 2446/07	Incorporanse medicinal SPECIALTIES certain active principles (Serolimus, Everolimus, Tacrolimus and mycophenolate) the requirement of bioequivalence studies / bioavailability, established by the provision no. 3185/99
DISPOSITION 5040/06 (WITH AMENDMENTS TO THE DISP. 1746/07 AND 4010/17)	Adopted the regime of good practices for the realization of studies of bioavailability / bioequivalence
DISPOSITION 2749/05	Pharmaceutical products - product reference for beginning active DIDANOSINE
DISPOSITION 4218/04	Settles as a product of reference for equivalence studies in vitro to the medical specialty called 3tc / LAMIVUDINE tablets coated 150 and 300 mg, oral solution 10 mg/ml, owned by the firm Glaxosmithkline Argentina S.A.
RESOLUTION 60/03	Repeal of resolution Ministerial No. 189/00
RESOLUTION 46/03	Approving the Plan and timetable for the realization of bioavailability/bioequivalence studies of all the pharmaceutical products containing active ingredients. Antiretroviral drugs
SPRRS RESOLUTION 19/03 (WITH AMENDMENTS TO THE RES. 46/03 OF THE SPRRS)	Suspension of the former resolution SPyRS No. 40/01
DISPOSITION 4290/02	Establishment of products for: phenytoin, warfarin, Ethosuximide, quinidine, Levodopa/Carbidopa and Levodopa/Benserazida
DISPOSITION 5318/02	Establishment of product for simple-release phenytoin
DISPOSITION 3598/02	Declaration sworn of the researcher
DISPOSITION 2814/02	Pharmaceutical forms that do not require studies of Equivalencia
DISPOSITION 7062/02	Establishment of products to theophylline
DISPOSITION 2807/02	Incorporation of the drug isotretinoin to bioequivalence schedule. Selection of products comparators for bioequivalence studies, the drug carbamazepine, Oxcarbazepine, valproate, Cyclosporine, theophylline, digoxin, Verapamil and isotretinoin

DISPOSITION 3311/01	Establishment of conditions for bioequivalence studies of antiretrovirals and schedule of presentation of results
SECRETARIAL RESOLUTION 40/01	Inclusion in the schedule of bioequivalence of drugs antiretroviral
SECRETARIAL RESOLUTION 229/00	Inclusion in the schedule of bioequivalence of Pyridostigmine
DISPOSITION 3185/99	Requirement study of bioequivalence
DISPOSITION 13054/17	Approving the requirements called "Guide of good practices of manufacture of products of Pharmacopoeia" for establishments authorized to do so
DISPOSITION 8417/16	Official medicines, encoded in the current of the pharmacopoeia Argentina Edition and listed in the list as annex I form an integral part of this provision, and the drug may only be bottled, made and marketed, bound to the inter-jurisdictional trade, laboratories enabled to do so before the ANMAT
DISPOSITION 6501/13	Approving the texts of volumes II, III and IV of the seventh edition of the PHARMACOPOEIA of ARGENTINA, made by the Permanent Commission of the Argentina Pharmacopoeia, based in this national administration, which, as annex I, is part of the present Provision
DISPOSITION 4675/08	Pharmacopoeia Argentina joining the Commission permanent of the pharmacopoeia Argentina
DISPOSITION 3409/99	Enabling building and functional for the manufacture of products of Pharmacopoeia and registration of products
DISPOSITION 12665/17	Incorporated into Schedule II of the law No. 19.303 of psychotropic substances, the substance DRONABINOL delta-9-tetrahydrocannabinol and its stereochemical variants [(6aR,10aR)-6a, 7, 8, 10a - tetrahydro-6,6,9-trimetil-3-pentil-6H-dibenzo[b,d]pirano-1-ol]
DISPOSITION 13831/16	All physical and/or legal person performing import, export, production, manufacture, fractionation, marketing and/or deposit, within national jurisdiction or destined for interprovincial trade, of substances listed in the annex of the This provision, as well as also for medicinal or pharmaceutical specialties containing them, must register with the DVSSCE of the INAME to obtain a special certification for the management of these substances
DISPOSITION 10692/16	Holders laboratories registration of pharmaceutical products which use or contain in their precursor chemicals, they must inform the national administration, with 45 days in advance, the date and time that will be carried out the weighing and mixing of substances concerned activities
DISPOSITION 3263/13	Incorporated into the national legal order the GMC Mercosur resolution N ° 30/12: "prior notification of export of EPHEDRINE, PSEUDOEPHEDRINE and medical SPECIALTIES to the contain", which is attached as an annex and an integral part of the present provision
DISPOSITION 8700/11	Incorporated into Schedule II of the 17.818 law of narcotic drugs to the active pharmaceutical ingredient (I.F.A.) HYDROCODONE, their salts and derivatives active, and those products pharmaceutical's use human that it contain
DISPOSITION 7927/11	Incorporated into Schedule I, of the 17.818 Act on narcotic drugs, the substance ORIPAVINE, main alkaloid of the opium poppy (papaver somniferum) straw
DISPOSITION 5319/10	Incorporated into the national legal order the resolution GMC N° 20/10 Mercosur "periodicity of the updating of lists in MERCOSUR and exchange of information on narcotic drugs, psychotropic substances, PRECURSORS and subject to CONTROL" Special (COMPLEMENTATION of the RES.) (No. 38/99 GMC) "
DISPOSITION 5317/10	Incorporated into the national legal order the resolution GMC N° 21/10 Mercosur "Common criteria of the MERCOSUR for factors of CONVERSION for substances controlled NATIONALLY by the States part which not are object of CONTROL international"
DISPOSITION 885/10	Adoptanse new definitions of potential, psychotropic and narcotic for the purposes deemed to correspond
DECREE 299/10	Narcotic update of the list of narcotic drugs and other chemical substances which must be included in the scope of the law No. = BA 23.737
RESOLUTION 1645/08	Ministry of health SPECIALTIES medical prohibited the manufacture, marketing and use of ephedrine as monodroga. Exception
RESOLUTION 932 JOINT, 2529 AND 851/08	Set the import ban, either as raw material or semi-finished products of ephedrine, its salts, optical isomers and salts of its optical isomers and pseudoephedrine; at drugstores and/or physical and/or juridical persons that are not holders of registration of pharmaceutical products in accordance with the regulations in force
DISPOSITION 7165/08	Established that the condition of the sale of all pharmaceutical products containing as active ingredient TRAMADOL as monodroga or the partner, shall be filed under RECIPE for the reasons given in recital of this provision. Holders of the pharmaceutical products containing as active ingredient TRAMADOL as monodroga or partner, must be the presentations related to modify its condition of sale, the Autorizantes certificates and labels and prospects, within a period of 30 days from the date of entry into force of this provision. Prohibited the manufacture and distribution of medical samples of pharmaceutical products containing TRAMADOL as monodroga or partner. The owners of the pharmaceutical products containing TRAMADOL as monodroga or associate active comoprincipio, must remove medical samples of such pharmaceutical products, within a period of 60 days from the date of entry into force of this provision, according to the procedures established by the ANMAT 1402108 available. Repeal is it available ANMAT 1863 / 2002
DECREE 2094/08	Create the inter-jurisdictional Committee of the register of chemical precursors
DISPOSITION 4712/08	Requirements for authorizing the import of the active ingredient ephedrine and Pseudo ephedrine
LAW 26052/05	Narcotic drugs. Modify the 23.737 law
DISPOSITION 3474/05	Apruebase the "technical regulation MERCOSUR on the common documents required for import and export of narcotic drugs and psychotropic substances", resolution GMC No. 29/2002-MERCOSUR
DISPOSITION 3682/03	Incorporated into Schedule II of the Act 19.303 of psychotropic substances, the substance ketamine (2-(2-chlorophenyl 1) - (methilamino) - cyclohexanone), being its status as 'Low official recipe' for sale
DISPOSITION 2621/02	Approve the document "Control input and output of psychotropic and narcotic drugs for use in special cases / compassionate use of drugs in patients" (resolution No. 66/00 GMC)
DISPOSITION 2385/02	Approve the document "Glossary of common terms for narcotic drugs, psychotropic substances and precursors", (resolutions GMC Nros. 70/00 and 10/02)

DISPOSITION 2340/02	Adopted the document "Use of systems of reimbursement for the purchase/sale of narcotic drugs and psychotropic substances" (resolution GMC N ° 46/99)
DISPOSITION 2339/02	Approve the document "distribution of samples for professionals and advertising of medicines containing narcotic drugs or substances psychotropic" (resolution GMC No 57/99)
DISPOSITION 2336/02	Pass is the document "Control and control of the origin of the narcotic" (resolution GMC N ° 24 / 00)
DISPOSITION 2334/02	Approve the document "authorization for the entrance and exit of drugs containing narcotic drugs and substances psychotropic for patients in transit" (resolution GMC N ° 74/00)
DISPOSITION 2322/02	Approve the document "technical regulation on Narcotic Drugs lists and subject to Control psychotropic substances" (resolution GMC N ° 38/99)
DISPOSITION 2316/02	Approve the document "technical regulation on associations of drugs containing anorectics in drugs and compounding"(Resolución GMC N° 39/99)
DISPOSITION 2315/02	Adopted the document "Technical regulation on controls and control of narcotic drugs and psychotropic to perform in areas zones and Areas Customs Special" (resolution GMC No 37/99)
DISPOSITION 2311/02	Apruebase document "technical regulation MERCOSUR on associations of drugs in medications and magistral preparations containing anxiolytics"(Resolucion GMC Nro. 57/00)
DISPOSITION 2310/02	Approve the document "the concentrations of Narcotics Control, master forms and pharmaceutical psychotropic substances" (resolution GMC N ° 22/00)
DISPOSITION 2308/02	Adopted the document "Control and control of poppy seeds (Papaver Somniferum)" (resolution GMC N ° 23/00)
DISPOSITION 5492/98	Pharmaceutical products - establish that the specialties and prepared medicinal containing as active ingredient drugs included in the list of law 17.818 have prescription on file status
DECREE 341/92	Unificanse the fines to be applied to offences committed against health rules identified in the annex 1
RESOLUTION 3329/91	Adopted as a complementary list of drugs subject to the checks provided for in the provision no. 38/90 of the Subsetaria of administration of health programs and services which add corro annex 1 to the present
DECREE 722/91	Actualizanse lists of narcotic drugs, psychotropic substances and other substances that can produce dependence physical or mental, for the purpose set forth in the last paragraph of article 77 of the code criminal
DISPOSITION 38/90	Psychotropic and narcotic drugs - billing, recipes
RESOLUTION 56/89	The establishments engaged in "Veterinary use" products that require any drug controlled by laws 17.818 and 19.303 preparedness specialties, must register previously in the national drug Directorate, Drugs and foods (national register)
RESOLUTION 1031/86	Psychotropic drugs. Maximum dose for Jack and day
LAW 19303/71 (WITH THE SUBSEQUENT REGULATORY AMENDMENTS IN THE RESPECTIVE LISTS)	Psychotropic
DECREE 4589/71	Adopted the body of provisions which constitute the regulation of the Law 19.303, and which as Annex forms an integral part of this Decree
LAW 17818/68 (WITH AMENDMENTS OF THE DISP. 4861/97 AND 7487/97)	Narcotic drugs
RESOLUTION 10874/17	Approve the exception regime of access to unregistered medicines (MSAR - NR), through which establishes the procedure for the approval of import of unregistered in the country medicines intended for the treatment of an individual patient for which there is no available a record of a product that is identical, similar or adequate therapeutic alternative
RESOLUTION 1537/17	The national program for the study and investigation of the use plant Medicinal Cannabis and its derivatives and non-conventional treatments, hereinafter "The programme", is located in the orbit of the Secretariat for policy, regulation and institutions
DECREE 738/17	Approval of the regulations of the law No. 27,350 "Research medical and scientific use MEDICINAL of the plant of CANNABIS and its derivatives", than as annex I (IF-2017-21401340-APN-DD #MS) is part of the present
LAW 27350/17	The ANMAT will allow the importation of oil of cannabis and its derivatives, when required by the patients who have the diseases referred to in the program and have appropriate medical indication. The provision will be free for those who are incorporated into the program. Enforcement authority must regulate this law within one period not exceeding sixty (60) days from its publication in the Official Gazette
JOINT RESOLUTION 942/01 AND 426/01	Exempt from payment of the right of import and port services rates, statistics and verification, imports for consumption of drugs for compassionate use which is not marketed in the country and that are necessary for the personal use of patients with diseases that compromise their life, that evolve towards the disability, renders or damage their quality of life
DISPOSITION 5482/15	This provision applies to those establishments that request the habilitation as fractionator, producer or importer of drugs plant, preparations of vegetable drugs or herbal medicines or herbal medicines for traditional
DISPOSITION 5418/15	Fall under the terms of this provision the authorisation of marketing and sale, import, export, production, fractionation and distribution, within national jurisdiction, or bound for trade inter-jurisdictional, of vegetable drugs, preparations of vegetable drugs, herbal medicines and natural and legal persons involved in such activities
RESOLUTION 1817/13	They fall under the terms of this resolution import, export, manufacture, fractionation, distribution - whether for payment or free - national jurisdiction, or with destination to the inter-jurisdictional drug trade vegetables, vegetable drug preparations, herbal medicines and natural and legal persons involved in such activities
DISPOSITION 1788/00	List of drugs plant to be excluded as constituents of medicines phytotherapy, on the grounds that have effects toxic to humans

DISPOSITION 9571-E/17	Established as substance of reference PHARMACOPOEIA Argentine - Brazilian PHARMACOPOEIA for physical and chemical tests, to ingredient pharmaceutical active nitrate of ECONAZOLE (113013 batch number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.9%, expressed over the dried substance
DISPOSITION 8640/17	Established as substance of reference PHARMACOPOEIA ARGENTINA - MERCOSUR PHARMACOPOEIA for physical and chemical tests, to ingredient pharmaceutical active LEVODOPA (113016 batch number), which has been packaged in vials ampoules containing approximately of 300 mg each and a title of 99.9%, expressed over the dried substance
DISPOSITION 8254/17	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active HYDROCORTISONE (control 115023 number), which has been packaged in vials ampoules containing approximately 300 mg each one and a title of 99.8%, expressed over the dried substance
DISPOSITION 13145/16	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active LORATADINE (control 115021 number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed over the dried substance
DISPOSITION 13144/16	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active ATORVASTATIN calcium (114019 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.5% on the anhydrous basis
DISPOSITION 5411/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active hydrochloride of PSEUDOEPHEDRINE (111007 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.4%, expressed over the dried substance
DISPOSITION 1857/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to ingredient pharmaceutical active IBUPROFEN (114018 control number) which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed on the anhydrous basis
DISPOSITION 1743/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active AMOXICILLIN (114017 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.8%, expressed on the anhydrous basis
DISPOSITION 6928/14	Established as substance of reference PHARMACOPOEIA ARGENTINA to the 6-AMINOPENICILLANIC acid IMPURITY, (control number 111006/6-APA) for physical and chemical tests, corresponding to the pharmaceutical ingredient active SULBACTAM sodium, which has been packaged in vials ampoules containing approximately 30 mg each and 97.2%, expressed on the substance of such title which
DISPOSITION 6217/14	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to ingredient pharmaceutical active FLUCONAZOLE (number of control 112010), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed over the dried substance
DISPOSITION 7926/11	Set as reference substance PHARMACOPOEIA ARGENTINA to SULBACTAM sodium (111006 control number) for physical and chemical tests, having been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed on the anhydrous basis
DISPOSITION 5510/11	Set as reference substances PHARMACOPOEIA ARGENTINA to the DICETOPIPERAZINA IMPURITIES, ENALAPRILAT and IMIDAZOLE of ENALAPRIL MALEATE (control numbers 110004/DICETOP., 110004/ENALAP. and 110004/IMIDAZ., respectively) for testing physicochemical, having been packed every one of them in bottles vials containing approximately 40 mg
DISPOSITION 3937/11	Reconocense as reference substances PHARMACOPOEIA ARGENTINA for physical and chemical tests, developed by the Brazilian PHARMACOPOEIA substances listed in annex I, which forms an integral part of the present
DISPOSITION 2728/11	Established as substance of reference PHARMACOPOEIA ARGENTINA to ENALAPRIL MALEATE (110004 control number) for physical and chemical tests, as a in vials ampoules containing approximately 300 mg each and a 99.8% degree, expressed above the dried substance
DISPOSITION 7591/10	Established as reference substances PHARMACOPOEIA ARGENTINA to the IMPURITIES A, B, C and D of TIOCONAZOLE (lot numbers 109003/A, B, / c and/d respectively) for testing chemical, having been packed each one of them in bottles containing blisters approximate 50 mg
DISPOSITION 3110/10	Established as substance of reference certified PHARMACOPOEIA ARGENTINA - PHARMACOPOEIA Brazilian to TIOCONAZOLE (batch No. 109003) for testing chemical, packaged in jars blisters with an approximate content of 300 mg. of TIOCONAZOLE each and a 99.8% degree expressed on the anhydrous basis
DISPOSITION 2604/10	Reconocense as reference substances PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the PHARMACOPOEIA Brazilian reference substances listed in annex I, which forms an integral part of the present
DISPOSITION 194/10	Set as reference substances PHARMACOPOEIA ARGENTINA impurities D, E and H of AMIODARONE hydrochloride (control numbers 107001/D, /E and/h respectively) for testing physical - chemical, having been packed every one of them in bottles, ampoules with content approximately of 25 mg
DISPOSITION 6829/08	Set as substance of reference PHARMACOPOEIA ARGENTINA hydrochloride of AMIODARONE (control 107001 number) for physical-chemical tests, packaged in vials ampoules containing approximately 250 mg of AMIODARONE hydrochloride each and a title of 100.6% expressed on the dried substance. Aware that the vials ampoules of AMIODARONE hydrochloride will be kept at the National Institute of medicine, which will be distributed to applicants, under the payment of the relevant fee and will be accompanied by a technical report summarized
DISPOSITION 7356/07	Established as reference substance to LOPERAMIDE hydrochloride (107053 control number) for physical and chemical tests, as a in vials ampoules containing approximately 300 mg LOPERAMIDE hydrochloride each and a title of 99.2% expressed on the anhydrous basis

DISPOSITION 5003/07	Established as reference substance to OMEPRAZOLE (106052 control number) for physical and chemical tests, as a in vials ampoules containing approximately 200 mg of OMEPRAZOLE each and a title of 100.5% on the anhydrous basis
DISPOSITION 615/07	Established as first reference substance to tobramycin for microbiological assessments
DISPOSITION 6975/06	MEDICINAL products set as first reference substance to Gramicidin, for microbiological assessments
DISPOSITION 1336/06	Set as reference to Diazepam for physical and chemical tests, as a substance to vials ampoules containing approximately 250 mg of Diazepam each and a title of 99.7% on the anhydrous basis
DISPOSITION 8285/05	Becoming a certified reference substance to Mebendazole for physical-chemical tests
DISPOSITION 6938/05	Public health - settle like reference substance certified to Amiodarone hydrochloride for testing physical chemists, packaged in bottles containing approximately 60 mg each-Amiodarone hydrochloride
DISPOSITION 3208/05	Public health-set as reference to Enalapril maleate for testing physical substance chemical
DISPOSITION 1927/05	Established as reference substance of furosemide to trials physicochemical
DISPOSITION 5535/04	Settles the second reference substance of NEOMYCIN for microbiological evaluations, packaged in vials ampoules containing approximately 300 mg each of NEOMYCIN sulfate
DISPOSITION 4198/04	Settles as first reference substance to VANCOMYCIN, for microbiological assessment
DISPOSITION 1489/04	Settles as a drug reference to the substance of CIPROFLOXACIN hydrochloride for testing physical-chemical, packaged in vials ampoules
DISPOSITION 998/04	Medicinal products set as first reference substance to streptomycin for microbiological assessments
DISPOSITION 5249/03	Set as first substance of reference to gentamicin for microbiological assessment, which has been packaged in vials ampoules containing approximately 300 mg each, to which has been assigned a power of 669 µg/mg gentamicin, expressed as on the dried substance
DISPOSITION 1507/02	Established as drug official reference to the substance metronidazole, to physico - chemical testing, as a in vials ampoules containing approximately 300 mg each and a title of 100.1%
DISPOSITION 5358/12	Approving the good practices of pharmacovigilance that annex I of this provision, which will be mandatory for holders of authorization for registration and marketing of pharmaceutical products
DISPOSITION 6083/09	ESPECIALIDADES MEDICINALES adopted the "program of intensive pharmacovigilance of prevention of pregnancy in women in fertile age who are prescribed isotretinoin systemic"
DISPOSITION 7720/06	Pharmaceutical products. Established medical specialties containing as active principle Thalidomide accession intensive pharmacovigilance program when it is indicated for any other illness other than the Erythema Nodosum lepromatous, in terms the provision no. 2552/95
DISPOSITION 4087/03	Joining the Nimesulide drug surveillance, controlled by the national pharmacovigilance system
DISPOSITION 2438/00	Accepted annex I of this provision as a guide of the pharmaceutical industry for participation in the national system of pharmacovigilance
DISPOSITION 935/00	Approval of the updated programme of monitoring for outpatient and treated with clozapine
RESOLUTION 498/08	Resolution 498/2008 standards national immunization adopted V update national standards of vaccination; regulations that will be incorporated into the national programme of Control warranty
DISPOSITION 705/05	Requirements for the registration of vaccines. Presentation of the technical documentation. Processing establishments. Forms
DISPOSITION 3962/17	Set is a procedure optional of pending unified for the request of registration in the registration and its authorization of marketing (first batch) of specialties medicinal elaborate and marketed in the country, as facturas, and whose active pharmaceutical ingredients (IFAs), are of proven efficacy and safety and condition of free sale
DISPOSITION 2038/17	Established that the holders of certificates enrolled in the registry of medicinal specialties (REM) which are marketed character shall notify this national administration the circumstances or facts under his knowledge that could put at risk the supply of products and cause your temporary or permanent discontinuity in the market
CIRCULAR 06/16	Procedures for change of ownership of pharmaceutical products
CIRCULAR 13/16	Attestation of certificates (available ANMAT No. 3366/12)
CIRCULAR 10/16	Records under special conditions
DISPOSITION 7030/15	This provision shall apply to submissions vending, in terms of its content expressed in units, ml, grams, etc., of those pharmaceutical products registered or entered in the register of medicinal specialties (REM), which active pharmaceutical ingredient (IFA) have antimicrobial activity
DISPOSITION 4622/12	Create the Committee assignment and evaluation of medicinal products that must be registered "Under special conditions"
DISPOSITION 2066/09	Pharmaceutical products limit the validity of the provision A.N.M.A.T. No. 818/98 which established requirements for information and documentation for a new registration in the register of pharmaceutical products
DISPOSITION 3022/06	ANMAT - medicinal specialties approve the operational procedure for the management of the procedures for dealing with requests for extension to testimonies of inscription in the registry of medicinal specialties of ANMAT (REM), for the export of products
DISPOSITION 1907/06	Approve the procedure operational for the management of the procedures for dealing with applications for unification of certificates of authorization of pharmaceutical products registered in the register of the ANMAT (REM), appearing as annex I to this provision and that is part of the same
DISPOSITION 163/03	Establishment requirements documentation to provide for the processing of requests for extension to testimonies of registration in the register of medicinal specialties (REM), for the export of products and information to overturn
DISPOSITION 818/98	Specialty medical establishment of information and documentation requirements for a new registration of medicinal specialties of specialty whose registration was cancelled
DISPOSITION 5755/96 (WITH AMENDMENTS TO THE DISP. ANMAT 1646/97)	Standard application to the management of the procedures for dealing with applications for registration of pharmaceutical products framed in articles 3, 4 and 5 of the Decree 150/92
DISPOSITION 858/89	MEDICINAL specialties registration transfer presentation that must be made to apply for the registration of transfer of a certificate authorizing

DISPOSITION 857/89	SPECIALTIES medicinal name change presentation that must be made to request the change of name of a medical-specialty
DISPOSITION 856/89	SPECIALTIES Medical Director technical presentation that must be carried out for the approval of the change of Technical Director of a lab producer of pharmaceutical-products
DISPOSITION 855/89	SPECIALTIES medicinal presentation of sale.-presentation which must be made to seek approval of a new presentation of sale regarding the content in units, ml, grams, etc
DISPOSITION 854/89	SPECIALTIES medicinal laboratory producer presentation to change it will be for the approval of change of laboratory producer of a medical specialty
DISPOSITION 853/89	ESPECIALIDADES MEDICINALES - excipient change or container-presentation that must be performed to request approval of a change of excipient or container
DISPOSITION 617/11	Suspend the marketing and the use, throughout the national territory, of all pharmaceutical products containing lindane as active pharmaceutical ingredient (IFA), in all of its pharmaceutical forms, concentrations and presentations
DISPOSITION 6533/10	Suspended the importation of active pharmaceutical ingredient SIBUTRAMINE (IFA) and the production, import, marketing, distribution and use, throughout the national territory, of all pharmaceutical products containing it as monofármaco or in association and in all of its pharmaceutical forms"
DISPOSITION 4430/09	Pharmaceutical products suspended the marketing and use in the whole country of all pharmaceutical products containing Nimesulide as ingredient pharmaceutical active (IFA) only or in partnership, in all its forms pharmaceutical
DISPOSITION 1743/09	Suspend the marketing and sale of RAPTIVA, medical specialty whose active drug ingredient is Efalizumab
RESOLUTION 1645/08	Prohibit the manufacture, marketing and use of ephedrine as monodroga. Exception
DISPOSITION 6238/08	Prohibited use and commercialization, and ordered the removal of market of the medicinal product labeled as Rimonabant
DISPOSITION 7398/07	Preventively suspended marketing, in any form, in concentrations of 100 mg and 400 mg of the pharmaceutical products containing as active ingredient Lumiracoxib
DISPOSITION 6628/07	Pharmaceutical products preventively suspended the production, marketing, distribution and dispensing of medicinal specialties containing aprotinin as monodroga or in association
DISPOSITION 5136/07	Preventive suspension of Clobutinol
DISPOSITION 5034/07	Pharmaceutical products suspended trade, marketing in any form of the concentration of 200 mg of the pharmaceutical products containing as a principle active Lumiracoxib
DISPOSITION 3110/07	Suspend the processing, marketing, distribution and dispensing of medicinal specialties containing as a principle active TEGASEROD
DISPOSITION 1955/07	Preventively suspended the production, marketing, distribution and dispensing of medicinal specialties containing as active ingredient pergolida
DISPOSITION 3435/06	Suspendese preventive registration, processing, marketing, distribution and dispensing of medicinal specialties containing CISAPRIDE, such as monodroga or other principles associated assets
DISPOSITION 2060/05	Prohibition principle active VALDECOXIB
DISPOSITION 5997/04	Prohibition principle active ROFECOXIB
DISPOSITION 4327/03	Prohibition principle active ASTEMIZOLE
DISPOSITION 6809/01	Prohibition of use and commercialization of the drug PHENYLPROPANOLAMINE
DISPOSITION 2227/98	Adopted a new list of dyes synthetic and its aluminium lacquers for use in pharmaceutical products for oral administration
DISPOSITION 2009/07	Establishment guidelines, documentation, and requirements to file for the authorization of drugs intended to be administered to human beings with diagnostic or monitoring products for diagnostic use so-called "in vivo"
RESOLUTION 102/98	Pharmaceutical products establish a regulation which specifically regulates the registration, preparation, fractionation, marketing or importation of products of diagnostic use "in vivo"
DISPOSITION 8277/11	Established that the primary packaging - blister - solid oral dosage forms that are intended for the use and hospital distribution, shall be punched in order to allow the division of the primary container in each dosage unit, preserving the unique identification, traceability and shelf life of the product
DISPOSITION 11857/17	Must be used closed infusion system in replacement of the open system. Approve the document "Solutions parenteral large volume in system closed"
DISPOSITION 1149/97	Approve the document 1/91 solutions for high-volume application is mandatory for all companies for manufacture, import and/or distribution of this product enabled
DISPOSITION 1682/12	Approving the requirements and guidelines contained as an annex to this provision which forms an integral part of it, on quality assurance and good manufacturing practice applicable to blood banks in its character of establishments Suppliers of human Plasma as a starting Material for the production of blood products
DISPOSITION 1582/12	Establishment scientific and technical requirements and specific requirements for the approval of operating blood banks
DISPOSITION 8278/08	Establishment conditions and colours that must carry the labels of the primary packaging of parenteral solutions of electrolytes of small volume, in accordance with Annex I to this provision
DISPOSITION 7266/08	Available 7266/08 adopted orphans, elaborate the operating procedure for the processing of applications for authorization of distribution with interprovincial transit and/or between provinces and the autonomous city of Buenos Aires, of lots of drugs in Laboratories of public production of medicines, not enrolled in the register of specialties medicinal (REM) of the A.N.M.A.T submitted by national or provincial government agencies or from the city of Buenos Aires, which, as annex I, is part integral of This provision, to cover emergency health risk or lack of productos
RESOLUTION 505/06	PUBLIC health - SADS-s - Adoptanse measures in connection with the sending of data and information by the companies producing drugs with inhalers, relative to the treatment of asthma and chronic Neuropathies obstructivas
DISPOSITION 2592/03	Preparation, control, distribution and marketing in national jurisdiction or destined for interprovincial trade in medicaments classified as mixtures of extemporaneous Parenteral Nutrition. Establishments enabled
DISPOSITION 2476/03	Establishments-physiologic solutions to Nebulize-processors enabling
DISPOSITION 4373/02	Technical standards for the development of medical oxygen through air separation by adsorption PSA. General requirements. Quality control of the finished product. Requirements of control of quality

DISPOSITION 3429/00	Set the mandatory declaration of the content of alcohol ethyl to the leaflets/information of medications that contain it. (Note: repealed by art.6 available ANMAT nro.1206-2002 b.o.12-04-2002)
RESOLUTION 1130/00	Regulation for medicinal Gases
DISPOSITION 617/99	The pharmaceutical products containing active ingredients phenolphthalein and/or dantrona, alone or in partnership, will have condition of sale "Low recipe", without exception
DISPOSITION 3779/98	General for the production of blood plasma-origin products SPECIALTIES medical establishment rules
DISPOSITION 2227/98	Pharmaceutical products adopted a new list of synthetic dyes and its aluminium lacquers for use in pharmaceutical products for oral administration
DISPOSITION 2795/97	It determined a standard on the manufacturing, marketing and distribution of concentrated solutions and mixtures salinas, to be used in the hemodialysis
RESOLUTION 508/94	They are subject to the present Res. fractionation, container and tank for the marketing and the sale to ethyl alcohol (ethanol) which is intended for use in cosmetics and human medicine and visible or legal persons involved in such activities
DISPOSITION 753/12	Establishment definitions and guidelines general information which shall include leaflets/tags/labels of condition of over-the-counter pharmaceutical products
DISPOSITION 6907/10	Laboratories holders of certificates of pharmaceutical products containing PSEUDOEPHEDRINE active ingredients, allowed or pending authorization, shall include the information contained in annex I, which forms in prospectuses an integral part of this provision"
DISPOSITION 751/09	Establish the condition of sale under prescription filed for all medical specialties containing pharmaceutical active Carisoprodol ingredient as facturas or in association
DISPOSITION 555/09	Pharmaceutical products established information that shall contain leaflets of medicinal specialties containing Zolpidem active principle
DISPOSITION 7726/07	Laboratories holders of certificates of pharmaceutical products containing STRONTIUM RANELATE as an active ingredient, they should add in the prospectus and the date authorized in highlighted form, as stated in annex I of this provision, forming an integral part of it
DISPOSITION 6290/07	Pharmaceutical products - Establish that laboratories holders of certificates of pharmaceutical products containing oral fluoroquinolones, ciprofloxacin, levofloxacin, Moxifloxacin and Ofloxacin should add in the prospect in highlighted form, information related to warnings and precauciones
DISPOSITION 5555/07	Pharmaceutical products established laboratories holders of certificates of pharmaceutical products containing gadolinium derivatives in any form shall add the package leaflet / Manual authorized use to date, in the form highlighted the warnings, precautions, and contraindications
DISPOSITION 5554/07	SPECIALTIES medicinal establish is that them laboratories holders of certificates of specialties medicinal that contain as principle active Escitalopram, indicated in the treatment of the disorder depressive greater and of maintenance for the relapse prevention, treatment of disorders of anxiety with or without agoraphobia, social phobia, generalized anxiety treatment must adapt their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects
DISPOSITION 5553/07	Pharmaceutical products establish that laboratories holders of certificates of pharmaceutical products containing as active ingredient Citalopram, indicated for the treatment of major depressive disorder, also indicated in the treatment of the disorder of anxiety (panic disorder) with or without agoraphobia, and in the treatment of obsessive-compulsive disorder, must modify their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects
DISPOSITION 5363/07	Pharmaceutical products established laboratories holders of certificates of pharmaceutical products containing as active ingredient Cabergoline, indicated in the treatment of Parkinson's disease, should change their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects
DISPOSITION 4719/07	Laboratories holders of certificates of pharmaceutical products containing OLIGO or as facturas or in associations, must add in the prospect to the date authorized, in highlighted form, warning that accompanies as annex I of this provision, and which forms an integral part of it
DISPOSITION 4372/07	Laboratories holders of certificates of pharmaceutical products containing active substance RIMONABANT should add in prospectus and the date authorized in highlighted form, as stated in annex I of this provision, shaping an integral part of the same
DISPOSITION 2123/07	Especialidades Medicinales.-modification of prospects beginning active methylphenidate and ATOMOXETINE indicated in the treatment of attention Deficit with hyperactivity-disorder
DISPOSITION 4562/06	Establish that laboratories holders of certificates of pharmaceutical products containing active substance in raloxifene, they must add in the prospect, in highlighted form, a warning of use
DISPOSITION 4525/06	Establish that laboratories holders of certificates of pharmaceutical products containing as active inhibitors type 5 Phosphodiesterase (PDE5), which are known to Sildenafil, Tadalafil or Vardenafil, must add in the prospectus, in highlighted form, a warning of use
DISPOSITION 3059/06	ESPECIALIDADES MEDICINALES - ANMAT - requirements that must be met laboratories holders of certificates of pharmaceutical products containing as a principle active only or associated with ibuprofen for intramuscular administration and endovenosa
DISPOSITION 7908/04	Modification of certain antidepressants such as paroxetine-prospects
DISPOSITION 1863/02	Established that the pharmaceutical products containing TRAMADOL as an active ingredient, should include the legend: "shows medical restricted."
DISPOSITION 1206/02	ESPECIALIDADES MEDICINALES established that the condition of over-the-counter specialties signs/labels or prescription, whose pharmaceutical form is liquid for parenteral or oral administration with ethyl alcohol in its formulation, must be declare the content thereof specified in % weight/volume
DISPOSITION 1970/01	Information that shall include the prospects of pharmaceutical products containing active substance hypericum perforatum-St. John's wort
DISPOSITION 1879/99	Information to be included, laboratories holders of certificates of pharmaceutical products containing as a principle active chlorzoxazone
DISPOSITION 1210/99	Information to be included in their leaflets, laboratories holders of certificates of pharmaceutical products containing as a principle active sildenafil
DISPOSITION 5214/98	Information to be included in prospectuses, laboratories holders of certificates of pharmaceutical products containing, alone or associated, as a principle active ginseng

DISPOSITION 3855/98	Mechanism to include information in prospectuses
DISPOSITION 593/98	Requirements that must comply with the labeling and packaging bags plastic used for the collection, storage, processing, and administration of blood
DISPOSITION 7096/97	Information that must be included in your prospect, laboratories holders of certificates of pharmaceutical products containing as active ingredient loperamide
DISPOSITION 4538/97	Modification provision 5904/96-limited art 2
DISPOSITION 2574/97	Information that must be included in your prospect, the laboratories holders of certificates of those specialties that contain as principle active Doxazosin
DISPOSITION 5904/96	Definition and guidelines about how information in leaflets include
DISPOSITION 5510/96	Information that must complete laboratories holders of those specialties containing active ingredients melatonin
DISPOSITION 5104/96	Information that should be disseminated through the prospect in the pharmaceutical products containing their actives to lindane
DISPOSITION 4856/96	Approve the model prospectus for those containing pyrethrins
DISPOSITION 3918/96	Information that should fill them laboratories holders of certificates of those specialties that contain between their principles active the drug Oxybutynin
DISPOSITION 3288/96	Information that laboratories holders of certificates of related specialties, containing Tretinoin for topical use in all their concentrations among its active principles must be completed
DISPOSITION 388/93	Laboratories holding certificates of pharmaceutical products containing as, or in its active principles to drug ketorolac, the only prospect that transcript appears in annex 1 of this provision should be adopted
DISPOSITION 573/88	Package inserts that accompany blood products, derived from placenta, glands, and other raw materials of human origin, should include a warning about the possible risks to the recitals of the present allude

Source: ANMAT. Prepared by CCGI-EESP/FGV.

Table 14.26 - Standards on Pharmaceuticals (Argentina)

STANDARDS	DESCRIPTION
IRAM- 37001-1	Medicaments. Good manufacturing practices. Aseptic processing of small volume solutions. Directives relating to the design, building specifications, operation conditions and the maintenance of manufacturing area.
IRAM- 37001-2	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37001-3	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives relating to the design and maintenance of equipment in the processing area.
IRAM- 37001-4	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37001-5	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for labeling and packaging.
IRAM- 37001-6	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for quality assurance.
IRAM- 37001-7	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for the quality control laboratory.
IRAM- 37002	Medicines. Water for the preparation of injectables of small volume.
IRAM- 37003-1	Medicines. Small volume injectable solutions Production with terminal sterilization. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37003-2	Small volume medications Production with terminal sterilization. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37003-3	Small volume medications Production with terminal sterilization. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37003-4	Small volume medications Production with terminal sterilization. Directives to prepare documentation and records related to the preparation area.
IRAM- 37003-5	Small volume medications Production with terminal sterilization. Guidelines for labeling and packaging.
IRAM- 37003-6	Small volume medications Production with terminal sterilization. Directives for quality assurance.
IRAM- 37003-7	Small volume medications Production with terminal sterilization. Directives for the quality control laboratory.
IRAM- 37004	Medicines. Good manufacturing practices. Liquid injectables of small volume. Process validation
IRAM- 37006-1	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37006-2	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37006-3	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37006-4	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37006-5	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Guidelines for labeling and packaging.
IRAM- 37006-6	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for quality assurance.
IRAM- 37006-7	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for the quality control laboratory.
IRAM- 37009-1	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37009-2	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives relating to the suitability, responsibility, hygiene, safety and clothing of the staff of the processing area.
IRAM- 37009-3	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for the design, maintenance and cleaning of the equipment in the processing area.

IRAM- 37009-4	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37009-5	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Guidelines for labeling and packaging.
IRAM- 37009-6	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for quality assurance.
IRAM- 37009-7	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for the quality control laboratory.
IRAM- 37010	Medicines. Criteria for selection, approval and qualification of suppliers. Conditioning materials for the pharmaceutical industry.
IRAM- 37011-1	Medicines. Good manufacturing practices. Process control Oral solid pharmaceutical forms. Directives for the control of the process.
IRAM- 37011-2	Medicines. Good manufacturing practices. Process control Oral solid pharmaceutical forms. Parameters to be controlled.
IRAM- 37012	Medicines. Good manufacturing practices. Oral solid pharmaceutical forms. Validation of processes.
IRAM- 37013-1	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for the design, construction specifications, operating conditions and maintenance of the processing area
IRAM- 37013-2	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37013-3	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37013-4	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37013-5	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Guidelines for labeling and packaging.
IRAM- 37013-6	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for quality assurance.
IRAM- 37013-7	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for quality control.
IRAM- 37014-1	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for design, construction specifications, conditions. of operation and maintenance of the area.
IRAM- 37014-2	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37014-3	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for the design, maintenance and cleaning of the processing area.
IRAM- 37014-4	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37014-5	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Guidelines for labeling and packaging.
IRAM- 37014-6	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for quality assurance.
IRAM- 37014-7	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for the quality control laboratory.
IRAM- 37015-1	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the design, specifications for the construction, operating conditions and maintenance of the area
IRAM- 37015-2	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37015-3	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37015-4	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives to prepare documentation and records related to the preparation area.
IRAM- 37015-5	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for labeling and packaging.
IRAM- 37015-6	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for quality assurance.
IRAM- 37015-7	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the quality control laboratory.
IRAM- 37016-1	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use.
IRAM- 37016-2	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use directed regarding the suitability, responsiveness, hygiene and dress of the personnel affected to the area of the elaboration.
IRAM- 37016-3	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37016-4	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use.
IRAM- 37016-5	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for labeling and packaging.
IRAM- 37016-6	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for quality assurance.
IRAM- 37016-7	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for the quality control laboratory.
IRAM- 37017-1	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the design, construction specifications, operating conditions and maintenance of the pharmaceutical plant.

IRAM- 37017-2	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives regarding the suitability, responsibility, hygiene and clothing of the staff of the pharmaceutical plant.
IRAM- 37017-3	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the design, maintenance and cleaning of the equipment of the pharmaceutical plant.
IRAM- 37017-4	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37017-5	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for labeling and packaging.
IRAM- 37017-6	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for quality assurance.
IRAM- 37017-7	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the quality control laboratory.
IRAM- 37018-1	Medicines. Conservation of the cold chain in its distribution. Storage.
IRAM- 37018-2	Medicines. Conservation of the cold chain. Transport and distribution.
IRAM- 37023	Medicines. Criterion of selection, approval and qualification of suppliers. Storage, distribution and transport for the pharmaceutical industry.
IRAM- 37024-1	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37024-2	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37024-3	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives relating to the design and maintenance of equipment in the processing area.
IRAM- 37024-4	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37024-5	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for labeling and packaging.
IRAM- 37024-6	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for quality assurance.
IRAM- 37024-7	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for the quality control laboratory.
IRAM- 37025-1	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37025-2	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37025-3	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives relating to the design, maintenance and cleaning of the processing area.
IRAM- 37025-4	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives to prepare documentation and records related to the preparation area.
IRAM- 37025-5	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Guidelines for labeling and packaging.
IRAM- 37025-6	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for quality assurance.
IRAM- 37025-7	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for quality control.
IRAM- 37026	Medicines. Good manufacturing practices in the preparation of medicines. Validation of cleaning procedures for equipment and accessories.
IRAM- 37031	Medicines. Traceability management system in the pharmaceutical chain.
IRAM- 37400	Administration of intravenous medications to patients with HIV + and AIDS. Security criteria
IRAM- 37401	Antineoplastic drugs. Preparation, storage, transportation and administration. Security and biosafety criteria.
IRAM- 9800-3	Good pharmaceutical practices Part 3 - Drugs in the pharmacy.

Source: IRAM. Prepared by CCGI-EESP/FGV.

14.8. Appendix 8 - Plastic

Table 14.27 - Standards on Plastic (Brazil)

STANDARD	CONTENT
ABNT NBR 14474:2018	Plastic films-determination of resistance to static puncture
ABNT NBR 15107:2017	Shredders for plastics machines — safety requirements for granulators and shredders
ABNT NBR 11992:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes by water blast — determination of the coefficient of friction
ABNT NBR 11993:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes by water blast — determination of the resistive force on passing through PVC TILDE
ABNT NBR 11996:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes, water blast — determination of bursting pressure after 1 000 cycles of flexion
ABNT NBR 14952:2017	Injected plastic pails for industrial use-requirements and test methods
ABNT NBR ISO 7206-2:2012	Implants for surgery--partial and total Prosthesis of hip joint
AMENDMENT 1:2017	Part 2: joint surfaces made of metallic material, ceramic and plastic
ABNT NBR ISO 7206-2:2017	Implants for surgery--partial and total Prosthesis of hip joint
	Part 2: joint surfaces made of metallic materials, ceramic and plastic
ABNT NBR 11995:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes for water-determination of resistance to hydrostatic pressure internally
ABNT NBR 16578:2017	Plastic glazing applied to road vehicles — requirements and test methods
ABNT NBR 11991:2017	Sanitary appliances plastic material-verification of mechanical characteristics
ABNT NBR 12450:2017	Monolithic sink plastic -material Dimensions
ABNT NBR 12451:2017	Material plastic tub to sink-dimensions
ABNT NBR 11994:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes for water-verification of resistance to abrasion
ABNT NBR 7394:2017	Traffic safety-Ballasts in plastic holder
ABNT NBR ISO 7207-2:2013	Implants for surgery--partial and total prosthesis components of knee joint
AMENDMENT 1:2016	Part 2: joint surfaces made of metal, ceramic and plastic materials
ABNT NBR ISO 7207-2:2016	Implants for surgery-partial prosthesis components and total knee joint
	Part 2: joint surfaces made of metal, ceramic and plastic materials
ABNT NBR 16544:2016	Copper and copper alloys-connections with compression terminals for use with plastic and multilayer tubes-Requirements
ABNT NBR ISO 3126:2016	Plastics piping systems--plastics Components-determination of dimensions
ABNT NBR 11479:2016	Motor road vehicles-fuel tank plastic -determination of resistance to fire
ABNT NBR 16491:2016	Implants for surgery-polymeric materials-Radiopacity of plastics
ABNT NBR 11473:2016	Fuel tank plastic for motor road vehicles-determination of resistance to impact
ABNT NBR 15870:2016	Horizontal road signs-cold Plastic resin based reactive metacrilicas-supply and application
ABNT NBR 13536:2016	Safety of machinery — plastic and rubber injection molding machine
ABNT NBR 15057:2016	Plastic containers for transport and/or storage of liquefied petroleum gas (LPG)-design, manufacturing and inspection
ABNT NBR 16242:2016	Plastic pallets-requirements and test methods
ABNT NBR NM 337:2014	Non-destructive testing-acoustic emission Testing (EA) in pots and plastic tanks reinforced with fiberglass (FRP)-Procedure
1:2015 ERRATA	
ABNT NBR NM 337:2014	Non-destructive testing-acoustic emission Testing (EA) in pots and plastic tanks reinforced with fiberglass (FRP)-Procedure
CORRECTED VERSION: 2015	
ABNT NBR 15174:2014	Metallic and plastic components for footwear and artifacts-Buckles, ornaments and trailers/fenders-determination of tensile strength and compression
ABNT NBR 15804-2:2013	Polymeric materials for medical applications
	Part 2: specification for polyethylene plastics for short-term Implantable devices

Table 14.28 - Plastic Standards (Argentina)

NAME	DESCRIPTION
IRAM-NM 337	Non-destructive tests. Test of acoustic emission (EA) in containers and tanks of reinforced plastic with fiber of glass (PRFV). Procedure.
IRAM-ISO 1133-1	Plastics. Determination of the index of mass flow (IFM) and of the index of volume flow (IFV) of thermoplastics. Part 1 – normalized method.
IRAM-ISO 1167-1	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 1 – General method.
IRAM-ISO 1167-2	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 2 – Preparation of the test tubes of tubes.
IRAM ISO 1167-3	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 3 – Preparation of components.
IRAM-ISO 1167-4	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 4 – Preparation of the mounting.
IRAM-1211	Thermoplastic coverings to pavement demarcation.
IRAM-1212	Reflecting thermoplastic coverings to pavement demarcation.
IRAM-1737	Thermal insulating materials. Cell plastics. Determination of apparent density.

IRAM-1745	Thermal insulating materials. Cell plastics. Determination of compression for rigid materials.
IRAM-1746	Thermal insulating materials. Cell plastics. Tests of dimensional stability.
IRAM-1747	Thermal insulating materials. Cell plastics. Determination of the temperature that produces permanent deformation on rigid materials submitted to compression.
IRAM-1749	Thermal insulating materials. Cell plastics. Determination of the apparent density by the displacement of the water.
IRAM-1861	Thermal insulating materials. Determination of absorption of water on cell plastics for use in thermal insulators.
IRAM-1863	Thermal insulating materials. Determination of the content of closed cells on cell plastics.
IRAM-2179	Cables of energy insulated with excluded solid dielectric. Test methods for insulators and wrappers (elastomeric and thermoplastic compounds).
IRAM-2217	Thermoplastic materials and synthetic rubber for coverage of electric cables with metal sheath.
IRAM-2350	Light naval cable with conductors of copper insulated with thermoplastic material based on polyvinyl chloride.
IRAM-ISO 3126	Systems of plastic tubes. Plastic components. Determination of measures.
IRAM-3548	Sleeves for fire extinguishing of synthetic fibers (polyesters, polyamide and its mixtures), covered internally with a flexible plastic material or with an elastomer.
IRAM-3574	Safety protections on machines. Molding machines for the insertion of plastic material and rubber.
IRAM-3633	Simple portable ladders of reinforced plastic with characteristics of safety, mainly electrical.
IRAM-3634	Simple portable ladders, of extension, of reinforced plastic with characteristics of safety, mainly electrical.
IRAM-6017	Screw cap of rigid plastic for glass recipients. Dimensions.
IRAM-FA L 7678	Cloth coated with vinyl plastic for seat upholstery.
IRAM-9021	Plastic sterile equipment for the extraction of blood applied on transfusions, applied with vacuum glass jar and to be used only once.
IRAM-9022	Plastic sterile equipment for transfusion of blood or of derivatives of blood to be used only once.
IRAM-9023	Plastic sterile equipment for the management of parenteral solutions to be used only once.
IRAM-9025-1	Plastic material for medicinal use. Biologic test methods: toxicological tests.
IRAM-9025-2	Plastic material for medicinal use. Biologic test methods: tests of pyrogens and bacterial endotoxins.
IRAM-9025-3	Plastic material for medicinal use. Methods of biological test. Tests of sterility.
IRAM-9037	Discardable sterile syringe, of plastic material, for insulin. Characteristics and test methods.
IRAM-9406-1	Surgical implants. Metallic materials. Alloys based on cobalt. Part 1: alloy of cobalt, chrome, nickel, molybdenum and iron to forge and form plastic at low temperatures.
IRAM-ISO-9854-1	Thermoplastic tubes for the transport of fluids. Determination of resistance to impact of the pendulum through the Charpy method. Part 1 – Method of general test.
IRAM-ISO-9854-2	Thermoplastic tubes for the transport of fluids. Determination of resistance to impact of the pendulum through the Charpy method. Part 2 – Test conditions for tubes of different materials.
IRAM-10501	Geotechnics. Method of determination of the liquid limit and of the plastic limit of a sample of the soil. Index of fluidity and index of plasticity.
IRAM-12523	Refractory materials. Refractory silica-aluminous and of high alumina plastic.
IRAM-12524	Refractory materials. Method of determination of the index of workability of refractory plastic and refractory tampers.
IRAM-12553	Refractory materials. Plastic and tampers materials that are refractory, silica-aluminous and of high alumina. Method of determination of permanent linear variation for drying and cooking.
IRAM-12563	Refractory concrete and refractory plastic. Method of determination of thermal conductivity.
IRAM-12609	Refractory materials. Refractory plastics and tampers. Method for determination of disintegration through thermal shock.
IRAM-13015	Plastics in general. Profiles of non-plasticized polyvinyl chloride for rolled up curtains. Requisites.
IRAM-13100	Plastic bags for family residues.
IRAM-13130	Sleeves of polyvinyl chloride or other thermoplastics with textile reinforcement. Internal diameters and discrepancies on longitudes.
IRAM-13131	Sleeves of polyvinyl chloride or other thermoplastics with textile reinforcement for air, water and non-corrosive liquids in general.
IRAM-13240	Plastics in general. Determination of the final degradation of flexible plastics of polyethylene (PE) and polypropylene (PP) under conditions of exposition to ultraviolet light (UV). Method through elongation at break.
IRAM-13251	Rigid cell plastics. Method of determination of the apparent density.
IRAM-13272	Bottles of plastic material. Method of determination of the seal tightness.
IRAM-13273	Bottles of plastic material. Method of compression test.
IRAM-13274	Bottles of plastic material. Method of impact test through accumulated falls.
IRAM-13276	Bottles of plastic material. Method of determination of fatigue resistance produced by the transport.
IRAM-13303	Plastics. Normal atmospheres to conditioning and tests of plastic materials.
IRAM-13304	Plastics. Recommended method to molding through compression of test tubes of thermoplastic materials.
IRAM-13305	Plastics. General principles to molding through injection of test tubes of thermoplastic materials.
IRAM-13306	Plastics. General principles to molding through compression of test tubes of thermo-rigid materials.
IRAM-13307	Plastics. Method of determination of the content of soluble materials in methanol of unmodified polystyrene.
IRAM-13308	Plastics. Method of determination of the content of free phenols on pieces molded of phenolic plastics.
IRAM-13309	Plastics. Method of determination of the content of free ammonia and ammonia components on pieces molded of phenolic plastics.
IRAM-13310	Plastics. Method of determination with Wijs solution of the content of styrene on unmodified polystyrene.
IRAM-13311	Plastics. Method of determination of soluble material on acetone on materials of phenolic molding.
IRAM-13312	Plastics. Qualitative method to determine free ammonia or other volatile basis on components molded of phenolic plastics.
IRAM-13313	Plastics. Method of red congo to the determination of the thermal stability of related copolymers of polyvinylchloride and its components.
IRAM-13314	Plastics. Method of change of color to the determination of the thermal stability of related copolymers of polyvinylchloride and its components.
IRAM-13315	Plastics. Polyethylene and components of polyethylene. Method of determination of the index of hot fluidity.
IRAM-13316	Plastics. Traction tests.
IRAM-13317	Tubes and accessories of thermoplastic material. Determination of the temperature softening Vicat.

IRAM-13318	Plastics. Method of determination of soluble materials in water and water absorption.
IRAM-13319	Plastics. Method of determination of the black of the smoke and its degree of dispersion on components of polyethylene.
IRAM-13320	Plastics. Methods of determination of antioxidants on components of polyethylene.
IRAM-13321	Plastics. Method of granulometric analysis of homopolymer resins or copolymers of polyvinylchloride.
IRAM-13322	Pieces of connection of rigid plastic material of plug for rigid plastic tubes applied on the conduction of fluids under pressure. Basic dimensions.
IRAM-13327	Plastics. Method of determination of absorption of boiling water.
IRAM-13328	Plastics. Method of determination of apparent density of molding materials capable of drain through a specific funnel.
IRAM-13329	Plastics. Method of determination of the index of viscosity of polyamide resins on diluted solutions.
IRAM-13332	Plastics. Method of determination of the temperature of deformation under load.
IRAM-13334	Plastics. Method of determination of the index of viscosity of homopolymer or copolymer resins of polyvinylchloride on solution.
IRAM-13335	Plastics. Test methods of resistance to chemical agents.
IRAM-13336	Plastics. Method of active carbon to determine the loss of plasticizers.
IRAM-13338	Plastics. Test method of flexion.
IRAM-13339	Plastics. Method of determination of extractable materials by water or ethyl alcohol on polyamide resins.
IRAM-13340	Plastics. Method of determination of resistance to Izod impact of rigid plastics.
IRAM-13341	Plastics. Method of determination of resistance to incandescence of self-extinguishing thermal-rigid plastics.
IRAM-13344	Plastics. Method to determine the changes on linear dimensions of blades or films of non-rigid thermoplastic materials.
IRAM-13347	Tubes and accessories of thermoplastic material. Determination of ashes.
IRAM-13348	Plastics. Method of determination of volatile materials on homopolymer or copolymer resins of polyvinylchloride.
IRAM-13349	Tubes of thermoplastic materials. Measures and nominal pressures.
IRAM-13352	Tubes of plastic material to conduction of drinking water. Bromatological requirements.
IRAM-13354	Plastics. Method of determination of strange materials on homopolymer or copolymer resins of polyvinylchloride.
IRAM-13355	Plastics. Method of determination of pH of watery extract of homopolymer or copolymer resins of polyvinylchloride.
IRAM-13356	Plastics. System of designation of resins of polyvinylchloride.
IRAM-13359	Pieces of connection of plastic material for tubes applied on conduction of drinking water. Bromatological requirements.
IRAM-13361	Thermal stable blade plastic, decorative. Method of determination of visible failures at a glance.
IRAM-13362	Thermal stable blade plastic, decorative. Method of determination of thickness.
IRAM-13363	Thermal stable blade plastic, decorative. Method of determination of superficial thermal resistance at 180°C.
IRAM-13364	Thermal stable blade plastics, decorative. Method of determination of dimensional stability.
IRAM-13365	Thermal stable blade plastics, decorative. Method of determination of moldability.
IRAM-13367	Thermal stable blade plastics, decorative. Method of determination of resistance to immersion in boiling water.
IRAM-13368	Thermal stable blade plastics, decorative. Method of determination of resistance to stained.
IRAM-13369	Thermal stable blade plastics, decorative. Test method of abrasion.
IRAM-13370	Thermal stable blade plastics, decorative. Test method of impact.

Source: IRAM. Prepared by CCGI-EESP/FGV.

PART II
MEXICO – COLOMBIA – CHILE

SECTION I - REGULATORY STRUCTURE

1. Economic Overview

The aim of this research is to examine how regulation, technical standardization and conformity assessment procedures (quality infrastructure system) adopted by Mexico Colombia and Chile can affect the international trade of these countries, especially in relation to Brazil, Argentina and Mercosur.

The first step of the analyses is to explore the trade flows among Brazil and these Latin American partners. The main destinations for Brazilian exports in 2018 are presented below.

Trade flows of Brazil

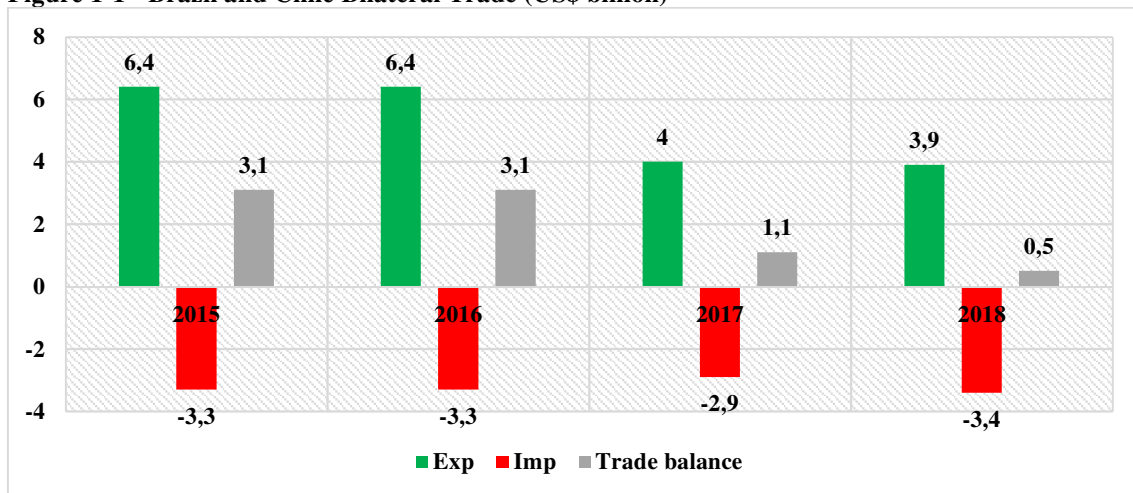
Table 1.1 - Brazil's main trading partners (Brazilian exports)

COUNTRIES	2018 - VALUE FOB (US\$)
1. CHINA	\$64.205.647.058
2. UNITED STATES	\$28.774.085.275
3. ARGENTINA	\$14.951.216.908
4. NETHERLANDS	\$13.068.031.040
5. CHILE	\$6.389.093.370
6. GERMANY	\$5.214.589.691
7. SPAIN	\$5.147.307.782
8. MEXICO	\$4.505.139.699
9. JAPAN	\$4.334.337.058
10. ÍNDIA	\$3.909.881.517
11. SINGAPORE	\$3.573.267.188
12. ITALY	\$3.560.280.793
13. SOUTH KOREA	\$3.437.332.669
14. CANADA	\$3.354.765.879
15. BELGIUM	\$3.198.649.428
16. URUGUAY	\$3.008.947.112
17. UNITED KINGDOM	\$2.985.888.930
18. PARAGUAY	\$2.945.451.249
19. COLÔMBIA	\$2.805.328.683

Source: ComexStat. Elaborated: CCGI-EESP/FGV.

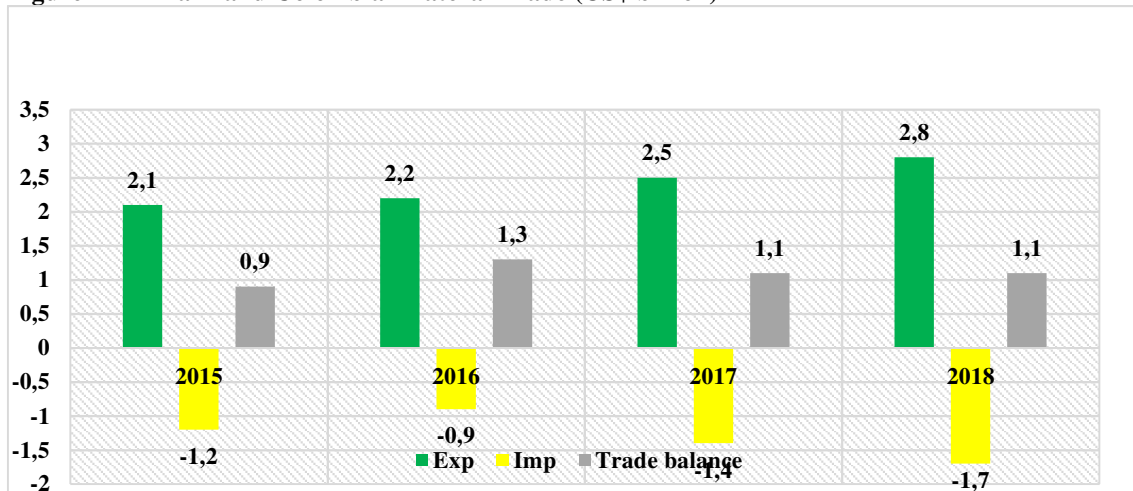
In bilateral trade, Brazil has had surpluses with Chile and Colombia. In the years 2015 and 2016, for example, Brazil presented a surplus of over US \$ 3 billion in trade relations with Chile. The relationship with Mexico is more balanced, because, in recent years, Brazil has alternated deficits and surpluses. In the case of Mexico, as inferred from the analysis of the bilateral trade pattern, the performance of the countries is strongly influenced by the commercialization of automotive goods, which occurs in a partially managed manner, according to the provisions of Economic Complementation Agreement n. 55, signed between Mexico and Mercosur, within the framework of ALADI.

Figure 1-1 - Brazil and Chile Bilateral Trade (US\$ billion)



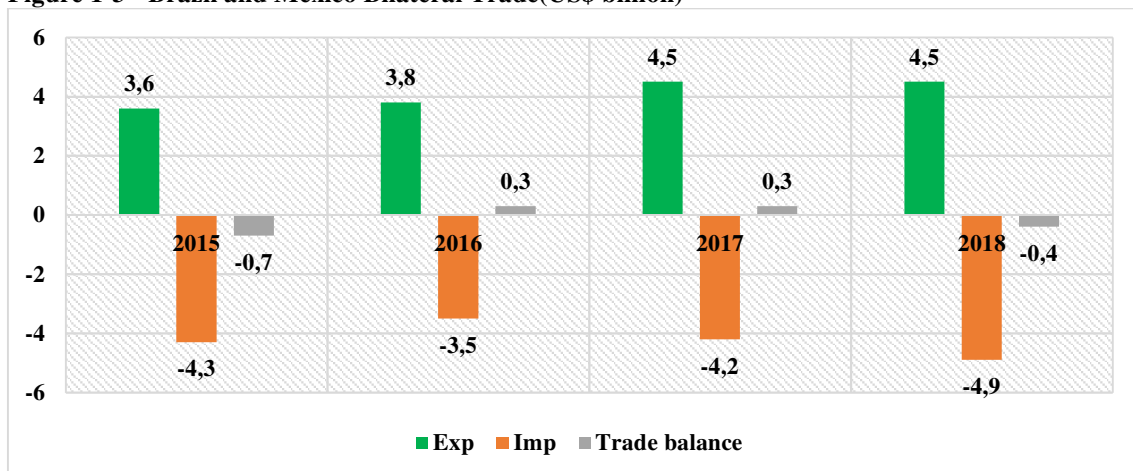
Source: ComexStat. Elaborated: CCGI-EESP/FGV.

Figure 1-2 - Brazil and Colombia Bilateral Trade (US\$ billion)



Source: ComexStat. Elaborated: CCGI-EESP/FGV.

Figure 1-3 - Brazil and Mexico Bilateral Trade (US\$ billion)



Source: ComexStat. Elaborated: CCGI-EESP/FGV.

The Brazilian trade with the three countries is quite diversified. Manufactured goods such as automotive vehicles (HS 87), mechanical and electrical (HS 84) and electrical (HS 85), basic

(HS 28 and 29) and processed (HS 30) chemicals, products minerals (e.g. HS 74), fossil fuels (HS 27), agricultural goods (e.g. HS 02, 03, 08).

The trade relations with Mexico, which is supported by three Agreements ACEs (n. 53, n. 54 and n. 55), totaled almost US \$ 10 billion in 2018. It is a pattern consisting predominantly of manufactured goods, with emphasis on automotive goods and electrical machinery and equipment. Trade in automotive goods totaled more than US \$ 3 billion in 2018, with a significant surplus for Mexico.

In trade with Chile⁶⁵, which is regulated by ACEs no. 35 and by more than sixty complementary agreements, in addition to manufactured products, it is highlighted the import of copper and other primary products (eg fruits and other minerals) and the export of fuels to the Andean country. In 2018, the trade flow between Chile and Brazil was close to US \$ 10 billion.

Although more modest, the trade flow between Brazil and Colombia, which occurs according to the provisions of ACE n. 59⁶⁶, has increased in a sustainable manner. The commercial pattern is also characterized by the strong predominance of manufactured products, including automotive vehicles, machinery and mechanical and electrical equipment, which are exported from Brazil to Colombia. Also noteworthy is the bilateral flow of processed and basic chemicals, which shows potential complementarity between this industrial branch in the two countries.

The table below details the main bilateral trade products between Brazil and the three selected countries, based on the two-digit classification of the Harmonized System:

Table 1.2 - Main trade products

Brasil → Chile (2018) (total: US 6,4 bi)			
Countries	Code SH2	Description SH2	2018 - Value FOB (US\$)
Chile	27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	\$2.070.194.562
Chile	87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$1.231.854.108
Chile	02	Meat and edible meat offal	\$636.071.041
Chile	84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof.	\$399.263.974
Chile	39	Plastics and articles thereof	\$268.773.440
Chile	48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	\$229.870.210
Chile	85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	\$195.096.930
Chile	72	Iron and steel	\$161.562.282
Chile	23	Residues and waste from the food industries; prepared animal fodder	\$126.944.697
Chile	29	Organic chemicals	\$73.583.56
Brasil ← Chile (US\$ 3,3 bi)			
Countries	Code SH2	Description SH2	2018 - Valor FOB (US\$)
Chile	74	Copper and articles thereof	\$1.161.805.739
Chile	03	Fish and crustaceans, molluscs and other aquatic invertebrates	\$584.546.911
Chile	26	Ores, slag and ash	\$416.069.773

⁶⁵ See Acordo de Complementação Econômica n. 35 – Mercosul/ Chile. Available in: http://www.aladi.org/biblioteca/publicaciones/aladi/acuerdos/ace/es/ace35/web/ACE_035_Acuerdo.pdf.

Additionally, see <http://www.itamaraty.gov.br/pt-BR/notas-a-imprensa/19656-conclusao-das-negociacoes-do-acordo-de-livre-comercio-entre-o-brasil-e-o-chile-santiago-16-a-19-de-outubro-de-2018>

⁶⁶ See Acordo de Complementação Econômica n. 59 celebrated between Mercosul, Colômbia, Equador e Venezuela. Available in: http://www.aladi.org/biblioteca/publicaciones/aladi/acuerdos/ace/es/ace59/ACE_059_Acuerdo_Texto.pdf.

Chile	29	Organic chemicals	\$191.013.477
Chile	08	Edible fruit and nuts; peel of citrus fruit or melons	\$168.024.029
Chile	22	Beverages, spirits and vinegar	\$146.211.305
Chile	31	Fertilisers	\$115.897.376
Chile	87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$88.108.177
Chile	73	Articles of iron or steel	\$65.949.889
Chile	39	Plastics and articles thereof	\$51.874.613
Brasil → Colômbia (US 2,8 bi)			
Countries	Code SH2	Description SH2	2018 - Valor FOB (US\$)
Colômbia	87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$463.890.600
Colômbia	84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$411.288.184
Colômbia	39	Plastics and articles thereof	\$278.335.736
Colômbia	72	Iron and steel	\$258.565.449
Colômbia	85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	\$127.594.918
Colômbia	40	Rubber and articles thereof	\$101.711.011
Colômbia	21	Miscellaneous edible preparations	\$100.850.490
Colômbia	48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	\$82.468.194
Colômbia	88	Aircraft, spacecraft, and parts thereof	\$73.254.594
Colômbia	30	Pharmaceutical products	\$69.696.803
Colômbia	38	Miscellaneous chemical products	\$69.132.669
Colômbia	33	Essential oils and resinoids; perfumery, cosmetic or toilet preparations	\$47.153.718
Colômbia	27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	\$46.224.360
Brasil ← Colômbia (US\$ 1,7 bi)			
Countries	Code SH2	Description SH2	2018 - Valor FOB (US\$)
Colômbia	27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	\$950.406.112
Colômbia	39	Plastics and articles thereof	\$329.891.447
Colômbia	15	Animal or vegetable fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes	\$90.562.846
Colômbia	38	Miscellaneous chemical products	\$55.566.307
Colômbia	40	Rubber and articles thereof	\$27.287.082
Colômbia	48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	\$25.215.556
Colômbia	84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$20.346.042
Colômbia	76	Aluminium and articles thereof	\$19.339.358
Colômbia	29	Organic chemicals	\$18.070.546
Colômbia	28	Inorganic chemicals; organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes	\$16.880.790
Colômbia	59	Impregnated, coated, covered or laminated textile fabrics; textile articles of a kind suitable for industrial use	\$14.605.901
Brasil → México (US\$ 4,5 bi)			
Countries	Code SH2	Description SH2	2018 - Valor FOB (US\$)
México	84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$1.159.971.864
México	87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$685.694.464
México	72	Iron and steel	\$275.045.583
México	44	Wood and articles of wood; wood charcoal.	\$225.977.644
México	02	Meat and edible meat offal	\$198.655.158
México	85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	\$183.337.648
México	26	Ores, slag and ash	\$155.573.104
México	12	Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder	\$151.905.613
México	29	Organic chemicals	\$151.151.302
México	88	Aircraft, spacecraft, and parts thereof	\$139.747.245
México	39	Plastics and articles thereof	\$127.762.666
México	40	Rubber	\$118.938.251
México	30	Pharmaceutical products	\$95.917.133

México	48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	\$70.912.172
México	76	Aluminium and articles thereof	\$57.138.126
Brasil ← México (US\$ 4,9 bi)			
Countries	Code SH2	Description SH2	2018 - Valor FOB (US\$)
México	87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$1.956.606.681
México	85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	\$656.186.529
México	84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$553.600.106
México	90	Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof	\$244.128.690
México	29	Produtos químicos orgânicos	\$218.076.326
México	32	Tanning or dyeing extracts; tannins and their derivatives; dyes, pigments and other colouring matter; paints and varnishes; putty and other mastics; inks	\$129.564.760
México	39	Plastics and articles thereof	\$126.973.129
México	40	Rubber and articles thereof	\$108.048.108
México	79	Zinc and articles thereof	\$93.102.423
México	38	Miscellaneous chemical products	\$76.750.281
México	27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	\$75.138.527
México	30	Pharmaceutical products	\$65.729.594
México	94	Furniture; bedding, mattresses, mattress supports, cushions and similar stuffed furnishings; lamps and lighting fittings, not elsewhere specified or included; illuminated signs, illuminated name-plates and the like; prefabricated buildings	\$59.278.139
México	83	Miscellaneous articles of base metal	\$49.674.298

Source: ComexStat. Elaboração CCGI-EESP/FGV.

On the basis of the trade data and the regulatory constraint, the following sectors will be further elaborated in Part III of this report:

Table 1.3 - Selected sectors

27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes
30	Pharmaceutical products
39	Plastics and articles thereof
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof

Source: ComexStat. Elaboração CCGI-EESP/FGV.

2. Mexico⁶⁷

This Chapter has the objective of analyzing the most comprehensive aspects of the system of technical regulation, standardization and conformity assessment in the United Mexican States (Mexico). After short introduction, the research scrutinizes the structure of the Mexican State, focusing on the bodies that participate directly in the regulation, standardization and conformity assessment processes. After that, these three dimensions of quality infrastructure will be studied separately. The last section is dedicated to a coherence analyses of Mexican system.

With the initiation of a new round of trade negotiations between Brazil and Mexico, the issue of a new generation of trade barriers measures will certainly be raised.

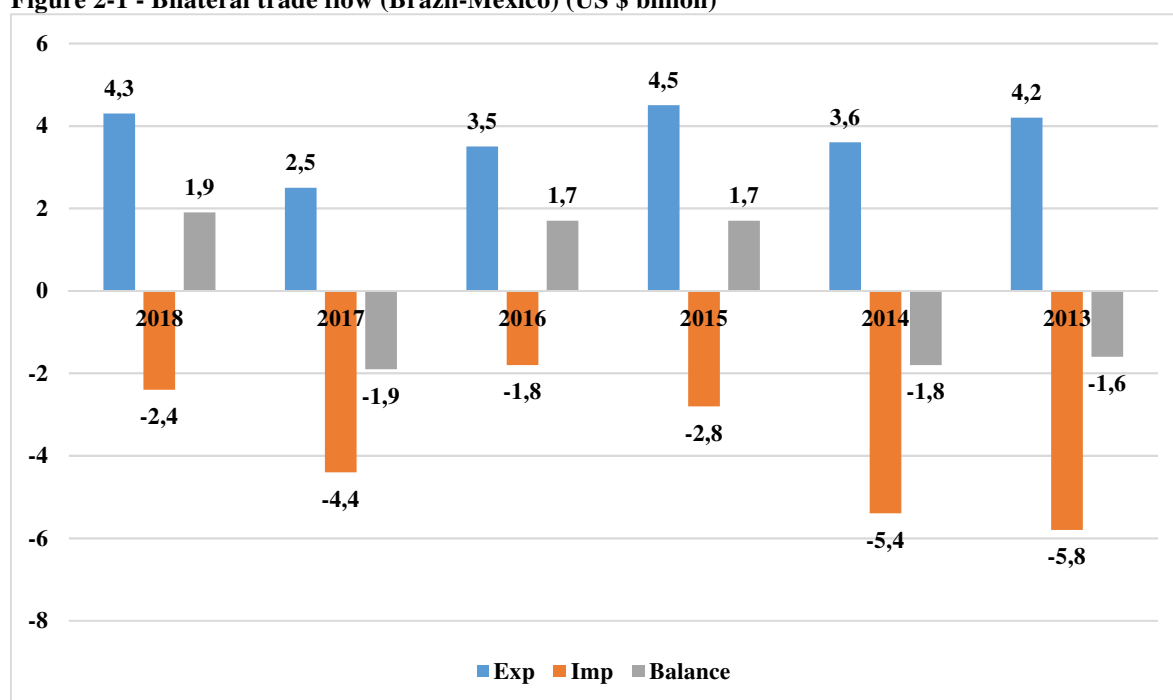
2.1.Introduction

⁶⁷ Ver WORLD TRADE ORGANIZATION. Trade Policy Review: Mexico. Disponível em: https://www.wto.org/english/tratop_e/tpr_e/tp452_e.htm. Acesso em: 23 jul. 2019.

Mexico is among the main economies of the world and has an important share in international trade flows.⁶⁸ The bilateral trade flow between Brazil and Mexico is insignificant, probably due to the lack of complementarity between the two economies⁶⁹, the close proximity of the Mexican market to the US and the absence of more comprehensive trade agreements between the two countries.⁷⁰

In 2013, the trade flow between the two countries was around US\$ 10 billion and showed a downward trend in the following years. Trade between the two countries is relatively balanced, alternating surpluses for Brazil (2015, 2016 and 2018) and Mexico (2013, 2014, 2017). The main products of bilateral trade between the two countries are manufactured, with emphasis on vehicles and auto parts (HS 87) and mechanical machines (HS 84). Brazil also exports primary products, such as minerals (HS 26), oilseeds (HS 12), meats (HS 02) and wood (HS 44). The list of products imported by Brazil from Mexico is complemented by the following types of manufactured goods: electrical apparatus and equipment (HS 85), medical equipment and other precision instruments (HS 90), plastics and plastic products (HS 39), rubber (HS 40) and chemicals (HS 29, 38). The tables below detail the types of products and values in bilateral trade for the year 2018.

Figure 2-1 - Bilateral trade flow (Brazil-Mexico) (US \$ billion)



Source: Comexstat. Elaboration: CCGI-EESP/FGV.

⁶⁸ For more details on the commercial situation of Mexico in the world, see data at <https://wits.worldbank.org/countrystats.aspx>

⁶⁹ For the composition of the Gross Domestic Product in the two countries, see: <http://statisticstimes.com/economy/countries-by-gdp-sector-composition.php>

⁷⁰ The list of preferential trade agreements in Mexico can be found at: <https://www.gob.mx/se/acciones-y-programas/exercices-exterior-paises-contracted-and-accepts-confirmed-con-Mexico>. The Brazilian agreements can be verified at: <http://www.mdic.gov.br/exercise-exterior/egociacoes-internacionais/796-international-companies-2>

Table 2.1 - Main export products - Brazil to Mexico (FOB/US\$)

Code SH2	Description SH2	2018
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$1.159.971.864
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$685.694.464
72	Iron and steel.	\$275.045.583
44	Wood and articles of wood; wood charcoal	\$225.977.644
02	Meat and edible meat offal	\$198.655.158
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles.	\$183.337.648
26	Ores, slag and ash	\$155.573.104
12	Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder	\$151.905.613
29	Organic chemicals	\$151.151.302
88	Aircraft, spacecraft, and parts thereof	\$139.747.245

Source: Comexstat. Elaboration CCGI-EESP/FGV.

Table 2.2 - Main import product - Brazil from Mexico (FOB/US\$)

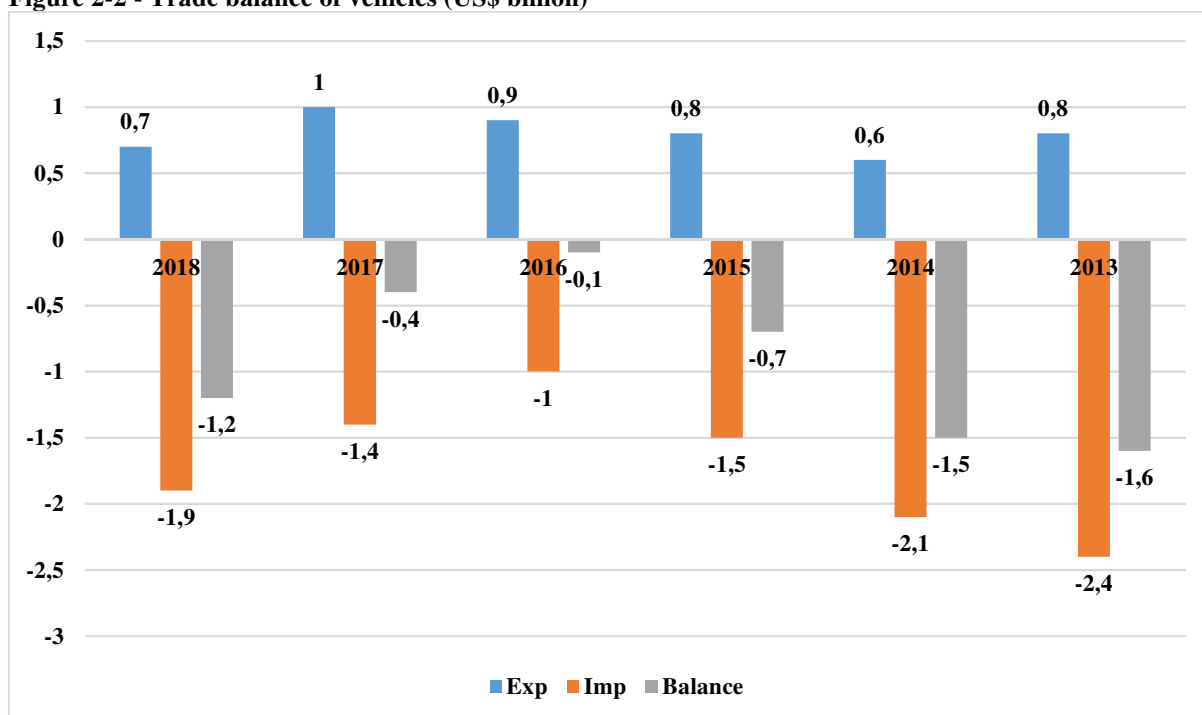
Code SH2	Description SH2	2018
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	\$1.956.606.681
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	\$656.186.529
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	\$553.600.106
90	Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof	\$244.128.690
29	Organic chemicals	\$218.076.326
32	Tanning or dyeing extracts; tannins and their derivatives; dyes, pigments and other colouring matter; paints and varnishes; putty and other mastics; inks	\$129.564.760
39	Plastics and articles thereof	\$126.973.129
40	Rubber and articles thereof	\$108.048.108
79	Zinc and articles thereof	\$93.102.423
38	Miscellaneous chemical products	\$76.750.281

Source: Comexstat. Elaboration CCGI-EESP/FGV.

An equally important sector for the two economies is the automobile, which is subject to specific agreement⁷¹. Although automobiles and autoparts are relevant in the trade agenda of the two countries, it is shown that Brazil has persistent deficits in the sector. In the period between 2013 and 2018, Brazil presented a deficit in this trade balance (HS 87) in all years, especially in 2013, 2014 and 2018, which presented negative balances of more than one billion dollars in favor of Mexico.

⁷¹ The full text of the agreement is available at <http://www.mdic.gov.br/index.php/exercise-exterior/egociacoes-internacionais/132-acordos-dos-quaes-o-brasil-e-part/1824-agreements-automotivo-mercosul-mexico-ace-55>.

Figure 2-2 - Trade balance of vehicles (US\$ billion)



Source: Comexstat. Elaboration CCGI-EESP/FGV.

2.2. Overview of Regulation in Mexico

In Mexico, the three relevant dimensions of technical regulation are organized into one main legislative act and complementary non-legislative normative acts. The Federal Metrology and Standardization Act and its enforcement regulations govern the Mexican System of Metrology, Standardization and Conformity Assessment (SISMENEC). The World Trade Organization Agreement on Technical Barriers to Trade (TBT Agreement) is part of Mexican domestic legislation. Mexican Official Norms (NOMs), which have a compulsory nature, are listed in the Decisions of the Secretariat of Economy, a fundamental body in the management of the stock of Mexican regulations and technical standards. Under the Foreign Trade Law and Customs Law, importers must demonstrate, generally upon presentation of documents and certificates, that goods conform to NOMs before goods can enter the country.

The National Standardization Commission (CNN) and the Directorate-General for Standardization (DGN), as will be detailed below, are the two main bodies responsible for the application of the Federal Law on Metrology and Standardization. The DGN is Mexico's point of contact for the TBT Agreement. CNN has the task of formulating the Mexican standardization policy and of adopting the National Standardization Program and complementary documents, published annually in the official journal of the Mexican central government. Through the National Advisory Committee on Standardization (CCNN), the DGN, in collaboration with other bodies, prepares, analyzes, amends, derogates and issues technical norms and regulations.

Mexico publishes the Mexican Official Standards (NOMs), in practice, the technical regulations, according to Annex 1 of the TBT Agreement and the Mexican Standards (NMXs), which are the technical standards in the strict sense. Reference Standards (NRFs), which are sector-specific industry or sectoral standards, are prepared, for example, by Petróleos Mexicanos (PEMEX) and the Federal Electricity Commission (CFE), but are no longer

produced in 2012. The remaining NRFs are currently reviewed by the process for the purpose of converting them into NOMs or NMXs. In situations where, due to content obsolescence, the transformation of NRFs into NOMs or NMXs is not technically feasible, the reference standards are simply repealed. Since 2013, the Federal Institute of Telecommunications, resulting from constitutional reform, publishes "technical determinations" for the telecommunications and broadcasting sector. These "technical determinations" are mandatory in the domestic market, but to be applicable to imports, the Ministry of Economy must issue a NOM based on relevant technical determination.

The technical regulations (NOMs) are compiled in the Decisions of the DGN. In addition, the DGN maintains a catalog of public access NOMs. In cases of emergency, the competent body may directly elaborate an NOM without the need to complete the ordinary process of preparation of the draft and approval after public consultation. Emergency NOMs remain valid for a maximum period of one semester and can be renewed for another six months (Article 48 of the Federal Law of Metrology and Standardization).

Both domestic and imported products must comply with relevant NOMs. To import a product subject to an NOM, it is necessary to obtain a certificate or authorization (which guarantees product conformity with the NOM). The certificate is issued by a competent body or accredited certification body (Article 53 of the Federal Law on Metrology and Standardization). These import procedures are currently carried out through the Digital Portal (Article 36 of the Customs Law, as amended in 2013).

Where the products or services covered by a particular NOM do not meet the relevant specifications, the competent authority shall immediately prohibit the marketing of such products and services and shall seize the products until they comply with a technical regulation. If it is impossible to seize, it should be ensured that non-conforming products are not used.

The Mexican Standards (NMXs), which are the technical standards *stricto sensu*, are used as reference and are voluntary compliance. They are prepared by the private national private standardization bodies or DGN. By 2016, Mexico had ten national standardization bodies (NSBs) registered in the SE. The standards can not contain specifications lower than those established in the NOMs (Articles 51A and 54 of the Federal Law of Metrology and Standardization). DGN also maintains a catalog of NMXs.

As in the case of NOMs, NMXs are included in the National Standardization Program, and are based on international standards (except where these are inadequate) and express the consensus of the sectors participating in the corresponding advisory committee. NMXs are published in the Official Journal for public consultation for a period of at least 60 days before being published in their final version as NMXs. The procedure for reviewing, updating, or canceling NMXs is the same for preparation.

The conformity assessment procedures are drawn up by the competent secretariats after consultation with the parties concerned. This procedure is formally provided for in the Federal Metrology and Standardization Act, as well as in its implementing regulations and in international guidelines on the general operation of conformity assessment procedures. Once finalized, the procedures are published in the Official Gazette, initially for public comment and then in final form (articles 73 of the Federal Law of Metrology and Standardization and almost a hundred of its executive regulations).

Conformity assessment based on NOMs is carried out by the competent authorities or accredited private bodies. Evaluators (eg certification bodies, test laboratories, calibration laboratories, and verification units) harmonize compliance by visual inspection, sampling, measurement, laboratory testing or document verification. Since 2014, one of the competent bodies is the Federal Institute of Telecommunications. The Secretariat of Economy maintains a list of accrediting bodies and accredited persons, as a rule, subject, sector or branch, as well as a list of the national standards bodies and international organizations recognized by the Mexican government.

For conformity assessment of NOMs and technical provisions related to telecommunications and broadcasting, compliance assessors must be accredited by the Mexican Accreditation Entity (EMA). EMA accredits test laboratories, calibration laboratories, clinical laboratories, verification units (inspection agencies) and certification bodies, proficiency testing providers, and GHG VVBs. These entities may be certification bodies, verification units and test or calibration laboratories (Articles 53 and 68 of the Federal Law on Metrology and Standardization). In addition to being accredited by the EMA, such entities must be approved by the competent authority to operate (articles 68 and 69 of the Federal Law of Metrology and Standardization).

The competent authorities may establish official marks indicating the conformity assessment of NOMs and, where appropriate, NMXs. Products or services subject to NOMs and NMXs may display these official marks voluntarily. However, the competent authorities may also require specific products to display such marks, in which case the competent authority or the persons accredited and approved by it shall be responsible for the conformity assessment.

In the following sections, the most important aspects of the three technical dimensions mentioned above will be detailed: regulation, standardization and conformity assessment. In addition, the coherence and convergence efforts of the Mexican quality system will be analyzed, with an emphasis on international arrangements for regulatory cooperation. In the last part, the study will be dedicated to the comparison between the Mexican system and the systems of Brazil and Argentina, studied in detail in previous works.

2.3. The technical regulation structure in the Mexican State

The United Mexican States is a federation constituted of representative, democratic and republican government⁷², based on a presidential system according to the Constitution of 1917.⁷³ The Constitution establishes three levels of government: the federal union, the state governments and the municipal governments, besides prescribing fundamental rights and guarantees, including in the social dimension. According to the constitutional text, all the constituent states of the federation must present a tripartition of powers, replicating, at the subnational level, the structure of the central government.

⁷² According to the Mexican Constitution: Article 40. It is the will of the Mexican people to establish themselves in a representative, democratic, secular and federal republic, composed of free and sovereign states in all matters concerning their internal regime, and for Mexico City, united in a federation established according to the principles of this fundamental law.

⁷³ According to Mexican Constitution: Article 80. The exercise of the Supreme Executive Power of the Union is deposited in a single individual, who will be called "President of the United Mexican States".

The Federal Executive Branch is headed by the Presidency of the Republic and is made up of several secretariats: *Secretaria de Gobernacion, Secretaria de Relaciones Exteriores, Secretaria de Defensa Nacional, Secretaria de Marina, Secretaria de Hacienda y Credito Publico, Secretaria de Bienestar, Secretaria Medio Ambiente y Recursos Naturales, Secretaria de Energia, Secretaria de Economia, Secretaria Educacion Publica, Secretaria Agricultura y Dessarollo Rural, Secretaria Comunicaciones y Transportes, Secretaria de la Funcion Publica, Secretaria de Salud, Secretaria del Trabajo y Prevision Social, Secretaria de Desarrollo Agrario, Territorial y Urbano, Secretaria de Turismo, Secretaria de Cultura*. They also include the Federal Exceptional Power, the Attorney General's Office and the Legal Department of the Federal Executive, both bodies with legal functions.

Table 2.3 - Bodies of the Executive Branch (direct administration / dependencies)

ACRONYM	GOVERNMENT AGENCY
SEGOB	Secretaria de Gobernacion
SRE	Secretaria de Relaciones Exteriores
SEDENA	Secretaria de Defensa Nacional
SEMAR	Secretaria de Marina
SHCP	Secretaria de Hacienda y Credito Publico
BIENESTAR	Secretaria de Bienestar
SEMARNAT	Secretaria Medio Ambiente y Recursos Naturales
SENER	Secretaria de Energia
SE	Secretaria de Economia
SEP	Secretaria Educacion Publica
SADER	Secretaria Agricultura y Dessarollo Rural
SCT	Secretaria Comunicaciones y Transportes
SFP	Secretaria de la Funcion Publica.
SALUD	Secretaria de Salud
STPS	Secretaria del Trabajo y Prevision Social
SEDATU	Secretaria de Desarrollo Agrario, Territorial y Urbano
SECTUR	Secretaria de Turismo
CULTURA	Secretaria de Cultura
PGR	Procuraduría General de la República
CJEF	Consejería Jurídica del Ejecutivo Federal
PRESIDENCIA	Presidencia de la República

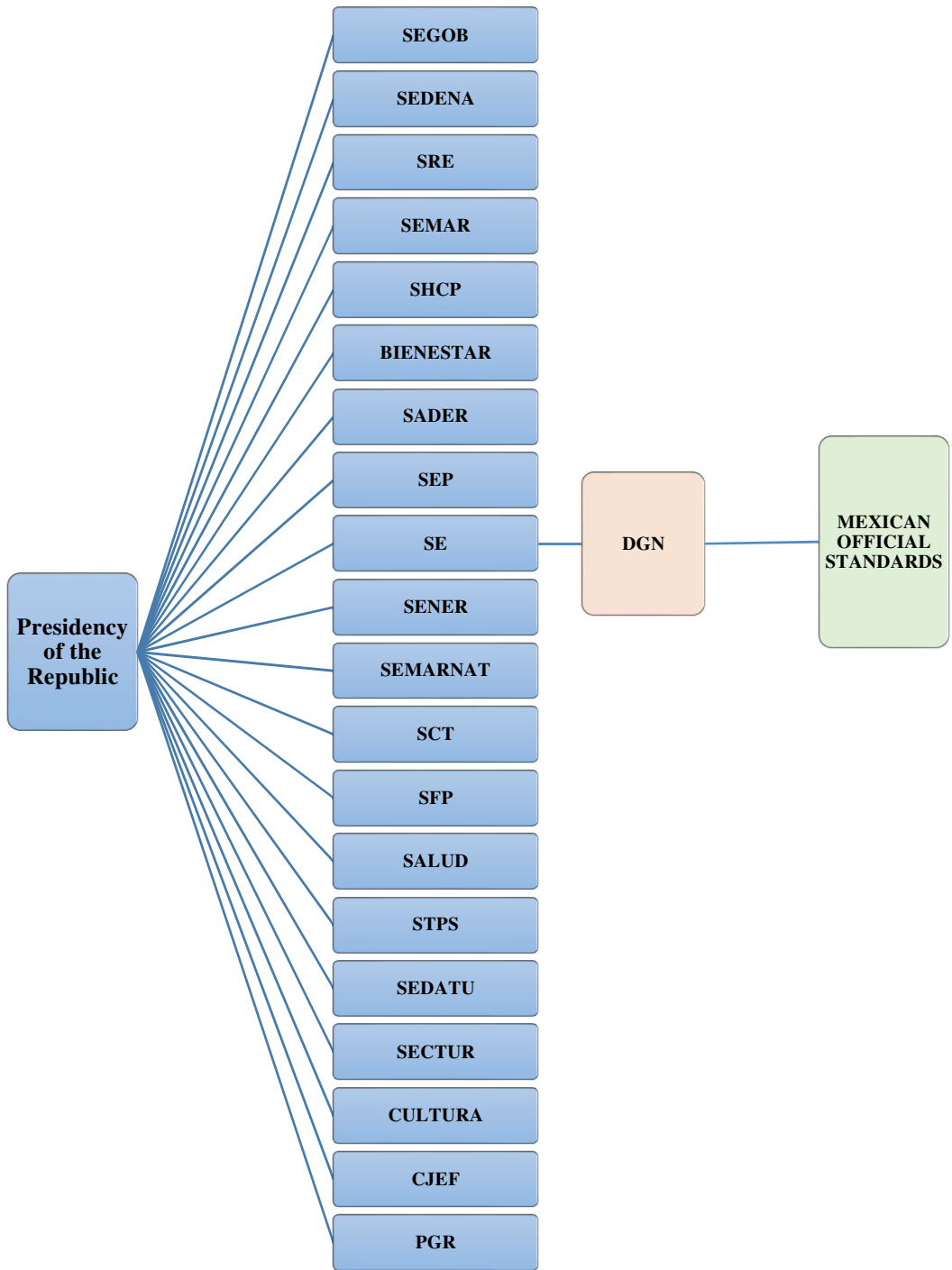
Source: Governo do México. Elaboration: CCGI-EESP/FGV.

In addition to the secretariats and other entities at the federal level, the Mexican administrative structure also has almost two hundred decentralized entities, with a diverse legal regime and objectives related to public administration. For the purpose of this work, focusing on the dimension of technical regulation, standardization and conformity assessment procedures, it is important to highlight the broad role of the Secretariat for the Economy, especially the General Directorate of Standards (DGN), which concentrates important part of the regulatory and standardization activities in Mexico. The DGN exercises the powers conferred by the Federal Law on Metrology and Standardization, the Federal Consumer Protection Law, the Hydrocarbons Law, the Federal Law of Telecommunications and Broadcasting, the regulations and other provisions applicable to standardization, metrology and evaluation of conformity with international agreements and treaties in this area.

The DGN establishes, by means of the Official Mexican Standards (NOM), of mandatory application, the minimum standards of quality of products and services. Despite the name, NOMs are technical regulations and therefore are mandatory, distinguishing themselves from

the Mexican Norms, which are of voluntary application, even if they are used technically for the creation of Mexican Official Standards⁷⁴.

Figure 2-3 - Structure of the Executive Power in Mexico (with emphasis on technical regulation body)



Source: Gobierno del México. Elaborated by CCGI-EESP/FGV.

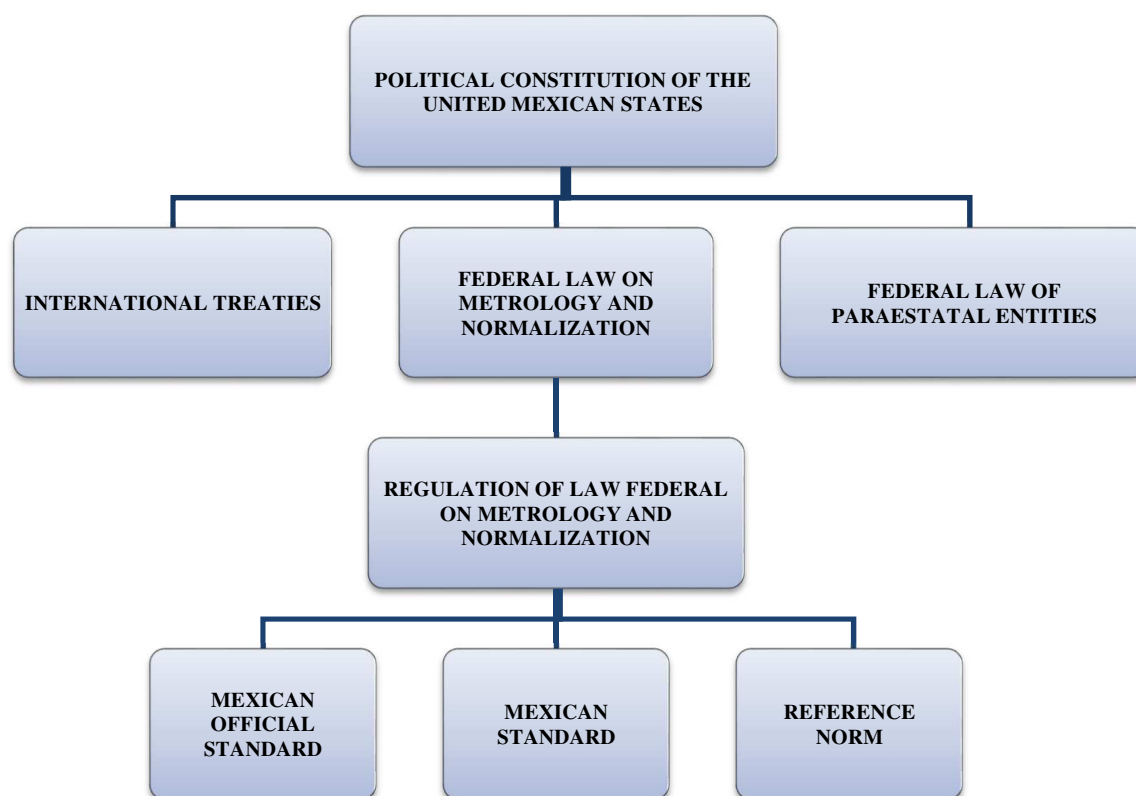
⁷⁴ WORLD TRADE ORGANIZATION. Trade Policy Review: Mexico. Disponível em: https://www.wto.org/english/tratop_e/tpr_e/tp452_e.htm. Acesso em: 23 jul. 2019.

In the structure of the Mexican State, the regulatory activity has a special link with the Secretariat of Economy. This does not imply that only this body has regulatory functions (these are distributed by several organs), but rather that the Secretariat of the Economy has the function of coordinating the activity of regulation (and normalization) in Mexico⁷⁵.

2.4. The quality infrastructure system in Mexico

The regulatory activity in Mexico has its center in the Secretariat of Economy with participation of other important organisms in the system. The system of technical regulation (in a broad sense) consists of the activities of regulatory bodies (mandatory compliance), standardization (producers of voluntary observance technical standards), metrology, accreditation and conformity assessment bodies. In terms of allocation in Mexico's legal framework, the regulatory system consists of a first level of general infra-constitutional standards (international treaties, federal law on metrology and standardization) and a specific federal law on metrology, standardization and conformity assessment. At a lower level, the regulation of this federal law stands out, which has the function of organizing at the infralegal level the technical skills of administration of the quality system. Subsequently, the Official Mexican Standards (NOX), the Mexican Standards (NMX) and the Reference Norms (NR), which consist of documents of an exclusively technical content and that can be used as support in standardization and but in the process of revision⁷⁶.

Figure 2-4 - Structure of Mexico's technical regulation system



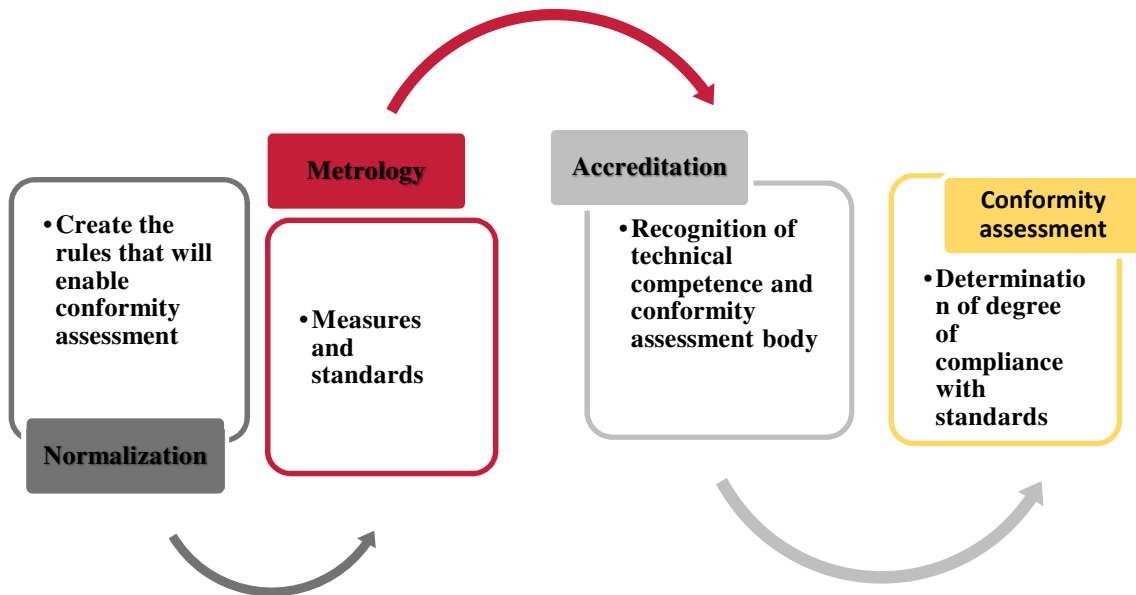
Source: Economy Secretariat. Elaboration: CCGI-EESP/FGV.

⁷⁵ SECRETARÍA DE ECONOMÍA. Gobierno de México. Disponível em <https://www.gob.mx/se/acciones-y-programas/comercio-exterior-reglas-de-comercio-internacional?state=published>. Access in 15/07/2019.

⁷⁶ WORLD TRADE ORGANIZATION. Trade Policy Review: Mexico. Disponível em: https://www.wto.org/english/tratop_e/tpr_e/tp452_e.htm. Acesso em: 23 jul. 2019.

In Mexico, the technical regulation system is made up of several agencies that interact in a coordinated way with the purpose of guaranteeing the quality of goods and services provided to consumers. Regulators, standards, accreditation and conformity assessment bodies are included in this system, as shown in the figure below.

Figure 2-5 - Dynamics of the Mexican quality system



Source: Dirección General de Normas. Elaboration: CCGI-EESP/FGV.

In addition to the DGN, the following organizations are prominent in the Mexican system: National Metrology Center (CENAM)⁷⁷, Potosino Institute for Scientific Research and Technology (IPICYT)⁷⁸ and the Federal Consumer Attorney's Office (PROFECO)⁷⁹. The presence of PROFECO as an important body in the Mexican quality infrastructure system indicates that one of the main scopes of the system is the protection of the diffuse rights of the country's consumers.

The National Metrology Center (CENAM) is the national reference laboratory for measurements.⁸⁰ CENAM establishes and maintains Mexican national standards, offering metrological services such as calibration of instruments, certification and development of reference materials, specialized courses in metrology, consultancies and sales of technical publications. The Center maintains close contact with other national laboratories and with

⁷⁷ CENAM. Información sobre Metrología. Disponible en: http://www.cenam.mx/inf_metrologia/. Acceso en: 31 jul. 2019.

⁷⁸ INSTITUTO POTOSINO DE INVESTIGACIÓN CIENTÍFICA Y TECNOLÓGICA. Acerca. Disponible en: <https://www.ipicyt.edu.mx/>. Acceso en: 1 ago. 2019.

⁷⁹ PROCURADURÍA FEDERAL DEL CONSUMIDOR. Acciones y Programas. Disponible en: <https://www.gob.mx/profeco>. Acceso en: 1 ago. 2019.

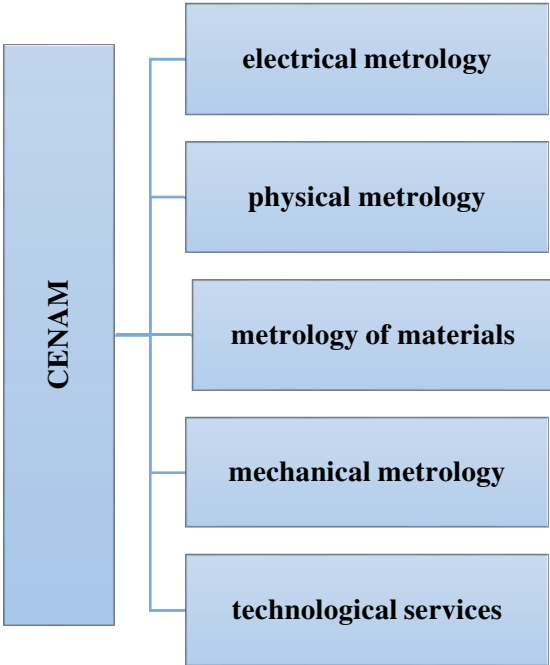
⁸⁰ In terms of metrology, the design of a national metrological system encompasses the operation of measuring instruments, which stipulate compulsory measurement in commerce, industry or services. The National Calibration System (article 24, 25, 26, 27 of the Federal Law of Metrology and Standardization) and the National Center of Metrology are also regulated (articles 29, 30, 31, 32, 33, 34, 35, 36, 37 of the Federal Law on Metrology and Standardization). In general, it can be stated that the measuring instruments are subject to mandatory initial, periodic or extraordinary checks and can be checked or calibrated when metrological deficiencies are detected in them.

international organizations related to metrology in order to ensure the international recognition of Mexico's national standards and, consequently, to promote the acceptance of products and services in our country.

CENAM, being the main laboratory in Mexico, does not carry out regulatory activities. The Federal Law on Metrology and Standardization and its Regulations establish the competence of the Ministry of Economy and other agencies, such as the National Standardization Commission and the Federal Consumer Attorney's Office, to apply the provisions established by law.

As explained in its official website, CENAM develops activities in the following areas: electric metrology; physical metrology; metrology of materials; mechanical metrology; technological services.

Figure 2-6 - CENAM and the dimensions of metrology



Source: CENAM. Elaboration: CCGI-EESP/FGV.

The Potosino Institute for Scientific Research and Technology (IPICYT) is a Public Research Center of the National Council of Science and Technology (CONACyT) which develops natural and exact sciences, with specialized multidisciplinary academic groups and high level infrastructure. The Institute generates and disseminates knowledge, trains human resources and develops technological projects and services for the academic, business, social and governmental sectors. The performance of its functions is considered important in the technical work of the organisms of the Mexican quality system.

The Federal Consumer Attorney's Office (PROFECO) is a decentralized and sectorized public agency of the Ministry of Economy of the Mexican Federal Government. It is designed to promote and protect consumer rights, promote smart consumption and ensure fairness and legal security in supplier-consumer relations. The Mexican regulatory system highlights PROFECO's work in post-market supervision of goods.

Within the scope of the Attorney General's Office, the functions performed by the Under-Secretary for Verification, which is responsible for ensuring compliance with the law in relations between suppliers and consumers, are highlighted. The Subsecretariat of Verification, through its agents, carries out visits and operational verification and monitoring of commercial establishments, as well as evaluating the quality of the different products. The undersecretary is competent to find irregularities and is authorized to use her police power. Its agents can impose penalties like fines, closures of establishments and even the destruction of products, as well as issuing alerts to the consumer about products or businesses that could be a risk.

According to the applicable legal framework, the Secretariat is competent to verify the following aspects: commercial, documentaries, volumetric, electronic, quality and safety.

Figure 2-7 - Competence of the subsecretariat of PROFECO's verification

Commercial	Documentaries	Volumetrics	Electronics	Quality and safety
• fuel price verification	• approval of the prototype model or instrument of measurement	• confirmation of the physical quantities of shipment correspond to what was requested	• supervision of the electronic instrumentation of the measuring instrument has not been	• make sure that the life or health of consumers is not at risk

Source: PROFECO. Elaboration: CCGI-EESP/FGV.

In terms of accreditation, the activity of the Mexican Accreditation Entity (EMA)⁸¹ stands out. EMA is the first privately managed entity in Mexico to provide accreditation for conformity assessment bodies, test laboratories, calibration laboratories, clinical analysis laboratories, verification units (inspection bodies) and certification agencies. The creation of the EMA is expressly related to the challenges posed by international trade, and to the need to supply industry and trade with the tools to compete adequately and to introduce products into the international market.

In terms of conformity assessment, Mexico has a network of agencies, which are capable of performing conformity assessment procedures, especially certifications, verifications and inspections. As in most countries, this network is composed mainly of private entities, legally constituted in the form of companies or civil companies.

2.4.1. Technical regulation

Preliminarily, it is necessary to distinguish between Mexican standard (NMX) and Mexican official standard (NOM). NMX is one developed by a national standardization body.⁸² This standard is equivalent to what is called a technical standard in Brazil (norma) and, therefore, it has a voluntary nature and usually a private origin. NOM, in turn, is in fact a technical regulation, regardless of its denomination. The qualification "official" to designate these standards confers, in the Mexican system, governmental nature to these technical prescriptive documents. Unlike Mexican regulations, observance of NOMs is compulsory, regardless of the legal form that they assume when they are issued by the Mexican State.

⁸¹ ENTIDAD MEXICANA DE ACREDITACIÓN (EMA). Quiénes somos?. Disponível em: https://www.ema.org.mx/portal_v3/. Acesso em: 23 jul. 2019.

⁸² The Technical Committees on National Standardization of the Mexican Institute for Standardization and Certification (IMNC / CTNN) are very active in that a standard is often the result of technical work and agreements reached between the interested parties of such committees.

In organizational terms, the Federal Law on Metrology⁸³ and is the most important legal document concerning the activities of regulation metrology and conformity assessment. This law establishes a national metrological system and generally regulates the standardization process, including NOMs.

The Mexican Official Standards (NOX) are listed in Section II of Chapter II of the Federal Law on Metrology and Standardization (articles 40 to 51). The provisions of this section prescribe how the regulatory technical process in Mexico should be, presenting its purposes (Article 40), its mandatory content of regulations (Article 41), regulatory entities (Articles 43 and 44), production mechanisms and amendments to regulations (Articles 45 to 51).

The general objectives of NOX are: protection of the health and safety of people, protection of the general and labor environment and preservation of natural resources, provision of information to the consumer, protection of general communication channels, provision of support for designations of origin. The art. 40 of the Federal Law on Metrology and Standardization lists, in greater detail, these purposes for the technical regulations in Mexico.

Purposes in art. 40 of the Federal Law on Metrology and Standardization:

- Provide the characteristics and / or specifications that the products and processes must meet when they pose a risk to the safety of humans or present potential harm to human, animal, plant, general and work environment, or the preservation of natural resources;
- Prescribe the characteristics and / or specifications of the products used as raw materials or parts or materials for the manufacture or assembly of subject final products;
- Determine the characteristics and / or specifications that the services must meet when they may constitute a risk to the safety of persons or to human or animal health or the general and labor environment;
- Provide the characteristics and / or specifications related to measuring instruments, measurement standards and their methods of measurement, verification, calibration and traceability;
- Determine specifications and / or packaging procedures for products which may constitute a risk to the safety of persons or to the detriment of human health or the environment;
- Determine the health, safety and hygiene conditions that must be observed in work centers and other public meeting centers;
- To prescribe nomenclature, expressions, abbreviations, symbols, diagrams or drawings that must be used in technical industrial, commercial, service or communication language;
- Provide for the description of emblems, symbols and passwords for the purposes of this Law;
- Determine the characteristics and / or specifications, criteria and procedures that allow to protect and promote the improvement of the environment and ecosystems, as well as the preservation of the natural resources environment;
- To determine the characteristics and / or specifications, criteria and procedures that allow to protect and promote the health of people, animals or plants;
- Determination of commercial, health, ecological, quality, safety and hygiene protection information and requirements that must be met by labels, packaging, packaging and advertising products and services to provide information to the consumer or user;
- Provide characteristics and / or specifications that must be met by industrial, commercial, service and domestic equipment, materials, appliances and installations for sanitary purposes,

⁸³ To consult the full text of the Law, see:

<https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>

aquaculture, agriculture, livestock, ecological, communications, safety or quality, and particularly when they are dangerous.

There are several organs of the Mexican administrative structure participating in the NOX production. The purpose of this openness for multi-stakeholder participation is to harness the technical knowledge of employees and employees in the production of mandatory technical prescriptions. Some of the bodies that participate in the process of elaborating Mexican official standards are the following:

- *Secretaria de Gobernacion* (SEGOB); *Secretaria de Medio Ambiente y Recursos Naturales* (SEMARNAT);
- *Secretaria de Energia* (SENER); *Secretaria de Economia* (SE); *Secretaria Comunicaciones y Transportes* (SCT);
- *Secretaria de Salud* (SALUD);
- *Secretaria del Trabajo y Prevision Social* (STPS);
- *Secretaria de Desarrollo Agrario, Territorial y Urbano* (SEDATU);
- *Secretaria de Turismo* (SECTUR);
- *Comision Reguladora de Energia* (CRE) e
- *Agencia de Seguridad Energia y Ambiente* (ASEA).

These entities are included in the Federal Law on Metrology and Standardization. The table below summarizes the activities of the main agencies that develop Mexican official standards, called dependencies by the Federal Law of Metrology and Standardization.

Table 2.4 - Production of official Mexican standards

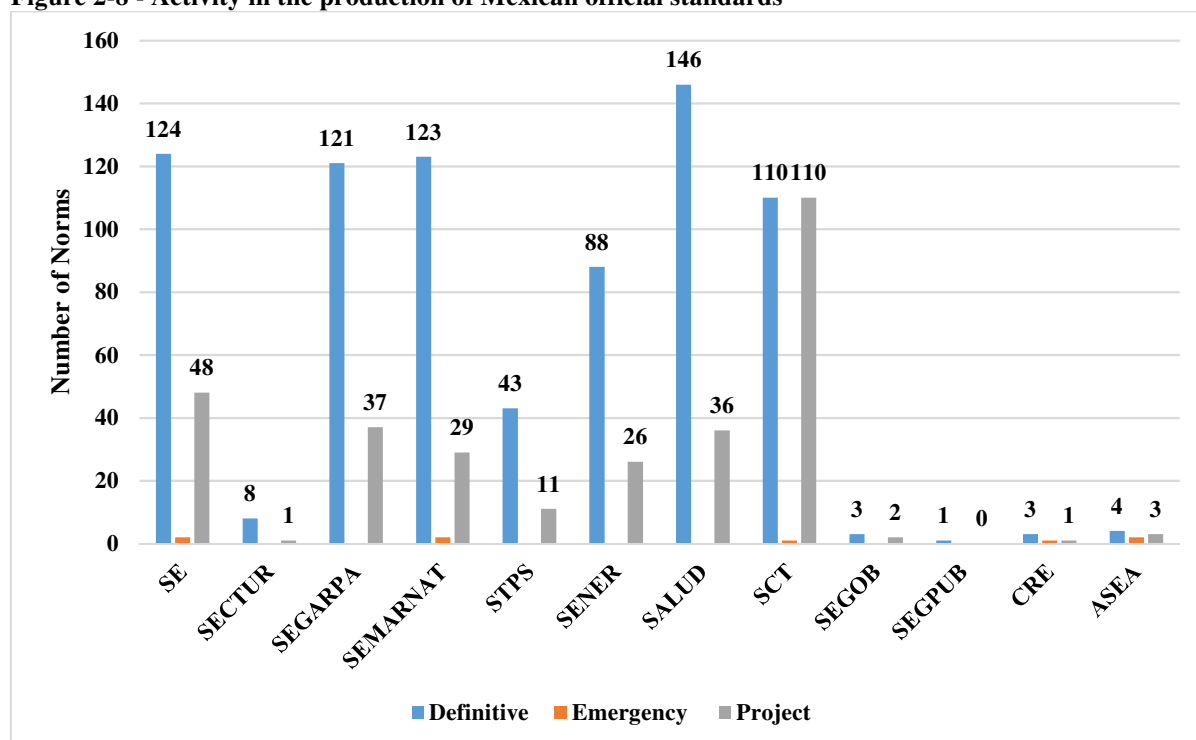
	Type of Norm			
	DEFINITIVE	EMERGENCY	PROJECT	TOTAL
<i>Secretaria de Economia</i>	124	2	48	174
<i>Secretaria de Turismo</i>	8	0	1	9
<i>SAGARPA</i>	121	0	37	158
<i>SEMARNAT</i>	123	2	29	154
<i>Secretaría de Trabajo y Provision Social</i>	43	0	11	54
<i>Secretaría de Energia</i>	88	0	26	114
<i>Secretaría de Desarrollo Social</i>	0	0	0	0
<i>Secretaría de Salud</i>	146	0	36	182
<i>Secretaria de Comunicaciones y Transportes</i>	110	1	110	221
<i>Secretaría de Gobernación</i>	3	0	2	5
<i>Secretaría de Seguridad Publica</i>	1	0	0	1
<i>Comisión Reguladora d Energía</i>	3	1	1	5
<i>ASEA</i>	4	2	3	9
Total	774	8	304	

Source: Dirección General de Normas. Elaboration: CCGI-EESP/FGV.

At present, Mexico has a stock of almost eight hundred official standards (see appendix)⁸⁴. The Secretariats of Health (HEALTH), Economy (SE), Agriculture and Rural Development (SAGARPA) and Environment and Natural Resources (SEMARNAT) are the entities (dependencies) with the highest number of effective standards and in the form of projects. The graph below shows, in a comparative way, the activities of Mexican organisms.

⁸⁴ The NOMs undergo mandatory five-year review, with the purpose of keeping them up to date and rationalizing the country's regulatory stock. After this review, the NOM may be modified, canceled or renewed without change for another five years. This decision shall be notified to CNN within 60 days after the end of the five year period. If such notification is not made, the NOM shall cease to have effect and the issuing agency shall publish its annulment in the Official Gazette (Article 51 of the Federal Law on Metrology and Standardization).

Figure 2-8 - Activity in the production of Mexican official standards



Source: *Dirección General de Normas*. Elaboration: CCGI-EESP/FGV.

The content of the regulation, although variable according to the disciplined object, should contain some basic elements, with the purpose of insertion into the Mexican regulatory system, control of the regulatory stock and adequate use by the recipients of the regulations. These basic elements are foreseen in art. 41 of the Federal Law on Metrology and Standardization. The figure below summarizes the necessary elements of the official Mexican standard.

Table 2.5 - Essential requirements of the official Mexican standard

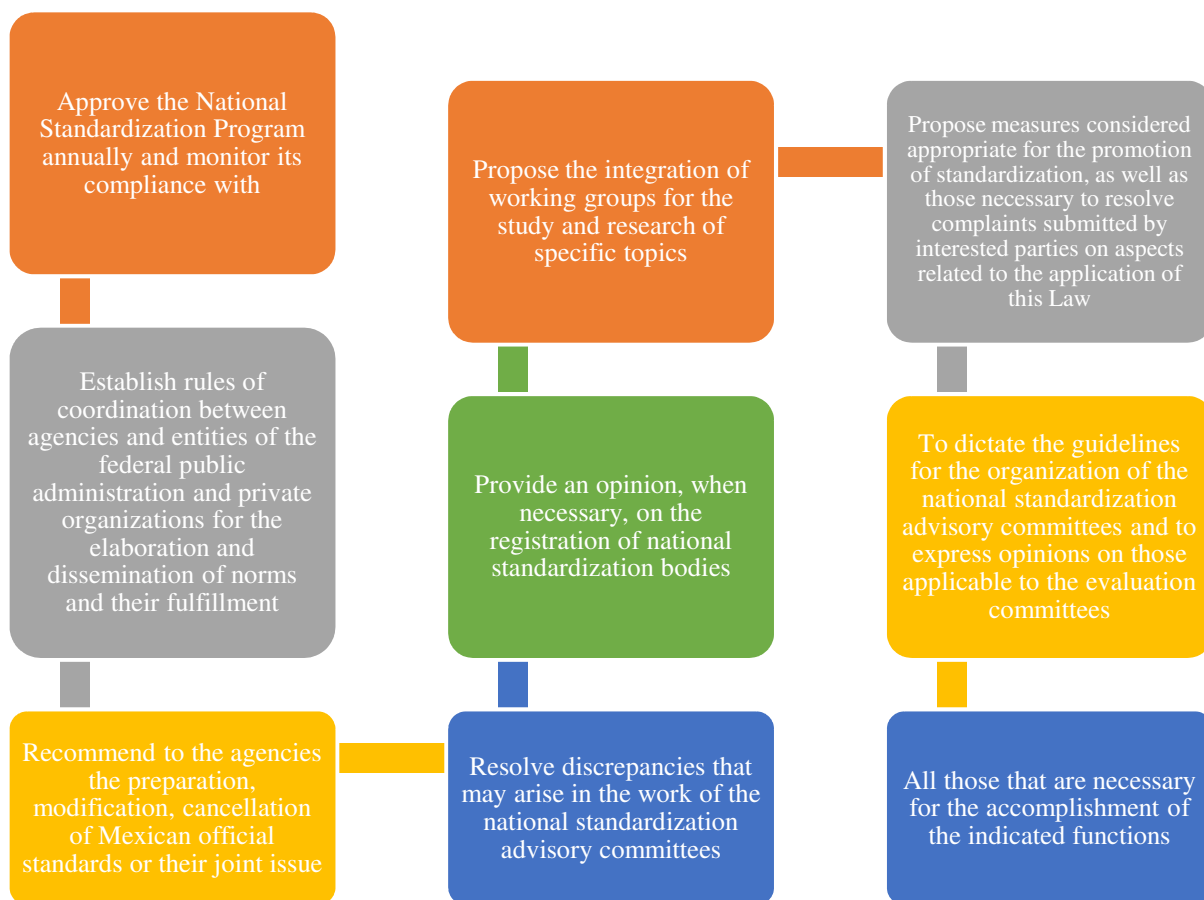
<i>Essential requirements of the official Mexican standard</i>	I. The name of the standard and its code or code, as well as the purposes of the standard in accordance with article 40;
	II. The identification of the product, service, method, process, installation or, where appropriate, the object of the standard in accordance with the provisions of the previous article;
	III. The specifications and characteristics that correspond to the product, service, method, process, installation or establishments that are established in the standard because of its purpose;
	IV. The test methods applicable to the standard and, where appropriate, sampling methods;
	V. The data and other information that the products must contain or, if not available, their packaging or packaging, as well as the size and characteristics of the various indications;
	VI. The degree of agreement with international standards and guidelines and with Mexican standards as the basis for their elaboration;
	VII. The bibliography that corresponds to the standard;
	VIII. The mention of dependencies or agencies that will monitor compliance with standards when there is simultaneity of competencies; and
	IX. The other mentions that they are considered convenient for proper compression and scope of the standard

Source: *Dirección General de Normas*. Elaboration: CCGI-EESP/FGV.

Some of these NOX requirements are key to standard identification and management. Others of these requirements are necessary conditions for their application, as, for example, item VIII, which refers to the entities that will be competent to supervise compliance with the standard. It is interesting to highlight item VI of art. 41, which makes it compulsory to mention the existence or non-existence of compatibility between the technical regulation and national and international technical standards, which facilitates the verification of convergence.

In the process of normalization, the Federal Law on Metrology and Standardization foresees the National Standardization Commission that assists in the standardization policy and allows the coordination of activities that must be carried out by dependencies and entities of the federal public administration (article 2 and article 58). The main functions of the Commission, as provided in art. 60 of the Law, are the annual approval of the national standardization program (item I) and inspection of compliance (item I), resolving any conflicts that may arise from the work of the national standardization advisory committees (item IV), (V), propose appropriate measures for the promotion of standardization (section VII) and present the guidelines for the organization of national standardization advisory committees (section VIII). Below the functions of the National Standardization Commission are described in more detail.

Figure 2-9 - Objectives of the National Standardization Commission



Source: *Dirección General de Normas*. Elaboration: CCGI-EESP/FGV.

As is shown from the legally determined objectives, the Commission plays an important role in the conduct of the National Standardization Program. In the production of Mexican official standards, the Commission has a central role, as it recommends the production of new technical regulations, as well as recommending the modification, replacement or cancellation of Mexican official standards.

The Mexican national standardization program consists of a list of topics to be regulated during the corresponding year (article 61-A). In Mexico, the idea of standardization has a broad meaning, encompassing what is commonly referred to in the TBT Agreement as a technical regulation, technical standards and support standards, which would be referred to as a technical substance in the context of prescriptive documents compulsory. Thus, the program comprises Mexican official standards, Mexican norms and reference standards elaborated by federal public administration standardization committees. This forecast of development of norms is predicted in work calendar for each theme. This program is published in the Official Gazette of the Federation (article 61-A).

The requirements for acting as national standardization bodies are laid down in the federal law on metrology and standardization. Each body should be able to participate in international standardization activities and have adopted the code for the development, adoption and application of standards. The formal requirements are to present the application for registration with the Secretariat of Economy and to present its bylaws to be approved by the Secretariat in

which the corporate purpose of standardization is to be presented, the normalization work carried out by means of committees integrated in a balanced manner by technical personnel and national coverage.

The obligations of national standards bodies seek to enable social participation, increase transparency and foster institutional cooperation. Among the obligations it can be highlighted:

- to allow the participation of all interested sectors in the committees for the elaboration of Mexican norms, as well as of the dependencies and competent entities of the federal public administration;
- make public the draft Mexican standards to be issued in the Official Gazette of the Federation and meet any request for information made by interested parties;
- enter into cooperation agreements with the Secretariat of Economy so that it can keep up to date the set of Mexican norms and
- submit to the technical secretariat of the National Standardization Committee the standards that have been prepared for the publication of its declaration of validity.

Figure 2-10 - Obligations of national standardization bodies



Source: *Dirección General de Normas*. Elaboration: CCGI-EESP/FGV.

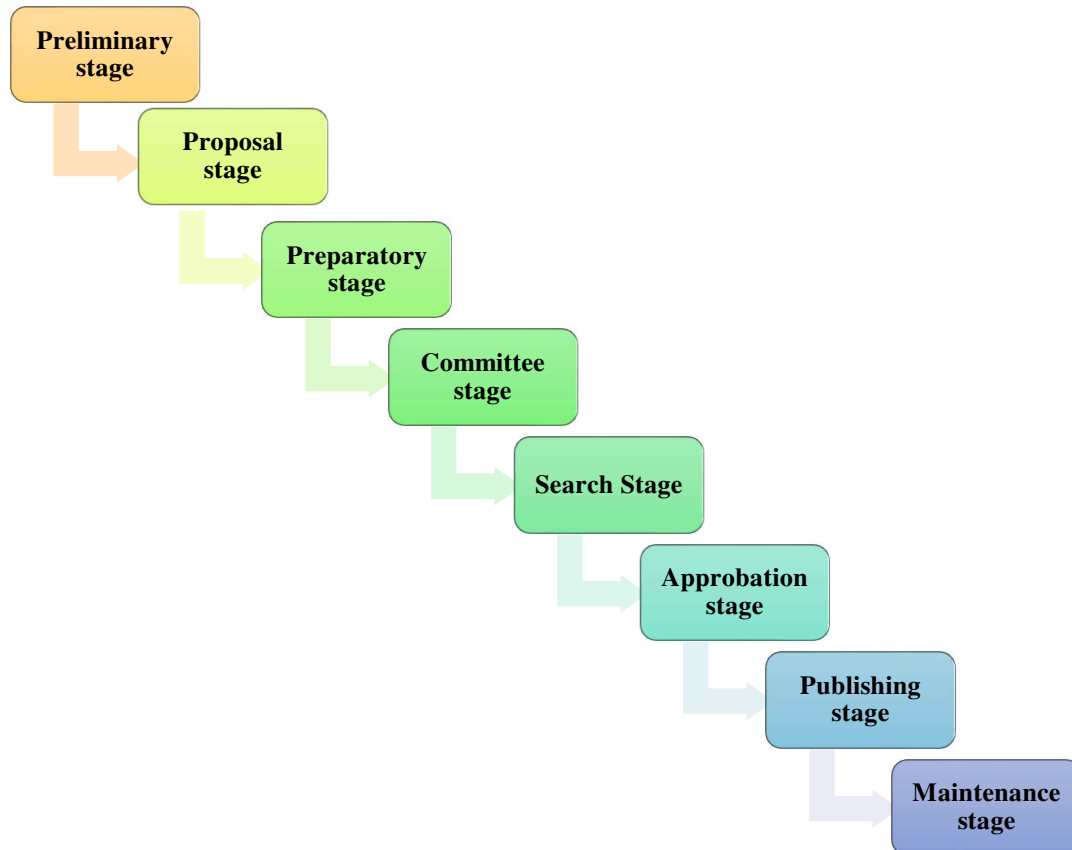
The powers of the dependencies and the Secretariat of Economy in normalization are also foreseen in the Federal Law on Metrology and Standardization⁸⁵. It is up to the units to contribute to the integration of the National Standardization Program with the Mexican official standards proposals, to implement the national standardization program in their respective areas of competence, and to set up and chair national advisory committees for standardization. The Secretariat of Economy is competent to integrate the national standardization program with Mexican official standards and with Mexican standards elaborated annually, to act as technical secretary of the national standardization committee and of the national standardization

⁸⁵ MEXICO. Ley Federal Sobre Metrología y Normalización. Disponible em: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acesso em: 22 jul. 2019.

committees, except for the committees appointing their own technical secretary, maintain a register of national standardization bodies, participate in national standardization advisory committees for industrial or commercial activities, coordinate and direct committees and international standardization activities, act as a standardization information center.

The requirements for the performance, the obligations and the institutional competences are inserted in the steps of the procedure of creation of technical norms. The steps to obey are as follows:

Figure 2-11 - Stages of technical standards creation



Source: IMNC. Elaboration: CCGI-EESP/FGV.

In addition to the presence of the national standardization bodies, agencies and the Secretariat of Economy, federal public administration bodies should establish standardization committees for the elaboration of reference standards. These standards have the function of regulating requirements that are not covered by Mexican or international standards or have become inapplicable or obsolete.

2.4.2. Technical Standardization

Although the sections above use the nomenclature "standard" and its derivations, the explanations refer mainly to the technical regulations (Mexican official standards), which are characterized by their obligatoriness and their governmental origin. In this section, it is analyzed specifically the technical norms, which are different from the official norms because they are voluntarily complied with by the addressees and emanating, in general, from the private initiative, although in the Mexican case, a public management of the stock of standards occurs.

In art. 51-A⁸⁶ of the Federal Law on Metrology and Standardization, there is a forecast of the voluntary Mexican standards, a characteristic that consists of the differential attribute in relation to Mexican technical standards. It is important to note that the wording of art. 51-A prescribes two situations in which these Mexican norms become mandatory: in case the company or the offerer of the good or service declares that it conforms to the norm; and if the standard is mentioned in the scope of technical regulation (official Mexican standard).

The Mexican technical standards must have the following characteristics:

- I. They must be included in the National Standardization Program;
- II. Adopt international standards as a parameter, unless they are ineffective or inadequate to achieve the desired objectives; and
- III. Be based on the consensus of the interested sectors that participate in the committee and present public consultation for a period of at least 60 calendar days before its issuance.

Table 2.6 - Characteristics of the process of elaboration of Mexican norms

Mexican standards (stricto sensu technical standards)		
Inclusion in the National Standardization Program	Observe International Standards	Sectorial consensus and publicity of procedures

Source: IMNC. Elaboration: CCGI-EESP/FGV.

It is important to highlight the role of the Secretariat of the National Standardization Commission, which has propositional and control functions. According to art. 51-B, the Secretariat may issue rules in different areas. The Secretariat, in its control function, may request the cancellation of norms that do not represent the interests of the standard sector. The Mexican Standards (NMXs), which are the technical standards stricto sensu, are used as reference and are voluntary compliance. They are prepared by the private national private standardization bodies or DGN. By 2016, Mexico had ten national standardization bodies (NSBs) registered in the SE. The standards can not contain specifications lower than those established in the NOMs (Articles 51A and 54 of the Federal Law of Metrology and Standardization). DGN also maintains a catalog of NMXs. As in the case of NOMs, NMXs should be included in the National Standardization Program, should be based on international standards (except where these are inadequate) and should express the consensus of the sectors participating in the corresponding advisory committee. NMXs shall be published by a notice in the Official Journal for public consultation for a period of at least 60 days before being

⁸⁶ Art. 51-A. Mexican standards are voluntary, except in cases where individuals declare that their products, processes or services are in agreement with them and without prejudice to the fact that the dependencies require in an official Mexican standard their observance for certain. Its field of application can be national, regional or local. See MEXICO. Ley Federal Sobre Metrología y Normalización. Disponible en: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acceso en: 22 jul. 2019.

published in their final version as NMXs. The procedure for reviewing, updating, or canceling NMXs is the same for your preparation. As in the case of NOMs, NMXs should be reviewed or updated at five-year intervals (Article 51-A of the LFMN). If the results of the review or update are not reported to CNN, CNN will order NMX to be revoked. The Secretariat of the Economy, *ex officio* or at the request of another agency, may also issue an NMX in the case of areas not covered by the national standardization bodies or when the standards issued by it are outside the interests of the sectors concerned (Article 51-A of the Federal Law of Metrology and Standardization). One of the main characteristics of standardization in Mexico is the plurality of standardization bodies. The list below lists the bodies authorized to operate in Mexican territory.

Table 2.7 - National standardization bodies

a) Sociedad Mexicana de Normalización (NORMEX)
b) Instituto Mexicano de Normalización y Certificación (IMNC)
c) Asociación de Normalización y Certificación (ANCE)
d) Instituto Nacional de Normalización Textil (INNTEX)
e) Organismo Nacional de Normalización y Certificación de la Construcción y Edificación (ONNCCE)
f) Normalización y Certificación Electrónica (NYCE)
g) Consejo para el Fomento de la Calidad de la Leche y sus derivados (COFOCALEC)
h) Centro de Normalización y Certificación de Productos (CNCP)
i) Cámara Nacional de la Industria del Hierro y del Acero (CANACERO)
j) Organismo Nacional de Normalización de Productos Lácteos, A.C. (ONNPROLAC)

Source: CGN. Elaboration: CCGI-EESP/FGV.

As it is clear from the standards of the bodies, some of these entities are sectorially specialized. The National Institute of Textile Standardization (INNTEX) and the National Organization for Standardization and Certification of Construction and Building (ONNCCE) are two bodies that produce technical standards for specific areas: textiles and civil construction specifically. Other organisms have a generalist scope, such as, for example, the Mexican Society for Standardization (NORMEX). It is interesting to note that in certain cases there is a clear relationship of competition between the bodies in the production of technical standards. This is the case, for example, with the activities of the Council for the Promotion of the Quality of Milk and Dairy Products (COFOCALEC) and the National Agency for the Standardization of Dairy Products, A.C. (ONNPROLAC).

Another important aspect that can be mentioned is the cumulativeness of functions in these organizations. The Mexican Institute of Normalization and Certification (IMNC), the Association of Standardization and Certification (ANCE), or National Organization for Standardization and Certification of Construction and Building (ONNCCE), Standardization and Electronic Certification (NYCE); Center for Standardization and Certification of Products (CNCP) act both on standardization activity and on conformity assessment activities.

The names of the Mexican norms are constituted by a letter that represents the economic sectors related to the standard. The table below lists the correspondence between the letter and the sector.

Table 2.8 - Correspondence between sectors and letters of the standards

INDUSTRIAL SECTOR	IDENTIFICATION LETTERS
Textile Industry	A
Environmental Protection	AA
Graphic Arts	AG
Steel Products	B
Blinds and metal rods	BA

Products and equipment for medical, hospital and laboratory use	BB
Construction Materials	C
Quality systems	CC
Control, measuring and statistical apparatus	CH
E-business	COE
Vehicles (incl. Autoparts)	D
Automotive Locksmith Services	DA
Plant and photocopy	DD
Technical drawing	DT
Plastics and Products	E
Conformity Assessment	CE
Container and packaging of products	EE
Solar energy	ES
Food Products	F
Unprocessed food products for human use	FF
Pharmaceutical products	G
Cranes and lifting devices	GR
Technology management	GT
Locksmithing, welding and metal coating products	H
Electronic industry	I
Electrical sector	J
Chemicals	K
Oil refining, distillation and exploration products	L
End-use chemicals	M
Office and school equipment and supplies	N
General purpose equipment in industry and agriculture	O
Glass Industry	P
Items used for optics	PA
Crafts and ceramics	PP
Products and equipment for household use	Q
Diverse Industries	R
Safety	S
Environmental management systems	SAA
Industrial hygiene	SS
Health and safety at work management systems	SAST
Rubber products	T
Tourism	TT
Paints, varnishes and lacquers	U
Alcoholic beverages	V
Non-Ferrous Metal Products	W
Toys	WW
Equipment for the handling and use of LP and natural gas	X
Agricultural industry	Y
Basic patterns and symbols	Z

Source: Economy Secretariat Elaboration: CCGI-EESP/FGV.

In short, the Mexican standardization activity has some important characteristics. The first of these is the full insertion of this conformity into the Mexican quality system, with legal provision (by the Federal Law of Metrology and Standardization) and management of the stock of standards by public bodies. The second important aspect of the Mexican system is the plurality of standardization organisms, a characteristic that brings the Mexican system closer to

the American system, in which the normalizing entities act in a competitive way in the production of technical standards⁸⁷.

2.4.3. Conformity Assessment Procedures

2.4.3.1. Accreditation

The accreditation process is one that ensures the reliability of conformity assessment procedures. Accreditation in Mexico is not the prerogative of a governmental body. They are private organizations that develop this type of activity. The most relevant of these is the Mexican Accreditation Entity - EMA⁸⁸.

The general aspects are established in Title Four of the Federal Law on Metrology and Standardization, in art. 68 to 72⁸⁹. These provisions establish specific rules for the accreditation system in Mexico. The articles therefore contain general rules on the functions of accreditation, their relationship to dependencies and importance in the context of conformity assessment.

In art. 68, aspects relating to the application for accreditation of conformity assessment bodies are determined. In accordance with the legal provisions, interested parties should:

- Submit a written request to the corresponding accrediting entity, accompanying the application its statutes and proposed activities;
- Indicate the standards used in the conformity assessment, informing the respective subject, sector, branch, field or activity and description of the services it intends to provide and procedures to be used;
- Demonstrate that it has the technical, material and human capacity appropriate to the services it intends to provide, as well as quality assurance procedures.

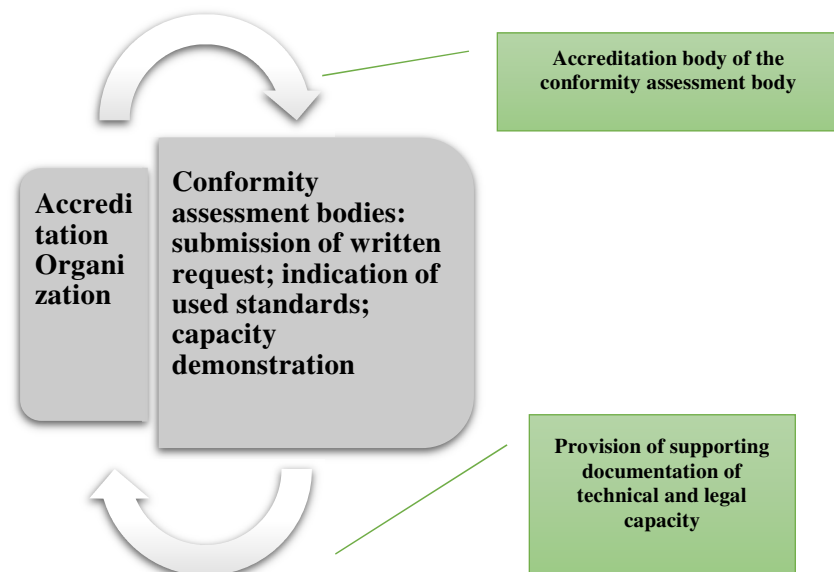
The accreditation body, therefore, initially performs a documentary analysis based on the information and documents provided by the applicants.

⁸⁷ MEXICO. Ley Federal Sobre Metrología y Normalización. Disponible en: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acceso en: 22 jul. 2019.

⁸⁸ ENTIDAD MEXICANA DE ACREDITACIÓN (EMA. Quiénes somos?. Disponible en: https://www.ema.org.mx/portal_v3/. Acceso en: 23 jul. 2019.

⁸⁹ MEXICO. Ley Federal Sobre Metrología y Normalización. Disponible en: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acceso en: 22 jul. 2019.

Figure 2-12 - Relationship between Accreditation Bodies and Conformity Assessment Bodies



Source: EMA. Elaboration: CCGI-EESP/FGV.

In art. 70-A, there are the operating conditions for the accreditation body. In the caput of the article, it is foreseen the necessity of authorization of the Secretariat of the National Commission of Normalization. The accreditation body must demonstrate some characteristics, such as legal, economic and technical capacity. Specific technical capacity should be demonstrated for distinct areas, since the entity must accredit agencies that operate in different areas. The scheme below summarizes the requirements for the accreditation body.

Table 2.9 - Requirements of the accreditation body

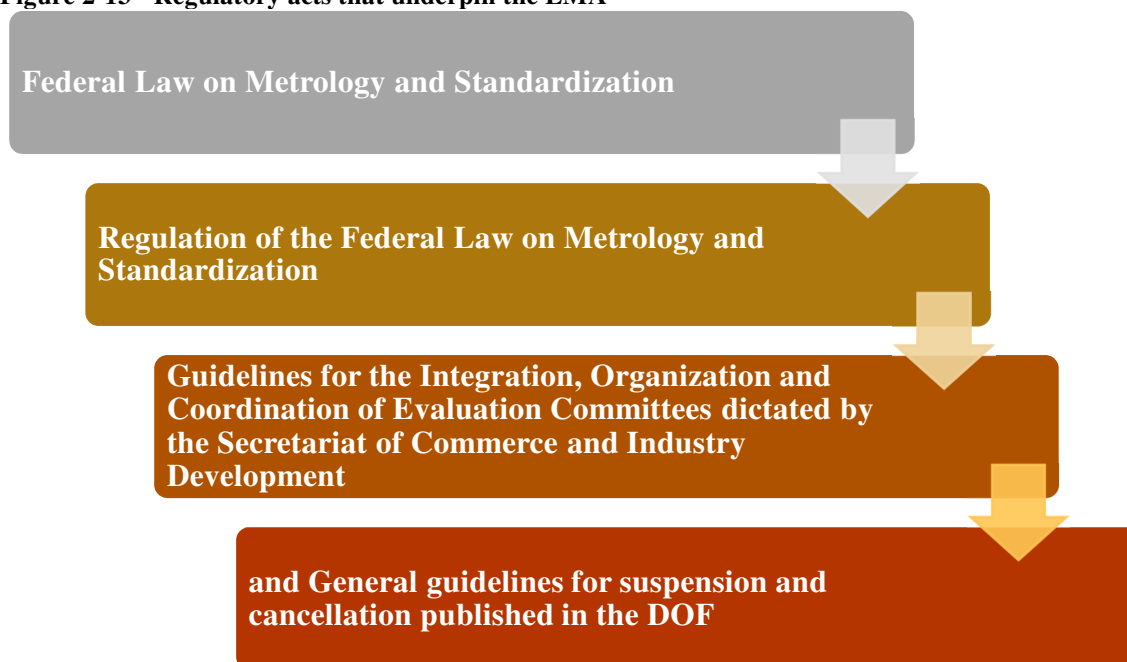
I. Demonstrate the legal, technical, administrative and financial capacity (through the presentation of a Statute or a project detailing the governing bodies and the functional technical structure of the entity where the balanced representation of the productive bodies is shown, a relation of material and human resources, documents proving their financial solvency to ensure the continuity of the accreditation system);
II. Demonstrate your ability to attend to various subjects, sectors or branches of activity;
III. Accompany, where appropriate, its agreements with other entities similar or specialized in the matters to which this Law refers;
IV. Indicate the maximum rates that would apply in the provision of your services.

Source: EMA. Elaboration: CCGI-EESP/FGV.

The performance of the Mexican Accreditation Entity (EMA), specifically, is based on impartiality, which allows objectivity, transparency and trust in accreditations and authorizations. Impartiality is verified in the administration of the policies and procedures under which the entity operates in a non-discriminatory manner.

The diagram below indicates the main legal documents that support EMA's performance.

Figure 2-13 - Regulatory acts that underpin the EMA



Source: EMA. Elaboration CCGI-EESP/FGV.

EMA recognizes the technical competence and reliability of testing laboratories, calibration laboratories, clinical laboratories, verification units, fitness test providers, producers of reference materials and certification bodies for conformity assessment. In any national quality system, accreditation plays a key role in attributing reliability to conformity assessment processes.

The EMA concept arose from the need to address the challenges posed by the international exchange of products, goods and services in the globalized world. Since January 2006, EMA complies with NMX-CE-17011-IMNC "Standard Conformity Assessment - General Requirements for Accreditation Bodies. Conformity Assessment Bodies." In addition, the EMA has international International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC), confirming that the organization works in accordance with international standards⁹⁰.

2.4.3.2. Overview of conformity assessment in Mexico

In the specific dimension of conformity assessment, the main legal instruments are listed below:

- Federal law for the protection of personal data held by individuals;
- Guidelines for the approval of test laboratories, calibration laboratories, certification bodies, and verification units to conduct conformity assessment based on Mexican official standards;
- Letter on the issuance of a general criterion regarding certification of subsection 9.6.1 of NOM-003-SCFI-2014;
- Report of voluntary withdrawal of the international testing facilities of 11/14/2018;
- Report of voluntary withdrawal of the international testing facilities of 07/01/2019;
- Report of international studies on nonconformity;

⁹⁰ ENTIDAD MEXICANA DE ACREDITACIÓN (EMA. Quiénes somos?. Disponible em: https://www.ema.org.mx/portal_v3/. Acesso em: 23 jul. 2019.

- 2018 annual report of laboratories recognized under good laboratory practice (GLP);
- Call for accreditation and approval of verification units with the objective of evaluating the conformity of Mexican official standards on breathalyzers;
- Call for accreditation and approval of verification units, certification bodies and testing laboratories with the objective of evaluating the official Mexican standard on alcoholic beverages;
- Call for the accreditation and approval of verification units with the objective of evaluating the conformity of the Mexican standard on safety devices in vehicles;
- List of measurement instruments dated 04/18/2016 and
- Report of studies of international testing facilities.

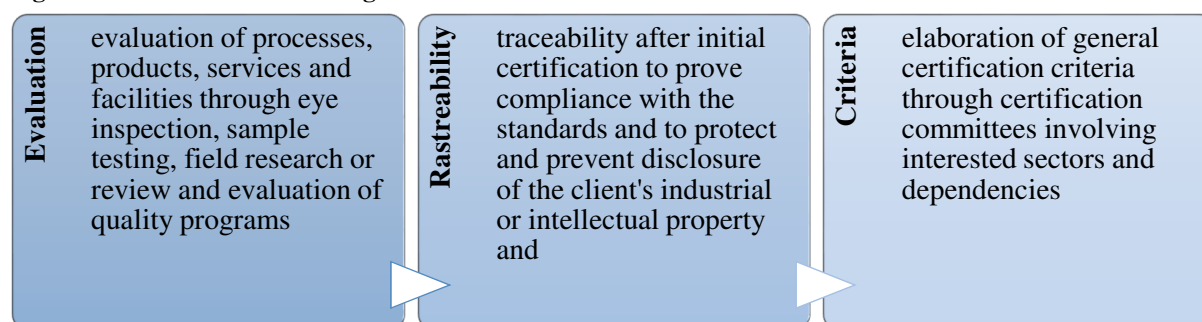
The main procedures for conformity assessment are provided for in the Federal Law on Metrology and Standardization. In the presence of Mexican official standards, such procedures shall be established by the competent agencies when it is necessary to prove compliance with such standards, which shall be done according to the level of risk or protection required to safeguard the objectives set forth in said law, following prior consultation with the sectors concerned (Article 73).

These procedures shall be published for public consultation in the Official Gazette of the Federation before being published definitively, except those provided for in a corresponding official Mexican standard. Certification activities, the main form of conformity assessment, shall be carried out in accordance with the rules, procedures and methods set forth in Mexican official standards and, in their absence, with international standards.

The following activities are covered:

- evaluation of processes, products, services and facilities through eye inspection, sample testing, field research or review and evaluation of quality programs;
- traceability after initial certification to prove compliance with the standards and to protect and prevent disclosure of the client's industrial or intellectual property and
- elaboration of general certification criteria through certification committees involving interested sectors and dependencies.

Figure 2-14 - Activities resulting from certification



Source: EMA. Elaboration: CCGI-EESP/FGV.

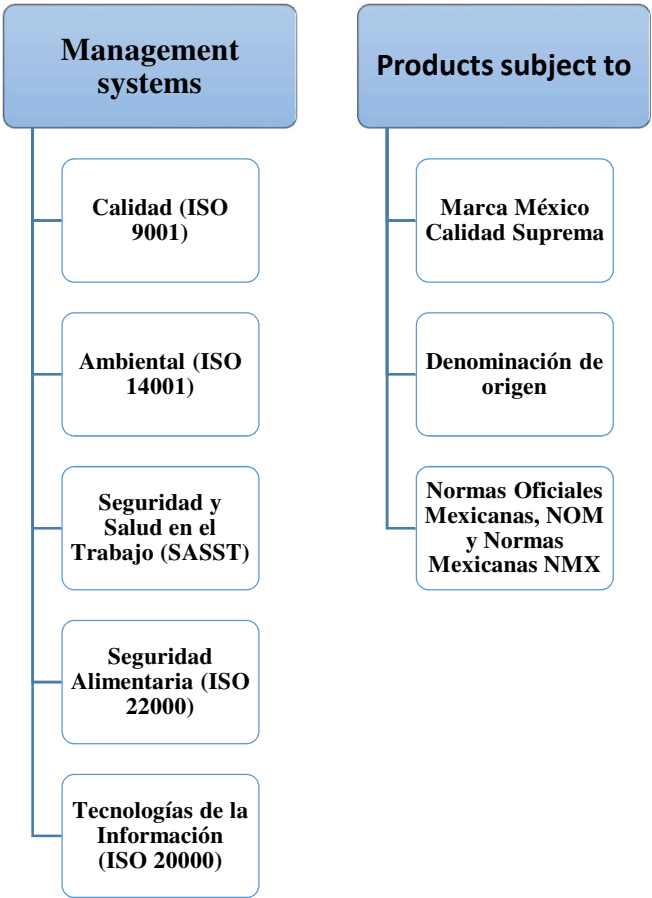
The Mexican Institute for Standardization and Certification (IMNC), one of the main bodies for conformity assessment, has developed rules on the central aspects of certification: conditions for granting, denying and maintaining certification. Secondary aspects have also been covered by IMNC rules: extending or reducing the scope of certification, renewal

procedures, grounds for suspension or conditions for restoring certification after a suspension or withdrawal.

Mexico presents an important network of conformity assessment bodies in the various economic areas. These bodies can be divided into two groups (but all of them make use of Mexican standards, official Mexican standards or international standards for conformity assessment): certification bodies, verification units, laboratories.

In a non-exhaustive way, the activities of these organisms can be organized according to the schemes below.

Figure 2-15 - Types of conformity assessment systems



Source: SE (México). Elaboration CCGI-EESP/FGV.

As can be seen from the table above, the conformity assessment can be divided into two large groups in Mexico. This division, in fact, stems from the type of product being evaluated. In the first case, it is a matter of assessing the conformity of a set of practices, behaviors and situations (management system); in the second case, it is an evaluation directed to material goods. Due to these differences in objects, the evaluation procedures also present important differences, even though they are subject to the same basic rules and general principles.

2.4.3.3. Conformity assessment of management systems

The certification for management systems was created in the areas of quality, environment, energy and safety and health at work. The quality certification is carried out based on the ISO

9001: 2015 technical standard and seeks to guarantee the quality of a product. The certification attesting to an organization's commitment to protecting the environment and sustainable development is based on the ISO 14001: 2015 technical standard.

The energy certification is based on the technical standard NMX-J-SAA-50001-ANCE-IMNC-2011 and allows the fomentation and the taking of actions that contribute to the energy saving, a reduction that, hopefully, guarantees financial return for the organization and provide a method for integrating energy aspects with other management systems. Finally, the health and safety at work certification, based on the NMX-SAST-001-IMNC-2008 technical standard, is intended to assist organizations in formulating occupational health and safety policies and objectives, to identify hazards in area and to assess related risks.

Table 2.10 - The applicable standards for certification of management systems

Management systems	quality certification	ISO 9001:2015
	protection of the environment and sustainable development	ISO 14001:2015
	energy certification	NMX-J-SAA-50001-ANCE-IMNC-2011
	safety and health at work certification	NMX-SAST-001-IMNC-2008
	food safety certification	ISO 22000
	information Technology	ISO 20000-1:2005

Source: IMNC. Elaboration CCGI-EESP/FGV.

The certification of management systems must be made in accordance with general rules. These rules stipulate several aspects that must be fulfilled, regarding the basic principles of transparency and impartiality, confidentiality of information, responsibility of agencies, deadlines for carrying out procedures. The table below systematizes these rules.

Table 2.11 - Rules on process certification

General rules for certification bodies for management systems (quality, safety of the work environment, food)	• compliance with the principles of transparency and impartiality
	• the accessibility of certification services to any applicant
	• the statement by the organization that it has read, understood and accepted the general conditions for the certification of management systems;
	• the fulfillment of the 30-day deadline by the client to make the adjustments pertinent to its management system to comply with the new General Conditions of Certification
	• the prohibition that, in order to avoid any obstacle arising from non-conformity in a process or places involved in the scope of certification, the organization attempts to exclude these or any of them from the scope of certification during the certification process
	• Ensure that decision makers on the certification are part of their Opinions Committee and are different from those who performed the certification audit
	• prohibition of granting certification when there are nonconformities present

	• stipulation of the certification cycle period of three years from the certification decision date, which includes monitoring audits every 12 to 24 months from the date the certification decision was taken; • the stipulation that subsequent certification cycles start from the renewal decision date or, in another case, from the decision date for restoration of the certification
Rules on the relationship with the Mexican Institute of Normalization and Certification	• the management by the IMNC of the information obtained or generated in the performance of its certification activities at all levels of its structure • the maintenance of the confidentiality of the information obtained or generated in the activities assigned to the IMNC by the IMNC staff, • the signing of a legally enforceable agreement between the IMNC and the certified organization, • the responsibility and authority of the IMNC regarding its decisions to grant, deny, maintain certification, extend or reduce its scope, renew, suspend or restore certification after a suspension or withdrawal • the obligation of the applicant to deliver to the IMNC the documentation provided for in item 5.1.8 of the general conditions for the certification of management systems • notification by the organization in writing to the IMNC, within a maximum period of 15 working days, of any changes that have occurred within its organization and that reach the original conditions in which the certification was granted, from the date of realization or application of such changes. • written information from the organization to the IMNC no later than the next business day of having received notification of its audit in any actual or potential situation that might compromise the impartiality of the certification service by the IMNC • the obligation of information on the part of the IMNC to its clients and through the means that considers pertinent of the changes made in the General Conditions of Certification. • the written notification by the IMNC and with the opportunity to customers certified sanctions applicable in cases of non-compliance with the General Conditions of Certification or a legally enforceable agreement in force; • 100% compliance by the client with the cost of service and the absence of outstanding debts with the IMNC in order to deliver the opinion resulting from its initial certification, monitoring, follow-up or renewal audit or by special audits and , where applicable, the corresponding certification document • the prohibition that the client or any part of the same legal entity intervene or suggest to the IMNC the appointment of the audit team, • permission to attend the audit process of observers accompanying the IMNC audit team in order to verify and evaluate the development of the audit process based on the procedures of the IMNC or the accreditation body and the competence of the audit team • the issuance by the IMNC of an audit report, which contains aspects of the management system evaluated, the results of the audit, the fulfillment of the planned audit objectives and the conclusions of the audit team. • presentation of all audit reports and all follow-up reports of non-conformities to the IMNC Advisory Committee for the corresponding certification decision; • the possibility of requesting the renewal of its certification to the IMNC, and it is recommended to start the process in month 33 of the certification cycle through a renewal audit;

Source: IMNC. Elaboration CCGI-EESP/FGV.

The granting of certification depends on compliance with the conditions set forth in item 6.2 of the document on general conditions for the certification of management systems. Initially, the IMNC should conduct the initial two-step audit to confirm that the organization actually operates a management system and meets the requirements of the standard that will base the certification.

Different consequences can follow after the audit of the first stage. In situations where the first stage audit did not identify nonconformity, the organization may receive its audit of the second stage immediately after the end of the audit of the first step or up to 60 calendar days after the first step. In cases where irregularities have been identified and then declared as resolved through the specific follow-up report of the process, the organization is obliged to receive, within a maximum period of 60 calendar days, counted from step 1, step 2 audit of the certification process.

A special procedure should be applied to the renewal of certification with a maximum term of 6 months. The IMNC shall conduct the service by conducting an audit of the first step, followed immediately by a second stage audit. These procedures apply only to certifications issued by certification bodies accredited by at least one accreditation body participating in an international accreditation scheme. Among the procedures:

- Multilateral Recognition Arrangement (MLA),
- Mutual Recognition Agreement (MRA),
- The International Accreditation Forum (IAF) and the Pacific Accreditation Cooperation (PAC).

Such international cooperation should take place specifically in the areas of quality management systems, environmental management systems and energy management systems.

After each audit, the IMNC shall provide the organization with a report, which shall include the conclusions about the organization's management system and the diagnosis of compliance with the objectives of the audit. Disclosures identified by the audit team and explicit recommendation on certification should be included in the final part of the report.

In situations of minor nonconformities, organizations must follow a specific procedure. It is incumbent upon each of them to present to the IMNC, within a period not exceeding 15 calendar days, a plan that includes the following corrective actions: the analysis of causes, corrective actions, dates of implementation and the personnel responsible for their execution. The action plan is evaluated by the designated lead auditor, who issues a completion report by following up on irregularities. The evidence of implementation derived from each proposed correction action will be verified in the next audit.

In situations where more serious nonconformities result from the audit procedure, a relatively more complex special procedure should be followed. The organization shall present to the IMNC, within a period of not more than 15 calendar days, a plan of action with corrective actions, analysis of the causes of nonconformities, corrective actions, dates of implementation and resources necessary for its execution. This action plan should be evaluated by the designated lead auditor to verify that the action plan conforms to the type and magnitude of the identified irregularity. The organization must also present to the IMNC the evidences of implementation of each of the proposed corrective actions. This evidence is evaluated by the lead auditor, who issues his findings in a follow-up report.

Serious nonconformity should be recorded in the audit report. The serious nonconformities are those related to the following aspects: General Conditions for the Certification of Management Systems, a legally enforceable agreement between the IMNC and an organization and / or the Regulation for the use of IMNC brands - Certification of management systems, RPEC01. In addition to the provision of rules applicable to the certification procedure, conditions to maintain the certification obtained must be fulfilled.

To that end, each organization must allow the IMNC to carry out, at its premises, audit activities to monitor its management system and, where applicable, satisfactorily resolve the nonconformities derived therefrom. The IMNC shall evaluate all requirements of the management system within a 3-year period of the certification cycle. Special audits are conducted to extend or reduce the scope of certification and in the form of audit with short-term notification.

In the former, the goal is to expand or reduce their processes, their products and services, locations and / or areas / departments involved in the organization's management system in an integral manner or not. In the second, the main objective is to investigate complaints in response to changes or in situations where customers have been certified suspended due to incidents occurring in the organization such as explosions, fires and accidents. In the first form of special audits, the organization shall submit a notification to the IMNC with a formal document, so that the change in certification can be analyzed. It is the responsibility of the IMNC to determine the need for a specific audit to verify the changes, the conduction of the special audit immediately and the need for amendments to the quotation / economic proposal initially agreed upon. In the second form, the purpose is to investigate complaints in response to changes or, as a follow-up to customers with suspended certification, incidents that have occurred such as explosions, fires and accidents. At the end of the audit, the IMNC will provide the organization with an audit report containing the conclusions about the objectives of the audit, identifying any disagreement identified by the audit team and possibly recommending the certification issued by the audit team.

The conditions for the suspension of certification by the IMNC are also provided in the document with the general conditions for the certification of management systems. Among the general guidelines for certification:

- when the customer management system no longer or repeatedly complies with the specified certification requirements, including requirements relating to the effectiveness of the management system;
- when the organization does not allow its certification oversight audit or special audit to be conducted by the IMNC;
- when the organization does not meet the conditions to maintain certification;
- when the organization misuses the certificate document or the IMNC property mark of conformity;
- when the customer makes a misleading statement about the certification granted;
- when there is a voluntary request by the certified organization itself;
- when the organization has not allowed observers to attend during the initial certification, monitoring or certification renewal audit;
- when the client has made changes to its organizational structure that mainly reach the key personnel or its management system and have not been notified to the IMNC in the specified period;
- when the organization does not satisfactorily resolve the nonconformities resulting from its audit within the time
- when the organization fails to meet the requirements of the IMNC Advisory Committee.

Once the issuance of certification by the IMNC has been suspended, the obligations are borne by the organizations. Each organization is required to discontinue using the certification document from the date of receipt of notification of suspension and to no longer refer to the condition of certificate, which includes use of the IMNC conformity mark for as long as it remains the suspension of certification.

Other provisions contain rules for suspension of certification. The suspension of certification should not last more than 6 months. When the problems that have given rise to the suspension within the aforementioned deadline, the IMNC will have the right to withdraw certification. Withdrawal of certification may also be conducted upon express request of the certified customer. In such cases, the record shall be submitted together with the corresponding request

from the client to the IMNC Advisory Committee for a decision on the voluntary withdrawal of the certification.

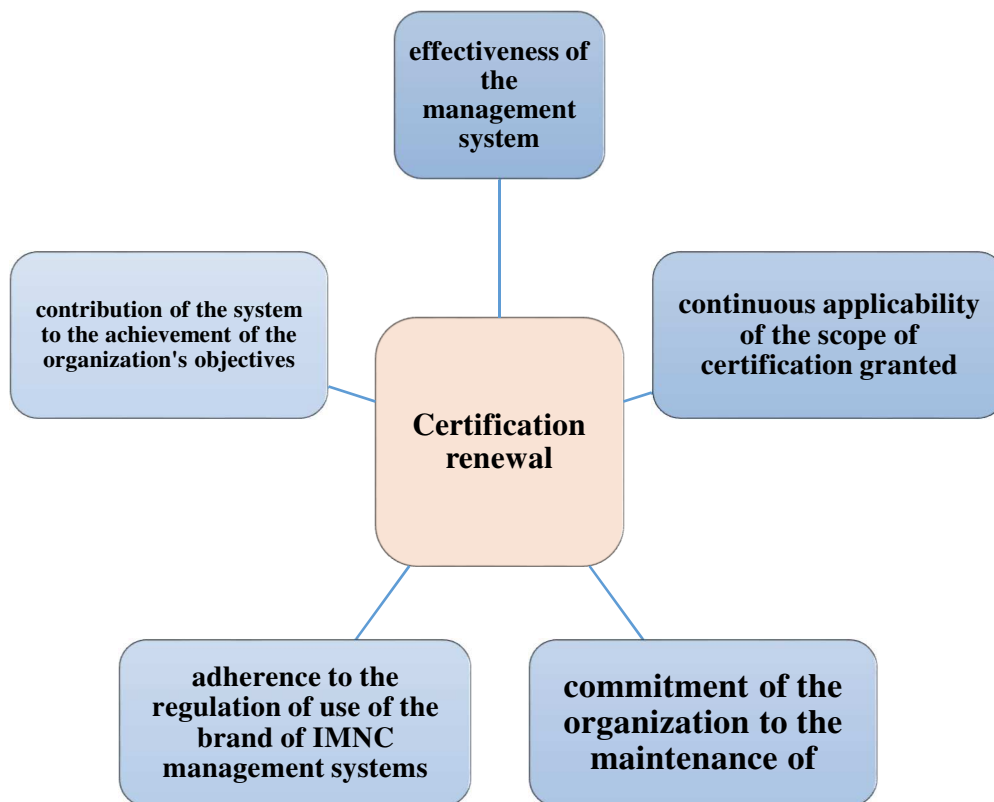
In Mexico, certification must be renewed after compliance with specific conditions. In order to renew certification, the following aspects should be checked in the respective audit: the effectiveness of the management system as a whole, the continuous applicability of the scope of certification granted, the organization's commitment to maintaining efficiency and improvement of the management system, the possible contribution of the operation of the certified management system to the realization of the organization's policy and objectives, and restricted adherence to the IMNC brand management regulations.

When the IMNC has not completed the renewal audit, it will not be possible to recommend renewal of the certification and the validity of the certification can not be extended. This reassessment procedure, based on an audit, is an assumption of the granting of certification renewal.

The restoration of the certification by the IMNC occurs within the next six months after the expiration of the certification. It occurs whenever pending renewal of certification activities are completed or through a renewal audit. The effective date of the new certification cycle defined by the IMNC shall be the date of the restoration decision or at a later date. The expiry date for the previous certification cycle must be maintained.

The organization may require the IMNC to renew its certification in advance. This depends on certain specific aspects: the current status of the certification, the validity of the certification for at least six months, the absence of debts with the IMNC for the provision of the certification service and the presentation to the IMNC of a document that formalizes the request and declares the agreement to waive on the date of the end of the certification. The IMNC must issue the corresponding amendment to the legally enforceable agreement signed by the IMNC and the client as well as issue a new economic proposal for the new certification cycle, which includes the cost of issuing a new certificate.

Figure 2-16 - Renewal of certification



Source: IMNC. Elaboration CCGI-EESP/FGV.

The transfer of certification can also be carried out. The following conditions must be observed: the validity of the certification subject to the transfer, the insertion in the current accreditation scope of the IMNC, the insertion of the IMNC or the proposed places to be transferred in the accredited certification, the current recognition of the certification to be transferred by the less an accreditation body which is a signatory to the MLA or the MRA, concluded with the IAF or the PAC in the areas of quality management systems, environmental management systems or energy management systems and absence of cancellation by the certification body of the agreement legally executed with the organization at the time of request for transfer.

Certifications that do not meet the above conditions will be treated as initial certification. In situations where the decision on the transfer of certification is favorable, the IMNC is obliged to issue a certification document to the requesting organization, respecting the initial certification cycle and with the continuity of the current program of surveillance and renewal audits . The programming of certification services makes it possible to guarantee the quality of the certification service. In this program, the IMNC and the organization undertake to respect the times provided by the IMNC for each stage and service of the certification audit. Once the initial certification audit is confirmed, it can be reprogrammed upon request of the client, without any economic sanction, provided that the application is submitted to the IMNC with up to fifteen calendar days in advance of the established date. In short the certification of management processes becomes progressively more important.⁹¹

⁹¹ Tourist certification is an example of the importance of certification for service savings. In Mexico, a country that receives large numbers of tourists. This type of certification reaches beaches, ecotourism and water health services (spas). The first tourist certification is based on the technical standard NMX-AA-120-SCFI-2016 and establishes requirements and specificities of beaches quality sustainability. This certification provides the prestige

2.4.3.4. Product conformity assessment

Industrial product certifications⁹² provide a level of confidence and safety to consumers of products processed, processed and / or distributed by organizations that comply with applicable regulations. The certification is valid for three years and during this period, surveillance visits should be carried out, when necessary.

During the validity of the certificate, every natural or legal person must carry out evaluations in a timely manner and keep records of activities pertinent to the certification of which they are carriers. In product certification, conformity assessment may be carried out by dependencies or by persons accredited and approved at the request of a party or for private, official or export purposes. The procedure can be performed by type, line, batch or start of products or by system, either directly in the corresponding facilities, or during the development of activities, services or processes. Specialists in the subject matter of the conformity assessment may also act.

Once the certification procedure is completed, the evaluation units assign the products a commercial information label, the H-tag and the *Ki Wo Tsuka* methodology (continuous improvement)⁹³. The first, which specifically concerns material goods, ensures that domestic and imported products comply with Mexican official standards, since the information available is clear, complete and timely so that consumers have a better purchasing option. The second is granted to restaurants, coffee shops, hotel restaurants and industrial canteens and certifies that the supplies are maintained with high hygiene standards and voluntarily comply with the requirements of the NMX-F-605-NORMEX-2004 standard. The third stimulates the generation of ideas to improve the daily activities of work and the products of an organization and helps the identification of internal and external clients.

It is also worth mentioning the presence of an official distinctive mark of products manufactured in Mexico and that can be recognized by consumers. The "Hecho en México" brand attests to world-class quality backed by the talent, creativity and innovation of producers who work to provide competitive goods and services and allows the presence of Mexican products in

of the tourist destination, plus foreign and domestic investments, the conservation of coastal ecosystems and the increase of quality and processes in accordance with international standards. The second tourism certification, based on technical standards NMX-AA-133-SCFI-2006 and NMX-AA-133-SCFI-2013, provides requirements and sustainability specificities of ecotourism. With this certification, ecotourism centers, community networks and all interested individuals or entities are encouraged to incorporate measures of sustainable ecotourism performance and local capacities and investment in equipment to achieve environmental benefits at destination in favor of natural resources. strengthened. The third certification, based on the technical standard NMX-TT-009-IMNC-2004, allows the homologation of quality in facilities and services, increasing the competitiveness of spas, greater professionalization of the spa industry, conservation and attracting national tourism and national and international promotion of health tourism.

⁹² There are two other types of specific certifications that should be highlighted: the certification of labor equality and the certification of people. The certification of labor equality guarantee is based on technical standard NMX-R-025-SCFI-2015 and establishes the necessary requirements to obtain certification and demonstrate that the organization adopts practices of equality and non-discrimination for equality between men and women. Personnel certification is based on technical standard NMX-CC-19011-IMNC-2012, attaches added value to improve an organization's performance and provides the confidence that the certified person meets minimum competency requirements.

⁹³ *Es una metodología de mejora continua, desarrollada por el MBA Alejandro Kasuga en Yakult de Puebla e implementada en más de 100 empresas a nivel internacional en países como México, EE. UU., Canadá, Japón, entre otros. En México se implementó con éxito en universidades como UPAEP, BUAP, Tecnológico de Monterrey, UDLAP, UMAD, entre otras y en empresas como: Africam Safari, Hino Motors, Café Punta del Cielo, La Zarza, Jumbo, Kreston, Endeavor.*

international markets. The validity of the authorization for the use of the mark will be determined based on the sector to which the company belongs, according to general criteria provided by the General Direction of Standards. The list below illustrates the figures that indicate the Mexican production of manufacture.

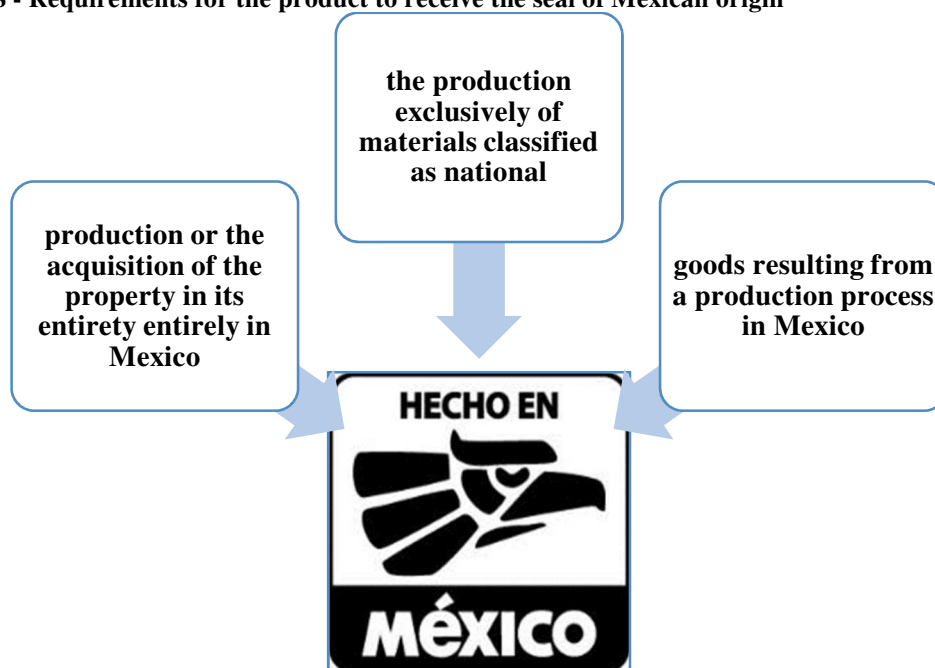
Figure 2-17 - Mark "Made in Mexico"



Source: Multiple

The acquisition of the certificate "hecho en mexico" of use of the mark is conditioned to the fulfillment of requirements. They are the production or the obtaining of the good in its totality entirely in Mexico; the production exclusively of materials classified as nationals in accordance with trade agreements in which Mexico participates; the production of a product with non-domestic goods but resulting from a production process in Mexico so that the good is classified under a subtitle other than that in which non-domestic goods are classified under the Harmonized System and the limits on value of transaction of the non-national materials that should not exceed the percentage established for each sector regarding the transaction value of the merchandise.

Figure 2-18 - Requirements for the product to receive the seal of Mexican origin



Source: General Direction of Standards. Elaboration CCGI-EESP / FGV.

The certifying bodies must undergo an approval process carried out by the competent agencies. This approval is granted whenever the organization has national coverage, demonstrates the participation in its functional technical structure of representatives of the interested sectors at the national level, has procedures that allow the performance of its activities in the certification process independent of private or collective interests and allow the presence of a representative of the competent agency in the performance of its duties.

The Mexican quality system has undergone major improvement processes. The country's entry into the Organization for Economic Co-operation and Development (OECD) and the conclusion of various trade (including advanced economy) agreements have led the country to reform its regulatory system and standardization and conformity assessment procedures. These reforms, in general, seek, in a broader context of modernization of public administration, to make the system more coherent and therefore more efficient and costly for companies.

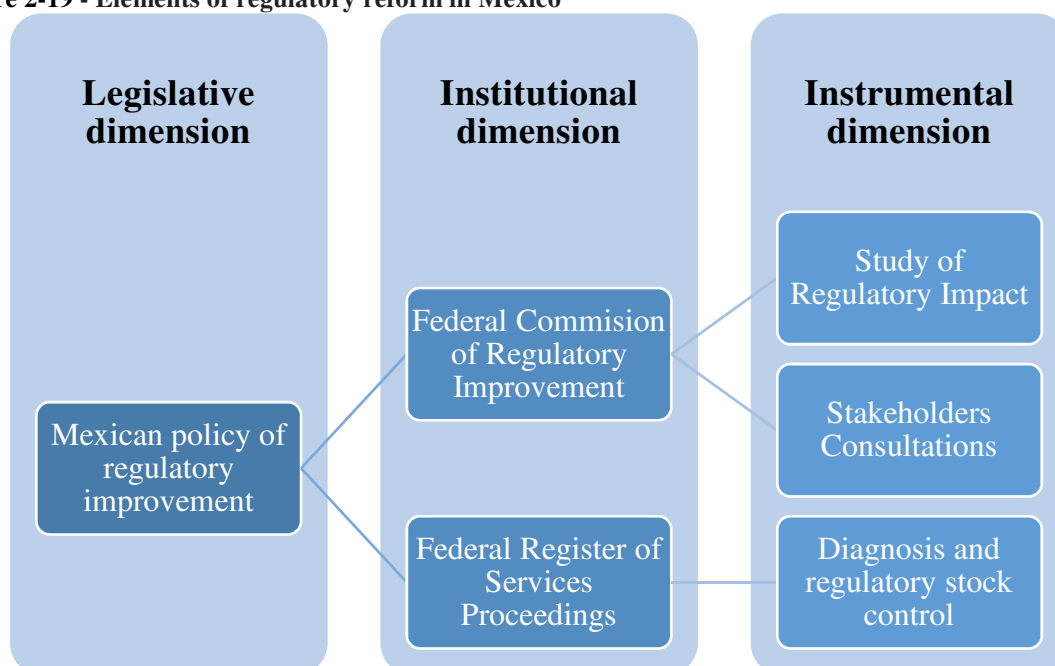
2.5. Regulatory Coherence

Regulatory reform actions were initiated, in 2012, by the Pact for Mexico, which was a historic agreement between the three major Mexican political parties (Institutional Revolutionary Party, Party of the Democratic Revolution, National Action Party). The Pact agreed on the basis for the country's development. The scope of the reform was broad and included several economic activities in the country. The pact was complemented by reforms aimed at improving the quality of education and health systems, stimulating the efficiency of the judiciary, liberalizing the financial sector, strengthening innovation, reducing informality and stimulating women's participation in the labor market.

The Mexican policy of regulatory improvement is formally provided for in the Federal Law on Administrative Procedures (Federal Law on Administrative Procedure - LFPA)⁹⁴.

The main elements of this policy include the establishment of the Federal Commission for Regulatory Improvement (Federal Commission for Regulatory Improvement - COFEMER) as a monitoring body responsible for stimulating regulatory improvement policy, forecasting the responsibilities of ministries and regulatory agencies as part of the policy the Federal Register of Procedures and Services (Federal Register of Procedures and Services - RFTS), which gave it a binding character, and the provision of instruments for the implementation of the policy as the study of regulatory impact (in spanish, EIR) administrative simplification, consultation and diagnosis of regulatory stock.

Figure 2-19 - Elements of regulatory reform in Mexico



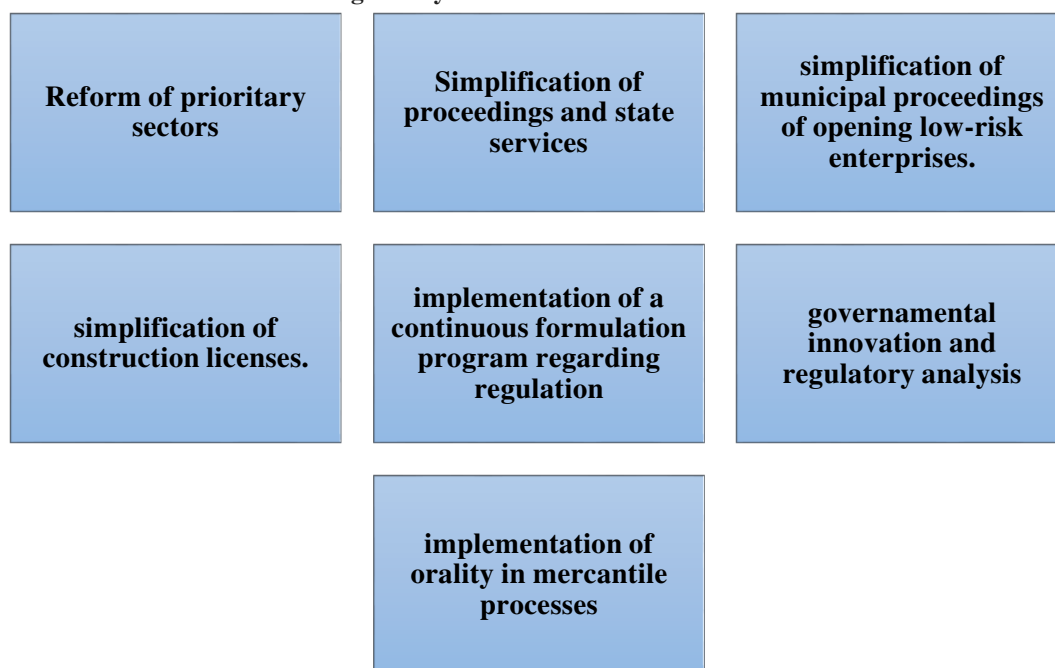
Source: OCDE. Elaboration: CCGI-EESP/FGV.

Regulatory reform covered national and subnational measures. Through an aggressive program that was finalized in 2016, Mexico reduced administrative burdens by 36%. The Justice Everyday program, launched in 2014, brought the federal government closer to state and municipal governments in order to make rules more understandable, simplify business licenses and construction permits, implement orality in legal proceedings related to commercial law, reduce local administrative burdens, diagnose regulatory reforms in core sectors, and stimulate the use of alternative dispute resolution mechanisms.

The main actions taken to implement the most recent phase of the project that was completed on May 30, 2018 can be classified in the following subareas: reform of priority sectors; simplification of state procedures and services; simplification of municipal opening procedures for low-risk companies; simplification of building permits; implementation of the continuing training program in regulation; government innovation and regulatory analysis; and implementation of orality in mercantile processes.

⁹⁴ For the full text of the law, consult:
<http://www.cofemer.gob.mx/documentos/marcojuridico/LEYES/lfpa.pdf>

Figure 2-20 - Latest dimensions of regulatory reform



Source: OCDE. Elaboration: CCGI-EESP/FGV.

The regulations imposed by the State on its managers and public service providers are also part of the regulatory improvement policy. The program of review and cutting (administrative guillotine), for example, has the objective of eliminating internal administrative rules, with the purpose of simplifying and standardizing the functioning of federal government institutions, as well as making possible the elimination of rules that hinder the efficient delivery of a service.

The overall results from the implementation of the program were verified in each subarea in which actions were implemented. In priority sectors, regulatory failures have been identified and reform memoranda have been drafted covering improvement proposals. In the simplification of state procedures and services, with the implementation of the simplification of charges program.

In the simplification of municipal procedures for opening low-risk companies, the recommendations formulated seek to improve rotation catalogs, exclusive formats, operating manuals, maximum resolutions, softwares and unique windows. For example, in the simplification of building permits, it was identified that the average term for the construction license is 66 days.

The following proposals were also tabled: (i) shorten the resolution period from 66 to 10 working days on average, (ii) reduce the applicant's interactions from 22 to 8 on average, (iii) reduce the requested requirements from 43 to 13 on average, (iv) simplify the procedures from 7 to 3 on average and (v) give a legal basis to 763 elements relating to procedures.

In the program of continuous training in regulation, governmental innovation and regulatory analysis, a diploma was created in regulation by the Institute of Legal Research of the National Autonomous University of Mexico (UNAM). The course includes the following topics: regulation, regulatory improvement and regulatory analysis. In addition, a master's course in regulation by the Faculty of Law and Criminology was created, based on a collaboration with

the Autonomous University of Nuevo León (Universidad Autónoma de Nuevo León - UANL), which includes a program of studies and content on regulatory improvement.

In 2013, the reforms had economic and fiscal bases and also consisted in the creation of national jurisdictions specialized in competition, telecommunications and radio transmission. Another significant reform was the application of the orality principle in the commercial processes mentioned above. The main objectives are to increase the quality of court rulings, shorten the duration of proceedings and to give effect to broader competition reforms. An essential aspect to be addressed was the lack of training and preparation of stakeholders in criminal justice, which may make the immediate positive effects of the reforms impossible.

In addition, the ex ante impact-checking system of draft technical regulations and public consultations is operative and enables technical regulations to be aligned with public policy objectives and to promote economic activities. Public consultations allow stakeholder perspectives to be taken into account and help to gather evidence for effective policy formulation.

The results of the reforms implemented were considered positive. Private investments, energy production, technological know-how, tax revenues and business confidence have been expanded. Some areas were also excluded from the regulatory improvement policy. These areas include the payment of taxes, agrarian law, labor law, the regulation of administrative responsibilities of public servants and the regulations produced by the ministries of defense and the navy. In terms of social security, formalities and procedures directly related to the provision and delivery of preventive medical services for diagnosis, rehabilitation, management and treatment in hospitals are excluded from the regulatory improvement program.

One form of regulatory coherence is to establish agreements and agreements for collaboration, coordination and coordination. In the period from December 1, 2017 to October 31, 2018, CONAMER subscribed 50 agreements with federal entities and municipalities, two with academic institutions and seven interinstitutional agreements. The purpose of such agreements is to establish the bases for coordination and collaboration between CONAMER, the state government and municipalities to stimulate the integral and strategic regulatory improvement agenda and for municipalities to establish their regulatory improvement programs.

The agreements with academic institutions are the agreement between the Center for Research and Economic Teaching A.C. (Centro de Investigación y Docencia Económicas A.C. - CIDE) and CONAMER) and the agreement between UANL and CONAMER. The first seeks to implement the daily justice project on regulatory improvement. The second objective is to carry out the consultancy, development and implementation of the Training Program for Regulatory Improvement in the distance masters modality, and later to create an academic postgraduate program corresponding to the masters degree in the field of regulatory improvement in the distance mode.

3. Colombia

The purpose of this Chapter is to analyze the main aspects of the system of technical regulation, standardization and conformity assessment in Colombia. After a brief introduction, in which trade flow data will be presented between Colombia and Brazil with the main products of the bilateral trade agenda. Then, the structure of the Colombian State will be analyzed, focusing on the identification of organisms that participate directly in the regulation processes, standardization and conformity assessment. These three dimensions will be studied separately, with special emphasis on procedures for coherence and the creation and application of technical rules.

3.1. Introduction

Colombia is Latin America's fourth largest economy measured by gross domestic product. The top exports of goods of Colombia in 2017 were crude petroleum (US\$11.1 billions), coal briquettes (US\$ 7.63 billions), coffee (US\$ 2.7 billions), refined petroleum (US\$ 2.06 billions) and gold (US\$ 1.45 billions). Its top imports of goods in 2017 comprised refined petroleum (US\$ 2.81 billions), broadcasting equipment (US\$ 1.99 billions), cars (US\$ 1.89 billions), packaged medicaments (US\$ 1.2 billions) and planes, helicopters, and/or spacecraft (US\$ 932 millions). The top export destinations of Colombia in 2017 were the United States (US\$ 11.1 billions), Panama (US\$ 2.58 billions), China (US\$ 2.02 billions), the Netherlands (US\$ 1.86 billions) and Mexico (US\$ 1.56 billions). The top import origins in 2017 were the United States (US\$ 11.7 billions), China (US\$ 8.58 billions), Mexico (US\$ 3.47 billions), Brazil (US\$ 2.42 billions) and Germany (US\$ 1.86 billions). Colombia is the 55th largest export economy in the world and the 53rd most complex economy according to the Economic Complexity Index (ECI). In 2017, Colombia exported US\$ 39.1 billions and imported US\$ 44.3 billions, resulting in a negative trade balance of US\$ 5.18 billions. In 2017, the GDP of Colombia was US\$ 314 billions and its GDP per capita was US\$ 14.5 thousand.⁹⁵

Commercial Relations with Brazil

Colombia is Brazilian 19th export partner and our 24th import partner. In 2018, it accounted for US\$ 2,805 billion in exports and US\$ 1,717 billion in imports, with a net result of US\$ 1,087 billion surplus favoring Brazil.⁹⁶ The tables below provide the main goods exported to Colombia and imported from Colombia in 2018 and are followed by a graphic that illustrates commercial relations between both countries.

⁹⁵ The Observatory of economic complexity. Available in: <<https://atlas.media.mit.edu/en/>>. Access on: 08 May 2019.

⁹⁶ Ministry of Development, Industry and Trade. Available in: <<http://www.mdic.gov.br/>>. Access on: 08 May 2019.

Table 3.1 - Exports to Colombia in 2018

Code SH2	Description SH2	Value FOB (2018/US\$)
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof.	463.890.600
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	411.288.184
39	Plastics and articles thereof	278.335.736
72	Iron and steel	258.565.450
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	127.594.918
40	Rubber and articles thereof	101.711.011
21	Miscellaneous edible preparations	100.850.490
48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	82.468.194
88	Aircraft, spacecraft, and parts thereof	73.254.594
30	Pharmaceutical products	69.696.803
38	Miscellaneous chemical products	69.132.669
33	Essential oils and resinoids; perfumery, cosmetic or toilet preparations	47.153.718

Source: Comexstat. Elaborated by CCGI-EESP/FGV.

Table 3.2 - Imports from Colombia in 2018

Code SH2	Description SH2	Value FOB (2018/US\$)
27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	950.406.112
39	Plastics and articles thereof	329.891.447
15	Animal or vegetable fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes	90.562.846
38	Miscellaneous chemical products	55.566.307
40	Rubber and articles thereof	27.287.082
48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	25.215.556
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	20.346.042
76	Aluminium and articles thereof	19.339.358
29	Organic chemicals	18.070.546
28	Inorganic chemicals; organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes	16.880.790

Source: Comexstat. Elaborated by CCGI-EESP/FGV.

3.2. Governmental Structure in Colombia

Colombia is a presidential Republic, a representative democracy and a unitary State, as established in the 1991 Constitution. In accordance with the principle of separation of powers, the government is divided into three branches: the executive, the legislative and the judiciary.

The head of the executive branch is the President of Colombia, who serves both as head of state and head of government, followed by the vice president and the Council of Ministers. The president is elected by popular vote for four-year terms and is currently limited to a maximum of two terms. He is also the commander-in-chief of the Armed Forces. Ministries are listed on the following table.

Table 3.3 - Ministries in Colombia

Ministries in Colombia
Ministry of Agriculture and Rural Development
Ministry of Environment and Sustainable Development
Ministry of Commerce, Industry and Tourism
Ministry of Culture
Ministry of National Defense
Ministry of National Education
Ministry of Finance
Ministry of the Interior
Ministry of Justice and Law
Ministry of Mines and Energy
Ministry of Foreign Affairs
Ministry of Health and Social Protection
Ministry of Information Technology and Communications
Ministry of Labor
Ministry of Transport
Ministry of Housing, City and Territory

Source: Comexstat. Elaborated by CCGI-EESP/FGV.

The legislative branch of government consists of the Senate and the House of Representatives. The 102 seats of the Senate are composed of national citizens and the representatives are elected by each region and minority groups. At the provincial level, the legislative branch is represented by departmental groups and municipal councils.

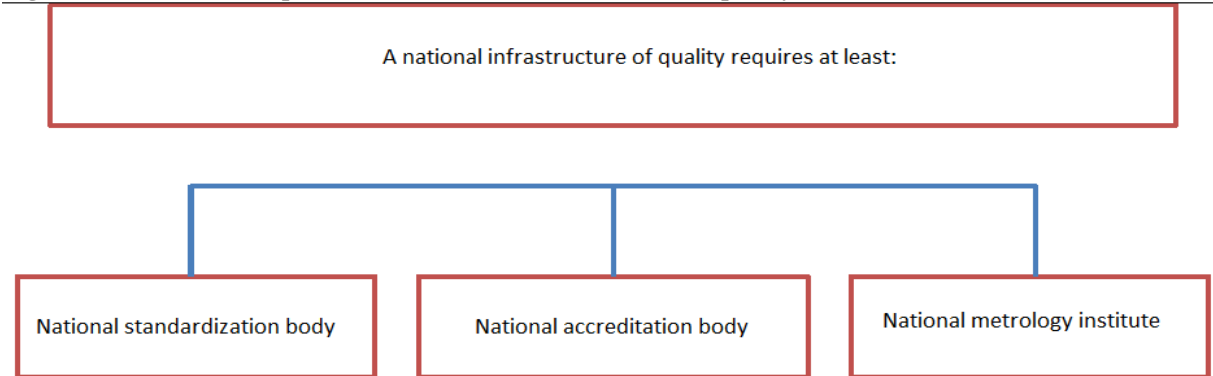
The judiciary is headed by the Supreme Court, composed of 23 judges divided into three chambers (Criminal, Civil and Agrarian and Labor). The judiciary also includes the Council of State, which has the special responsibility of administrative law and also provides legal advice to the executive, the Constitutional Court, responsible for ensuring the integrity of the Colombian Constitution and the Superior Council of Magistracy, responsible for auditing the Judicial power. Colombia operates under a civil law system.

3.3. Colombian national system of quality

The description and analysis of the Colombian system will be preceded by the presentation of Colombian national system of quality. This system comprises a national standardization body, a metrology network, services of conformity assessment and accreditation and the interconnections between them all. The quality infrastructure is one of the basis that allows the efficiency of modern industry and trade and the modern pattern of modern life.

In Colombia, a national system of quality (*Sistema Nacional de la Calidad* - SNC) gathers different aspects. A SNC can be defined as all the frameworks of (public), legal, regulatory and administrative policy and (public or private) institutional arrangements that are required to establish and implement in practice standardization, metrology, accreditation and the set of services of the conformity assessment, which include inspection, testing, and certification that are necessary to provide sufficient evidence that the products and services comply with requirements demanded by the market or by users or by the authorities. The three essential pillars of a SNC are provided on the diagram below.

Figure 3-1 - Essential requisites of a national infrastructure of quality



Source: Inter-American Development Bank

The national standardization body was designed for the development, access and dissemination of national and international technical standards. However, the benefits of having a good level of standardization in the improvement of economic efficiency and the access to markets cannot be obtained without the ability to have reliable measurements and the ability to demonstrate that the goods meet the requirements specified in the standards. Besides the national standardization body, Sectoral Standardization Units (*Unidades Sectoriales de Normalización* - USNs) draft sectoral technical standards (STCs). Their creation must be approved by the MINCIT Regulation Directorate in accordance with decree 210/2003.

The international memberships and recognitions, the number of ISO 9001 certificates, the most common ISO standard, the number of technical committees (comités técnicos - CT) allow the measurement of advances of quality infrastructure in the area of standardization. The first indicator reveals that over time became a member of ISO, COPANT, the ISO Technical Management Board (TMB) and IEC. The institute also sought international accreditations as the one of the ANSI-ASQ National Accreditation Board (ANAB) and the one of the Ecuadorian Accreditation Body (Organismo de Acreditación Ecuatoriano - OAE).

In the country, besides a national standardization body, a metrology network was also created. The network is a synergistic union of test and calibration laboratories of public and private network, of comparison program providers, of producers of reference materials, of natural persons involved in the topics of metrology and of users of metrological products coordinated by INM. Inside the network, the following working groups deal with conformity assessment activities: calibration, providers of inter-laboratory comparison programs, producers of certified reference materials, support to accreditation and training, courses and consultancies. The general objectives of the network are the identification of technical metrological capacity in terms of the existing national supply, determination of metrological needs and expectations of the Colombian laboratories, stimulus and support to the creation of processes and projects that

allow the generation of products and services according to the needs and requisites and generation, update and exchange of metrological knowledge between its members to integrate and strengthen the metrological capacity. In order to achieve this infrastructure, CONPES 3446 was decisive in tracking the very few efforts and governmental funds on the institutional reorganization and on the creation of a normative framework that led to the development of the SNC.

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The SIC is responsible for activities relating to legal metrology in Colombia. In August 2017 it received ONAC's Accreditation Certificate for its mass and volume calibration laboratories, which were set up in order to bolster the country's metrological control work⁹⁷. The National Institute of Metrology (INM)⁹⁸, created by decree 4175/2011 and regulated more recently by Resolution DG 28/2016, is responsible for scientific and industrial metrology.

In order to perform its functions, the INM establishes, coordinates, directs and oversees the national industrial quality control, weights, measures and metrology programmes, and organizes the quality control and metrology laboratories it needs to carry out its work. It also offers the technical traceability capability for verifying the quality of products made or marketed in Colombia and compliance with international undertakings relating to quality. The Colombian Metrology Network (RCM) brings together public and private testing and calibration laboratories, providers of comparison programmes, producers of reference materials, natural persons involved in metrology activities and users of metrological products, and is coordinated by the National Institute of Metrology. Pursuant to Resolution DG 92/2014, which governs the RCM, the latter's main general objectives are, inter alia, to identify the country's technical metrological capacity in terms of the existing supply, determine the metrological needs of Colombian laboratories, and promote and support joint processes and projects to generate the products and services that match those needs and requirements.

On its turn, the Metrology Institute is charged to supervise the national standards of measurement that can have their international traceability and exercise the function of transferring that traceability to secondary and industrial standards. Metrology includes scientific, industrial and legal metrology. Scientific metrology reaches the research and development of measurement norms as well as conservation and custody of measurement

⁹⁷ ORGANISMO NACIONAL DE ACREDITACION COLOMBIANO. Quiénes somos?. Disponível em: <https://onac.org.co/>. Acesso em: 1 ago. 2019.

⁹⁸ INSTITUTO NACIONAL DE METROLOGIA. Quiénes somos. Disponível em www.inm.gov.co/. Acesso em 16/07/2019.

standards. Industrial metrology is directly related to measurement methods, calibration processes, tests, inspection and control that serve as support for business activity. This area provides to any national producer instruments and procedures that allow him to comply national or foreign standards, that can be foreseen on technical norms, technical regulations or on international references.

Examples of services that fall on the scope of the National Institute of Metrology are equipment calibrations, inter-laboratory comparisons, technical assistance on metrological issues and capacitation and training of human resources in metrology. Finally, legal metrology is directly related to the activities of inspection, supervision and control and of the accuracy of measurements. Therefore, in Colombia, legal metrology includes all those procedures of a legal or administrative character or procedures that are carried out by public authorities or appointed by them, with the purpose of ensuring the quality and credibility of the measurements in relation to the official controls, trade, safety and environment.

3.3.1. Technical regulation

The preparation of technical regulations in Colombia is not centralized and is the responsibility of various institutions, primarily ministries, regulatory commissions and decentralized bodies. According to the authorities, as a general rule technical regulations are based on international good practices. Each entity has its own internal procedure for preparing the technical regulation, within its sphere of competence; the MINCIT is responsible for regulating products. However, in practice similar procedures are adopted pursuant to decree 1595/2015 and the recommendations of the Intersectoral Quality Commission. In 2017, the procedure for the drafting of technical regulations was updated through the MINCIT Integrated Management System (SIG). A procedure, the PAINERT has since been agreed for the preparation and issuance of technical regulations, which compiles recommendations on good practices⁹⁹.

The authorities have noted that, in general, draft technical regulations are submitted for discussion with all interested persons or entities. The discussion of the regulatory drafts takes place throughout the process of preparing the regulation and up to the international notification of the technical regulation. Thereafter, the procedures established by the TBT Agreement are followed, respecting the established time-frames. Thus, since 2001, Colombia has applied the recommended time-limit of 90 days or more for making comments on notifications. Technical regulations are issued through decrees and resolutions, and exceptionally through laws. Most technical regulations reflect or are based on ICONTEC standards, although there are also technical regulations based on international standards.

The Supervisory Authority for Industry and Trade (SIC) is responsible for monitoring compliance with technical regulations in the following fields: in the area of personal consumer goods, labelling of footwear and clothing, and toys, for example; industrial products such as plain and deformed steel wire and electrowelded mesh; electric and gas-powered equipment subject to energy efficiency labelling; corrugated bars and rods; electric fittings; reflective tape for motor vehicles; household consumer products such as ceramic tiles and dishware, batteries, refrigerators, freezers and pressure cookers; in transport, products such as public service vehicles, safety belts, safety windows, braking systems and tyres; and vehicular natural gas (VNG) and household gas.

⁹⁹ WORLD TRADE ORGANIZATION. Trade Policy Review Colombia 2018. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s372_e.pdf.

With respect to technical regulations and legal metrology, the SIC fixes permitted tolerances for purposes of metrological control and establishes the applicable requirements for measuring instrument models or prototypes and measurement standards that are to be marketed. The SIC also carries out administrative investigations of manufacturers, importers, producers and marketers of goods and services subject to compliance with technical regulations, and may impose the corresponding measures and penalties. In accordance with law 1480/2011, the Consumer Protection Statute, the SIC may suspend the marketing of a specific product or service when there is reliable evidence of a risk to the legitimate objective which the technical regulation supervised by the SIC is designed to protect.

Producers and importers of products (goods or services) that are subject to compliance with technical regulations which the SIC is responsible for supervising and monitoring must be registered in the SIC Register of Producers and Importers before the products concerned can be placed on the market or imported. Each trading establishment under the same business name is linked to a single registration. The Register of Producers and Importers has a public consultation module. The SIC also ensures that conformity assessment bodies register all conformity certificates and inspection reports that they issue in the Conformity Certificates Information System (SICERCO).

Most of the technical regulations are issued by the MINCIT and the Ministry of Health and Social Welfare. The criteria most used for the drafting of technical regulations include the protection of human life and health, consumer protection and protection of the environment. In December 2017, 105 technical regulations were in force in Colombia. The products covered include a range of food products, additives, fuels, medicines, chemical products, containers and fertilizers, and products that have an environmental impact.

Since the previous review in 2012, when an automatic mechanism for reviewing the expiry of technical regulations did not exist in Colombia, there has been a major change in this area. According to decree 1595/2015, technical regulations must be reviewed by the regulatory entity in order to determine whether they should be maintained, modified or repealed, at least once every five years, or earlier if there is a change in the circumstances that gave rise to them.

After the description of the elements of a SNC and their connections, it is possible to identify the advantages arising from the implementation of a SNC. Examples of benefits are the following: overcoming challenges and barriers to free trade and globalization, access to international markets and increased competitiveness in the local market, promotion of competitiveness of companies through increased innovation, protection of consumers through the guarantee that products and services comply with the minimum requirements, support of governments in the development of standards and regulations on quality issues and strengthening of sustainable economic development by strengthening the national industry in its internal and external competitiveness.

Quantitative data illustrate the essential character of conformity assessment in the country. According to ISO information, Colombia is the third Latin American country with the highest number of certificates ISO 9001, being overtaken only by Brazil and Argentina and is the fourth country in the region in number of certificates ISO 14000 and automotive certificate TS 16949. CONPES 3446/2006 also provides that the vast majority of certifiers are located in Bogotá, with only few in Medellín, Pereira and Cali. Seven organizations accredited by SIC certify quality management systems under ISO 9001. Personnel certification in Colombia, on the contrary, is very restricted. The different forms of conformity assessment will be described

through their legal bases provided in decree 1595/2015 and their conceptualizations followed by the description of entities that perform them.

Decree 1595/2015 provides rules applicable to conformity assessment. It establishes that conformity assessment for goods subject to technical regulations is compulsory and that importers and domestic producers are obliged to prove compliance by means of an inspection report or a conformity certificate, which can be a first-party certificate issued by an accredited body or a certificate issued by a designated body before the marketing.

The validity of a conformity certificate in Colombia is conditioned to the following requisites: it is issued by the certification body accredited by the national accreditation body and the scope of the accreditation encompasses the product and the RT; or it is issued by a foreign certification body accredited by an accreditation body recognized under the multilateral recognition agreements to which the national certification body is a party.

Calibration consists on the establishment of a comparative relation, in specific conditions, between the values obtained and the corresponding values of the same magnitude indicated by standards. In order to guarantee the validity of a calibration, it is essential to maintain a metrological chain of traceability. Traceability is the property attributable to a result of a measurement or to a standard that allows its relation with determined references that are generally in national or international standards, through an uninterrupted chain of comparisons considering all the determined uncertainties. Measurements can be concentrated on basic magnitudes as temperature, mass, weight, volume, pressure and length and can be more complex as the ones that involve chemicals and flows. Examples of products that undergo calibration are food, beverages, chemical products, paper, paperboard and plastic and rubber products.

Test and calibration laboratories are key entities in conformity assessment and can be classified as laboratories created by industrial companies and private laboratories. They, however, are not enough to perform conformity assessment on the whole national territory, are sectorial and geographically concentrated and some of them are not accredited. The country also lacks sufficient supply of laboratories that perform chemical and physicochemical measures.

Certification consists on a procedure through which a third party through a written record or through a conformity label attests that a product, a process or a service complies requisites foreseen on the regulation, national or international standards, as well as standards defined by a client. ICONTEC is the main certifying entity and is recognized in more than 150 countries¹⁰⁰. Certification by accredited bodies abroad is accepted in Colombia by most ministries and agencies. In the case of most public entities, with the exception of MINCIT, acceptance is conditional upon whether the country where the certifying body is located has a mutual recognition agreement with Colombia or an Andean country, and the certifying body is registered with the CAN General Secretariat, in accordance with decision 506.

Inspection consists on the check of the condition and weight of products marketed in transshipments that supports the control of quantity and quality and the compliance with relevant regulatory requirements in different regions and markets.

¹⁰⁰ INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

Tests consist on the determination of one or more features of a sample of a product, process or service according to a specific procedure. In order to foster trust on the results, quality and repetition of the tests are essential requisites. Test laboratories can be classified as laboratories that produce data that will be used by third parties and as laboratories for internal use of organizations.

For Colombia, the main benefits arising from conformity assessment procedures are a trustworthy infrastructure for conformity assessment and quality demonstration, access to test laboratories to the development of new products, improvement of the national metrological infrastructure and improvement of the consumption culture.

The following technical regulations are applied to conformity assessment in Colombia:

Table 3.4 - Technical Regulations applied to conformity assessment

Commentaries on the update of Resolution 686/2018 - Technical Regulation of toys
Resolution 67759/2018, which changes Resolution 77506/2016, which regulates the metrological control applicable to weighing instruments of non automatic operation
Decree 1411/2018 that creates the Intersectorial Commission of Technical Regulation and establishes its functions
Decision 827/2018 that provides guidelines for the creation, adoption and application of technical regulations and conformity assessment procedures on member countries of the Andean Community and on the community level
Resolution 5405/2018
Resolution 1856/2017 applicable to low alloy corrugated bars to the reinforcement of concrete on buildings resistant to earthquake that are manufactured, imported or traded in Colombia
Decree 1595/2015 that dictates rules relative to the National Quality Subsystem
Decree 1844/2013 that regulates the faculty of coordination of the Ministry of Trade, Industry and Tourism, ahead of the creation and international notification of technical regulations and conformity assessment procedures, foreseen on items 6 and 7 of article 28 of Decree 210/2003
Decree 865/2013 that designates the National Body of Accreditation of Colombia (<i>Organismo Nacional de Acreditación de Colombia</i> - ONAC)
Decree 2124/2012 that designates ONAC as the national accreditation body
Resolution 688/2010 that approves the creation of a sectorial unit of normalization
Decree 323/2010 that stipulates conditions of operation of ONAC
Resolution 228/2009 that integrates and adjusts normativity on normalization sectorial unities
Decision 615/2005 of the system of information of notification and technical regulation of the Andean Community
Law 872/2003 that creates the management system in the executive branch of public power and in other service providers
Resolution 8728/2001 that establishes the rules for accreditation
Resolution 3742/2001 that establish criteria and conditions that must be complied for the issuance of technical regulations
Decision 506/2001 on recognition and acceptance of certificates of products traded in the Andean Community
Decree 2360/2001
Decree 1112/1996 that creates the National Information System about Normalization Measures and Conformity Assessment Procedures and provides rules to harmonize the issuance of technical regulations and to assure compliance of Colombian international commitments
Decree 2269/1993 that organizes the National System of Accreditation, Normalization, Certification and Metrology (<i>Sistema Nacional de Acreditación, Normalización, Certificación y Metrología</i> - SNNCM)
Agreement between Venezuela and Colombia about normalization and quality certification

Source: Government of Colombia. Elaborated by CCGI/EESP-FGV.

In accordance with decree 1595/2015, conformity assessment for products subject to technical regulation is mandatory, and both importers and domestic producers must demonstrate compliance through an inspection report or a conformity certificate, whether a first-party

certificate issued by an accredited body or a certificate issued by a designated body prior to marketing.

The mechanisms and methods for conformity assessment and proof are in general set out in the technical regulation itself, and depending on the level of risk may consist in certification, inspection or testing carried out by bodies accredited or designated by the regulatory body. In general, the accredited certification bodies subcontract the services of accredited laboratories to assess product conformity. Conformity assessment bodies (certification, inspection, calibration, testing and assays) established in Colombia and accredited in accordance with international practices and rules are grouped in the National Association of Conformity Assessment Bodies (ASOCEC).

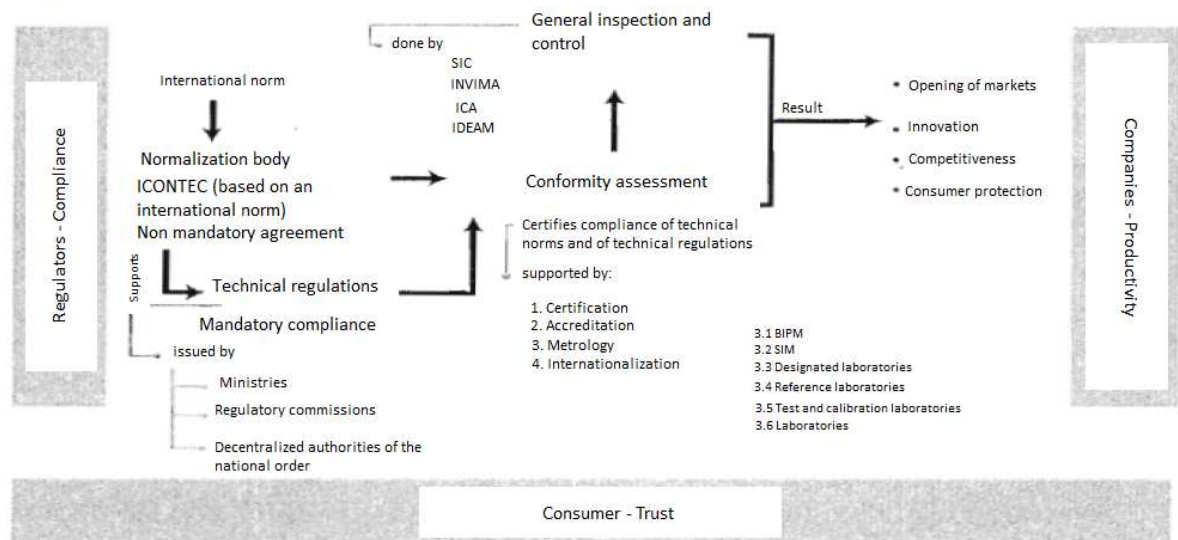
Decree 2269/1993 provided the legal framework of the SNNCM that was the national system of quality¹⁰¹. The main objectives that were maintained on the new system are the promotion on the markets of safety, quality and competitiveness of the productive or importer sector of goods and services and the protection of the consumers' interests. The existence of a system allows a trustful infrastructure for conformity assessment and quality demonstration, access to testing laboratories and the improvement of the consumption culture through recognition of certificates. In 2008, through decree 3257, the system was converted in the National Subsystem of Quality (*Subsistema Nacional de la Calidad* - SNCA) that constitutes a subsystem of the National Administrative System of Competitiveness (*Sistema Administrativo Nacional de Competitividad* - SNC) that was created through Decree 2828/2006. Despite the transformations on the previous system, some features were kept as the competences of SIC. Functions performed by the subsystem are the coordination of formulation and follow-up activities on normalization and the articulation of public and private entities that participate on the creation and issuing of technical regulations, accreditation, designation, conformity assessment and metrology.

On the last years, SNCA led advancements that deserve to be highlighted. On the accreditation area, ONAC was created in 2010 and the accreditation functions were concentrated in only one entity. Moreover, rules were established that allowed the increase of coverage of functions of surveillance and control according to criteria of transparency and technical competence that are coherent with international techniques. The diagram below illustrates the SNC.

¹⁰¹ According to the Colombian Ministry of Trade, Industry and Tourism, a national quality system encompasses technical normalization, creation and issuing of technical regulations, accreditation, designation, conformity assessment and metrology.

Figure 3-2 - National Administrative System of Competitiveness

General scheme of the SNCA



Source: BID. Elaborated by CCGI/EESP-FGV.

Decree 1844/2013 establishes procedures that must be followed by authorities that perform conformity assessment procedures. The competent authorities must first require a concept to the Direction of Regulation of the Ministry of Trade, Industry and Tourism about the compliance of guidelines of the National Subsystem of Quality and about the potential creation of potential technical obstacles to trade. The Ministry will then render previous concept on the following ten businesses days after the date of establishment of the requirement of the concept. On the preamble of administrative acts in which technical regulations or conformity assessment procedures are issued, there must be the information that the previous concept was required to the ministry and the terms in which the concept was issued.

Decree 1595/2015 highlights the objective of reorganizing the SNCA on the topics of conformity assessment and accreditation. Firstly, new functions are designated to ONAC and ICONTEC. The first one is designated as the monitoring authority of OECD good laboratory practices and the second one is obliged to maintain a repository of norms that reflect the international state of art of products, processes, persons, systems and services.

Circulars are documents in which issues of diverse nature are communicated that can be of technical or administrative character. The table below provides circulars applied on conformity assessment and accreditation procedures.

Table 3.5 - Circulars and updates

Circulars and updates
Circular n° 13/2019 on fees for technical professionals
Circular n° 10/2019 Version 2017 of the Norm NTC 6001 Management Systems for Small and Medium Enterprises (SMEs)
Circular n° 09/2019 "Application Norm ISO/IEC TS 17021-10
Circular n° 08/2019 of Financial and Administrative Direction "Filling and payment of bills or invoices"
Circular n° 07/2019 Transition plan of the version 2018 of the Norm ISO 50001 Management System of Energy. Requisites with user guide
Circular n° 06/2019 version 2017 of the norm ISO/IEC 17011 Conformity Assessment. General requisites for accreditation bodies that perform accreditation of conformity assessment bodies
External Circular n° 05/2019 Transition Plan of Version 2018 of the Norm ISO 14064-1 Greenhouse Gases - Part 1: Specification with guide at the level of the organization to quantify and inform gas emissions and eliminations
Circular n° 04/2019 "Transition plan of 2018 version of norm ISO 22000 Management System of Food Safety. Requisites for any organization on the food chain"
Circular n° 01/2019 "Clarification and implementation plan of mandatory documents (MD) of the International Accreditation Forum - IAF"
"Tariffs of accreditation service V10" RAC-3.0-02
Circular n° 21/2018 Rates of fees of Expert Technical Professionals
Circular n° 19/2018 Deposit of Collection Accounts and Sales Invoices at the end of the year 2018
Circular n° 18/2018 Entry into force of document RAC-3.0-01 V.8
Circular n° 16/2018 Changes on Sectorial Coordination of Certification Bodies of Product, Processes and Services, Certification Bodies of Management Systems and Certification Bodies of Persons
Circular n° 14/2018 Update and Expansion of Accreditation Scope for the Accreditation Scheme of Calibration Laboratories
Circular n° 13/2018 Period of collective holidays ONAC 2018-2019 (Annex Holiday Terms 2018-2019)
Circular n° 12/2018 Movements in Technical Directions
Circular n° 11/2018 Implementation of Decree 1273/2018 - New scheme of contributions of independent workers to the General System of Social Security - SGSST
Circular n° 10/2018 Version 2 - Activities and evaluation guidelines for the Product Certification Bodies, (Annexes H: Outcome Grouping, Annex I. Risk Matrix)
Circular n° 9/2018 Changes on International Technical Direction, Sectorial Coordination of Calibration Laboratories and Administrative and Financial Management
Circular n° 7/2018 Exclusive exercise of the ONAC accreditation activity
Circular n° 6/2018 Update of the scope of accreditation including Resolution No. 40302, of April 2, 2018, issued by the Ministry of Mines and Energy, for inspection bodies with scope on CNG service stations
Circular n° 11/2017 Admission of International Technical Director and Head of Customer Service
Circular n° 9/2017 File collection of accounts and sales invoices at the end of 2017
Circular n° 8/2017 Measures before the expiration of the validity of the contract for the granting and use of the accreditation certificate
Circular n° 7/2017 Audits under standards ISO 9001-14001 2015
Circular n° 6/2017 Accreditation Tariffs 2018
Circular n° 4/2017 Changes in the Technical Directorate and ONAC sectorial coordination
Circular n° 3/2017 Actions regarding the information given by the District Secretary of Mobility, on the occasion of the apostolic visit of His Holiness Pope Francis
Circular n° 2/2017 Numeral clarification 4 accreditation criteria of the R-AC-01 accreditation service rules version 7
Circular n° 1/2017 RAC Update 1.3-02 Rates of Accreditation services
Circular n° 9 2016 Tariffs of accreditation services performed in 2017
Circular n° 8/2016 Collective Vacations Period ONAC 2016
Circular n° 6/2016 Instructions for determining the expiration date of terms and terms contained in the rules of the accreditation service, procedures and communications of ONAC
Circular n° 4/2016 Exercise of exclusivity of ONAC accreditation
Circular n° 3/2016 Adoption Algorithm signature SHA2 and Scope subcontracting requirement CEA 4.1-10
Circular n° 2/2016 Relocation of ONAC headquarters
Circular n° 1/2016 Update of the RAC 1.3-02 Rates of the Accreditation Service
Circular n° 17/2015 Collective vacations ONAC - 2015

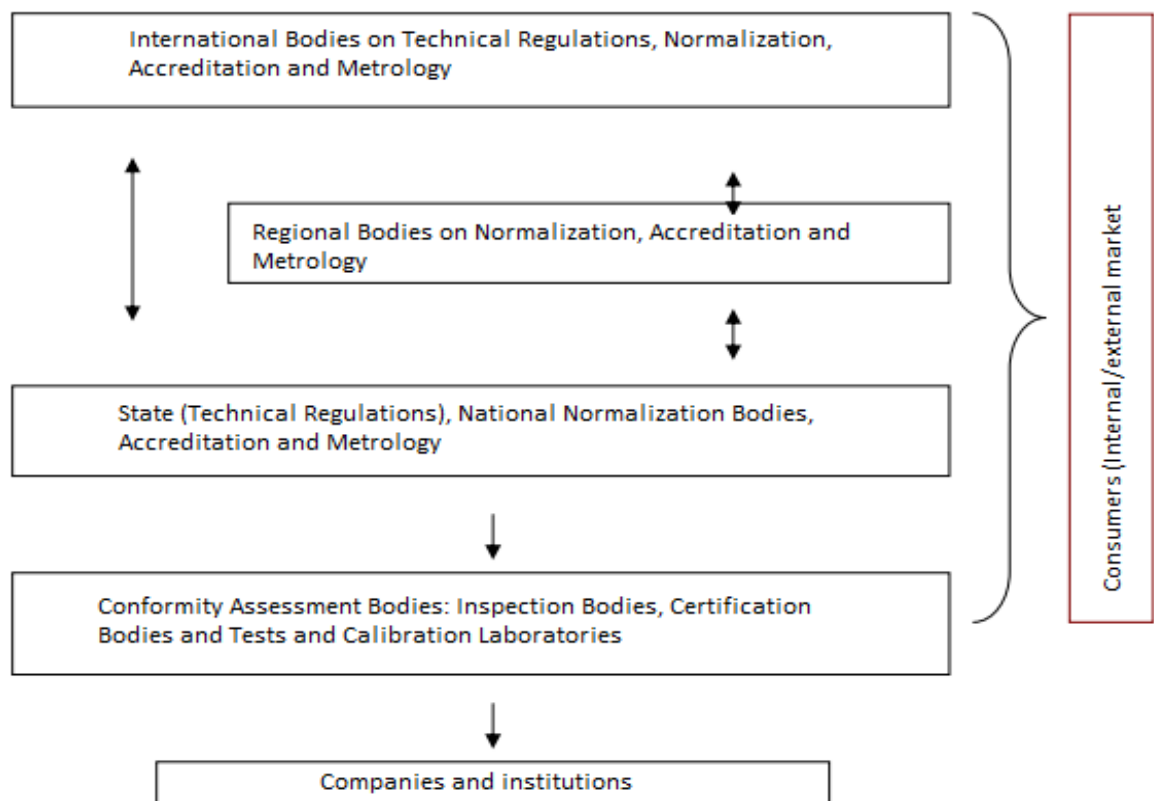
Source: ONAC. Elaborated by CCGI-EESP/FGV.

Moving to standards, according to the BID Report, ISO 9001 is very popular in Colombia and in Latin America. Moreover, the potential impact of State reforms on the infrastructure quality seems to have affected the proper dynamic to obtain standards ISO 9001 in the country as, between 2007 and 2014, according to data obtained from ISO and according to the graphs in topic 6 of the report, the increase on the use of these standards was around 100%. The ISO technical norms that are more frequently used on conformity assessment procedures are listed below.

Table 3.6 - ISO technical norms

ISO technical norms
ISO 9001 - Quality Management Systems
ISO 13485 - Medical Services Instruments - Quality Management Systems
ISO 14001 - Environmental Management Systems
ISO/TS 16949 - Quality Management System for the Automotive Industry
ISO 22000 - Food Safety Management System
ISO/IEC 27001 - Information Security Management Systems
ISO 50001 - Energy Management Systems

Source: BID. Elaborated by CCGI-EESP/FGV.

Figure 3-3 - World Network of Support of National Systems of Quality**Scheme - Global Network of Support of National Systems of Quality**

Source: INM. Elaborated by CCGI-EESP/FGV.

After the description of the Colombian regulatory framework on conformity assessment, this report moves to the analysis of institutions that act on standardization and conformity assessment. The analysis begins with the presentation of the structure and the functions of

ICONTEC, the main certifying entity in the country and is followed by an explanation of the action of key public institutions, namely INM, MINCIT and ICA on certification. Groups of entities, with special emphasis on the National Association of Conformity Assessment Bodies (ASOSEC) will lastly be analyzed.

3.3.2. Colombian Institute of Standards and Certification (ICONTEC)¹⁰²

ICONTEC, created in 1963, is a national government advisor, performs technical normalization on the country, constitutes the national standardization body and is recognized as the national standards body by the Colombian government through decree 1545/2015 and as a leader on the issue in international fora as ISO, IEC, the regional forum of COPANT and on the normalization forum in APEC. The institute also supports the national government on negotiation groups for the Andean Community and for the free trade agreement with the USA. The main activity of the body is the study, adoption and promotion of Colombian technical standards (NTCs) on a range of economic and social activities inside the private and governmental sectors in the country. ICONTEC's mission is to promote, develop and guide the application of NTCs and other standard-setting documents. The five stages in the standardization process are the following: feasibility and planning; committee-stage work, in which the study is carried out and the standard-setting documents are approved in technical standardization committees; public consultation; approval, at which stage the document is submitted for consideration by an entity that is independent of the committee, in order to endorse the committee's technical decisions and ensure regulatory coherence; and publication and dissemination.

ICONTEC's standardization work is carried out through 253 standardization committees, which have drafted over 6300 standards. The institute is also the largest national body for certification of management systems and products in the country and provides certification to ISO 9001, 14001, 22000, OHSAS 18001 standards among others. There are 42 different specific areas of standardization and around 162 active technical committees.

In sectorial normalization, ICONTEC recognizes USNs, according to guidelines foreseen on decree 2269/2003. The function of these units is the preparation of norms of a sector, according to international parameters established for this activity, with the possibility of submitting them, during the NTC adoption and publication, to ICONTEC. The table below describes the USNs approved in December 2017.

¹⁰² INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

Table 3.7 - USNs approved in December 2017

Sectoral Standardization Unit	Responsible entity
Occupational medicine, industrial hygiene, industrial safety, fire protection, ergonomics	Colombian Security Council
Identification standards (barcode, radiofrequency identification -RFID- and electronic product code -EPC-), electronic data exchange -EDI-, palletizing and traceability	GS1 Colombia
Labor competences, quality in the hotel operation, quality of hotel services, quality of commitment to the environment, categorization by stars	COTELCO - Vice ministry of Tourism
Skills of the human resource, quality in the operation of the agency, quality of services, social development policies. (Travel agencies)	Professional Council of Travel Agents and Tourism - Vice ministry of Tourism
Quality in the provision of the service, abilities and skills of the human resource, related to the tourist guides	Professional Council of Tourism Guides - Vice ministry of Tourism
Labor competences: skills and abilities of the human resource. Quality in the operation of gastronomic establishments. Quality in the service	Colombian Association of the Gastronomic Industry, ACODRES - MINCIT
Sustainability for tourist services provided by lodging establishments, travel agencies, restaurants, tourist guides and for tourist destinations in Colombia	University Externado de Colombia - MINCIT
Health	Ministry of Health and Social Protection
Valuatory Activity and the Appraisal Service	National Registry of Appraisers - RNA
Quality of Training for Work	Ministry of National Education
Quality in the provision of the service and skills and abilities of the human resource	ASTIEMPO - Vice ministry of Tourism
Sectoral Unit for Standardization of Real Estate Services	FEDELONJAS

Source: ICONTEC. Elaborated by CCGI-EESP/FGV.

Table 3.8 - units that are in the process of creation

Sectoral Standardization Unit	Responsible entity
Defense sector	Ministry of National Defense
Labor competences in the National Service of Learning SENA	National Service of Learning SENA
Normalization for the Conformity Assessment	ASOSEC
Labor competences in the public sector	Office of the Attorney General of the Nation - Institute of Studies of the Public Ministry
Artisan Sector	Crafts of Colombia

Source: ICONTEC. Elaborated by CCGI-EESP/FGV.

In the case of voluntary certification, ICONTEC¹⁰³, which is a member of ASOCEC, certifies products by means of its ICONTEC Quality Seal. ICONTEC product certification is accredited by ONAC in Colombia and by the American National Standards Institute (ANSI) of the United States. In order to obtain the ICONTEC Quality Seal, after receiving a request from an enterprise ICONTEC audits the manufacturer's quality system and has the product tested in reliable laboratories. If the product satisfies the quality requirements, ICONTEC issues the corresponding certificate, which is valid for three years. After receiving the ICONTEC Quality Seal, the manufacturer must mark the certified product with the appropriate logo. Follow-up audits are subsequently carried out.

¹⁰³ INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

It is also noteworthy that ICONTEC provides conformity assessment services (certification of management systems, product certification, and inspection) as well as health accreditation, and has calibration laboratories. On certification, the institute reached important international achievements when entering the World Net of Certification IQNet and when becoming the Colombian representative on the Technical Committee of Administration and Management TMB (Technical Management Board), a relevant internal body of ISO. More recently, ICONTEC obtained a new and important international recognition by the American National Standards Institute (ANSI) that recognizes its accreditations.

ICONTEC conformity marks constitute a differential element on the market that improve the image of offered products and services and generate confidence to consumers and institutions. ICONTEC conformity assessment activity is accredited and recognized by entities as the National Body of Accreditation of Colombia (*Organismo Nacional de Acreditación de Colombia* - ONAC)¹⁰⁴, the German Association of Accreditation (*Asociación Alemana de Acreditación* - TGA), the National Institute of Normalization (*Instituto Nacional de Normalización* - INN) of Chile, the Ecuadorian Accreditation Body (*Organismo Ecuatoriano de Acreditación* - OAE) and the National Institute of Competition Defense and Protection of Intellectual Property (*Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual* - Indecopi).

ICONTEC integrates the National Association of Conformity Assessment Bodies (*Asociación Nacional de Organismos de Evaluación de la Conformidad* - ASOSEC) that aims to implement a quality culture in Colombia. The organization gathers conformity assessment bodies and aims to contribute in an organized manner the efforts to implement a quality culture in the country. Equally, it seeks to establish clear and transparent legal and administrative rules of conformity assessment in the country. Under this perspective, ASOSEC provides technical support on the areas of quality and conformity assessment to the Colombian State, unions, entrepreneurs and the academy.

3.3.3. National Institute of Metrology (INM)

The National Institute of Metrology (*Instituto Nacional de Metrología de Colombia* - INM)¹⁰⁵ performs conformity assessment activities through comparisons between laboratories that provide calibration services. Two key factors demonstrate the importance of INM. The number of key and supplementary comparisons reveals that, up to 2015, INM has obtained 21 supplementary comparisons, the majority of them in the area of mass and three of them in the areas of length, thermometry and electricity and magnetism. The institute, moreover, incorporated to its offer of services inter-laboratory comparison programs, production and marketing of certified reference materials, technical assistance service and calibrations.

The Comparison Interlaboratories (*Comparación Interlaboratorios*) is one tool used to evaluate measurement systems implemented on calibration laboratories. The quality standards currently required by consumers of products and services must be backed up by quality systems that have reliable metrological assurance processes backed by calibration laboratories that can demonstrate quality in the measurements obtained. The preliminary reports published in 2019

¹⁰⁴ ORGANISMO NACIONAL DE ACREDITACION COLOMBIANO (ONAC). Quiénes somos?. Disponível em: <https://onac.org.co/>. Acesso em: 1 ago. 2019.

¹⁰⁵ INSTITUTO NACIONAL DE METROLOGIA. Quiénes somos. Disponível em www.inm.gov.co/. Acesso em 16/07/2019.

regard, for example, the test of electrical magnitudes, the calibration of a digital caliper for outdoor from 0 mm to 150 mm and the low alloy corrugated bars for concrete reinforcement.

Decree 2269/1993 and Decision 506 of the Andean Community of Nations are key technical regulations on conformity assessment. They establish that Colombian certification bodies must be accredited by the SIC. The accredited certification body, in its conformity assessment process, must support the issuance of the certificate in the results of tests carried out in accredited laboratories before the SIC. Certificates issued by a certification body accredited by the accrediting entity of the country of origin of these products are valid in the country, provided that said country maintains a mutual recognition agreement in force with Colombia. Certificates issued by a certification body of the member countries of the Andean Community are valid in the country.

Weaknesses are present on Colombian conformity assessment procedures. The infrastructure is often insufficient to perform conformity assessment procedures and, in many areas in which conformity assessment is required, there are no accredited laboratories in the country. The existence of non-accredited test laboratories reduce the confidence on the conformity assessment system of the country. On the accreditation process, there is a reduced number of professionals to perform audits and conflicts of competence between State entities are present. These features create difficulties to attain mutual recognition agreements.

3.3.4. Ministry of Commerce, Industry and Tourism (MINCIT)

MINCIT has as its main objective the support of business activities producer of goods, services and technology and of the touristic management of the regions of the country, in order to improve its competitiveness and sustainability and to stimulate the generation of higher added value. This objective will allow the ministry to consolidate its presence on the local market and on international markets. Specifically, in trade, the ministry aims to increase exports of non-mining energy goods and services and to increase the volume of foreign direct investment with emphasis on the use of trade and investment agreements. Recently, decree 4176/2011 reassigned the functions of issuing certifications that are pertinent to contracts for the importation of technology and exportation of services and of issuing origin certifications of Colombian products destined to exportation from MINCIT to the Special Administrative Unit of the Directorate of Taxes and National Customs (*Dirección de Impuestos y Aduanas Nacionales* - DIAN).

The Ministry performs since 2008 its certification process on its system of management of quality according to standards NTCGP 1000:2009 and ISO 9001:2008. Considering that ISO 9001:2008 migrated in September 2018 to ISO 9001:2015, the Ministry prepared a transition plan in order to allow that efforts for the continuous improvement and satisfaction of consumers be an element on the entity. The subsystem of environmental management received its first certification according to standard ISO 14001:2004 in 2014 that later migrated to its following version, ISO 14001:2015. Certificates issued abroad are accepted by MINCIT provided that a type-approval or validation procedure is followed or there is a mutual recognition agreement.

3.3.5. Colombian Agricultural Institute (ICA)

The main ICA's activity in conformity assessment is the performance of risk analysis (*análisis de riesgos* - AR). The competent institute to perform this analysis is the Technical Direction of Risk Assessment, a technical and scientific support of the Deputy Manager of Sanitary and

Phytosanitary Regulation. The basis for the risk analysis are the guidelines of the World Organization for Animal Health (WOAH), of the International Plant Protection Convention (IPPC) and of other international reference bodies. The analyses are previous to the importation of agricultural products of animal or vegetal origin and aim to justify the adoption of sanitary and phytosanitary measures with the effects of allowing, restricting or denying the importation. During the conduct of an AR, official systems of certification are taken into account. The AR evaluates the probability of entry, establishment or spread of pests or diseases in the territory of an importing country and establishes the sanitary or phytosanitary measures that could be applied, as well as the possible biological and economic consequences associated and includes hazard identification, risk assessment, risk management and risk communication.

The analyses are performed on the following situations:

- when there are no sanitary and/or phytosanitary requirements for the importation of animals, vegetables and products originating in a country or region, with specific use and destination in Colombia;
- when the sanitary or phytosanitary status of a country or region of origin changes;
- when new information comes up in relation to a disease or plague;
- when a country or zone is required to demonstrate that an export product does not pose a significant risk to the importing country;
- when a regionalization process begins and
- when the ICA considers it technically necessary to safeguard the sanitary or phytosanitary status of the country.

Table 3.9 - Technical regulations that regulate the AR

Technical regulations
CAN decision 686/2008 on community AR of diseases of animals, exotic to the subregion, considered important for member countries
International Phytosanitary Measurement Standard (Norma Internacional de Medida Fitosanitaria - NIMF) n° 2 on the procedure for risk analysis of pests (análisis de riesgos de plagas - ARP)
NIMF n° 11 details the risk analysis for quarantine pests, included the analysis of environmental risk and living modified organisms
Decree 4765/2008 that modifies ICA's structure and provides other rules
Resolution 9942/2016 that regulates the requests for risk analysis of pests and diseases for the import to Colombia of animals, plants and their products

Source: ICA. Elaborated by CCGI-EESP/FGV.

3.3.6. National Association of Conformity Assessment Bodies (ASOSEC)

ASOSEC is an organization that encompasses conformity assessment entities and seeks to contribute in an organized manner to the efforts to implement a quality culture in the country. The members of the association can have direct or indirect interests in the conformity assessment. Key objectives of the association are to become a permanent and valid interlocutor in representation of the conformity assessment bodies before the Colombian State and civil society, in matters of regulation and national activities in the fields of quality and conformity assessment and the establishment of clear and transparent legal and administrative rules for the development of conformity assessment activities in Colombia.

Inside the association, members with direct and indirect interests must also comply binding obligations. Members with direct interests must develop their activities with strict subjection to the technical, legal, ethical and healthy and loyal competition that should govern the exercise of the activity of the conformity assessment organisms; pay timely the rights of admission and

support fees for the association; comply with the statutes and decisions of the general assembly, board of directors and of the other bodies of the association and collaborate with the association in the achievement of its objectives. Members with indirect interests must develop their activity with strict subjection to the technical, legal, ethical and healthy and loyal competition that should govern the exercise of their activity; pay timely the rights of admission and support fees for the association; comply with the statutes and decisions of the general assembly, the board of directors, the special chambers to which it belongs and of the other organs of the association and collaborate with the association in the achievement of its objectives.

3.3.7. Accreditation in Colombia

The aspects to be evaluated in an accreditation process are organization, guarantee of quality and technical competence. The conformity assessment bodies can be accredited voluntarily or according to a technical regulation and then demonstrate its competence on a specific area. According to decree 4738/2008, accreditation activities may be carried out under market conditions by entities established under the rules of private law, in accordance with the requirements laid down by the MINCIT. Resolution 8728/2001 provides rules and a procedure for accreditation in Colombia and subjects to accreditation the following modalities of bodies: certification bodies, inspection bodies, testing bodies and calibration laboratories. Moreover, CONPES 3446/2006 establishes the current basis of accreditation in the country as it determines the formation of a national accreditation body as a strategy for the conformation of the SNCA¹⁰⁶.

In order to obtain full international recognition, an accreditation entity must adopt international accreditation standards and establish agreements with other countries according to peer evaluation and reciprocal acceptance of the respective national accreditation systems. The capacity to obtain a mutual recognition agreement (MRA) on this level of the system is subject to the demonstration by the accreditor of technical capacity, efficacy, impartiality, independence and efficiency on the management. The ISO standards that are more frequently used on accreditation procedures are listed below.

Table 3.10 - ISO Standards used on accreditation procedures

ISO standards
ISO/IEC 17065 on certification of products, processes and services
ISO 22000 on certification of management systems of food safety
ISO/IEC 27001 on certification of management of safety of information
ISO 9001 on certification of management of quality
ISO 14001 on certification of environmental management
ISO/IEC 17021 on requirements for bodies providing audit and certification of management systems

Source: BID. Elaborated by CCGI-EESP/FGV.

When the activities of the accreditation entity are not recognized, the tests, calibrations, inspections and certifications performed in a country must be repeated by an accreditation body of another country with international recognition. The accreditation activities in Colombia, however, face the following difficulties: lack of international recognition of accreditation entities that generates atomization and dispersion of accreditation in Colombia and the variation of requisites between entities with accreditation faculties and functions, which leads to cost overruns to entrepreneurs.

¹⁰⁶ CONSELHO NACIONAL DE ACREDITAÇÃO. Disponível em <https://www.cna.gov.co/1741/article-186365.html>. Acesso em 15/07/2019.

A specific accreditation system is inside the Mandatory System of Quality Guarantee in Health (*Sistema Obligatorio de Garantía de Calidad en Salud* - SOGCS). The Unique Accreditation System in Health consists on a group of processes, procedures and tools of voluntary and periodical implementation by entities that must prove the gradual compliance of quality levels higher than the minimum mandatory requisites for health care, under the direction of the State and the inspection, surveillance and control of the National Superintendence of Health. ICONTEC is the first registered and authorized accreditor that performs the management on health accreditation. Qualified and trained staff perform the accreditation and the final result is evaluated by accreditation entities authorized for this function. The applicable standards are established by the Sectorial Unity of Normalization Health. The table below provides the technical regulations applicable to this modality of accreditation.

Table 3.11 - Technical regulations for Health

Technical regulations
Decree 903/2014 on provisions related to the Unique Accreditation System in Health
Decree 2082/2014 on provisions for the operation of the Unique Accreditation System in Health
Resolution 2427/2014 on registration of an entity on the Special Registry of Health Accreditors
Resolution 6055/2016 that determines the integration and functioning of the Advisory Body for the Unique Accreditation System in Health
Resolution 346/2017 on the enrollment of an entity on the Special Registry of Health Accreditors
Resolution 5095/2018 on the adoption of the Accreditation Manual in Ambulatory and Hospital of Colombia Version 3.1

Source: Ministry of Health and Social Protection.

ONAC is the national accreditation body of the country pursuant to decree 1575/2015 and its functions to be performed and its objectives to be achieved are foreseen in decree 4738/2008¹⁰⁷. ONAC is also the sole official source of information about accreditation in Colombia and is responsible for granting, maintaining, broadening, restricting, suspending and withdrawing accreditations. ONAC grants accreditation for a three-year period in the case of a conformity assessment body that is accredited for the first time. In other cases, and as from the first renewal, accreditation is granted for five years. In all cases the validity is subject to the results of annual compliance audits. Its activities and programs are subject to MINCIT administrative control.

The body must perform the following functions:

- provide its services under non-discriminatory conditions and observe the other provisions regarding economic competition,
- establish an internal procedure that allows the members of the Board of Directors, the members of the body in which it delegates the decision of accreditation, and the members of the committees and work committees to declare themselves impeded and to excuse themselves from acting when they incur a conflict of interest,
- process and respond in accordance with applicable international technical standards the requests submitted by interested parties,
- permanently guarantee the suitability of the personnel involved in their activities,
- accredit a previous verification of compliance with the relevant requirements, to the different conformity assessment bodies that request to operate as entities belonging to the National Quality Subsystem,

¹⁰⁷ ORGANISMO NACIONAL DE ACREDITACION COLOMBIANO (ONAC). Quiénes somos?. Disponível em: <https://onac.org.co/>. Acesso em: 1 ago. 2019.

- maintain a monitoring and surveillance program that allows demonstration at any time that the accredited bodies continue to meet the conditions and requirements that served as the basis for their accreditation,
- provide to the Ministry of Commerce, Industry and Tourism, the information requested about the exercise of the accreditation activity, without prejudice to compliance with the principle of confidentiality and
- ensure its international recognition through membership, participation, evaluation and other programmed actions in regional and international institutions and forums related to accreditation activities.

ONAC's accreditation work is done in accordance with the NTC ISO/IEC 17011 standard, using the generally accepted technical rules for each of the modalities of conformity assessment bodies. According to the authorities, the implementation of standard ISO/IEC 17011 implies the use of control mechanisms to ensure impartiality and transparency as well as procedures for complaint and appeal resolution.

The accreditation certificate is issued by the ONAC Executive Director on the basis of the corresponding official report of the Accreditation Committee. Some other entities still have accreditation powers within their sphere of competence, such as, for example, the Institute of Hydrology, Meteorology and Environmental Studies (IDEAM), the National Food and Drug Surveillance Institute (INVIMA), the National Institute of Forensic Medicine and Forensic Sciences, and the ICA. At present, only the IDEAM is engaged in this activity, in connection with testing laboratories. In order to deal with problems of fraud in connection with conformity certificates, the SIC established the Conformity Certificates Information System (SICERCO), governed by SIC Resolution 41713/2014, as amended by SIC Resolution 61971/2014, which established the obligation for conformity assessment bodies to enter in a register maintained by the SIC the conformity certificates they issue relating to the RTs supervised by the SIC. In addition, a Register of Certification and Inspection Bodies whose accreditation is linked to compliance with RTs supervised by the SIC was created. ONAC is responsible for this register¹⁰⁸.

A requisite for the maintenance of the program and for the maintenance of the accreditation granted is the entry of conformity assessment bodies with accreditation in force and granted at any time by SIC in the monitoring and surveillance program established by ONAC. The evaluations will be scheduled and carried out in accordance with the procedures, conditions and fees of the National Accreditation Body of Colombia, ONAC. The conformity assessment body accredited by SIC that, despite having applied to the ONAC for its inclusion in the monitoring and surveillance program, does not subject itself to the follow-up evaluation on the occasion and under the conditions set forth in the ONAC, will lose the accreditation, from the day following the scheduled date for the corresponding visit.

ICONTEC was the first institution accredited by ONAC to certify management systems, products, processes and services. The institute can then offer certification services applied on products according to voluntary technical norms in more than 34 economic sectors in the country.

A practical example of ONAC's action is the accreditation that it granted to ICA in 2018. The accreditation granted is a recognition of competence based on globally accepted requisites as standard ISO/IEC 17025 and offers a recognition of the results of ICA laboratories on the

¹⁰⁸ WORLD TRADE ORGANIZATION. Trade Policy Review Colombia 2018. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s372_e.pdf.

international level. The accreditation of the Internal Support Laboratory in Metrology (*Laboratorio de Soporte Interno en Metrología* - LASIM) also brings metrological traceability to the 52 ICA testing laboratories on the issues of temperature, mass and volume and supports trust on the results of the laboratories.

In broader terms, ONAC performed the significant task of increasing the number of accredited bodies in the country, given the strictly voluntary nature of accreditation. The main reasons that underlie the recent increase of conformity assessment bodies are the continuous rise of the total number of vehicles, which generated a great demand for automotive services and considerable rise of the number of new drivers. The programs of testing and calibration laboratories were the ones that had the greatest dynamic of growth as, in 2009, their numbers were of 11 and 0 respectively and in 2014 reached 173 and 106 in their order. The table below shows the evolution of the total of accredited bodies by ONAC according to nine programs¹⁰⁹.

Figure 3-4 - Bodies accredited by ONAC

Accreditation program	Normative document	2009	2010	2011	2012	2013	2014	2015
CDA	ISO/IEC 17020	109	198	243	265	271	294	310
CRC	ISO/IEC 17024	58	95	121	150	186	313	354
LAB	ISO/IEC 17025	11	30	65	93	121	173	202
LAC	ISO/IEC 17025	0	17	48	72	89	106	114
OIN	ISO/IEC 17020	4	11	24	30	43	56	76
CPR	ISO/IEC 17065 - ISO/IEC GUI DE 65	1	6	12	17	20	25	25
CSG	ISO/IEC 17021	3	5	10	10	13	13	13
OCF	ISO/IEC 17024	0	0	2	4	7	14	20
PEA	ISO/IEC 17043	0	0	0	0	0	0	1
LCL	ISO 15189	0	0	2	3	4	5	6
TOTAL		186	362	527	644	754	999	1121

Source: BID. Notes: Center of Automotive Diagnosis (*Centro de Diagnóstico Automotor* - CDA); Driver Recognition Center (*Centro de Reconocimiento de Conductores* - CRC); Testing Laboratories (*Laboratorios de Ensayo* - LAB); Calibration Laboratories (*Laboratorios de Calibración* - LAC); Inspection Body (*Organismo de Inspección* - OIN); Product Certification Body (*Organismo de Certificación de Producto* - CPR); Management Systems Certification Bodies (*Organismos de Certificación de Sistemas de Gestión* - CSG); People Certification Bodies (*Organismos de Certificación de Personas* - OCP); Suppliers of Essay of Fitness (*Proveedores de Ensayo de Aptitud* - PEA); Clinical Laboratories (*Laboratorios Clínicos* - LCL).

Data contained on CONPES' national policy of science, technology and innovation for the period 2015-2025, however, do not reveal an encouraging scenario. According to ONAC, the number of existing testing and calibration in 2015 is of 3200, but only 10% of them are accredited to perform tests and calibrations. The BIS report also points out the low level of human capital present on personnel in charge of activities of test laboratories and the small participation of those laboratories in research, development and investment projects, which leads to a poor profile of this segment of services in the country.

The main ONAC action in order to provide to the countries accredited bodies in their respective programs is the annual announcement of accreditation committees. Each committee must be professional in the sense of providing a favorable or unfavorable conception about the accreditation requirements. As a consequence of ONAC efforts, it was possible to obtain recognition in four key areas of accreditation, the operational capacity of the ONAC, measured by the number of accreditations, is undoubtedly excellent given the high growth of the number

¹⁰⁹ WORLD TRADE ORGANIZATION. Trade Policy Review Colombia 2018. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s372_e.pdf.

of OEC accredited in the last three years and ONAC financial condition was recently strengthened as a consequence of the sale of their specialized services¹¹⁰.

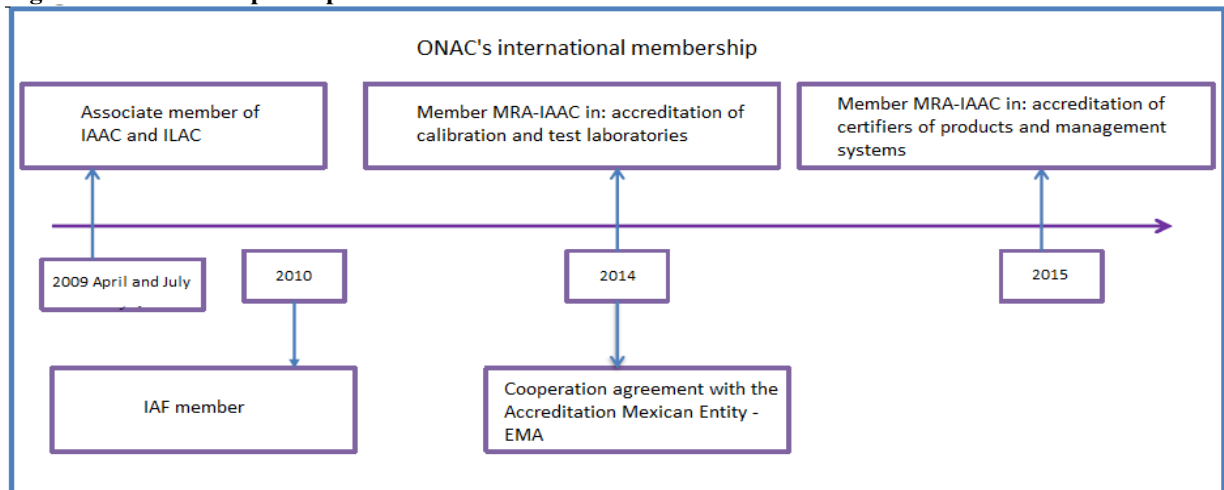
ONAC was also designated on decree 1595/2015 as the national monitoring authority of the OECD good laboratory practices (*buenas prácticas de laboratorio* - BPL). The main function performed by ONAC as the national monitoring authority of BPL is the monitoring of adequate compliance of BPL of test facilities in the country.

Besides ONAC, other entities as public entities that legally perform accreditation and foreign accreditation entities recognized within the framework of multilateral recognition agreements perform accreditation functions. Examples of these entities are the Institute of Hydrology, Meteorology and Environmental Studies (*Instituto de Hidrología, Meteorología y Estudios Ambientales* - IDEAM) that acts on themes relative to water and environment, the Colombian Agricultural Institute (*Instituto Colombiano de Agricultura* - ICA) that acts on agricultural products, the National Institute of Food and Medicine Surveillance (*Instituto Nacional de Vigilancia de Alimentos y Medicamentos* - INVIMA) for foods and medicine and ICONTEC for health and education. These entities can be accreditors as, according to article 2.2.1.7.7.5 of decree 1595/2015, accreditation can be granted by public entities that legally perform this function.

The accreditation theme is inserted on regional bodies, which encompass national entities of its zones of influence. A regional body in which ONAC participates is the Inter-American Accreditation Cooperation (IAAC), with particular emphasis to the multilateral recognition agreement on accreditation of calibration and test laboratories according to requisites of the standard ISO-IEC 17025 and to the multilateral recognition agreement on accreditation of certifiers of products and management systems. Both recognitions contribute positively to the competitiveness of Colombian business through the reduction of international transaction costs and through the adding of value to goods and services derived from the trust generated by these memberships. ONAC also integrates management positions in international accreditation fora as the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). The diagram below illustrates ONAC's participation in international institutions.

¹¹⁰ WORLD TRADE ORGANIZATION. Trade Policy Review Colombia 2018. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s372_e.pdf.

Figure 3-5 - ONAC's participation in international institutions



Source: ONAC. Elaborated by CCGI/EESP-FGV.

3.4. Regulatory Coherence

Over the last decade, Colombia has notably led to improvements in its regulatory environment through the simplification of the process to start a business, pay taxes, protect investors and eliminate insolvency, as well as through the reduction of entry costs and barriers to entrepreneurs. In a prospective perspective, the government is determined to continue the enhancement of the investment framework, the simplification of procedures and the removal of unnecessary administrative burdens to investors. Colombia is currently close to the OECD average in around half of the scopes of product market regulation. Product market restrictiveness, nonetheless, continues to be above the OECD member average in some key areas such as the state's participation in business, regulatory procedures in some sectors and competition in some network sectors as gas.

In Colombia, while low tariffs are present, high non-tariff barriers and other costs inherent to exportation and importation, such as transport and logistics, and restrictive practices in many service modalities create obstacles to integration into GVCs. Many companies face huge costs of quality certification due to the few internationally certified laboratories that are capable to certify the quality of their goods. This constitutes an important barrier to the participation in GVCs and to exportations to countries with high quality standards such as those in North America and Europe.

A condition to facilitate GVC participation is the reduction of the numerous fragmentation-related costs of production. Certain costs come out at the border as regulatory barriers and costs related to customs inefficiencies, but many are accumulated in places far from the border, namely costs relative to infrastructure, quality of logistics facilities and regulatory burdens. Colombia should thus seek the reduction of export costs which are high due to poor infrastructure quality. Opportunities to boost trade are the improvement of infrastructure for trade and logistics, and the mitigation of negative effects of other behind-the-border issues.

Colombia, moreover, is implementing a National Logistics Policy, whose objectives are, for instance, reduction of logistics costs, restructuring and institutional strengthening, regulation modernization, improvement of the quality of national logistics services and increasing the use of technologies. A strategic infrastructure upgrade program that deserves to be highlighted is

the port expansion plan that seeks to upgrade port infrastructure and access channels to ports, as well as to improve inspection areas of goods for trade facilitation.

Technical cooperation was a key factor that allowed the achievement of the objectives of the policy. Different forms of technical cooperation supported the consolidation of technical groups in logistics inside the National Department of Planning (DNP) and inside the Transport Ministry (MdT). They also allowed the structuring of the National Observatory of Logistics (ONL), of the System of Logistics Indicators in Urban Centers (SILCU) and of the Georeferenced Logistics Information System (SIGLOG).

According to OECD indicators, Colombia has a very good record in information availability, participation of the trade community, simplification and harmonization of documents and internal border agency cooperation. An improvement of performance was verified between 2013 and 2015 on the issues of involvement of the trade community, automation and external border agency cooperation.

Despite the positive facts and the great numbers, the country still has to overcome deficiencies. The DNP is frequently the sole institution competent to coordinate regulatory efforts across the administration. Comprehensive standards do not provide a guide to the preparation of regulations. Despite the governmental interest on the introduction of regulatory impact analysis towards the quality improvement of new regulations, political will is needed to guarantee the implementation of the tool at the subnational level.

4. Chile

The purpose of this Chapter is to analyze the system of technical regulation, standardization and conformity assessment in Chile. After a brief introduction, in which data will be informed of the trade flow between Chile and Brazil, identifying the main products of the bilateral trade agenda, the structure of the Chilean State will be analyzed, focusing on the identification of organisms that participate directly in the regulation processes, standardization and conformity assessment. Then, these three dimensions will be studied separately, with special emphasis on the explanation of coherence procedures for the creation and application of technical rules.

4.1.Introduction ¹¹¹

Chile is ranked as a high-income economy by the World Bank and is considered as the South American most prosperous nation. In May 2010, Chile became the first South American country to join the OECD. Chile is the 42nd largest export economy in the world and the 61st most complex economy according to the Economic Complexity Index (ECI).

In 2017, Chile exported US\$ 70.1 billions and imported US\$ 62.7 billions, resulting in a positive trade balance of US\$ 7.48 billions. In 2017 the gross domestic product (GDP) of Chile was US\$ 277B and its GDP per capita was \$24.6k. The top export products of Chile are copper ore (US\$ 16.6 billions), refined copper (US\$ 14.9 billions), fish fillets (US\$ 2.86 billions), sulfate chemical woodpulp (US\$ 2.67 billions) and raw copper (US\$ 2.41 billions), according to the 1992 revision of the HS (Harmonized System) classification. Its top imported products are cars (US\$ 4.28 billions), refined petroleum (US\$ 3.64 billions), crude petroleum (US\$ 2.81 billions), broadcasting equipment (US\$ 2.49 billions) and delivery trucks (US\$ 2.32 billions). The top export destinations of Chile are China (US\$ 19.2 billions), the United States (US\$ 10.3 billions), Japan (US\$ 6.38 billions), South Korea (US\$ 4.06 billions) and Brazil (US\$ 3.44 billions). The top origins of importations are China (US\$ 15.4 billions), the United States (US\$ 11.5 billions), Brazil (US\$ 5.32 billions), Argentina (US\$ 2.77 billions) and Germany (US\$ 2.63 billions).¹¹²

Commercial Relations with Brazil

Regarding the bilateral trade with Brazil, Chile is one important trading partners, the 5th most important destination to exports and the 12th partner in terms of imports. In 2018, Brazil exported US\$ 6,389 billion in goods and services and imported US\$ 3,381 billion, accounting for a Brazilian surplus of US\$ 3,007 billion. In the chart below, the bilateral trading relations during the last 3 years is shown. As it can be observed, Brazil has increased considerably the amount of exported goods to Chile in the last 3 years.

¹¹¹ Based on Trade Policy Review of Chile https://www.wto.org/english/tratop_e/tpr_e/tp415_e.htm

¹¹² Observatory of economic complexity. Available in <<https://atlas.media.mit.edu/en/profile/country/chl/>>. Access on: 14 May. 2019.

Table 4.1 - Brazilian exports to Chile (FOB/US\$)

Code SH2	Product SH2	2018	2017	2016	2015
27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes	2.070.194.562,00	1.513.861.495,00	1.093.837.779,00	1.125.396.071,00
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	1.231.854.108,00	909.053.306,00	652.366.309,00	569.811.284,00
02	Meat and edible meat offal	636.071.041,00	435.860.616,00	428.560.117,00	349.166.716,00
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	399.263.974,00	357.691.438,00	318.355.370,00	286.862.192,00
39	Plastics and articles thereof	268.773.440,00	259.289.937,00	230.692.344,00	226.595.931,00
48	Paper and paperboard; articles of paper pulp, of paper or of paperboard	229.870.210,00	123.813.115,00	120.753.041,00	133.660.849,00
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	195.096.930,00	185.386.936,00	139.987.614,00	130.859.802,00
72	Iron and steel	161.562.282,00	134.777.265,00	89.464.495,00	101.018.326,00
23	Residues and waste from the food industries; prepared animal fodder	126.944.697,00	115.641.501,00	64.044.027,00	91.676.397,00
29	Organic chemicals	73.583.564,00	53.898.810,00	43.362.603,00	62.285.178,00
40	Rubber and articles thereof	73.567.363,00	60.029.789,00	63.932.721,00	65.540.469,00

Source: Comexstat. Elaborated by CCGI/EESP-FGV.

Table 4.2 - Brazilian imports from Chile (FOB/US\$)

Code SH2	Product SH2	2018	2017	2016	2015
74	Copper and articles thereof	1.161.805.739,00	1.075.593.853,00	790.506.687,00	1.061.595.335,00
03	Fish and crustaceans, molluscs and other aquatic invertebrates	584.546.911,00	589.433.959,00	533.782.567,00	471.553.917,00
26	Ores, slag and ash	416.069.773,00	545.294.995,00	421.252.891,00	728.754.714,00
29	Organic chemicals	191.013.477,00	158.606.759,00	95.639.106,00	72.335.390,00
08	Edible fruit and nuts; peel of citrus fruit or melons	168.024.029,00	169.363.821,00	209.195.640,00	186.903.091,00
22	Beverages, spirits and vinegar	146.211.305,00	147.132.916,00	123.890.401,00	108.777.459,00
31	Fertilisers	115.897.376,00	180.135.305,00	151.278.979,00	154.602.634,00
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof	88.108.177,00	77.488.869,00	81.819.305,00	91.369.140,00
73	Articles of iron or steel	65.949.889,00	89.673.174,00	67.951.563,00	94.937.921,00
39	Plastics and articles thereof	51.874.613,00	46.631.531,00	38.503.761,00	46.600.408,00

Source: Comexstat. Elaborated by CCGI/EESP-FGV

4.2. Governmental Structure in Chile

Chile is a unitary country, as it is established in the 1980 Constitution, with a territory divided into regions. The sovereignty lies within the Nation, as stated in the Constitution and is exercised through the election of their representatives by suffrage or by making particular decisions through plebiscite. Chile is a presidential republic, which basically means that the president of the republic is both head of State and head of government¹¹³. The Constitution establishes some important institutions to govern the country such as the Constitutional Court, the Central Bank, the National Security Council and other bodies. Some of the prerogatives of the president of the Republic are the following: convocation of plebiscites, appointment of State ministers, exclusive initiative in various matters of law, imposition on states of constitutional exceptions, and the possibility of issuing binding decrees provided that the Congress grants the authorization.

In Chile, the president, as head of state, heads the Armed Forces in case of war. Moreover, he also appoints the ministers of the Supreme Court, with previous approval of the Senate, besides possessing other competences such as the application of states of exception. The president is also the head of government, with functions corresponding to the government and the

¹¹³ CHILE. Gobierno de Chile. Disponível em <https://www.gob.cl/>. Acesso em 16/07/2019.

administration of the State. It has the direct and immediate collaboration of the Ministers of State. Territorially, the Government is represented by intendants in the regions and governors in the provinces, and all these positions are designated by the president. The Ministries of State are represented in the local level through Regional Ministerial Secretariats.

The Legislative power corresponds to the National Congress (of bicameral type, composed by a Senate and a Chamber of Deputies) and to the president of the Republic, both acting as co-legislators, who are the ones in charge of elaborating the laws. An organic constitutional law regulates the internal processing or formation of the law¹¹⁴.

The Judicial power corresponds to all the courts of the republic, ordinary or special, under the superior vigilance of the Supreme Court. Article 82 of the Chilean Constitution states that the Supreme Court performs the directive, correctional and economic oversight with respect to the other courts, except for the Constitutional Court, the Electoral Qualification Tribunal, and the regional electoral courts. The courts are charged with judging and executing all those causes that the Constitution and laws have placed in the sphere of their powers.

The ministers are the direct and immediate collaborators of the President of the Republic in the government and administration of the State. The ministries, as superior bodies of collaboration of the President of the Republic in the functions of government and administration of their respective sectors, must propose and evaluate the corresponding policies and plans, study and propose the rules applicable to the sectors under their charge, ensure compliance with the regulations issued, allocate resources and supervise the activities of the respective sector. The table below provides the Chilean ministries that integrate the Executive power.

Table 4.3 - The Government in Chile

State Ministries
Ministry of the Interior and Public Security
Ministry of Foreign Affairs
Ministry of National Defense
Ministry of Treasury
Ministry of Economy, Development and Tourism
Ministry of Social Development
Ministry of Education
Ministry of Justice and Human Rights
Ministry of Labor and Social Security
Ministry of Public Works
Ministry of Health
Ministry of Housing and Urbanism
Ministry of Mining
Ministry of Transport and Telecommunications
Ministry of National Goods
Ministry of Energy
Ministry of the Environment
Ministry of Sport
Ministry of Women and Gender Equity
Ministry of Culture, Arts and Heritage
Ministry of Science, Technology, Knowledge and Innovation

Source: TPR-Chile. Elaborated by CCGI-EESP-FGV

¹¹⁴ CHILE. Gobierno de Chile. Disponível em <https://www.gob.cl/>. Acesso em 16/07/2019.

4.3. The quality infrastructure in Chile

The system coordinating the regulatory measures, in accordance with the requirements of the Chilean legislation, is transparent and open. The measures are drafted on the basis of principles of non-discrimination and transparency and recourse to international standards. Through its regulatory agencies and in accordance with the Transparency Law, in force since 2008, Chile is required to publish on its website all the technical regulations and conformity assessment procedures in effect. Chile also has a Technical Regulations Gateway intended to centralize this information, making it easier for potential new exporters to find information on access to its market.

Chile legislation on technical regulations includes: the Agreement on Technical Barriers to Trade (TBT Agreement), which came into force in Chile in May 1995; Decree No. 77 of the Ministry of the Economy of 14 June 2004, which lays down the requirements to be met by competent institutions when drafting, adopting and applying technical regulations and conformity assessment procedures; Decree No. 308 of 15 February 2008, amending the aforementioned Decree and the series of RTAs signed by Chile. In this connection, most of the Regional Trade Agreements (RTA) signed by Chile include a chapter on technical regulations, standards and conformity assessment procedures, covering rules in areas such as: transparency, equivalence, technical and regulatory cooperation and creation of a TBT committee¹¹⁵.

Decree No. 77 of the Ministry of the Economy of 14 June 2004 constitutes the basic regulations for all agencies involved in preparing technical regulations and conformity assessment procedures and lays down the principles that should govern the drafting of technical regulations. They must, as far as possible, be based on domestic or international regulations, not create unnecessary barriers to trade, and be founded on operational criteria. MFN and national treatment principles also have to be taken into account when drafting technical regulations.

The Regulations Department in the Directorate-General of International Economic Relations (DIRECON)¹¹⁶, within the Ministry of Foreign Affairs, is responsible for administering the TBT Agreement, acting as the enquiry point for matters relating to technical regulations and conformity assessment procedures and making notifications to the World Trade Organization (WTO). The National Standardization Institute (INN) is in charge of drafting technical regulations, applied on a voluntary basis.

The role of the National Commission on Technical Barriers to Trade, chaired by the DIRECON, is to comply with the commitments in the TBT Agreement and to coordinate Chile's position in the relevant trade negotiations among participating bodies. Work on preparing technical regulations is conducted in cooperation with the private sector and, in general, all regulatory aspects were coordinated. The authorities indicated that each of the regulatory agencies has internal mechanisms for coordination with the private sector when drafting technical regulations and conformity assessment procedures. Some examples of these are the Ministry of Health's Committee on Food Health Regulations and the Ministry of Agriculture's Round Table on Meat.

¹¹⁵ WORLD TRADE ORGANIZATION. Trade Policy Review Chile 2017, WTO. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s315_e.pdf. Acesso em 16/07/2019.

¹¹⁶ DIRECON. Quiénes somos. Disponível em: <https://www.subrei.gob.cl/quienes-somos/>. Acesso em: 23 jul. 2019.

An Export Competition Council has recently been created, under the Ministry of the Economy, and DIRECON acts as its technical secretariat. One of this Council's aims is to eliminate the trade barriers faced by the export sector¹¹⁷. Chile is a member of various international organizations involved in standardization and related activities: the International Organization for Standardization (ISO), the Inter-American Metrology System (SIM), the Panamerican Standards Commission (COPANT), the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC), the Inter-American Accreditation Cooperation (IAAC), the International Bureau of Weights and Measures (BIPM) and the Codex Alimentarius. It is also an associate member without voting rights in the MERCOSUR Standardization Association (AMN).

Technical regulations are issued at Central Government level in the form of laws, decrees or resolutions. They are drafted by the government authorities responsible for regulating their respective areas of competence, for example, the Ministries of the Economy, Health, Agriculture, Transport and Telecommunications, Housing and Urban Planning, and the SEC (Superintendence of Electricity and Combustibles). Those technical regulations in the form of laws have to be approved by Congress. In accordance with the procedures set out in Decree No. 77 of 2004 (regulatory powers of the Executive) and the amendments thereto in Decree No. 308 of 2010, where technical regulations and/or conformity assessment procedures are required and relevant international standards exist or are shortly to be finalized, the ministries or agencies empowered to adopt them shall use such international standards or their relevant parts as a basis for their technical regulations or procedures, unless these institutions consider that they would be an ineffective or inappropriate means of fulfilling the legitimate objectives pursued.

It is also provided that technical regulations and/or conformity assessment procedures should not be more trade-restrictive than is necessary to fulfil a legitimate objective, taking account of the risk non-fulfilment would create. Such legitimate objectives include national security requirements, protection of human health or safety, animal or plant life or health, or the environment, or the prevention of misleading practices. The rules provide that technical regulations shall be drafted, adopted and applied in such a way that imported products are accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country. The same provisions apply to conformity assessment procedures.

Concerning the procedure to be followed, the rules state that the ministry or body having regulatory authority shall publish, in the form of a notice in the national media or on its website, the draft of the technical regulation or conformity assessment procedure that it intends to adopt. This notice shall include at least an extract from the draft technical regulation or conformity assessment procedure and shall state where the text can be consulted in full. At the same time, a copy of the extract and the draft regulation shall be sent to the DIRECON. The notice shall be published long enough in advance of the adoption of the measure to enable anyone to submit comments in writing during a period of at least 60 days, except in cases of emergency relating to safety, health, environmental protection or national security.

After they have been approved, technical regulations and conformity assessment procedures are published in the Official Journal and on the websites of the competent regulatory agencies. Technical regulations and/or conformity assessment procedures must provide for a period of at

¹¹⁷ DIRECON. Quiénes somos. Disponível em: <https://www.subrei.gob.cl/quienes-somos/>. Acesso em: 23 jul. 2019.

least six months between their adoption and their implementation. There is no centralized mechanism for reviewing or abolishing technical regulations. Nevertheless, it is customary practice for the competent agencies to review technical regulations and conformity assessment procedures on a regular basis in order to amend or repeal them, as appropriate. All domestic and imported goods must comply with the corresponding technical regulations.

Technical regulations and/or conformity assessment procedures must include the following information, as appropriate: (a) identification of the product, including its classification in the Harmonized Commodity Description and Coding System (HS) and the purpose of the measure; (b) the specifications and characteristics of the product, method or process established in the regulation in accordance with its purpose; (c) conformity assessment methods; (d) the data and other information to be displayed on the products or else on their containers or packaging and their marking requirements; (e) the extent of their consistency with international standards and guidelines used as a basis in their formulation; and (f) mention of the institution or institutions responsible for enforcing the regulations.

Any technical regulations and/or conformity assessment procedures adopted shall be substantiated by documentary support, for example, the technical grounds for the decision adopted; detailed information on the process for receiving comments; a description of the amendments made to the original proposal as a result of the comments received; and the replies to the comments received. There should also be a description of the possible impact on the domestic market, the costs of implementation and the costs of supervision, as well as of the impact on small and medium-sized enterprises, as appropriate. This description should be at least in qualitative terms if it is not possible in quantitative terms.

The National Standardization Institute (INN) is responsible for drafting Chilean technical standards (NCh)¹¹⁸, whose use is voluntary, and for disseminating them. The INN is a private-law, non-profit-making foundation set up by the Chilean Economic Development Agency (CORFO), with the aim of boosting the development of Chile's production, promoting the drafting and use of Chilean standards, coordinating the National Metrology Network and accrediting conformity assessment bodies. It is also the INN's role to assist in ascertaining the need for new standards.

The internal procedure for drafting Chilean standards is set out in Chilean Standards NCh1, following criteria internationally accepted by the ISO and the International Electrotechnical Commission (IEC). In Chile, there is an important degree of standardization in the areas of construction, foodstuffs, health, safety, quality of life and risk prevention. The INN considers that standardization promotes the lowering of technical barriers to trade and makes the best use of production resources in companies as they have better information available to choose the safest and most suitable products. Standards may also be of service to the regulatory authorities, which use them to support technical regulations. Any government or private body may ask the INN to draw up one or more standards, using one of the following two procedures: the traditional and the associative nucleus procedures. In the traditional system, the INN remains responsible for the whole process of drawing up the standard, from preparation of the preliminary draft up to its approval by the INN Council. The cost of drafting a standard depends on the complexity of the subject. In the associative nucleus procedure, the body associated with

¹¹⁸ INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponível em: <https://www.inn.cl/quienes-somos>. Acesso em: 23 jul. 2019.

the INN, with the latter's technical support, assumes responsibility for obtaining background material and preparing the preliminary draft of the standard, and finances some of the costs of the standardization procedure, from the public consultation stage up to approval of the standard by the INN Council.

In the traditional system, when the necessary financing has been obtained, a technical committee is set up to prepare the preliminary draft of the standard. If international standards exist, they are adapted; if there are none, regional standards, those of other countries or companies in the same sector are consulted. Once the standard has been prepared, the draft is put up for public consultation and made available on the INN website (<http://www.inn.cl>). Comments received as a result of the public consultation are again forwarded to the technical committee, which takes a decision and prepares the final text, and this is forwarded to the INN Council for approval. After approval, the Chilean Standard is sent to the competent ministry (ministries) for a decision on whether to include it among the technical regulations or to replace references to previous versions therein. Unless some legal provision makes it mandatory, the "officialized" standard is voluntary. In general, this is the case for standards whose main objective is to protect the health and/or safety of persons, goods, animals or plants.

In Chile, conformity assessment includes mandatory mechanisms defined by the competent regulatory authority, which set out the requirements to be met by the conformity assessment bodies involved, and a voluntary accreditation system for conformity assessment bodies, administered by the INN.

In general terms, for both imported and domestic products, compliance with technical regulations is verified after the products have been placed on the market. Nevertheless, for the import of certain products, mostly foodstuffs, beverages, medicines, weapons, radioactive substances, electrical goods and fuels, verification takes place at the border. In most cases, conformity assessment is the responsibility of bodies accredited by the INN, although in some cases, the ministry or government authority that issued the technical regulation performs the inspection using its own infrastructure. A declaration of conformity by the supplier is not acceptable.

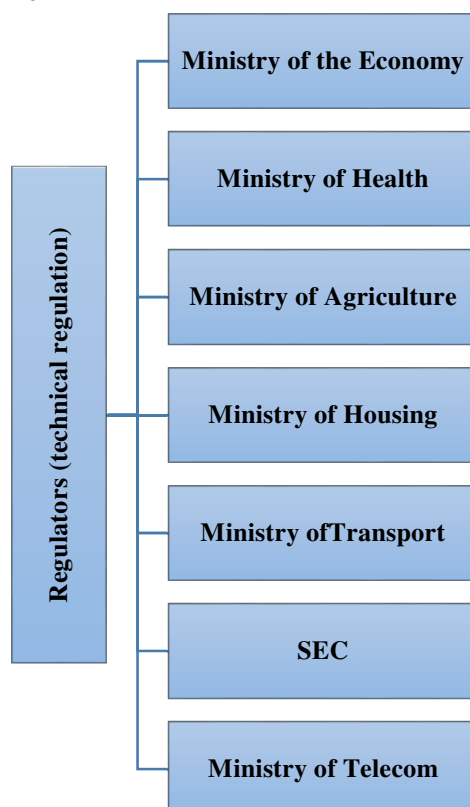
The preparation of conformity assessment procedures defined by the competent regulatory authority follow the same stages as technical regulations. The INN operates the national accreditation system, which accredits conformity assessment bodies that comply with internationally accepted requirements and the relevant regulations and directives. The types of conformity assessment body which may request accreditation include bodies: certifying systems, products and persons, inspection bodies, testing laboratories, calibration laboratories, clinics and providers of proficiency tests. Accreditation is given for a four-year period. The INN keeps a list of bodies accredited and this is available on its website.

Chile has no mutual recognition agreements (MRA) for technical regulations with its trading partners. The SEC does, however, recognize the results of tests and certification by a list of organizations from 14 countries (Austria, Belgium, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom and the United States). It also has multilateral recognition agreements (MLA/MRA) on accreditation of: quality management and environmental management systems certification bodies (MLA in the IAF and MLA in the IAAC), testing laboratories, clinical and calibration laboratories (MRA in the ILAC and MLA in the IAAC). The INN has requested the extension of its MLA to accreditation of product and inspection certification bodies.

4.3.1. Technical Regulations

Technical regulations are issued at Central Government level in the form of laws, decrees or resolutions. Such regulations are developed by the government authorities responsible for regulating their respective areas of competence, for example, the Ministries of the Economy, Health, Agriculture, Transport and Telecommunications, Housing and Urban Planning, and the SEC (Superintendence of Electricity and Combustibles).

Figure 4-1 - Regulators in Chile

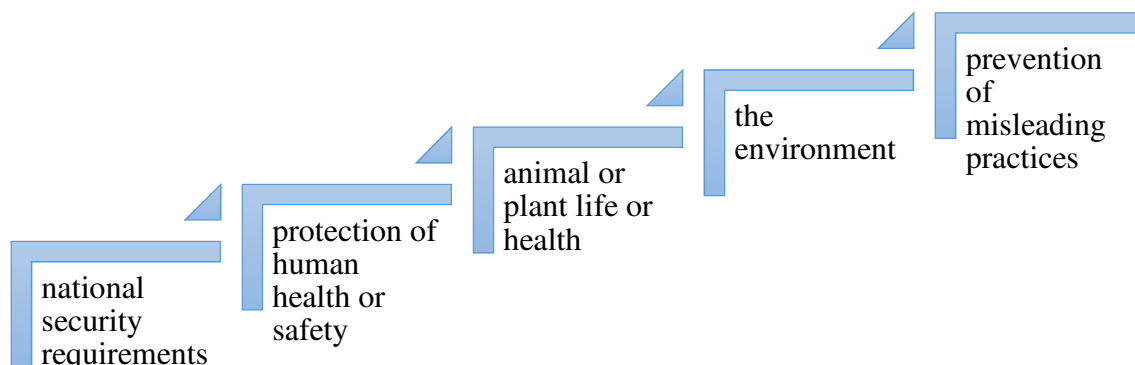


Source: TPR-Chile. Elaborated by CCGI-EESP-FGV

Those technical regulations in the form of laws have to be approved by legislative Branch. In accordance with the procedures set out in Decree No. 77 of 2004 (regulatory powers of the Executive) and the amendments thereto in Decree No. 308 of 2010¹¹⁹, where technical regulations and/or conformity assessment procedures are required and relevant international standards exist or are shortly to be finalized, the ministries or agencies empowered to adopt them shall use such international standards or their relevant parts as a basis for their technical regulations or procedures. It is not applied if these institutions consider that they would be an ineffective or inappropriate means of fulfilling the legitimate objectives pursued. In accordance to Art. 2 of TBT Agreement, it is also established that technical regulations and/or conformity assessment schemes should not create more restriction than is necessary to fulfil a legitimate purposes, taking account of the risk non-fulfilment would create. Such legitimate purposes include national security requirements, protection of human health or safety, animal or plant life or health, or the environment, or the prevention of misleading practices.

¹¹⁹ See <https://www.leychile.cl/Navegar?idNorma=226280&idVersion=2010-02-15>

Figure 4-2 - Legitimate purposes of technical regulation



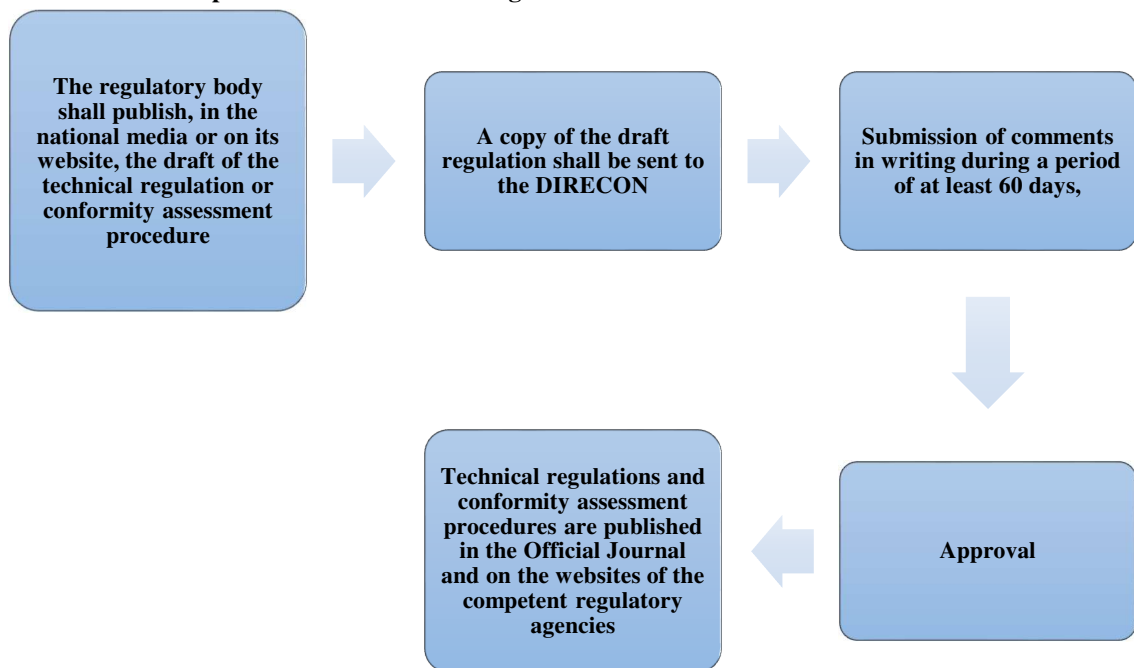
Source: TPR-Chile. Elaborated by CCGI-EESP-FGV

The rules provide that technical regulations shall be drafted, adopted and applied in such a way that imported products are accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country. The same provisions apply to conformity assessment procedures.

The principle of transparency, which can be identified in different parts of TBT Agreement (e.g. Art. 2, 5, 10) is also observed by regulatory procedures in Chile. Concerning the procedure to be followed in regulatory activity, the rules state that the ministry or body having regulatory authority shall publish, in the form of a notice in the national media or on its website, the draft of the technical regulation or conformity assessment procedure that it intends to adopt. This notice shall include at least an extract from the draft technical regulation or conformity assessment procedure and shall state where the text can be consulted in full. At the same time, a copy of the extract and the draft regulation shall be sent to the DIRECON¹²⁰. The notice shall be published long enough in advance of the adoption of the measure to enable anyone to submit comments in writing during a period of at least 60 days, except in cases of emergency relating to safety, health, environmental protection or national security. After they have been approved, technical regulations and conformity assessment procedures are published in the Official Journal and on the websites of the competent regulatory agencies.

¹²⁰ DIRECON. Quiénes somos. Disponível em: <https://www.subrei.gob.cl/quienes-somos/>. Acesso em: 23 jul. 2019.

Figure 4-3 - Process of publication of technical regulation



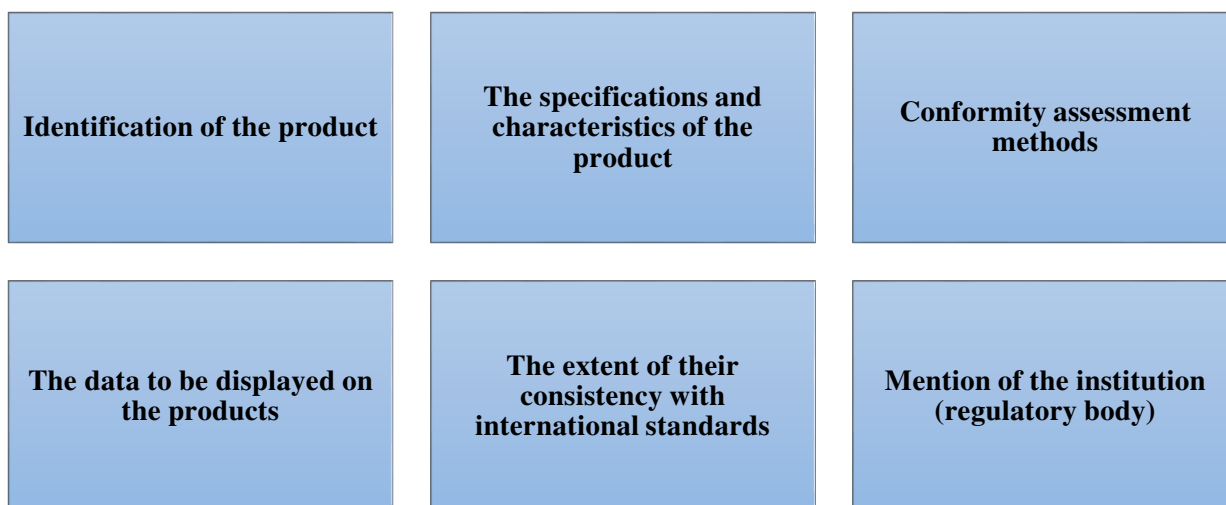
Source: TPR-Chile. Elaborated by CCGI-EESP-FGV

Technical regulations and/or conformity assessment procedures must provide for a period of at least six months between their adoption and their implementation. There is no centralized mechanism for changing technical regulations. However, it is customary practice for the competent agencies to review technical regulations and conformity assessment procedures on a regular basis in order to amend or repeal them, as appropriate. All domestic and imported goods must comply with the corresponding technical regulations.

Technical regulations and/or conformity assessment procedures must include the following information, as appropriate:

- (a) identification of the product, including its classification in the Harmonized Commodity Description and Coding System (HS) and the purpose of the measure;
- (b) the specifications and characteristics of the product, method or process established in the regulation in accordance with its purpose;
- (c) conformity assessment methods;
- (d) the data and other information to be displayed on the products or else on their containers or packaging and their marking requirements;
- (e) the extent of their consistency with international standards and guidelines used as a basis in their formulation; and
- (f) mention of the institution or institutions responsible for enforcing the regulations.

Figure 4-4 - Mandatory itens of tecnical regulation



Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

Any technical regulations and/or conformity assessment procedures adopted shall be substantiated by documentary support, for example, the technical grounds for the decision adopted; detailed information on the process for receiving comments; a description of the amendments made to the original proposal as a result of the comments received; and the replies to the comments received.

There should also be an explanation of the possible impact on the domestic market, the costs of implementation and the costs of supervision, as well as of the impact on small and medium-sized enterprises. This description should be at least in qualitative terms if it is not possible in quantitative terms.

The following table has technical regulations¹²¹ that provide rules for products safety in Chile.

Table 4.4 - Technical Regulations in Chile

TECHNICAL REGULATION	REGULATORY BODY
Law 19496/1997 on the protection of the rights of consumers	Act approved by the Parliament
Decree 114/2005 that approves regulation on toy safety	<i>Ministerio de Salud</i>
Decree 157/2005 that regulates pesticides for sanitary and domestic use	<i>Ministerio de Salud</i>
Decree 144/2005 on harmful organic solvents	<i>Ministerio de Salud</i>
Decree 754/1998 that prohibits the use of toluene	<i>Ministerio de Salud</i>
Decree 374/1997 that fixes maximum permissible limit of lead in paints	<i>Ministerio de Salud</i>
Decree 79/2007 that regulates solariums or sunbeds	<i>Ministerio de Salud</i>
Decree 298/2006 that regulates the certification of electric products and fuels	<i>Ministerio de Economía, Fomento y Reconstrucción</i>
Decree No. 176/2006: Provides requirements that must be met for children under four years of age traveling in the back seats of light vehicles	<i>Ministerio de Transporte y Telecomunicacione</i>
Resolution No. 336 - SEC: Establishes labeling with safety warnings for electric kettles (jars), with a nominal capacity of up to 10 liters	<i>Ministerio de Economía Fomento y Reconstrucción</i>
Resolution No. 592 - SEC: Establishes a preventive and transitory measure for gas lighters, marketed in the national territory	<i>Ministerio de Economía Fomento y Reconstrucción</i>

Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

¹²¹ Available in http://www.seguridaddeproductos.cl/leyes_reglamentos/?tipo=leyes_reglamentos

As noted above, the Chilean technical regulators are elaborated by the ministerial authority endowed with adequate technical expertise. The Consumer Law is a framework of general application, which aims at product quality in order to meet or interest the consumer.

4.3.2. Chilean Standards

The National Standardization Institute (INN) is responsible for drafting Chilean technical standards (NCh¹²²). The use of such standards is voluntary and can be determined by market demands. The INN is a private-law, non-profit-making foundation set up by the Chilean Economic Development Agency (CORFO). The purpose of INN is boost the development of Chile's production, promoting the drafting and use of Chilean standards, coordinating the National Metrology Network and accrediting conformity assessment bodies. It is also the INN's role to assist in ascertaining the need for new standards¹²³.

The internal procedure for drafting Chilean standards is set out in Chilean Standards NCh1, following criteria internationally accepted by the ISO and the International Electrotechnical Commission (IEC). In Chile, the main areas for standardization activities are construction, foodstuffs, health, safety, quality of life and risk prevention.

Figure 4-5 - The issues of standardization activities



Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

The INN considers that standardization attempts to promote the lowering of technical barriers to trade and makes the best use of production resources in companies as they have better information available to choose the safest and most suitable products. Standards may also be of service to the regulatory authorities, which use them to support technical regulations. Both the INN and the public and private sectors may decide when it is necessary to draw up a standard.

Any government or private body may ask the INN to draw up one or more standards, using one of the following two procedures: the traditional and the associative nucleus procedures. In the traditional system, the INN remains responsible for the whole process of drawing up the standard, from preparation of the preliminary draft up to its approval by the INN Council.

¹²² INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponível em: <https://www.inn.cl/quienes-somos>. Acesso em: 23 jul. 2019.

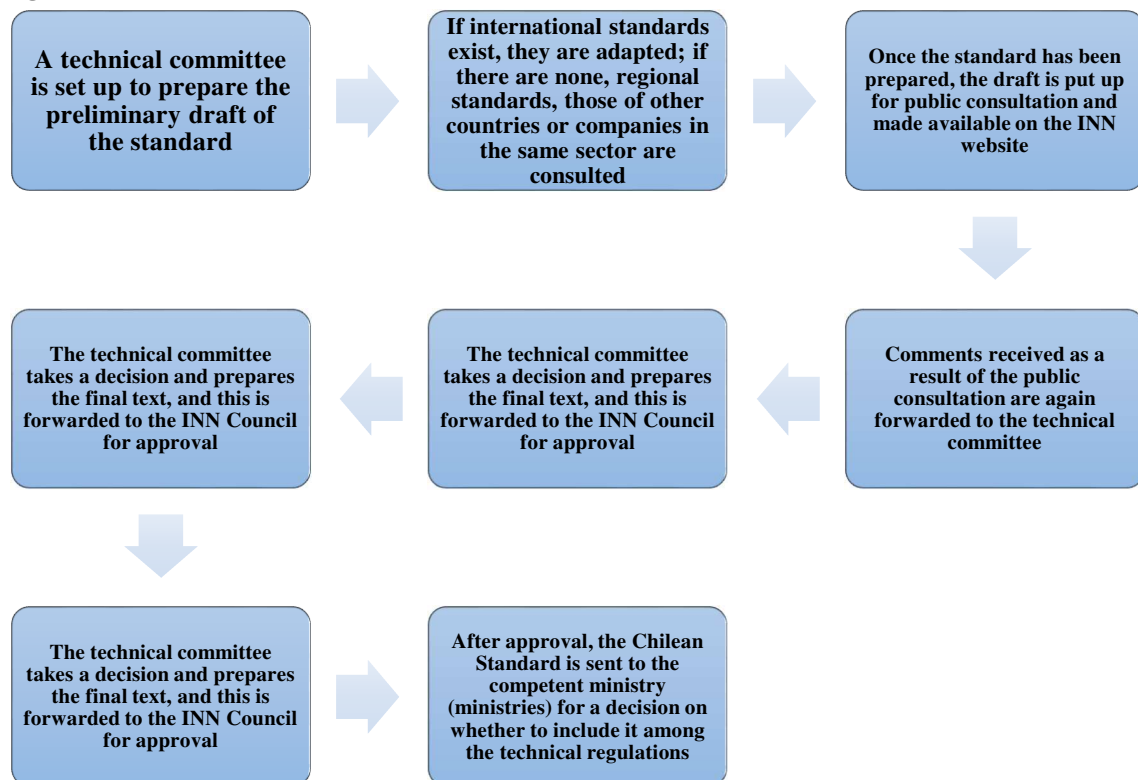
¹²³ INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponível em: <https://www.inn.cl/quienes-somos>. Acesso em: 23 jul. 2019.

The cost of drafting a standard depends on the complexity of the issue. In the associative nucleus procedure, the body associated with the INN, assumes responsibility for obtaining background material, and finances some of the costs of the standardization procedure.

The process to approve a Chilean Standards is the following:

- a) In the traditional system, when the necessary financing has been obtained, a technical committee is set up to prepare the preliminary draft of the standard;
- b) If international standards exist, they are adapted; if there are none, regional standards, those of other countries or companies in the same sector are consulted;
- c) Once the standard has been prepared, the draft is put up for public consultation and made available on the INN website (<http://www.inn.cl>);
- d) Comments received as a result of the public consultation are again forwarded to the technical committee;
- e) The technical committee takes a decision and prepares the final text, and this is forwarded to the INN Council for approval;
- f) After approval, the Chilean Standard is sent to the competent ministry (ministries) for a decision on whether to include it among the technical regulations or to replace references to previous versions therein.

Figure 4-6 - Process of elaboration of standards



Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

Unless some legal provision makes it mandatory, such technical standards are voluntary. In general, this is the case for standards whose main objective is to protect the health and/or safety of persons, goods, animals or plants.

The INN develops technical standards in different sub-fields (Special Committees):

Table 4.5 - Special Committees of Instituto Nacional de Normalización (INN)

Special Committees
Ingeniería de la energía y de la transferencia de calor
Agricultura
Sistemas y componentes de fluidos de uso general
Mecánica
Industria automotriz
Alimentos
Calidad del agua
Turismo y servicios relacionados
Industria caucho y plástico
Información geoespacial
Información y documentación
Industria química
Tecnologías de la información
Energía solar
Minería y metalurgia
Electricidad y electrotecnia
Petróleo
Discapacidad y accesibilidad
Medio ambiente
Consumidores
Salud y medicina
Papeles y cartones
Envases y embalajes
Gestión de la calidad
Gestión de activos
Ergonomía
Gestión de la emergencia
Seguridad personal - Ropa de protección y equipamiento
Compras sustentables
Gestión de riesgos
Evaluación de la conformidad
Prevención de riesgos y salud ocupacional
Industria de la construcción

Special Committees
Especialidades de la construcción
Materiales de construcción
Prevención de incendios
Magnitudes y unidades básicas
Textiles, confecciones, pieles y cueros
Normas básicas
Acústica y vibraciones
Metrología
Combustibles gaseosos
Combustibles sólidos
Laboratorios clínicos
Pesca y acuicultura
Procesos de innovación
Calidad del suelo
Calidad del aire
Gestión de proyectos

Source: INN. Elaborated by CCGI-EESP/FGV.

These committees were responsible for the more than five thousand Chilean standards currently in force. In the appendix dedicated from Chile, there is a list of the main Chilean norms according to the sectors.

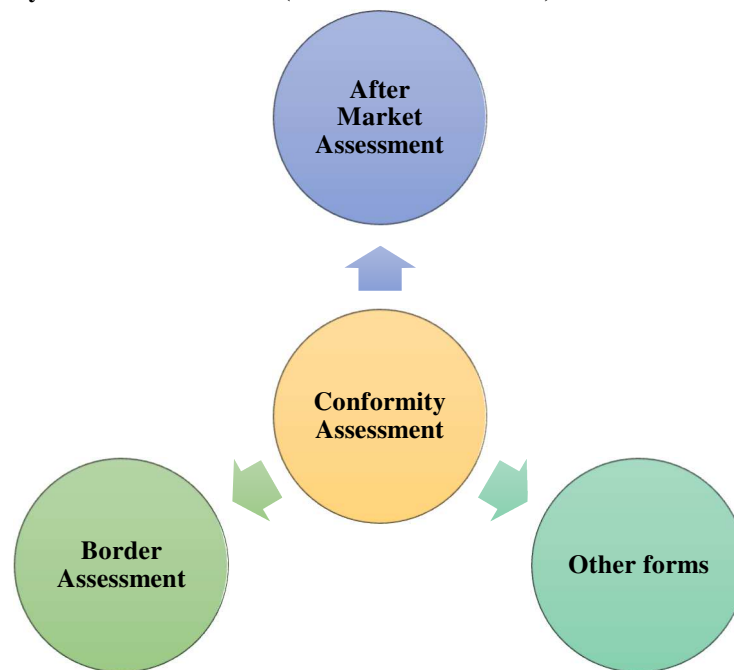
4.3.3. Conformity Assessment in Chile

In Chile, conformity assessment includes mandatory mechanisms defined by the competent regulatory authority, which set out the requirements to be met by the conformity assessment bodies involved, and a voluntary accreditation system for conformity assessment bodies, administered by the INN¹²⁴.

As a general rule, for both imported and domestic products, compliance with technical regulations is verified after the products have been placed on the market. Nevertheless, for the import of certain products, mostly foodstuffs, beverages, medicines, weapons, radioactive substances, electrical goods and fuels, verification takes place at the border. In most cases, conformity assessment is the responsibility of bodies accredited by the INN, although in some cases, the ministry or government authority that issued the technical regulation performs the inspection using its own infrastructure. A declaration of conformity by the supplier is not acceptable.

¹²⁴ INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponible en: <https://www.inn.cl/quienes-somos>. Acceso en: 23 jul. 2019.

Figure 4-7 - Conformity Assessment in Chile (moment of assessment)



Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

The preparation and application of conformity assessment procedures defined by the competent regulatory authority follow the same stages and time-limits as technical regulations. The INN, as the accreditation body, operates the national accreditation system, which accredits conformity assessment bodies that comply with internationally accepted requirements and the relevant regulations and directives.

The different types of conformity assessment body which may request accreditation include bodies: certifying systems, products and persons, inspection bodies, testing laboratories, calibration laboratories, clinics and providers of proficiency tests. Accreditation is given for a four-year period. The INN keeps a list of bodies accredited and this is available on its website¹²⁵.

¹²⁵ To search for na accredited body in Chile, see: <http://acreditacion.innonline.cl/>

Figure 4-8 - Types of Conformity Assessment Bodies



Source: TPR-Chile. Elaborated by CCGI-EESP-FGV.

Chile has no mutual recognition agreements (MRA) for technical regulations with its trading partners. The SEC does, however, recognize the results of tests and certification by a list of organizations from 14 countries (Austria, Belgium, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom and the United States). It also has multilateral recognition agreements (MLA/MRA) on accreditation of: quality management and environmental management systems certification bodies (MLA in the IAF and MLA in the IAAC), testing laboratories, clinical and calibration laboratories (MRA in the ILAC and MLA in the IAAC). The INN has requested the extension of its MLA to accreditation of product and inspection certification bodies.

The table below provides Chilean standards applicable to conformity assessment procedures.

Table 4.6 - Chilean standards applicable to conformity assessment procedures

Technical standard	Description
NCh-ISO17023: 2015	Conformity assessment - Guidelines for determining the duration of management system certification audits
NCh-ISO17021 / 7: 2015	Conformity assessment - Requirements for bodies that perform audits and certification of management systems - Part 7: Competencies required for the audit and certification of road safety management systems
NCh-ISO / IEC Guia 68: 2015	Agreements for the recognition and acceptance of the results of the conformity assessment
NCh-ISO17021 / 5: 2015	Conformity assessment - Requirements for bodies performing the audit and certification of management systems - Part 5: Competency requirements for the audit and certification of asset management systems
NCh-ISO17027: 2015	Conformity assessment - Vocabulary relating to the competence of people used in the certification of persons

NCh-ISO17021 / 1: 2015	Conformity assessment - Requirements for bodies performing audit and certification of management systems - Part 1: Requirements
NCh-ISO 19122: 2016	Geographical / Geomatical Information - Qualification and certification of personnel
NCh-ISO / IEC TS17021 / 9: 2016	Conformity assessment - Requirements for bodies performing the audit and certification of management systems - Part 9: Competency requirements for the audit and certification of anti-bribery management systems
NCh-ISO IEC 27006: 2016	Information Technology - Security Techniques - Requirements for bodies that perform audits and certification of information security management systems
NCh-ISO / IEC TR17026: 2017	Conformity assessment - Example of a certification scheme for tangible products
NCh-ISO / IEC TS17021 / 6: 2017	Conformity assessment - Requirements for bodies performing audit and certification of management systems - Part 6: Competency requirements for auditing and certification of business continuity management systems
NCh-ISO IEC 17021/2: 2017	Conformity assessment - Requirements for bodies performing the audit and certification of management systems - Part 2: Competency requirements for the audit and certification of environmental management systems
NCh-ISO IEC 17011: 2017	Conformity assessment - Requirements for accreditation bodies that carry out the accreditation of conformity assessment bodies
NCh-ISO / IEC 17021/3: 2017	Conformity assessment - Requirements for bodies performing the audit and certification of management systems - Part 3: Competency requirements for the audit and certification of quality management systems
NCh-ISO IEC 17007: 2018	Conformity assessment - Guidance for the drafting of appropriate normative documents for the assessment of conformity
NCh-ISO9712: 2018	Non-destructive testing - Qualification and certification of personnel performing non-destructive testing
NCh3553: 2018	Energy efficiency of buildings - Methods to express energy efficiency and for the energy certification of buildings
NCh-ISO / IEC TS17021 / 10: 2018	Conformity assessment - Requirements for bodies performing the audit and certification of management systems - Part 10: Competency requirements for the audit and certification of safety management systems and health
NCh-ISO / IEC TR 17028: 2019	Conformity assessment - Guidelines and examples of a certification scheme for services

Source: INN. Elaborated by CCGI-EESP/FGV.

The Chilean metrology is governed by several decrees issued by the Ministry of the Economy. These decrees specify the values for mass, temperature, force, length and pressure standards, and designate the laboratories responsible for chemical metrology of minerals, electric metrology, liquid flow metrology and for microbiology and food chemistry metrology.

The authority responsible for developing and maintaining national measurement standards is called the RNM (National Metrology Network)¹²⁶ and has been recognized by the State for the purpose of developing and administering the system of metrological guarantees to ensure that measurements made in Chile are comparable and traceable to the International System of Units (SI), and are accepted by other countries.

The RNM is built around the following bodies: the Ministry of the Economy, Development and Tourism (MEFT), the INN and the institutes appointed. The MEFT, representing the Chilean State, is responsible for appointing the laboratories composing the RNM, once they have met the requirements laid down by the INN, in their specific area of metrology. The INN is the coordinating and supervisory authority for laboratories belonging to the RNM so it also has the task of administering the public funds transferred for its development. The institutes appointed are those laboratories which, either on their own or as part of a larger structure, have been

¹²⁶ See *Red Nacional de Metrología*: <http://www.metrologia.cl/>

recognized as responsible for all or part of an area of metrology, by means of a supreme decree issued by the MEFT. Their function is to ensure that measurements made in Chile can be traced to the SI. Its main activities are: dissemination of the SI units to accredited laboratories, industry, education and lawmakers; undertaking research on metrology and developing new and improved measurement standards and methods; and participating in comparisons at the international level. The institutes appointed provide calibration models services to calibration laboratories and reference material to testing laboratories. They also act as pilot laboratories for proficiency testing at the national level.

4.4. Regulatory Coherence in Chile

The Chilean regulatory structure currently comprises a National Agenda for Productivity, Innovation and Growth that can lead to an upgrade of regulatory quality. The agenda aims to improve the efficiency of regulation and public service delivery. Besides the agenda, administrative and legal arrangements created by the State can support the creation and application of regulation and, at the same time, control quality mechanisms that frame the intervention of regulatory entities. Once progress has been made, the creation, review and enforcement of regulations can lead to the expansion of the economy, to the lifting of productivity, to the attraction and retention of investment, to the improvement of services and to the increase of public welfare.

Standardization is a key process for regulatory coherence in Chile. INN understands that fundamental advantages of standardization are the lowering of technical barriers to trade and the best use of production resources in firms as they have better information that will allow them to choose the safest and most suitable products. Regulatory authorities also apply standards to complement technical regulations. It is up to the INN and the public and private sectors to decide when the drawing up of a standard is necessary. The creation of standards according to the associative nucleus procedure is a concrete example of regulatory coherence. In this procedure, the body associated with the INN, with the latter's technical support, is responsible to obtain background elements and to prepare the preliminary draft of the standard, and to finance certain costs of the standardization procedure. The associated body acts from the public consultation stage until the standard's approval by the INN Council.

SECTION II - REGULATORY CONVERGENCE

5. Notes on Regulatory Convergence

The aim of this section is to examine how regulation, technical standardization and conformity assessment procedures (quality infrastructure system) adopted by Mexico, Colombia and Chile can affect the international trade of these countries, especially in relation to Brazil and Argentina and also to Mercosur.

In the contemporary context of international trade, regulatory barriers are increasingly relevant. After successive multilateral negotiations and preferential trade agreements tariff barriers were consistently reduced. This did not happen with regulatory barriers. The World Trade Organization, in particular the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS), together with international standards and regulatory bodies, prescribe the broader normative framework for regulatory, standardization and conformity assessment activities. Simply observing these international rules and recommendations, however, may be insufficient to eliminate barriers to trade. In this case, regulatory convergence initiatives among trading partners become necessary.

In view of the relevance of the regulatory theme for international trade, the scope of this research will include: the mapping of the regulatory policies and structures of regulation, standardization and conformity assessment in Chile, Mexico and Colombia, which are important trade partners of Brazil. The main purpose is to identify the difficulties these systems represent for trade between these Mercosur partners. The research will also investigate the possible solutions offered by those countries to mitigate or eliminate the non-tariff barriers through regulatory convergence initiatives.

Since the perspective adopted is toward Brazilian interest in international trade, it will be important not only to compare national regulatory and standardization structures of the three selected countries, but also to study the regional and international regulatory cooperation and convergence initiatives adopted, especially those that may have positive effects on trade relations with Brazil. Thus, it will be fundamental to analyze the mechanisms used within the institutional structure of the Latin American Integration Association (ALADI, according initials in Spanish)¹²⁷, the Organization of American States (OAS)¹²⁸, the Pan American Commission of Technical Standards (COPANT)¹²⁹, the Andean Community (CAN)¹³⁰, the former North American Free Trade Agreement (NAFTA)¹³¹ and the new US-Mexico-Canada Agreement (USMCA)¹³².

The results of the analysis may enable further regulatory convergence between major trading partners, focusing on resolving trade barriers stemming from technical, health, phytosanitary and environmental measures. This regulatory convergence, in turn, may favor the increase of Brazil's trade relations with these important regional partners.

¹²⁷ See <http://www.aladi.org/sitioaladi/acuerdosP.html>

¹²⁸ See <http://www.oas.org/pt/>

¹²⁹ See <http://www.copant.org/index.php/es/>

¹³⁰ See <http://www.comunidadandina.org/>

¹³¹ Available in: <https://ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta>

¹³² Available in <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement>

In addition to integrating the Latin American Integration Association (ALADI)¹³³, which is the region's most comprehensive legal framework, the three countries with which Mercosur has specific economic complementation agreements¹³⁴ are among Brazil's main trading partners. If, in quantitative terms, the Brazilian trade with the three countries is important, in the qualitative dimension, this relevance becomes more evident, since the commercial exchange between these partners is made up of products with high added value.

The Brazilian trade with the three countries is quite diversified. Manufactured goods such as automotive vehicles (HS 87), mechanical and electrical (HS 84) and electrical (HS 85), basic (HS 28 and 29) and processed (HS 30) chemicals, products minerals (e.g. HS 74), fossil fuels (HS 27), agricultural goods (e.g. HS 02, 03, 08).

The trade relations with Mexico, which is supported by three ECAs (n. 53, n. 54 and n. 55), totaled almost US \$ 10 billion in 2018. It is a pattern consisting predominantly of manufactured goods, with emphasis on automotive goods and electrical machinery and equipment. Trade in automotive goods totaled more than US \$ 3 billion in 2018, with a significant surplus for Mexico.

In trade with Chile¹³⁵, which is regulated by ACE no. 35 and by more than sixty complementary agreements, in addition to manufactured products, it is highlighted the import of copper and other primary products (eg fruits and other minerals) and the export of fuels to the Andean country. In 2018, the trade flow between Chile and Brazil was close to US \$ 10 billion.

Although more modest, the trade flow between Brazil and Colombia, which occurs according to the provisions of ACE n. 59¹³⁶, has increased in a sustainable manner. The commercial pattern is also characterized by the strong predominance of manufactured products, including automotive vehicles, machinery and mechanical and electrical equipment, which are exported from Brazil to Colombia. Also noteworthy is the bilateral flow of processed and basic chemicals, which shows potential complementarity between this industrial branch in the two countries.

Some convergence initiatives

Considering the characteristics of the current trade and the existence of a legal framework for trade liberalization in Latin America (formalized in ALADI and its various EACs), trade between Brazil and the three selected countries could be substantially stimulated through regulatory convergence efforts, as tariffs between these trading partners are relatively low¹³⁷.

¹³³ See <http://www.aladi.org/sitioAladi/indexp.html>

¹³⁴ List of ACEs can be seen in <http://www.aladi.org/nsfaladi/textacdos.nsf/vacewebR>

¹³⁵ See Acordo de Complementação Econômica n. 35 – Mercosul/ Chile. Available in: http://www.aladi.org/biblioteca/publicaciones/aladi/acuerdos/ace/es/ace35/web/ACE_035_Acuerdo.pdf. Additionally, see <http://www.itamaraty.gov.br/pt-BR/notas-a-imprensa/19656-conclusao-das-negociacoes-do-acordo-de-livre-comercio-entre-o-brasil-e-o-chile-santiago-16-a-19-de-outubro-de-2018>

¹³⁶ See Acordo de Complementação Econômica n. 59 celebrated between Mercosul, Colômbia, Equador e Venezuela. Available in: http://www.aladi.org/biblioteca/publicaciones/aladi/acuerdos/ace/es/ace59/ACE_059_Acuerdo_Texto.pdf.

¹³⁷ See tariffs of ALADI countries:

http://consultawebv2.aladi.org/sicoexV2/jsfAranceles/arancel_vigente_item_entrada.seam?cid=1373530

The approximation of the regulatory, standardization and conformity assessment systems¹³⁸ of the countries could also strengthen regional industrial production chains as well as create new chains for dynamic and important industrial sectors in these countries.

In this context, a comparative analysis between the regulatory frameworks related to technical barriers to trade (TBT) in Mexico, Colombia and Chile can offer solutions to problems and impasses observed in Brazil and within Mercosur. As with bilateral trade with Argentina, the Brazilian trade pattern with the three countries is heavily concentrated in industrialized products with high added value. Considering the export difficulties of Brazilian industry, the study of these markets that demand Brazilian manufactured goods becomes even more relevant.

This study attributes special relevance to several international initiatives to promote convergence and regulatory coherence. For example, the Organization for Economic Cooperation and Development (OECD) has made an important contribution, especially with regard to delimitations of concepts and the proposition of regulatory models of specific sectors, such as for the Chemicals. The OECD recommendations and non-prescriptive documents are often used in the processes of administrative modernization and reform of States.

The OECD contains a number of reports and guides that analyze and prescribe procedures for good regulatory practice (OECD, 2005, 2010, 2012, 2013, 2015, 2016). Transparency in the elaboration of regulations and technical standards, periodic review of rules stock, prior impact analysis and openness to stakeholder participation are some of the practices highlighted by the OECD, so that the regulatory system is internally coherent. Compliance with standards produced by relevant international organizations, the adoption of schemes for the mutual recognition of conformity assessment procedures and ongoing dialogue between technical authorities are important practices for the convergence of different regulatory systems.

Use of international standards

An example of the pursuit of convergence widely mentioned in OECD reports and prescribed in the rules of the multilateral trading system is the use of standards produced by international standardization bodies.

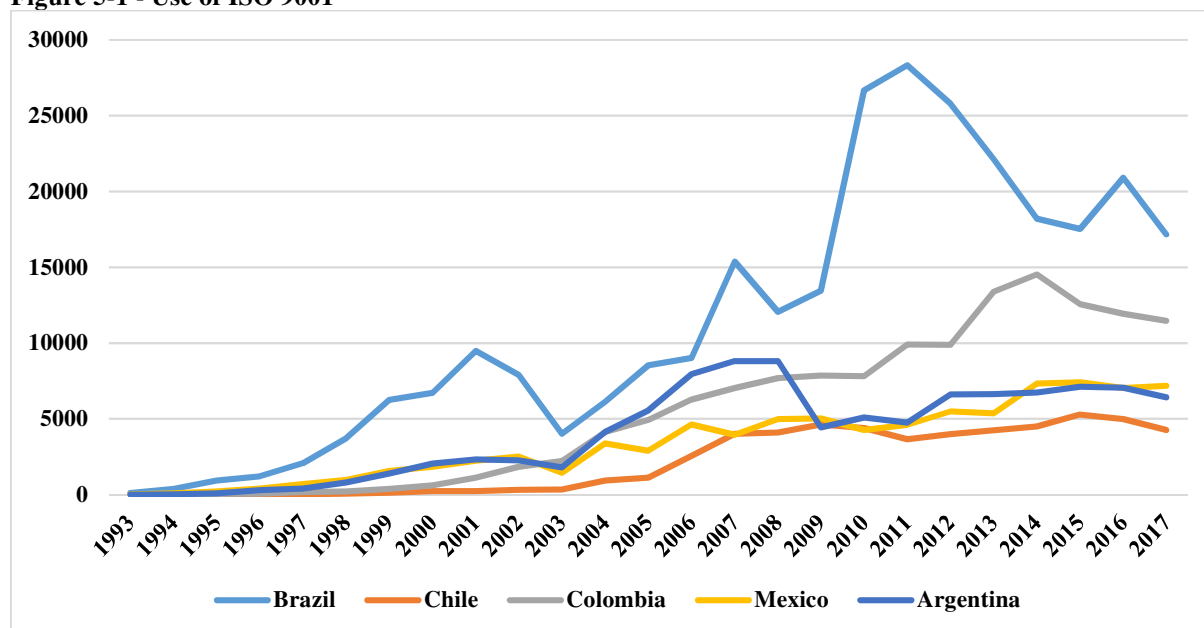
The use of international standards by adopting minimum product and process quality standards would preclude allegations of discriminatory and unjustifiable restrictions on trade.

For example, the use of ISO 9001, 14001 and 27001 family standards, which deal, respectively, with quality management, environmental management and information security management system indicates the penetration of international standards in the studied countries and indicates the lack of discriminatory restriction to trade.

The following graphs indicate the number of certifications issued based on three ISO standards.

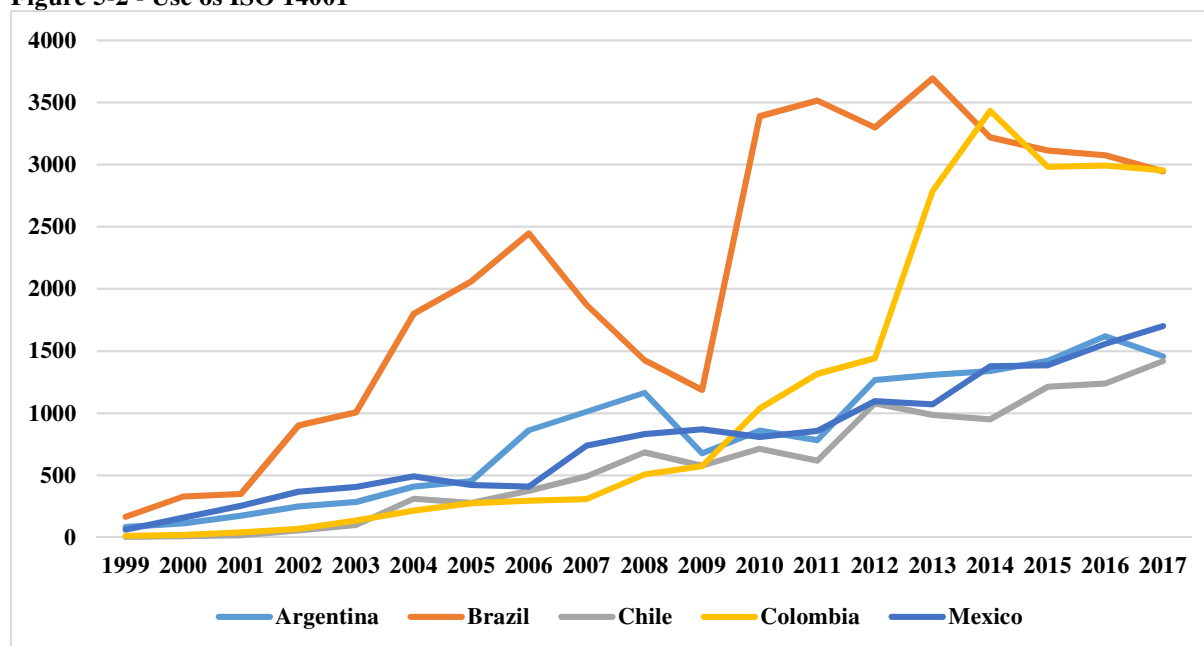
¹³⁸ There is important evidence that the countries analyzed have medium or high regulatory complexity. For international trade, this complexity may represent costs and barriers to the exchange of goods and services. See, for example, the indicators of regulatory complexity calculated by the OECD for Chile, Mexico and Brazil: <http://www.oecd.org/eco/reform/indicatorsofproductmarketregulationhomepage.htm>

Figure 5-1 - Use of ISO 9001



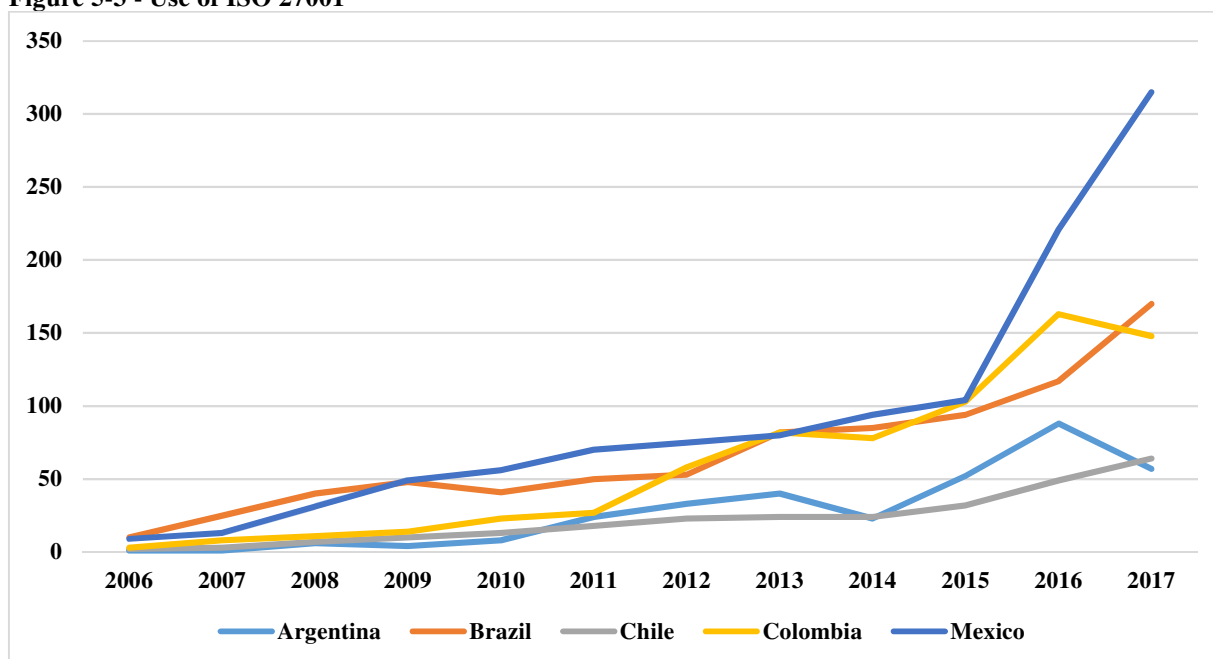
Source: BID and ISO. Elaborated by CCGI-EESP/FGV.

Figure 5-2 - Use os ISO 14001



Source: BID and ISO. Elaborated by CCGI-EESP/FGV.

Figure 5-3 - Use of ISO 27001



Source: BID and ISO. Elaborated by CCGI-EESP/FGV.

The information provided on the graphics is, however, limited. The graphics do not make the distinction between technical standards obtained by Colombian companies and the technical standards obtained or issued in other countries. The achievement and the implementation of a ISO standard by a company also do not imply the certification as it is a voluntary and costly process for a company that must be submitted to a conformity assessment in order to demonstrate compliance with tests and requirements of the respective standard. Moreover, the *coeteris paribus* comparison of the number of technical norms does not take into account the variation in each country on the size of the GDP, total population and number of companies.

One of the main practical results of the research will be the strengthening of communication between business communities, industry associations and regulatory bodies, with the aim of promoting bilateral trade and investment, as well as cooperation in innovation, research and development. There is great potential to strengthen the economic relationship between Brazil and the three selected countries, through regulatory convergence based on mandated requirements and recommendations from international organizations.

This project, therefore, could provide subsidies for ambitious regulatory cooperation between Brazil and Argentina with Chile, Colombia and Mexico and the Pacific Alliance, raising some of the main obstacles in bilateral and regional trade. The initiatives adopted on the basis of this study could therefore result in greater economic integration and increased business competitiveness and growth in all countries involved.

6. Mexico

The objective of this Chapter is to analyze the regulatory convergence efforts of Mexico and its trading partners through the operation of the multilateral trading system, the conclusion of trade agreements and the establishment of mechanisms and specific arrangements for regulatory cooperation. The last part is dedicated to the comparison between the Mexican system and the systems of Brazil and Argentina, both studied in detail in previous works¹³⁹.

6.1. Regulatory Convergence

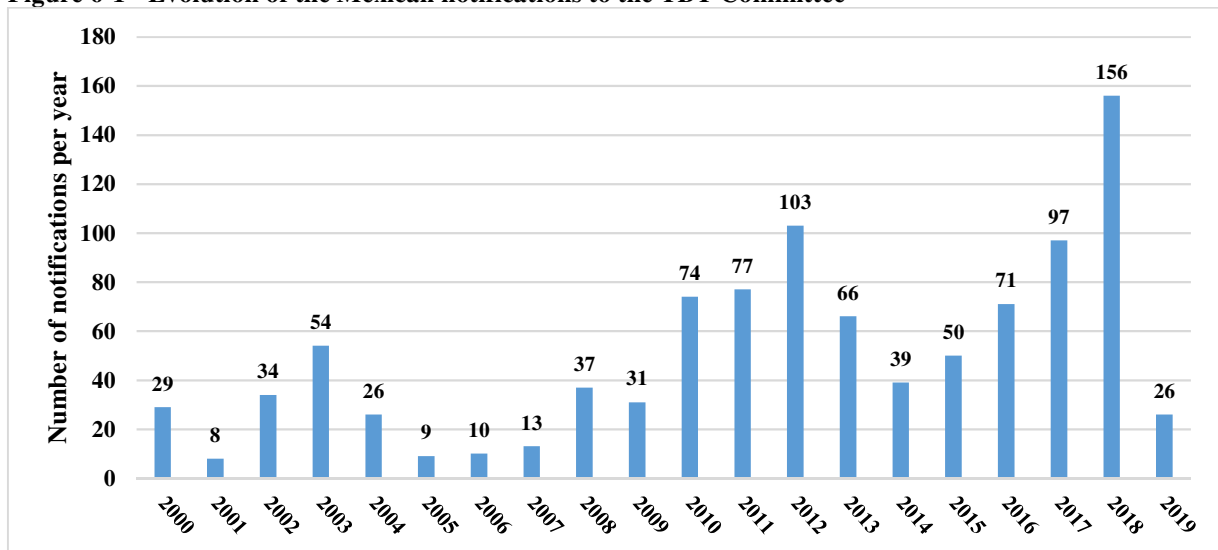
Convergence presupposes the existence of two or more distinct international regulatory systems and possibly divergent aspects. There are different ways of seeking convergence between systems, through mechanisms of cooperation endowed with formalization and variable effectiveness. From the perspective of international trade, three forms of instrumentalization of convergence are important: those adopted at the multilateral level, especially within the framework of the multilateral trading system, those formalized in preferential trade agreements and those established through agreements and arrangements between specialized subnational actors.

6.2. Mexico in TBT Committee

At the multilateral level, the investigation of the notifications made by Mexico to the WTO TBT Committee provides an overview of the country's regulatory technical activity. In more recent years, coinciding with the period of deepening of regulatory reform in Mexico, the number of notifications rises consistently. The year 2018 shows the highest number of notifications in the selected interval, as shown in the graph below.

¹³⁹ See the following reports on Brasil and Argentina:
http://www.ipea.gov.br/portal/index.php?option=com_content&view=article&id=34629&Itemid=444
http://www.ipea.gov.br/portal/index.php?option=com_content&view=article&id=34569&Itemid=4

Figure 6-1 - Evolution of the Mexican notifications to the TBT Committee

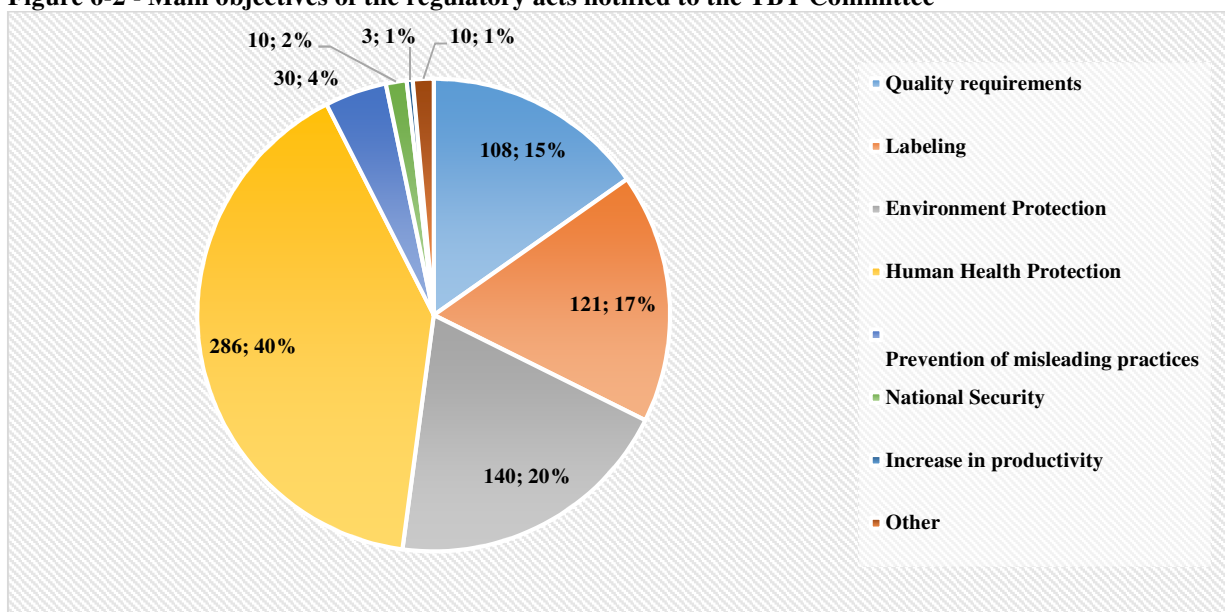


Source: OCDE. Elaboration: CCGI-EESP/FGV.

The topics covered in the regulatory measures notified to the TBT Committee are: product quality requirements, labeling and provision of consumer information, environmental protection and sustainable practices, prevention of misleading practices, national security, costs.

The table below shows the frequency of these issues in Mexico's notifications to the TBT Committee.

Figure 6-2 - Main objectives of the regulatory acts notified to the TBT Committee



Source: OCDE. Elaboration: CCGI-EESP/FGV.

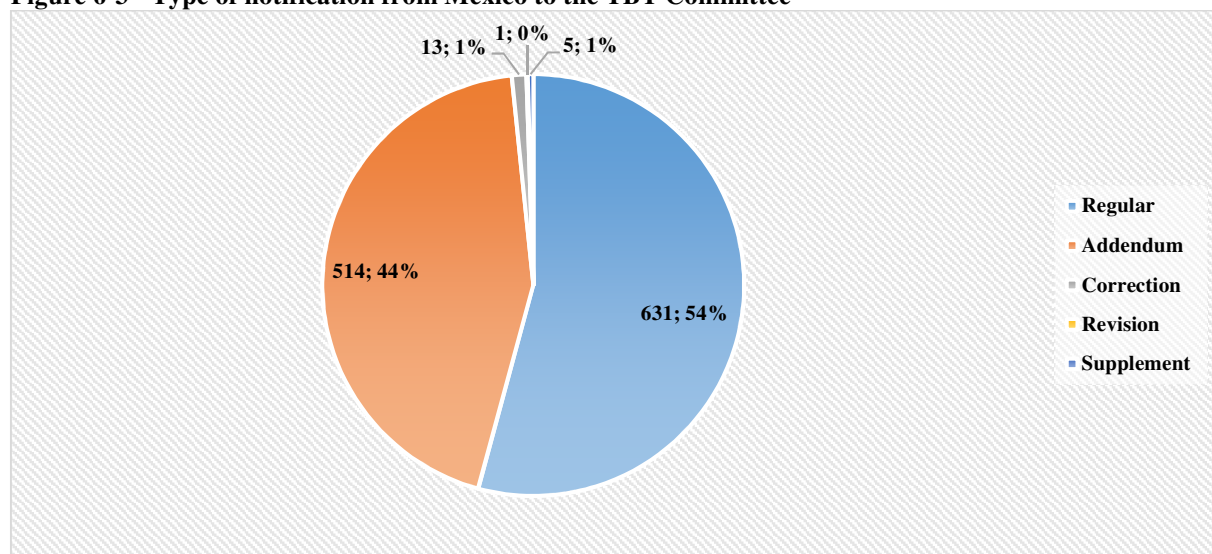
The most frequent objective of the regulatory acts notified to the TBT Committee is to protect human health. More than 40% of draft regulations or technical standards notified to the WTO body are intended to ensure the protection of human health. Also relevant are environmental

protection objectives (20%), consumer information, which basically takes the form of labeling (17%), and to ensure product quality requirements (15%).

Notifications can be classified into two broad categories: new measurement notification or previously notified measurement notification. In the first case, the notification is called regular. In the second case, the name varies according to the type of relationship that the notification maintains with the regular notification, and may add new information (addendum, supplement) or correct the substance of what was previously reported (correction, revision).

The table below shows the distribution of Mexican notifications according to the modality.

Figure 6-3 - Type of notification from Mexico to the TBT Committee



Source: OCDE. Elaboration: CCGI-EESP/FGV.

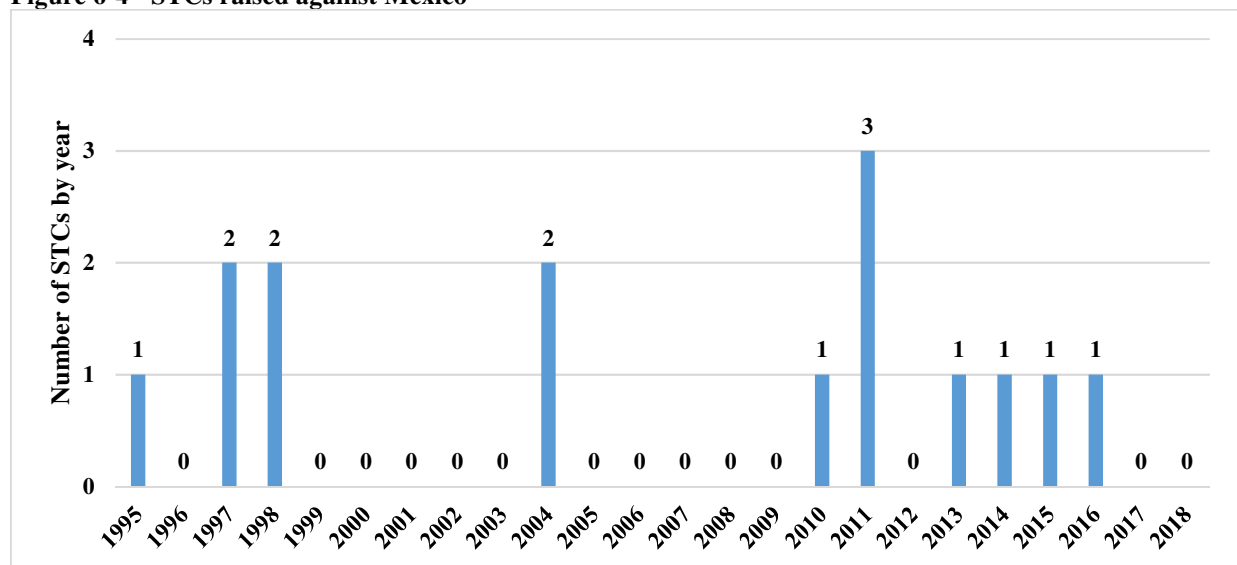
Most of the Mexican notifications to the TBT Committee consist of regular notifications, which indicate innovation in the country's regulatory and regulatory framework. More than 54% of notifications are about new rules and measures adopted in Mexico. Also relevant are the addenda, which generally bring some kind of new or more precise information about the regulation or the notified standard.

Another way of ascertaining the convergence between the Mexican regulatory system and that of other countries, as well as their compatibility with the rules of the TBT Agreement, is to analyze the so-called Specific Trade Concerns (STCs). STCs consist of a non-contentious way of resolving possible disputes, upon request by WTO member states to clarify a potentially obstructive trade measure. Through STCs, Members may require explanations of measures that appear to be inconsistent with the provisions of the TBT Agreement.

In this sense, by concentrating the analysis on the active and passive condition of a given Member, one can study the degree of compatibility of its regulatory system with that of other countries and with the rules of the multilateral system.

The two graphs below indicate the STCs raised against and by Mexico within the TBT Committee.

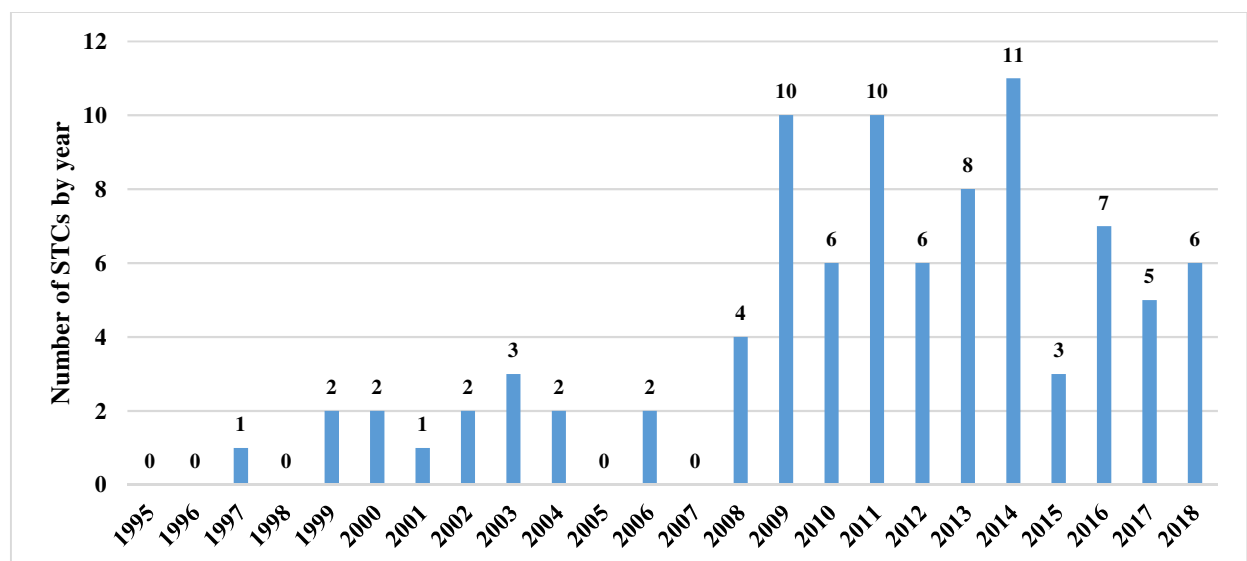
Figure 6-4 - STCs raised against Mexico



Source: OCDE. Elaboration: CCGI-EESP/FGV.

Mexico is relatively active on the TBT Committee. The country has raised STCs in consistent numbers in recent years, few STCs are raised against it. Mexico, together with other countries, has initiated ten or more procedures in the Committee in the years 2009, 2011 and 2014.

Figure 6-5 - STCs raised by Mexico



Source: OCDE. Elaboration: CCGI-EESP/FGV.

6.3. Preferential Trade Agreements and other Agreements

The trend towards fragmentation of the regulatory framework for international trade is corroborated by the reality of production dispersion, distribution and the formation of global value chains led by transnational corporations dominating international production and trade, as well as the demand for specialized services. Regulatory fragmentation also deepens with the diversity and consequent incompatibility of the regulatory models adopted by different countries. These two fragmentation effects, in turn, bring new challenges to the governance of the multilateral trading system, reflected in the inability of its members to overcome the

stalemate of the negotiations and exacerbate the trend of proliferation of preferential trade agreements (APCs), which have shown themselves to be appropriate instruments for the regulation of the new world reality.

Understanding the contemporary importance of preferential agreements, Mexico has a network of twelve free trade agreements with forty-six countries. The country has signed thirty-two agreements for the promotion and reciprocal protection of investments with thirty-three countries and nine agreements of limited scope (Economic Complementation Agreements and Partial Scope Agreements) within the framework of the Latin American Integration Association (ALADI). as well as being part of the new Framework Agreement for the Trans-Pacific Partnership Treaty (CPTPP) as defined in the acronym in English).

Relevant part of the trade agreements signed by Mexico, especially the last ones, have provisions on non-tariff aspects related to trade. These agreements include the network of agreements that constitute the Latin American Integration Association (ALADI), the two North American Free Trade Agreements and the United States, Mexico, Canada Agreement, the agreement concluded with the European Union and the Trans-Pacific Partnership Agreement.

The table below presents a chronology of the trade agreements signed by Mexico and provides some information on the characteristics of the agreement, highlighting the existence of specific rules on TBT and possible developments in the agreement on regulatory cooperation.

Table 6.1 - Trade Agreements Celebrated by Mexico

Year	Partner	Type of Agreement	General Carachteristic	Rules on TBT	Developments
1986	Panama	Partial Reach Agreement (ALADI) - AAP 14	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote conditions of fair competition in commerce. Substantially increase investment opportunities. Protect and enforce, properly and effectively, intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.	Contained in specific chapter (8)	Memorandum of Understanding between CONAMER and the Ministry of the Presidency of the Republic of Panama of 2018. The objective is to strengthen the development and implementation of regulatory policy tools. Work Plan 2018-2019 with the Secretariat of Competitiveness and Logistics of Panama. Regulatory improvement implementation meeting in 2018 on the procedures related to construction permits.
1987	Argentina	Economic Complementation Agreement (ALADI) - ACE 6	Article 1 provides that the object of the Agreement is: a. Intensify and diversify, at the highest possible levels, reciprocal trade between the signatory countries; B. Promote the increase in trade by calling for the consolidation, on a stable basis, of the previous understandings adopted by both countries to encourage compensated exchange programs; W. Coordinate and complement economic activities, especially related industry and technology, through an effective improvement of production systems and operational scales; d. Stimulating market-intensive investments and the competitive capacity of signatory countries in global trade flows; and. Facilitate the creation and operation of bi and multinational companies of a regional nature.	Absent	
1994	USA and Canada	Free Trade Agreement	Eliminate barriers to trade and facilitate the cross-border movement of goods and services. Promote conditions of fair competition. Protect and enforce, properly and effectively, intellectual property rights. Create effective	Contained in specific chapter	Memorandum of understanding between the Secretariat of Economy (SE) of Mexico and the Secretariat of the Treasury Council of Canada.

			procedures for the application and compliance of the treaty, for their joint administration and dispute resolution. Establish guidelines for greater trilateral, regional, and multilateral cooperation to expand and improve benefits. Reduce the vulnerability of exports to unilateral and discretionary measures. Strengthen the domestic industry through a solid and competitive export sector. Contribute to job creation.		The objective is to promote and advance the adoption of good regulatory practices in Latin America and the Caribbean. Work Plan between CONAMER and the Secretariat of the Canadian Treasury Council of 2018. The objective is to strengthen the exchange of experiences in the analysis of regulatory impact, public consultation and administration of procedures. Technical mission in the workshops of the Secretariat of the Canadian Treasury Council of 2018.
1995	Colombia and Venezuela	Free Trade Agreement (G3)	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote conditions of fair competition in commerce. Substantially increase investment opportunities. Protect intellectual property rights. Create guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution. Promote equitable relations by recognizing the differential treatments established in ALADI	Contained in specific chapter	Memorandum of Understanding between CONAMER and the National Department of Planning (National Planning Department - DPN) of Colombia. Virtual meeting on good regulatory practices with public officials and civil servants of the TLD in 2018.
	Costa Rica	Free trade agreement	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote conditions of fair competition in commerce. Substantially increase investment opportunities. Protect and enforce, properly and effectively, intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and	Contained in specific chapter	

			compliance of the treaty, their joint administration and dispute resolution.		
	Bolivia	Economic Complementation Agreement (ALADI) - ACE 66	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote fair competition in trade. Increase investment opportunities. Protect intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.	Contained in specific chapter	
1998	Ecuador	Partial Scope Agreement (ALADI) - AAP 29		Contained in specific chapter	
	Nicaragua	Free Trade Agreement	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote conditions of fair competition in commerce. Substantially increase investment opportunities. Protect intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.	Contained in specific chapter (9)	
1999	Chile	Tratado de Livre Comércio	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote fair competition in trade. Increase investment opportunities. Protect and enforce, properly and effectively, intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the	Contained in specific chapter	Agreement "Strengthening the regulatory systems of Mexico and Chile: implementation of regulatory improvement tools in COFEMER and the Agricultural and Livestock Service (Servicio Agrícola y Ganadero - SAG) for a State Policy". First Meeting on Good Regulatory Practices in Santiago,

			implementation and compliance of the treaty, their joint administration and dispute resolution.		Chile, in 2018 with training in ex post evaluation, good regulatory practices, regulatory improvement policy, biennial programs and computer systems for registration of regulations and procedures. Second Meeting on Good Regulatory Practices in Mexico City in 2018. International Seminar and Regulatory Improvement Meeting in Santiago de Chile in 2018.
2000	European Union	Free Trade Agreement	Encourage the development of exchanges of goods and services. Liberalize preferential, progressive and reciprocal trade in goods and services. To stimulate commercial and economic activity. Attract supplies and technology to Mexican companies. Generate more jobs. Promote direct investment. Enhance strategic opportunities and alliances for enterprises of States Parties.	Only the art. 18 contains general provisions on cooperation in the area of technical regulations.	
	Israel	Free Trade Agreement	Eliminate barriers to trade and facilitate the international movement of goods and services. Promote fair competition. Increase investment opportunities. Establish effective procedures for the implementation of the treaty, for their joint administration and for the resolution of disputes. Establish guidelines for further bilateral and multilateral cooperation with a view to expanding and improving the benefits of the treaty.	Contained in specific chapter	
	Paraguay	Partial Reach Agreement (ALADI) - AAP 38	As provided in art. 1 of the AAP, the purpose of this Agreement is to incorporate the concessions granted in the period 1962-1980 to the integration scheme established by the Montevideo Treaty of 1980.	Contained in specific chapter	
2001	Guatemala, Honduras and El Salvador	Free Trade Agreement	Promote conditions of free competition. Eliminate barriers to trade and facilitate the circulation of original goods and services. Eliminate barriers to the movement of capital and entrepreneurs. Increase investment opportunities. Protect and enforce, properly and effectively, intellectual property	Contained in specific chapter	Work plan between CONAMER and the El Salvador Regulatory Improvement Organization (OMR) of 2017. Virtual meeting on the

			rights. Establish guidelines for greater cooperation between the parties, aiming to expand and improve the benefits of the Free Trade Agreement. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution		implementation of regulatory improvement policy tools. Participation of OMR members from El Salvador during a technical visit to CONAMER workshops, where they were trained in the use of good regulatory practices in 2018.
	Cuba	Economic Complementation Agreement (ALADI) - ACE 51		Contained in specific chapter	
	Iceland, Liechtenstein, Norway and Switzerland (EFTA)	Free Trade Agreement	Create a commercial space in a context of multinational integration through the establishment of a Free Trade Zone to open up external development opportunities. The extensive network of trade agreements signed by Mexico is extended with the agreement signed with the members of the European Free Trade Association. This agreement came into effect on July 1, 2001 and places Mexico as the only Latin American country with free commercial access to countries with the highest per capita income in the world.	Contained in specific chapter	
2003	Brazil	Economic Complementation Agreement (ALADI) - ACE 53	This is a fixed tariff preference agreement granted to approximately 800 Naladi / SH 96 codes. The agreement has three additional protocols: First Additional Protocol (establishes the Dispute Settlement Regime), Second Additional Protocol (Incorporates note to the Certificate of Origin , concerning products subject to preferential tariff quotas) and Third Additional Protocol (Increases tariff preference granted by Brazil to item Naladi / SH 96 2917.36.00)	Contained in specific chapter	
	Mercosur (Automotive)	Economic Complementation Agreement	Specific agreement for the vehicle and auto parts sector.	Absent	

		(ALADI) - ACE 55			
2004	Uruguay	Free Trade Agreement	Reaffirm the special bonds of friendship and cooperation among your nations. Strengthen regional economic integration, which is one of the essential instruments for the countries of Latin America to advance in their economic and social development, guaranteeing a better quality of life for their peoples. Develop their respective rights and obligations under World Trade Organization agreements. Develop a legal framework that provides the necessary conditions for the growth and diversification of trade flows, in a manner compatible with the existing potential. Provide economic agents with clear and predictable rules for the development of trade and investment in order to encourage their active participation in economic and trade relations between the two countries. Create a broader and safer market for goods and services produced in their territories. Encourage innovation and creativity and encourage trade in goods and services protected by intellectual property rights.		
2005	Japan	Free Trade Agreement	Liberalize and facilitate trade in goods and services between the Parties. Increase investment opportunities and strengthen the protection of investment and investment activities in the Parties. Increase opportunities for suppliers to participate in public sector procurement in the Parties. Promote cooperation and coordination for the effective enforcement of competition laws in each Party. Create effective procedures for the implementation and operation of this Agreement and for the resolution of disputes. Establish a structure to encourage bilateral cooperation and the improvement of the business environment.	Contained in specific chapter	
2006	Mercosur	Economic Complementation Agreement (ALADI) - ACE 54	The art. 1 provides for: (a) the establishment of a Free Trade Area through the elimination of taxes, restrictions and other obstacles affecting reciprocal trade in order to achieve the expansion and diversification of trade; b) establish a legal framework that allows security and transparency to the economic agents of the Parties; c)	Contained in specific chapter	

			establish a regulatory framework to promote and encourage reciprocal investments; and d) promote economic complementarity and cooperation.		
2011	Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua	Free Trade Agreement	Promote conditions of free competition. Eliminate barriers to trade and facilitate the circulation of original goods and services. Eliminate barriers to the movement of capital and entrepreneurs. Increase investment opportunities. Protect and enforce, properly and effectively, intellectual property rights. Establish guidelines for greater cooperation between the parties, aiming to expand and improve the benefits of the Free Trade Agreement. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.	Contained in specific chapter	
	Alliance of the Pacific (Chile, Colombia and Peru)	Specific Arrangement	In addition to reducing trade barriers, the Pacific Alliance has initiated several other regional integration projects, including visa-free tourist travel, a joint stock exchange and joint embassies in several countries.	Contained in specific chapter	
2012	Peru	Free Trade Agreement	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote fair competition in trade. Increase investment opportunities. Protect and enforce, properly and effectively, intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.	Contained in specific chapter	Technical visit by Peruvian authorities to the CONAMER workshops in 2018. Training was given in the implementation of the policy of regulatory improvement and good regulatory practices.
2014	Panama	Free Trade Agreement	Encourage trade expansion and diversification. Remove barriers to trade and facilitate the movement of goods and services. Promote fair competition in trade. Increase investment opportunities. intellectual property rights. Establish guidelines for greater cooperation at the bilateral, regional and multilateral levels, by expanding and	Contained in specific chapter	

			improving the benefits of the treaty. Create effective procedures for the implementation and compliance of the treaty, their joint administration and dispute resolution.		
2015	CPTPP (Australia, Brunei, Canada, Chile, Japan, Malaysia, New Zeland, Peru, Cingapura e Vietnam)	Free Trade Agreement	The agreement was reached on October 5, 2015 after seven years of negotiations. Its stated objectives are: "to promote economic growth, to support job creation and maintenance, to strengthen innovation, productivity and competitiveness, to raise living standards, to reduce poverty in our countries, and to promote transparency, good governance and environmental protection.	Contained in specific chapter	

Fonte: SICE. Elaborado por CCGI-EESP/FGV.

6.3.1. Mexico in Latin American Integration Association (ALADI)

One of the purposes of the Latin American Integration Association (ALADI), of which Mexico is a founding member, is the formation of a common market in the region of Latin America, according to the provision of art. 1 of the Montevideo Treaty (1980). The members of the Association agreed to phase out barriers to trade, including non-tariff barriers to the regional exchange of goods (Article 13 of the Montevideo Treaty). As has been seen in the multilateral and regional spheres, overcoming this kind of barrier presupposes regulatory cooperation among the countries of the region (Article 2 of the Montevideo Treaty).

The most important document on regulatory cooperation in ALADI is the Framework Agreement for the Promotion of Trade through Overcoming Technical Barriers to Trade, signed in 1997 and in force since 1998. The agreement is designed to prevent the development, adoption and application of regulations, technical standards and conformity assessment procedures which constitute unnecessary technical barriers to intrabloc trade (Article 1). By complying with the TBT Agreement of the WTO (Article 2), members have sought to achieve this objective through harmonization of technical regulations that may affect trade, without neglecting the adequate levels of protection of animal and plant life and health, environment, safety and consumer protection (Article 3).

In the process of harmonization, a form of enhanced regulatory cooperation, explicitly adopted in ALADI, the region's regulatory and standardization activities should make use, whenever possible, of existing international technical standards or in the design phase (Article 6). Priority is given to the harmonization of technical regulations which potentially constitute unnecessary technical barriers to intraregional trade (Article 7).

In ALADI, the states opted for selective harmonization as the main form of regulatory cooperation. In other words, the members of the Association choose the priority areas in which to focus the efforts of regulatory harmonization, seeking consequently areas that are economically relevant and very vulnerable to such barriers. In this way, the automotive sector, for example, was considered a priority for ALADI regulatory harmonization efforts.

According to the text of art. 8, the establishment and strengthening of conformity assessment systems and the mutual recognition of conformity assessment systems are also instruments for the further development of regulatory cooperation. The main foundations for this strengthening are recommendations from specialized international organizations such as the International Organization for Standardization (ISO) and other international forums that bring together accreditation bodies such as the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC).

The IAF is the worldwide association of Accreditation Conformity Assessment Bodies and related bodies interested in conformity assessment in the following areas: management systems, products, services, human resources and other similar conformity assessment programs. Its primary job is to develop a single global compliance assessment program, with the aim of reducing the risk to companies and their customers by ensuring certificates issued by credentialed entities are reliable. Accreditation assures users of the competence and impartiality of the accredited body (IAF, 2016).

ILAC is the international organization for ISO / IEC (17011) accredited accreditation bodies and involved in the accreditation of conformity assessment bodies, including calibration

laboratories, based on ISO / IEC standards (17025), testing laboratories using ISO / IEC standards (17025), medical testing laboratories, using ISO standards (15189) and inspection bodies, using ISO / IEC standards (17020).

In parallel to the construction of conformity assessment systems, a harmonized regime was also established regarding responsibility for the veracity of the certificates and other documentation issued by the accredited institutions and the penalties applicable in cases of fraudulent certification (article 10).

Within the framework of conformity assessment systems and the harmonized regime, the signatory countries are working to encourage the participation of their official accreditation bodies in the Inter-American Accreditation Cooperation (IAAC) and to participate in multilateral recognition agreements. Such measures are intended to enable the mutual recognition of conformity assessment structures of countries (Article 12).

The IAAC consists of a regional association of accreditation bodies and other related organizations interested in improving conformity assessment activities in the Americas. Briefly, it is verified that the IAAC promotes direct cooperation between accreditation bodies in the American continent. Its primary objective is to develop conformity assessment structures to achieve product, process and service improvement, reducing the risk to business owners and consumers by strengthening trust in accredited certificates.

The IAAC has multiple objectives and carries out various functions within the American continent in regulatory matters. First, the IAAC administers the Multilateral Recognition Agreements between its member accreditation bodies. As a complement to this function, the IAAC promotes the harmonization of accreditation programs of its members with the objective of eliminating the need for separate accreditations in each country. Thirdly, the entity promotes collaboration and cooperation throughout the world between accreditation bodies and their members and other relevant bodies and groups. Fourth, the IAAC assures the representation of the Americas in the international accreditation forums and provides a wide variety of training activities. In this way, the interaction between ALADI and IAAC is important and can facilitate the cooperation efforts of the Latin American region.

In compliance with the principle of transparency, which is fundamental in regulatory cooperation initiatives, the signatory countries, in a joint effort with the General Secretariat of ALADI, the Pan American Technical Standards Commission (COPANT) and other relevant regional entities, efforts to develop and integrate information systems on draft technical regulations, technical standards and conformity assessment systems. The system shall be able to respond promptly to requests made to it regarding the technical regulations, technical standards adopted and conformity assessment procedures in place.

Permanent contacts between the national standardization, regulatory and conformity assessment bodies of the signatory countries and with specialized regional bodies are intended to strengthen the above-mentioned instruments of regulatory convergence and harmonization. As a result of the dialogue between these different institutions, the signatory countries can formalize, through additional protocols, the results of harmonization and other concerted actions and structure a conceptual framework for technical regulation and standardization, as well as for conformity assessment.

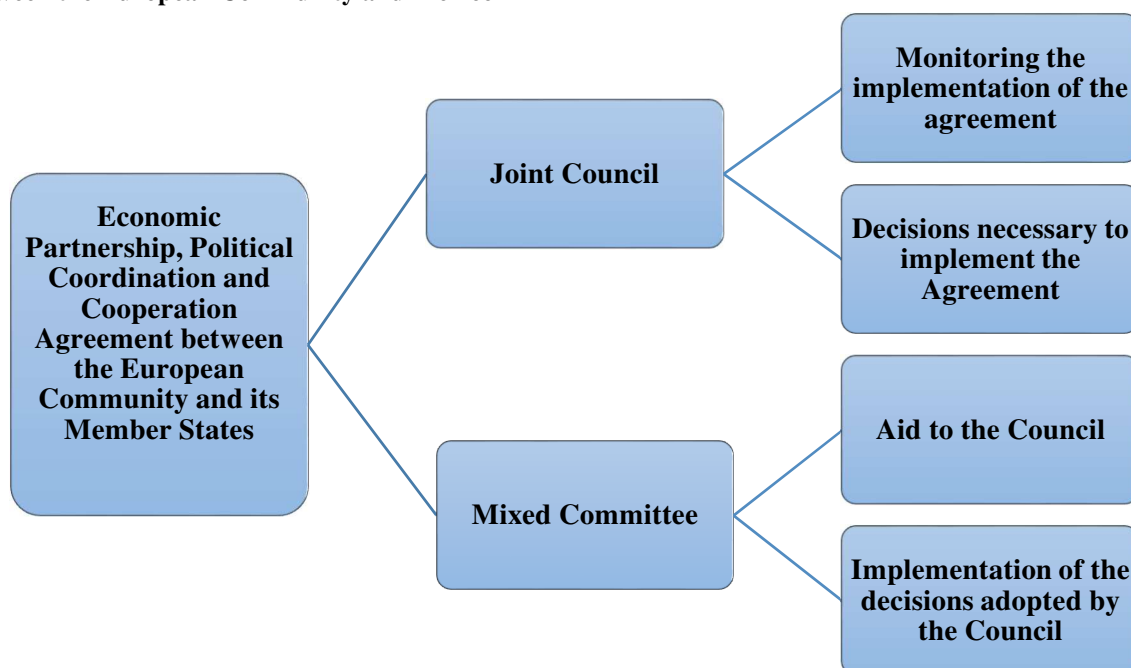
6.3.2. Mexico-European Union Agreement

In 1997, Mexico was the first country in Latin America to sign a cooperation, political coordination and economic partnership agreement with the EU. The agreement entered into force in 2000 and initially covered political dialogue, trade relations and cooperation. The rules on trade were further detailed in a free trade agreement which now covers trade in goods and trade in services. These rules governing the two areas came into force in October 2000 and 2001 respectively. The negotiations between Mexico and the EU to update the agreement began in May 2016 and both sides reached an agreement in principle in the commercial area in April 2018.

Free Trade Agreement has the official name of the Agreement on Economic Partnership, Political Coordination and Cooperation between the European Community and its States. The Free Trade Agreement is endowed with a follow-up body for the implementation of the treaty, the Joint Council for Economic Partnership, Political Coordination and Cooperation, composed of members of the Government of Mexico, the Council of the European Union and the European Commission. The Council shall be chaired alternately by a member of the Government of Mexico and a member of the Council of the European Union.

The agreement also envisaged a Joint Committee whose purpose is to assist the Joint Council, to prepare its meetings and deliberations, to monitor the implementation of its decisions and recommendations, and, in general, to ensure the implementation of the agreement. The Joint Committee is also responsible for submitting proposals for decisions or recommendations to the Joint Council for approval. The Committee is composed of representatives of the members of the Council of the European Union and of the European Commission and representatives of the Government of Mexico. The Joint Council meets biennially, while the Joint Committee meets annually.

Figure 6-6 - Agencies of the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and Mexico



Source: Mexico. Elaboration: CCGI-EESP / FGV.

With the implementation of the agreement, a significant part of the trade in goods between Mexico and the EU will be exempt from tariffs and simpler customs procedures will benefit the European industry such as the pharmaceutical, machinery and equipment transport sectors.

It should also be noted that the two contracting parties agreed to implement the obligations under the Paris Agreement on climate change and regulate corruption in the public and private sectors. Other important issues addressed in the agreement are small and medium-sized enterprises, public procurement, competition, labor standards and digital commerce, as well as traditional issues such as trade defense, market access and trade facilitation. The part devoted to the internal regulation of States, including on technical barriers to trade, should also occupy important space in the text of the new agreement.

6.3.3. NAFTA I and United States - Mexico - Canada Agreement (USMCA) or NAFTA II

During the last few years, Mexico's main trade agreement was the North American Free Trade Agreement (NAFTA), celebrated between the United States, Mexico and Canada. However, Mexico - Canada Agreement (USMCA) or NAFTA II has already been signed in 2018.

Analysis of the evolution between the TBT chapters of the two agreements is relevant.

6.3.3.1. North American Free Trade Agreement (NAFTA I)

In NAFTA I, the parties have inserted a chapter devoted exclusively to technical barriers to trade (Chapter 9, Standards-Related Measures). In this regard, the parties to the agreement affirmed their existing rights and obligations regarding measures related to technical standards under the GATT and other international agreements to which the two States are parties (Article 903).

The rights and obligations under the Agreement include measures relating to technical standards and technical regulations, the definition of a level of protection, non-discriminatory treatment in trade. Like the WTO TBT Agreement, Chapter 9 of NAFTA seeks to discipline the use of regulatory measures and standardization and conformity assessment activities, so that, without subtracting the right of the Parties to determine the appropriate level of protection of some public goods, such measures and activities do not restrict international trade.

Each Party may, in accordance with the Agreement, adopt, maintain or apply any measure related to technical standards, including measures related to safety, protection of life and human, animal and plant health, the environment, consumption and ensuring implementation or implementation (article 904,1). In addition, each Party may also establish levels of protection that it deems appropriate as long as it avoids arbitrary or unjustifiable distinctions between similar goods or services at the level of protection it deems appropriate (article 904, 2).

As provided in art. 904,3 in terms of measures related to technical standards, each party shall assign to goods and services supplied by another party national treatment and treatment no less favorable than that accorded to similar goods or in similar circumstances to service providers from any other country. The application of the principle of national treatment, therefore, should therefore govern the activities of technical regulation and standardization in the States Parties.

Lastly, no Party may prepare, adopt, maintain or apply any measure related to technical standards with the aim or effect of creating an unnecessary obstacle to trade between the Parties (Article 903 (4)). As is provided for in the TBT Agreement, the need for the regulatory action or the standardization act is required to be in compliance with the provisions of Chapter 9 of NAFTA.

The conditions for the use of international technical standards are also laid down in the agreement. Each Party shall use, as a basis for the elaboration of standards and technical regulations, relevant international technical standards or technical standards whose conclusion is imminent. Non-use of these international standards is permitted where these technical standards are not efficient or adequate to fulfill legitimate objectives (Article 905). It should be noted that the level of protection, as outlined above, is determined by the Parties.

Institutes for compatibility and equivalence are also provided for in the agreement as a means of facilitating trade in goods and services between the Parties (Article 906). As stated in art. 906, the adoption of ideas of compatibility and equivalence not fully enforceable without the adoption of additional measures by the Parties. In a trade activity, the importing Party shall treat the technical regulation adopted or maintained by the exporting Party as equivalent to its own where the exporting Party, in cooperation with the importing Party, demonstrates that its technical regulation adequately meets the objectives of the importing Party. The importing Party shall also submit to the exporting Party the reasons for not treating a technical regulation as equivalent.

In the conformity assessment procedure, each Party shall accept the results of procedures conducted in the territory of another Party provided that it is demonstrated that the procedure provides a guarantee equivalent to that provided by a procedure conducted in its own territory (Article 908). The results of the procedure are then accepted to the extent that the relevant good or service complies with the applicable technical regulation or technical standard adopted or maintained in the territory of the Party. Prior to acceptance of the results, the parties may consult on the technical competence of the conformity assessment bodies involved, which includes verification of compliance with international technical standards for accreditation procedures.

The Agreement also provides for rules, based on the national treatment principle, for international accreditation of conformity assessment bodies. In this regard, each Party shall accredit, approve, authorize or recognize conformity assessment bodies in the territory of another Party on terms no less favorable than those accorded to conformity assessment bodies in its national territory. As a result of this rule, the parties must adopt non-restrictive, quick procedures, open to participation. The prices of the procedures, likewise, can not be prohibitive, in order to make the products' competitiveness unfeasible.

Figure 6-7 - NAFTA rules on conformity assessment procedures

Conformity assessment procedures of the Parties	it shall not adopt or maintain any procedure which is more restrictive or apply the procedure more narrowly than is necessary to confer the confidence that the good or service is in conformity with the technical regulation or the applicable technical standard taking into account the risks that nonconformity could create
	it should start and complete the procedure as soon as possible
	it should publish the normal processing period for each procedure or communicate the anticipated processing period to a petitioner upon request
	should limit the information that the petitioner is required to provide to the extent necessary to conduct the procedure and to determine the appropriate fees
	it shall accord to confidential information arising out of or supplied in connection with the conduct of the procedure for a good of another party or for a service provided by the other party the same treatment as that assigned to a good or service of the party and in any event, treatment that protects the legitimate commercial interests of the petitioner to the extent provided by the law of the party
	ensure that any fee imposed for the conduct of the procedure and for a good of another party or for a service provided by another party is not greater than equitable in relation to any fee imposed for providers of similar goods or services or for providers of goods or services; services of any other country
	ensure that the location of premises where a conformity checking procedure is conducted does not cause unnecessary inconvenience to a petitioner or his agent.
	limit the procedure for a modified good or service following a determination that the good or service is in conformity with the technical regulation or with the applicable technical standard to the extent necessary to determine that the good or service remains in conformity with a technical regulation or a technical standard and
	limit any application for samples of a good for which it is reasonable and to ensure that sample selection does not cause unnecessary inconvenience to a petitioner

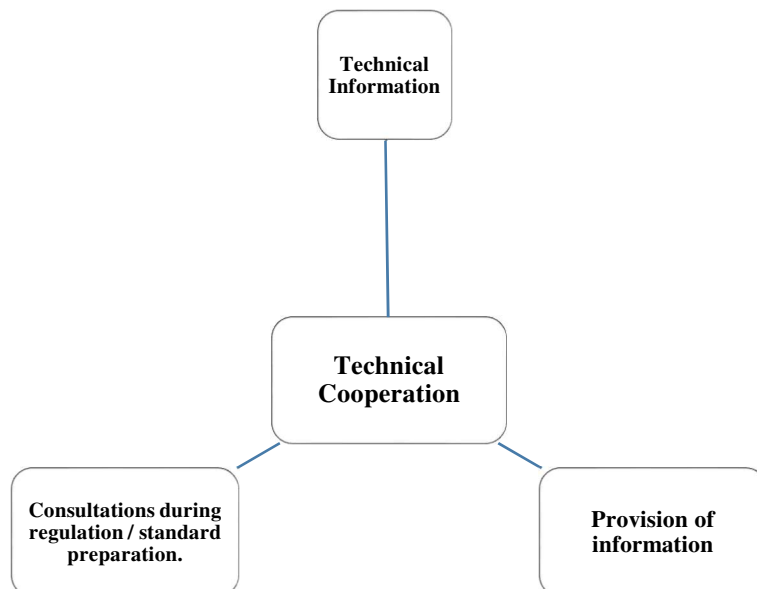
Source: NAFTA. Elaboration: CCGI-EESP/FGV.

The agreement also provides for obligations regarding the performance of more than one Party in a conformity assessment procedure. Each Party shall, at the request of the other Party, take reasonable measures that are available to facilitate access to its territory for conformity assessment activities. This rule corresponds to the idea of strengthening cross-border conformity assessment schemes.

In terms of technical cooperation (Article 911), the obligations envisaged cover the provision of information to the other Party and consultations between the Parties. Upon request, each Party shall: (i) provide the other Party with technical advice, information and assistance on mutually agreed terms; (ii) provide to the other Party information on its cooperation programs of measures relating to technical standards and regulations of specific areas of interest; (iii) consult with that Party during the development of technical regulations and technical standards. Each Party shall also encourage standardization bodies in its territory to cooperate with

standardization bodies in the territories of other Parties in their participation in standardization activities such as membership of international standards bodies.

Figure 6-8 - Mechanisms for technical cooperation in NAFTA



Source: NAFTA. Elaboration: CCGI-EESP/FGV.

In institutional terms, the agreement establishes a committee on measures relating to technical regulations, technical standards and conformity assessment procedures, made up of representatives of each party (Article 913). The committee is responsible for:

- monitoring the implementation and administration of the chapter of the agreement on technical barriers, including verifying the performance of subcommittees and working groups and the operation of the consultation points,
- facilitating the process of harmonizing measures relating to technical standards
- setting up a forum for the parties to consult on issues relating to measures relating to technical standards
- encouraging cooperation in the development, implementation and implementation of measures related to technical standards
- consideration of non-governmental, regional and multilateral developments on measures related to technical standards, including those under the GATT.

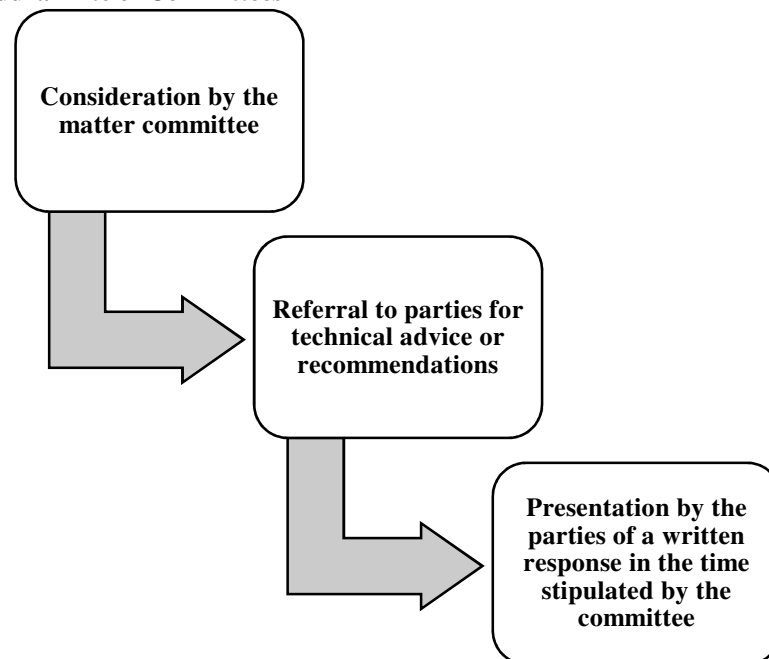
The Committee may also, as far as it deems appropriate, establish and determine the scope and mandate of subcommittees or working groups that bring together representatives of each Party to the agreement. Subcommittees that regulate ground transportation technical standards, technical standards of communication, automotive technical standards, and the labeling of textiles and clothing goods may also be established.

Subcommittees and working groups can also address a number of standardization and compliance issues. Examples of these topics are the identification and nomenclature of goods subject to measures related to technical standards; technical standards of quality and identity; packaging, labeling and presentation of consumer information; approval of post-market surveillance products and programs; principles for the accreditation and recognition of

conformity checking bodies, procedures and systems; promotion and implementation of good laboratory practices and promotion and implementation of good production practices.

Finally, technical consultations may be requested on the application of the chapter on technical barriers to a measure related to technical standards. In the procedure, the Committee shall be notified and may then facilitate consultations by not considering the measure itself and by referring the matter to a subcommittee, working group or forum charged with providing technical advice or recommendations. The party alleging that the measure relating to technical standards of the other party is inconsistent with the chapter has the burden of demonstrating such inconsistency. The procedural rite that demonstrates the performance of the committee is shown in the chart below.

Figure 6-9 - Procedural Rite of Committees



Source: NAFTA. Elaboration CCGI-EESP/FGV.

The automotive industry was more closely regulated in the agreement (Annex 913.5-13). In institutional terms, the Automotive Industry Technical Standards Board (which, in practice, deals with all aspects of quality infrastructure) was set up, which assembles representatives from each Party and seeks to facilitate the achievement of compatibility between regulatory, standardization and conformity assessment systems in the automotive sector. In order to facilitate implementation of the objectives, the Council may create subgroups, consultation procedures and other Representatives of state and provincial government and the private sector can integrate or subgroups.

The recommendations of the Council shall be agreed in advance by the Parties. In situations where the adoption of a law is not required by a Party, the recommendations of the Council shall be implemented by the Party within a reasonable period of time in accordance with legal and procedural requirements and with the international obligations of the Party. When the adoption of a law is required by a Party, it should make better efforts to ensure the adoption of the law and implement it within a reasonable period of time. The Council should also make better efforts to assist state and provincial authorities and private sector organizations, particularly in identifying priorities and setting work schedules.

Where disparities are recognized in measures of the Parties related to technical standards, the Council shall develop a work program to harmonize national measures related to technical standards applicable to automotive goods and other related topics. The criteria applied are the impact on industrial integration, the extent of barriers to trade, the level of trade reached and the extent of disparity. In developing the work program, the Council may address issues related to emissions from road and non-road mobile sources.

6.3.3.2. United States - Mexico - Canada Agreement (USMCA) (NAFTA II)

In the year 2018, Mexico, the US and Canada signed a new free trade agreement to replace NAFTA. In terms of technical barriers to trade (subject to chapter 11), the United States-Mexico-Canada Agreement (USMCA) further elaborates and details some points concerning regulation, technical standardization and conformity assessment. In general terms, these aspects strengthen cooperation mechanisms, enhance transparency obligations and facilitate the cross-border activity of conformity assessment bodies.

Firstly, it should be noted that the new agreement is more detailed, a characteristic that occurs in the extension of the text and the amount of rules contained therein. Then, in defining the scope of the USMCA, the parties use more precise terms, enshrined in international technical organizations and in WTO jurisprudence. The table below compares the articles concerning the definition of chapter scope in the two agreements.

Table 6.2 - Comparison of the scope of TBT chapters in USMCA and NAFTA

USMCA	NAFTA
Article 11.2: Scope	Article 901: Scope and Coverage
1. This Chapter applies to the preparation, adoption and application of <u>standards</u> , <u>technical regulations</u> , and <u>conformity assessment procedures</u> , including any amendments, of central level of government bodies, which may affect trade in goods between the Parties.	1. This Chapter applies to <u>standards-related measures</u> of a Party, other than those covered by Section B of Chapter Seven (Sanitary and Phytosanitary Measures), that may, directly or indirectly, affect trade in goods or services between the Parties, and to measures of the Parties relating to such measures.

Source: NAFTA. Elaboration: CCGI-EESP/FGV.

The wording of the text of art. 11.2 is more accurate in defining the scope of the chapter. The provision mentions the three fundamental dimensions in terms of technical barriers to trade and which, in the technical language developed by specialized agencies, has been consecrated as a quality infrastructure. These three dimensions, as embodied in a number of subsequent agreements (eg TPP 12), consist of the practice of regulation (stricto sensu), technical standardization and conformity assessment activities, as explicitly stated in the text of chapter 11 of the USMCA. In a different way, the NAFTA text makes use of the language commonly adopted by the US and which, for the trading partners, presented problematic generality and imprecision. In the US, the term "standard" is used in several senses, referring, for example, to (voluntary) technical standards, some types of (compulsory) technical regulations, and a set of measures, which could consist of a type of regulatory framework.

One of the most important aspects of Chapter 11 of the USMCA is art. 11.4 (3), which refers to international standards and international standardization bodies. The text of the referred art. has an unusual structure and language, as they refer to negative requirements.

3. Each Party shall apply no additional principles or criteria other than those in the TBT Committee Decision on International Standards in order to recognize a standard as an

*international standard. **For greater certainty, criteria that are not relevant to determining whether a standard is an international standard include: (a) the domicile of the standards body; (b) whether the standards body is non-governmental or inter-governmental; and (c) whether the standards body limits participation to delegations.***

According to the highlighted fragment, the Parties cite, in an exemplary role, three aspects that would not be relevant to the identification of an international standard: the domicile of the organism, the nongovernmental or intergovernmental origin of the organism and the possible limitation to the participation of delegations in the activities of the organization.

The provisions on technical regulations are much broader and detailed in the USMCA. Indeed, as the NAFTA text adopts the generic concept of standard, there is almost no explicit mention of technical regulations. The USMCA, in art. 11.5, there are provisions on the production and revision of the stock of technical regulations of the parties, use of international standards as support for formulating the content of technical regulations, constant information exchange and through institutionalized and specialized mechanisms, specific rules about product labeling.

In the conformity assessment dimension, art. 11.6 of the USMCA reproduces the need to approximate the certification schemes, verification, inspection of the Parties. The provisions of the new agreement also emphasize the importance of cross-border accreditation and the full development of conformity assessment activities in any of the States parties. The principle of national treatment is mentioned explicitly at the beginning of art. 11.6, indicating that it will govern all subsequent conformity assessment provisions. Some of the sub-topics dealt with in the article are: provision of information and explanations to interested parties, subcontracting of bodies for the partial or full performance of conformity assessment procedures, accreditation, scientific basis and choice of conformity assessment procedure, fees and amounts paid for the performance of the conformity assessment service.

It is interesting to look more closely at the provisions on accreditation, which consists of a formal procedure that ensures the credibility of the conformity assessment bodies. Similar to the rules on the identification of international standardization bodies, the agreement also provides for negative requirements for the identification of accreditation bodies. Thus, art. 11.6 (6) lists five items that can not be used to disqualify the accreditation body.

6. In addition to Article 9.2 of the TBT Agreement, no Party shall refuse to accept, or take actions that have the effect of, directly or indirectly, requiring or encouraging the refusal of acceptance of conformity assessment results performed by a conformity assessment body located in the territory of another Party because the accreditation body that accredited the conformity assessment body:

***(a) operates in the territory of a Party where there is more than one accreditation body;**
(b) is a non-governmental body;
(c) is domiciled in the territory of a Party that does not maintain a procedure for recognizing accreditation bodies, provided that the accreditation body is recognized internationally, consistent with paragraph 7;
(d) does not operate an office in the Party's territory; or
(e) is a for-profit entity.*

According to art. 11.6 (6), the following items may not be required to disqualify the accreditation body: the plurality of accreditation bodies, the non-governmental nature of the accreditation body, recognition of the body by the Party, existence of the body's office in the territory of the Party, nature of the organization (for profit).

The issue of advertising of regulations and technical standards was also elaborated differently in the USMCA. In NAFTA I, art. 909, there were rules on the publicity of technical measures with restrictive potential for international trade. The USMCA adopts the principle of transparency, which, semantically, has greater scope and depth. In the new agreement, in art. 11.7, various measures of advertising of technical acts are envisaged. The drafting process must be open and stakeholders can raise questions, request additional information and ultimately interfere with the process.

As one of the most interesting ways to address the issue of regulatory trade barriers and the design of cooperation schemes, the USMCA contains detailed forecasts on cooperation. Unlike NAFTA, which contained scattered predictions about cooperation in regulation, standardization, and conformity assessment, the USMCA has a lengthy paper on the topic. The art. 11.9 presents options and rules on TBT cooperation. It is interesting to note that a relevant part of the rules on cooperation are concentrated on the dimension of conformity assessment, which would be the last step in the ordinary process of operating the quality infrastructure. Some of the cooperation instruments in the area of conformity assessment are listed in the table below.

Table 6.3 - Cooperation in conformity assessment

(a) implement the mutual recognition of results by conformity assessment bodies within their territory and in the territory of another Party with respect to specific technical regulations;
(b) recognize existing mutual recognition agreements and multilateral agreements between accreditation or conformity assessment bodies;
(c) use accreditation to qualify conformity assessment bodies, including international accreditation systems;
(d) designate the conformity assessment bodies or recognize the conformity assessment bodies of the other Party;
(e) recognize unilaterally the results of conformity assessment procedures carried out in the territory of the other Party; and
(f) accept the supplier's declaration of conformity.

Source: USMCA. Elaboration: CCGI-EESP / FGV.

Broadly speaking, the USMCA deepens the rules on technical regulation, standardization and conformity assessment. The main aspects of the chapter on the subject indicate that the agreement does not simply aim to harmonize technical standards and regulations, which may remain different in the three States Parties. The main concern is to enable advances in terms of conformity assessment, which can not adopt discriminatory or restrictive practices between the parties to the agreement.

6.3.4. Other cooperative arrangements for regulatory convergence

International regulatory cooperation is provided for in Article 25, item XIV of the General Law on Regulatory Improvement and covers different forms, including the conclusion of specific agreements. Examples of forms of cooperation are participation in forums, conferences, seminars, workshops, meetings, events, conventions and congresses held with national and foreign authorities and with national and international organizations and organizations within the competence of CONAMER. The actions described below contributed to consolidate mechanisms that stimulate regulatory cooperation among countries and to implement mechanisms for the exchange of experiences and information at the international level in the area of regulatory governance.

Mexico has entered into cooperation agreements in the form of memoranda of understanding and work plans. The following table indicates agreements with countries and their content.

Table 6.4 - Celebrated Agreements

Agreement	Content
Memorandum of Understanding with Canada	Promotion of good regulatory practice, including regulatory development, international regulatory cooperation, stakeholder participation and openness and transparency between CONAMER and the Secretariat of the Canadian Treasury.
Workplan 2018-2020 with the Secretariat of the Treasury of Canada	Evaluation activities and mechanisms with the objective of establishing evaluation activities and mechanisms.
Memorandum of Understanding with Panama	Cooperative activities aimed at strengthening the development and implementation of regulatory policy tools.
Work plan 2018-2019 with the Secretariat of Competition and Logistics of Panama	Implementation of cooperation work aimed at strengthening the development and implementation of regulatory policy tools.
Memorandum of Understanding with the Dominican Republic	Cooperative activities to strengthen the development and implementation of regulatory policy tools.
Work plan 2018-2019 with the National Competition Council of the Dominican Republic	Works to support the development and implementation of regulatory policy tools.
Agreement within the framework of the Work Plan 2018-2019 with the National Competition Council of the Dominican Republic	Implementation of the charge simplification program in the Dominican Republic.

Fonte: CONAMER. Elaboration: CCGI-EESP / FGV.

In addition to the agreements, there are different types of arrangements that allow for regulatory cooperation on different issues. The table below lists cooperative arrangements in which Mexico participates.

Table 6.5 - Regulatory cooperation established by other arrangements

International Organization	Type of regulatory cooperation
APEC	11th Conference of Good Regulatory Practices. Online Training Program on Regulatory Improvement. Study on costs of regulatory divergence in trade and its relation with international regulatory cooperation. Organization by CONAMER of the 11th International Conference on Good Regulatory Practices of APEC in 2018.
OCDE	Participation of CONAMER in the 2018 meeting of the OECD Regulatory Policy Committee. CONAMER presented the details of the general law of regulatory improvement. Organization by CONAMER of the 10th International Conference on OECD Regulatory Performance Measurement in 2018.
Latin American Network	Organization by CONAMER of the 6th Meeting of the Ibero-American and Caribbean Regulatory Improvement Network in 2018, in which experiences and good regulatory practices among the countries of the region were shared and exchanged. Organization by CONAMER of the 7th Meeting of the Ibero-American and Caribbean Network for Regulatory Improvement in 2018, in which progress was made in the implementation of good regulatory practices in the region.

Source: CONAMER. Elaborated by CCGI-EESP / FGV.

Mexican quality infrastructure agencies have also entered into cooperation agreements, in the form of memoranda of understanding, with national agencies in other countries. With the National Institute of Metrology, Quality and Technology (INMETRO), three memoranda of understanding were formed, as set forth in the table below.

Table 6.6 - Memoranda of Understanding between Mexican institutions and INMETRO

INMETRO and CENAM (MEXICO)
Complementary Agreement between Inmetro and Cenam (Mexico) with the objective of creating a basis of collaboration between the Parties, promoting the development of a scientific and technological base in the areas of scientific and industrial metrology and other advanced metrology areas.
INMETRO and IPICYT (MEXICO)
Cooperation Agreement between Inmetro and the Potosino Institute for Scientific and Technological Research (IPICYT) in the areas of common interest between the signatory parties regarding the research on Carbon Nanotube and its applications.
INMETRO and PROFECO (MEXICO)
Memorandum of understanding for mutual assistance in technical and scientific cooperation between the Federal Prosecutor's Office - Profeco (Mexico) and the National Institute of Metrology, Quality and Technology - Inmetro (Brazil).

Source: Inmetro. Elaborated by CCGI-EESP/FGV.

Due to INMETRO broad functional competence, three different agreements are signed with Mexican entities. The agreements with CENAM and IPICYT would cover INMETRO's metrology and scientific research competence. The agreement with PROFECO, on its behalf, would cover INMETRO's functions related to the protection of diffuse consumer interests, by controlling the quality of products.

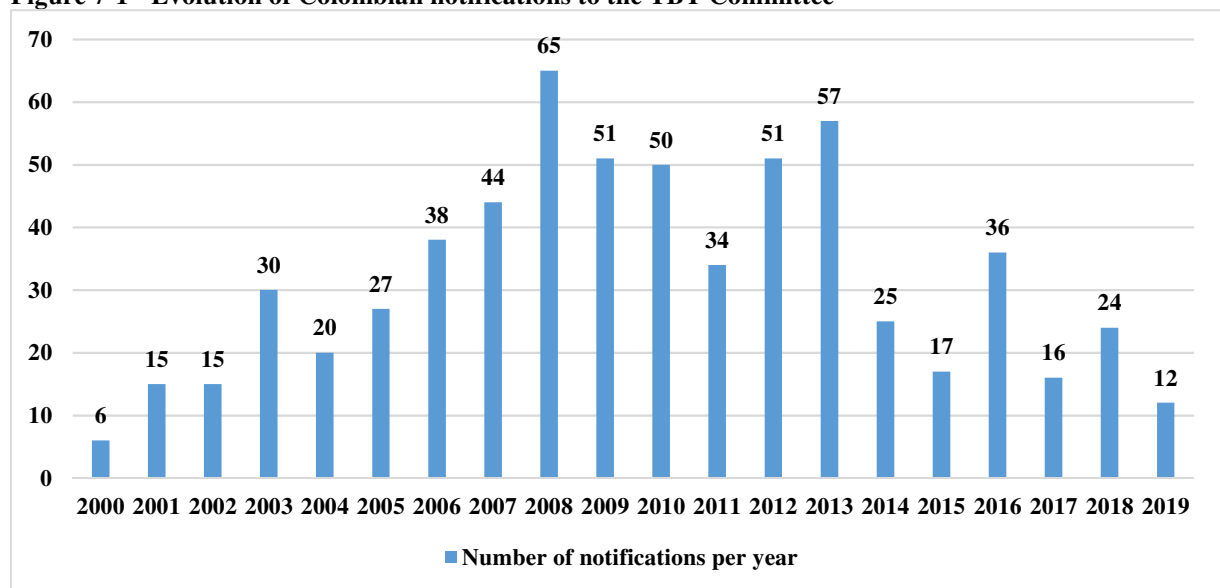
7. Colombia

The objective of this Chapter is to analyze the regulatory convergence efforts of Colombia and its trading partners through the operation of the multilateral trading system, the signature of trade agreements and the establishment of mechanisms and specific arrangements for regulatory cooperation.

7.1. Regulatory convergence in the multilateral level

In the multilateral level, the investigation of Colombian notifications to the WTO TBT Committee can offer a framework of the technical regulatory activity in the country. The graphic below illustrates Colombian notifications on the interval between 2000 and 2019.

Figure 7-1 - Evolution of Colombian notifications to the TBT Committee

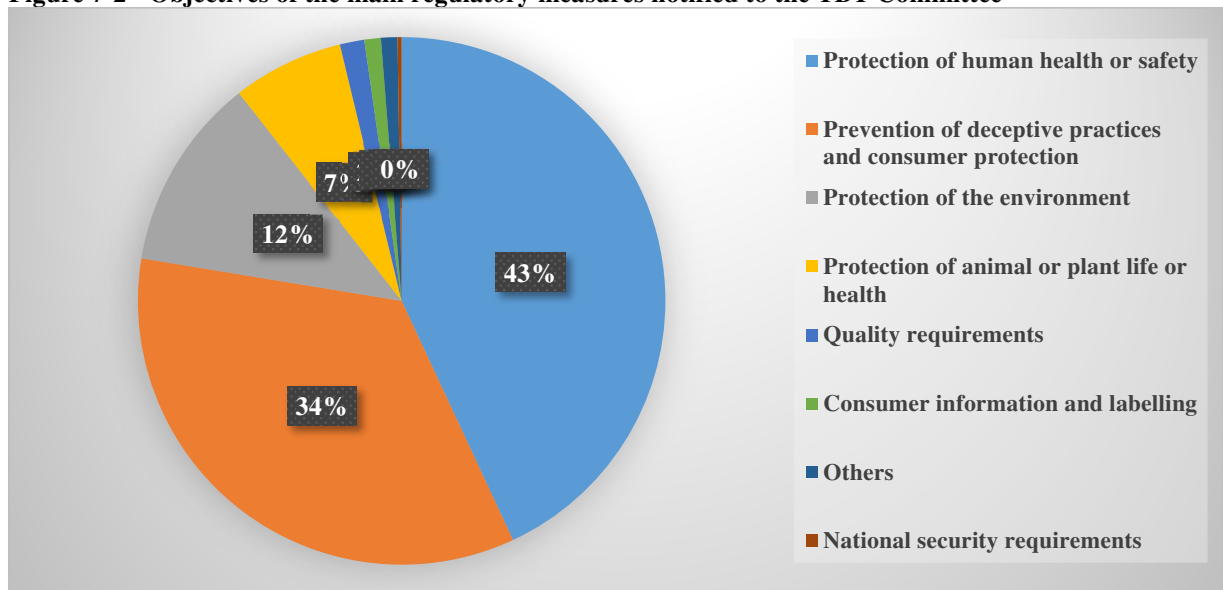


Source: WTO. Elaborated by CGTI-EESP/FGV.

Examples of themes present in regulatory measures notified to the TBT Committee are the following: apparel, chemicals, containers, cosmetics, electric products, food, fuel, measuring instruments, pharmaceutical products and telecommunications.

The chart below shows the frequency of the themes on Colombian notifications to the TBT Committee.

Figure 7-2 - Objectives of the main regulatory measures notified to the TBT Committee



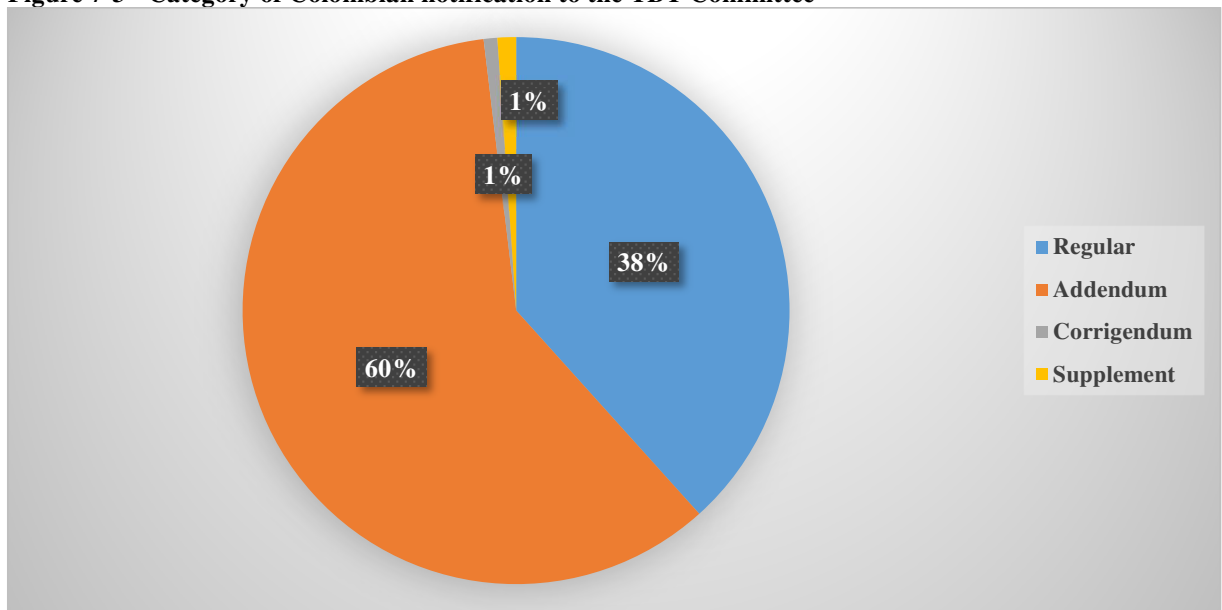
Source: WTO. Elaborated by CCGI-EESP/FGV.

The most frequent objective of the regulatory measures notified to the TBT Committee is the protection of human health or safety. More than 40% of draft regulations or technical standards notified to the TBT Committee are intended to ensure the protection of human health or safety. Other objectives that are relevant are the prevention of deceptive practices and consumer protection (34%), the protection of the environment (12%) and the protection of animal or plant life or health (7%).

Notifications can be classified in two broad categories: notification of a new measure or notification of a previously notified measure. In the first case, the notification is named regular. In the second case, the name changes according to the link between the notification and the regular notification. The notification can add new information or correct the substance of what was previously informed.

The chart below shows the distribution of Colombian notifications according to the category.

Figure 7-3 - Category of Colombian notification to the TBT Committee



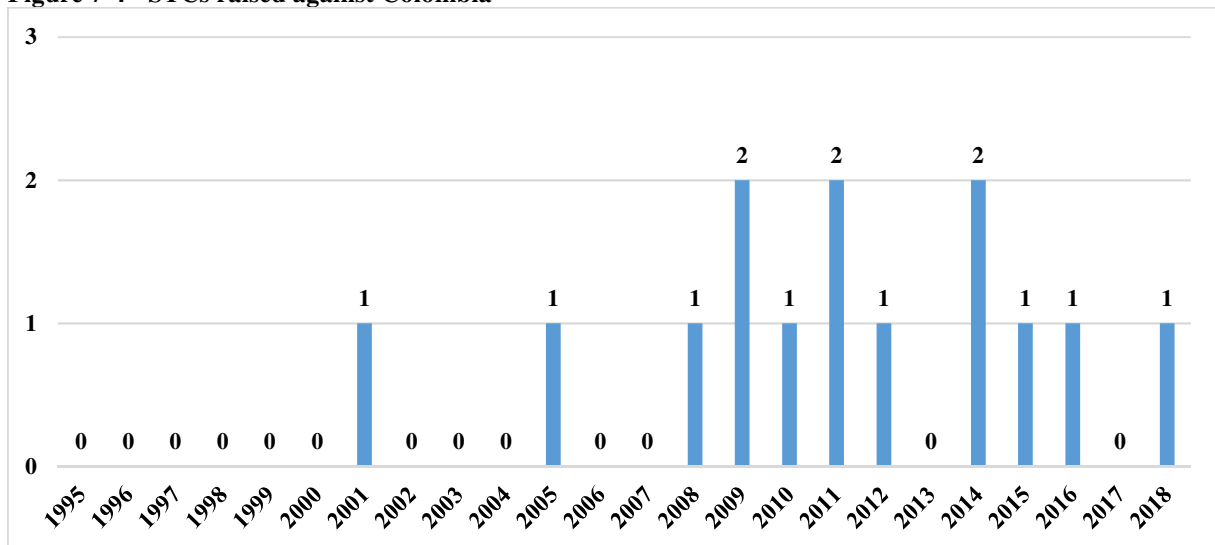
Source: WTO. Elaborated by CCGI-EESP/FGV.

The majority of Colombian notifications to the TBT Committee is constituted of addenda, which, in general, bring a new type of new information or more precise one about the regulation or the notified regulatory measure. Around 60% of the notifications add information to previous notifications. The regular notifications are also relevant, as they indicate innovations to the regulatory framework of the country.

Another indicator of the convergence between the Colombian regulatory system and the ones of other countries, as well as its compatibility with the rules of the TBT Agreement are the Specific Trade Concerns (STCs). The STCs constitute a non-contentious form of dispute settlement, through a requirement of clarification by WTO member countries about the regulatory measure that can create obstacles to trade. The STCs allow States to require explanations about measures that can be in disconformity with the rules of the TBT Agreement. In this sense, the concentration of the analysis on the active and passive conditions of a specific State can allows the identification of the degree of compatibility of its regulatory system with the ones of other countries and with the multilateral trade system rules.

The two graphics below illustrate STCs raised against and by Colombia inside the TBT Committee.

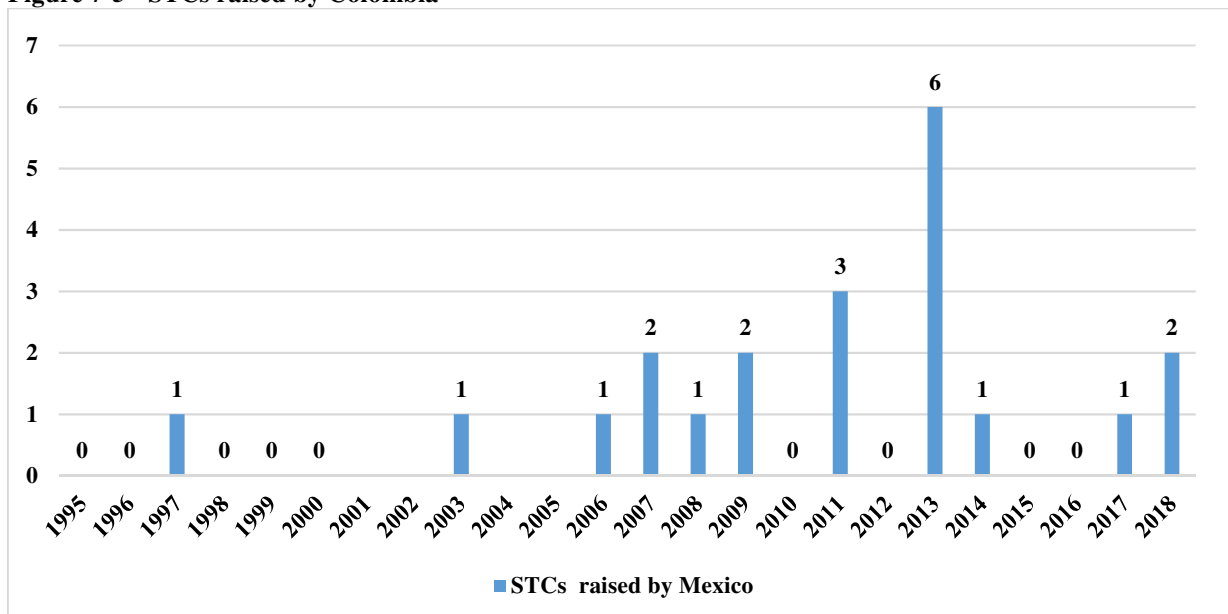
Figure 7-4 - STCs raised against Colombia



Source: WTO. Elaborated by CCGI-EESP/FGV.

Colombia is not an active member in the TBT Committee. Few STCs have been raised against the country during the whole existence of the multilateral trade system. The country has raised at maximum 6 STCs in 2013 and, in the last four years, raised only 4 STCs.

Figure 7-5 - STCs raised by Colombia



Source: WTO. Elaborated by CCGI-EESP/FGV.

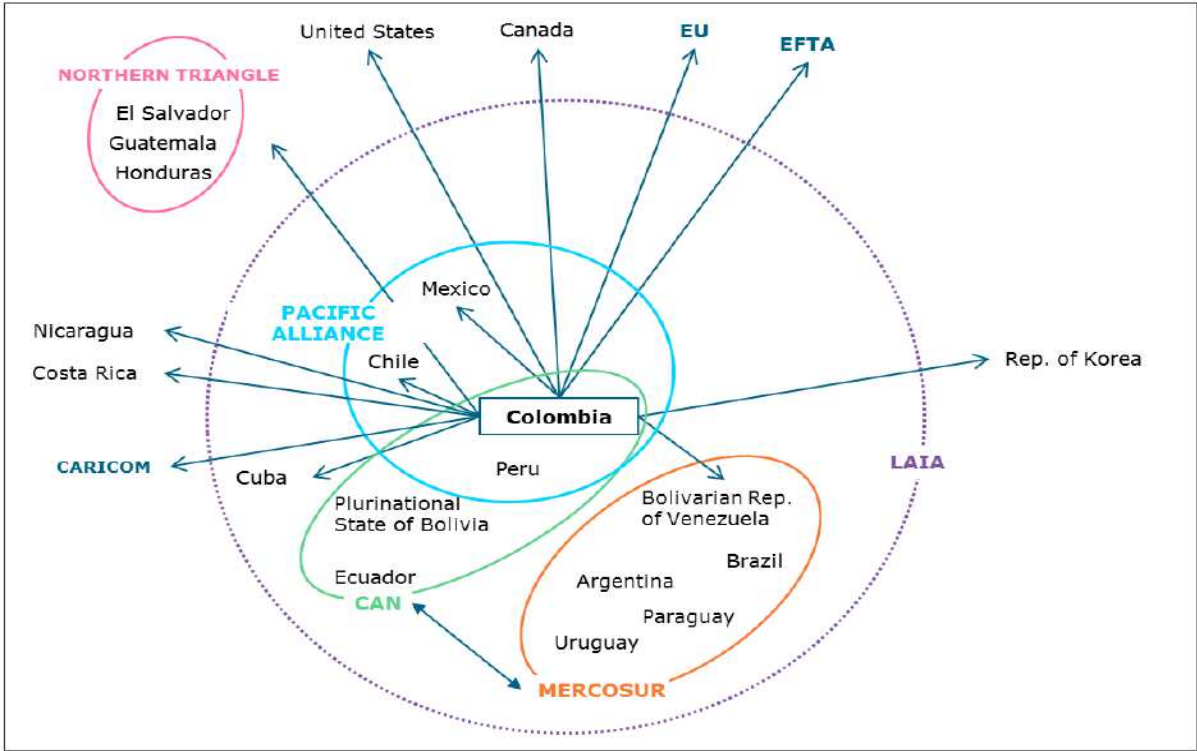
7.2. Preferential agreements and other arrangements of regulatory cooperation

The trend towards fragmentation of the regulatory structure for international trade is substantiated by the reality of production and distribution dispersion and of the formation of global value chains led by transnational corporations that dominate international production and trade, as well as the demand for specialized services. Regulatory fragmentation is also deepened with the diversity and consequent incompatibility of the regulatory models adopted by different countries.

A general overview reveals that Colombia participates in regional agreements mainly in South America and seeks preferential agreements with Caribbean, North-American and European partners. Colombia is a member of the Latin American Integration Association (ALADI), in which framework it has signed partial scope agreements with member and non-member partners. Colombia is a founding member of the Andean Community of Nations (CAN) and of the Pacific Alliance and participates in several bilateral and plurilateral trade agreements, as shown in the chart ahead. Colombia signed preferential trade agreements with Israel and Panama in 2013, and in early 2018 was engaged in negotiations with Japan and Turkey. In the framework of the Pacific Alliance, negotiations began in 2017 on a free trade agreement with Australia, Canada, New Zealand and Singapore, which are candidates for associate membership of the Pacific Alliance.

The chart below illustrates Colombian presence in regional trade agreements.

Figure 7-6 - Colombian presence in regional trade agreements



Source: WTO.

The chart below provides a chronology of trade agreements signed by Mexico and provides information about the features of each agreement, with highlights to specific TBT rules and to possible developments in the agreement in terms of regulatory cooperation.

by Colombia

General features	TBT rules	Developments
strengthen trade through the granting of tariff and non-tariff preferences	Absent	The signatory country of the present agreement undertakes to carry out negotiations with the other member countries of ALADI, with the purpose of proceeding to the progressive multilateralization of the benefits derived from it.
strengthen trade through the granting of tariff and non-tariff preferences	Absent	Colombia is committed to advancing negotiations with the remaining member countries of ALADI, in order to proceed to the progressive multilateralization of the benefits deriving from the agreement.
facilitate, expand, diversify and promote both trade between the Parties, as well as all operations associated with it; ensure that bilateral trade flows are based on harmonious and balanced relations, with actions that promote the expansion and dynamic equilibrium of trade and strengthen trade through the granting of tariff and non-tariff preferences between Colombia and Panama	The Parties will sign specific agreements and protocols aimed at strengthening the technical and administrative capacity of reciprocal trade to prevent the application of technical standards and regulations and quality requirements from becoming obstacles to exchange.	The enabled entities for certification must verify the veracity of the declarations presented by the producer or exporter.
facilitate the expansion and diversification of trade between the Parties, eliminate barriers to trade, facilitate the circulation of goods and services between the Parties, promote conditions for competition in trade between the parties, substantially increase investment opportunities in the territories of the	The parties create a Working Group on Agricultural Technical and Marketing Standards composed of representatives of each of	The agreement provides a full chapter on technical norms. Each Party shall accept a technical regulation adopted by another Party as equivalent to its own, when, in

			expanding and improving the benefits of the treaty, create effective procedures for the application and enforcement of the treaty, for its joint administration and for the settlement of disputes and promote equitable relations between the parties recognizing the differential treatments due to the categories of countries established in the ALADI	The Working Group will review the application and effects of technical norms or commercialization of goods of the agricultural sector that affect trade between the parties, and recommend possible solutions to the questions that may arise in relation to them. Each party shall grant to the imported goods of another party a treatment no less favorable than that granted to its goods in the application of technical norms or of commercialization to goods of the agricultural sector in the aspects of packaging, grades, quality and size of the goods. Each party, whenever possible, will accept the results of the conformity assessment procedures carried out in the territory of another party, even if those procedures differ from their own, provided that these procedures offer a satisfactory guarantee, equivalent to those offered by the procedures that the party carries out or that are carried out in its territory, whose result it accepts, that the relevant good or service complies with the applicable technical regulations or with	technical regulation adequately meets the legitimate objectives of the importing Party, and if appropriate, it will review it.

				the standards that are elaborated or maintained in the territory of that Party, and, if applicable, review the relevant standardization measure. The treaty provides an extensive article on conformity assessment.	
2004	Ecuador, Venezuela and Mercosur	Free trade agreement	Establish the legal and institutional framework for cooperation and economic and physical integration that contributes to the creation of an expanded economic space that tends to facilitate the free movement of goods and services and the full utilization of productive factors, in conditions of competition between the contracting parties, form a free trade area between the contracting parties through the expansion and diversification of trade and the elimination of tariff and non-tariff restrictions that affect reciprocal trade, achieve harmonious development in the region, taking into consideration the asymmetries derived from the different levels of economic development of the signatory parties, promote the development and use of physical infrastructure, with special emphasis on the establishment of integration corridors that will allow the reduction of costs and the generation of competitive advantages in reciprocal regional trade and with third countries outside the region, promote investments among the economic agents of the signatory parties, Promote economic, energy, scientific and technological complementation and cooperation and promote consultations, when appropriate, in trade negotiations conducted with third countries and groups of extra-regional countries		
2006	United States	Trade promotion agreement	The parties to the agreement aim to establish a free trade area		
2007	Northern Triangle ¹⁴⁰	Free trade agreement	The parties to the agreement aim to establish a free trade area. The objectives of the treaty are the following: promote the		

¹⁴⁰ The Northern Triangle comprises El Salvador, Guatemala and Honduras.

			expansion and diversification of trade in goods and services between the parties, eliminate barriers to trade and facilitate the cross-border movement of goods and services within the free trade area, promote conditions of fair competition for trade between the parties, promote, protect and substantially increase investments in each party, create effective procedures for the execution and enforcement of the treaty, for its joint administration and for the settlement of disputes and establish guidelines for bilateral cooperation aimed at expanding and improving the benefits of the treaty		
2008	EFTA	Free trade agreement	The parties to the agreement aim to establish a free trade area. The objectives of the agreement are the following: achieve the liberalization of trade in goods and services, substantially increase investment opportunities in the free trade area, achieve further liberalization on a mutual basis of the government procurement markets of the parties, promote competition in their economies, particularly as it relates to economic relations between the parties, ensure adequate and effective protection of intellectual property rights, contribute, by the removal of barriers to trade and investment, to the harmonious development and expansion of world trade and ensure cooperation related to trade capacity building, in order to expand and improve the benefits of the agreement, especially for small and medium-sized enterprises		
2011	Venezuela	Partial scope agreement	The agreement aims to define the preferential treatment applicable to importations of products originating from the parties.		
2012	EU	Trade agreement	The objectives of the agreement are the following: progressive and gradual liberalization of trade in goods, facilitation of trade in goods, progressive liberalization of trade in services, development of an environment conducive to an increase in investment flows and, in particular, to the improvement of the conditions of establishment between the parties, facilitation of trade and investment among the parties through the liberalization of current payments and capital movements related to direct investment, effective and reciprocal opening of		

			government procurement markets of the parties, adequate and effective protection of intellectual property rights, conduct of economic activities, in particular those regarding the relations between the Parties, in conformity with the principle of free competition, establishment of an expeditious, effective and predictable dispute settlement mechanism, promotion of international trade in a way that contributes to the objective of sustainable development, and to work in order to integrate and reflect this objective in the Parties' trade relations and insurance that the cooperation for technical assistance and the strengthening of the trade capacities of the parties contribute to the implementation of the agreement and to the optimal utilization of the opportunities offered by it according to the existing legal and institutional framework		
2013	Republic of Korea	Free trade agreement	The parties to the agreement aim to establish a free trade area.		
2013	Costa Rica	Free trade agreement	The parties to the agreement aim to establish a free trade area.		
2017	Mercosur	Economic complementation agreement	The agreement has the following objectives: establish the legal and institutional framework for cooperation and economic and physical integration that contributes to the creation of an expanded economic space that tends to facilitate the free movement of goods and services and the full utilization of productive factors, under conditions of competition between the contracting parties, form a free trade area between the contracting parties through the expansion and diversification of trade and the elimination of tariff and non-tariff restrictions that affect reciprocal trade, achieve harmonious development in the region, taking into account the asymmetries derived from the different levels of economic development of the signatory parties, promote the development and utilization of the physical infrastructure, with special emphasis on the establishment of integration corridors that allow the reduction of costs and the generation of competitive advantages in reciprocal regional trade and with third countries outside the region, promote investments among the economic agents of the signatory		

			parties, promote economic, energy, scientific and technological complementation and cooperation and promote consultations, when appropriate, in trade negotiations with third countries and groups of extra-regional countries		

Source: SICE

7.2.1. Colombia in the Andean Community of Nations (CAN)

At the Andean Community level, Colombia is a founding member of the group. CAN is an international organization that comprises different bodies and institutions that are members of the Andean Integration System (SAI), whose objective is to reach an autonomous, equilibrated and integral development through Andean integration, with a projection towards a South American and Latin American integration. The Cartagena Agreement of 1969 is the constitutive treaty of the community that establishes the objectives of the Andean integration, defines its institutions and establishes mechanisms and policies to be developed by the bodies of the community.

The Cartagena Agreement has the aforementioned purposes of promoting the autonomous, equilibrated and integral development, as well as the acceleration of growth, generation of jobs and facilitation of participation in the process of regional integration. The members of the community agreed to coordinate their development plans in specific sectors and gradually harmonize their economic and social policies, with the aim of achieving the integrated development of the area (art. 54). As verified on the multilateral and regional scopes, the elimination of barriers to trade that lead to economic harmonization presupposes social and economic cooperation (art. 1).

The Andean System of Standardization, Accreditation, Testing, Certification, Technical Regulations and Metrology, known as the Andean Quality System, was created by decision 376/1995 and amended by Decision 419/1997. The Andean Quality System is intended to eliminate unnecessary technical barriers, and covers activities in the fields of standardization, accreditation, testing, certification, technical regulations and metrology. The system is administered by the Andean Quality Committee (CAC), comprising representatives of the member countries.

Standardization activity is carried out in the framework of the Andean Standardization Network (RAN), governed by the regulations set out in resolution 313, whose purpose is to harmonize and adopt Andean standards for the production sectors and services deemed of subregional interest, such as food, textiles and clothing, leather and footwear, wood and furniture, and the motor-vehicle sector.

Andean Community decision 562/2003 establishes guidelines for the preparation, adoption and application of technical regulations in the member countries and at Community level, in order to avoid technical regulations becoming unnecessary barriers to trade within the subregion. However, technical regulations are prepared, adopted and applied in member countries by the various bodies of the central, regional, departmental, local or municipal governments or by a number of them within their respective spheres of competence.

The Andean Community Notification and Technical Regulation Information System (SIRT), created by decision 615/2005, is part of the Andean Quality System. The SIRT consists of the four focal points in member countries and the Community contact point in the Andean Community General Secretariat, and operates an exporter alert system to warn exporters of mandatory technical requirements.

Pursuant to decision 615, notifications concerning technical regulations adopted, as well as the conformity assessment procedures applicable to them, are made through the SIRT. They must be notified by the authorities responsible for notification through the SIRT within no more than

30 calendar days from their official publication. The relevant comments must also be sent through the SIRT.

At the Andean Community level, accreditation is carried out in the framework of the Andean Network of National Accreditation Bodies. The Andean Metrology Network (RAM), created by decision 376, as amended by decision 419, has as its general objective the harmonization of the national metrology systems so that they foster, at Andean level, the traceability of member countries' calibration standards and systems and support trade by avoiding the creation of trade barriers.

According to information from the Andean Community, there is currently an Andean Technical Regulation Plan under which the priority subjects for member countries are being harmonized. Technical regulations in the areas of footwear and leather goods and clothing are also being harmonized.

On the sectorial level, decision 516/2002 on the legislative harmonization on the issue of cosmetic products deserves to be highlighted. This decision was updated on decision 833/2018 that provides a general regulatory framework for the production and trade of cosmetic products, leaving aside specific aspects that correspond to a technical regulation as labelling and good manufacturing practices.

7.2.2. Colombia in the Latin American Integration Association

One of the purposes of the Latin American Integration Association (ALADI), of which Colombia is a founding member, is the formation of a common market in the region of Latin America, according to the provision of art. 1 of the Montevideo Treaty (1980). The members of the Association agreed to phase out barriers to trade, including non-tariff barriers to the regional exchange of goods (Article 13 of the Montevideo Treaty). As has been seen in the multilateral and regional spheres, overcoming this kind of barrier presupposes regulatory cooperation among the countries of the region (Article 2 of the Montevideo Treaty).

The most important document on regulatory cooperation in ALADI is the Framework Agreement for the Promotion of Trade through Overcoming Technical Barriers to Trade, signed in 1997 and in force since 1998. The agreement is designed to prevent the development, adoption and application of regulations, technical standards and conformity assessment procedures which constitute unnecessary technical barriers to intrabloc trade (Article 1). By complying with the TBT Agreement of the WTO (Article 2), members have sought to achieve this objective through harmonization of technical regulations that may affect trade, without neglecting the adequate levels of protection of animal and plant life and health, environment, safety and consumer protection (Article 3).

In the process of harmonization, a form of enhanced regulatory cooperation, explicitly adopted in ALADI, the region's regulatory and standardization activities should make use, whenever possible, of existing international technical standards or in the design phase (Article 6). Priority is given to the harmonization of technical regulations which potentially constitute unnecessary technical barriers to intraregional trade (Article 7).

In ALADI, the states opted for selective harmonization as the main form of regulatory cooperation. In other words, the members of the Association choose the priority areas in which to focus the efforts of regulatory harmonization, seeking consequently areas that are

economically relevant and very vulnerable to such barriers. In this way, the automotive sector, for example, was considered a priority for ALADI regulatory harmonization efforts.

According to the text of art. 8, the establishment and strengthening of conformity assessment systems and the mutual recognition of conformity assessment systems are also instruments for the further development of regulatory cooperation. The main foundations for this strengthening are recommendations from specialized international organizations such as the International Organization for Standardization (ISO) and other international forums that bring together accreditation bodies such as the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) .

In parallel to the construction of conformity assessment systems, a harmonized regime was also established regarding responsibility for the veracity of the certificates and other documentation issued by the accredited institutions and the penalties applicable in cases of fraudulent certification (article 10).

Within the framework of conformity assessment systems and the harmonized regime, the signatory countries are working to encourage the participation of their official accreditation bodies in the Inter-American Accreditation Cooperation (IAAC) and to participate in multilateral recognition agreements. Such measures are intended to enable the mutual recognition of conformity assessment structures of countries (Article 12).

The IAAC consists of a regional association of accreditation bodies and other related organizations interested in improving conformity assessment activities in the Americas. Briefly, it is verified that the IAAC promotes direct cooperation between accreditation bodies in the American continent. Its primary objective is to develop conformity assessment structures to achieve product, process and service improvement, reducing the risk to business owners and consumers by strengthening trust in accredited certificates.

The IAAC has multiple objectives and carries out various functions within the American continent in regulatory matters. First, the IAAC administers the Multilateral Recognition Agreements between its member accreditation bodies. As a complement to this function, the IAAC promotes the harmonization of accreditation programs of its members with the objective of eliminating the need for separate accreditations in each country. Thirdly, the entity promotes collaboration and cooperation throughout the world between accreditation bodies and their members and other relevant bodies and groups. Fourth, the IAAC assures the representation of the Americas in the international accreditation forums and provides a wide variety of training activities. In this way, the interaction between ALADI and IAAC is important and can facilitate the cooperation efforts of the Latin American region.

In compliance with the principle of transparency, which is fundamental in regulatory cooperation initiatives, the signatory countries, in a joint effort with the General Secretariat of ALADI, the Pan American Technical Standards Commission (COPANT) and other relevant regional entities, efforts to develop and integrate information systems on draft technical regulations, technical standards and conformity assessment systems. The system shall be able to respond promptly to requests made to it regarding the technical regulations, technical standards adopted and conformity assessment procedures in place.

Permanent contacts between the national standardization, regulatory and conformity assessment bodies of the signatory countries and with specialized regional bodies are intended

to strengthen the above-mentioned instruments of regulatory convergence and harmonization. As a result of the dialogue between these different institutions, the signatory countries can formalize, through additional protocols, the results of harmonization and other concerted actions and structure a conceptual framework for technical regulation and standardization, as well as for conformity assessment.

7.2.3. Colombia in the Pacific Alliance

In the Pacific Alliance framework, Colombia has made efforts to eliminate tariffs on the whole tariff universe, with the exception of sugar, some food preparations and ethyl alcohol. The country uses longer tariff elimination periods (the longest being 17 years) for sensitive goods as rice, coffee, black beans, flour, maize (corn) and plantains. There are no tariff lines subject to tariff quotas. The authorities have stated one of the major benefits of the Trade Protocol is present in the greater flexibility of preferential rules of origin in comparison to existing trade agreements. In particular, cumulation of origin is possible, as is, for the textiles and clothing sector, the use of the short supply mechanism, which was not foreseen in the existing trade agreements with Chile and Peru, and the use of which has been simplified with respect to provisions under the existing trade agreement with Mexico.

8. Chile

The objective of this Chapter is to analyze the regulatory convergence efforts of Chile and its trading partners through the operation of the multilateral trading system, the signature of trade agreements and the establishment of mechanisms and specific arrangements for regulatory cooperation.

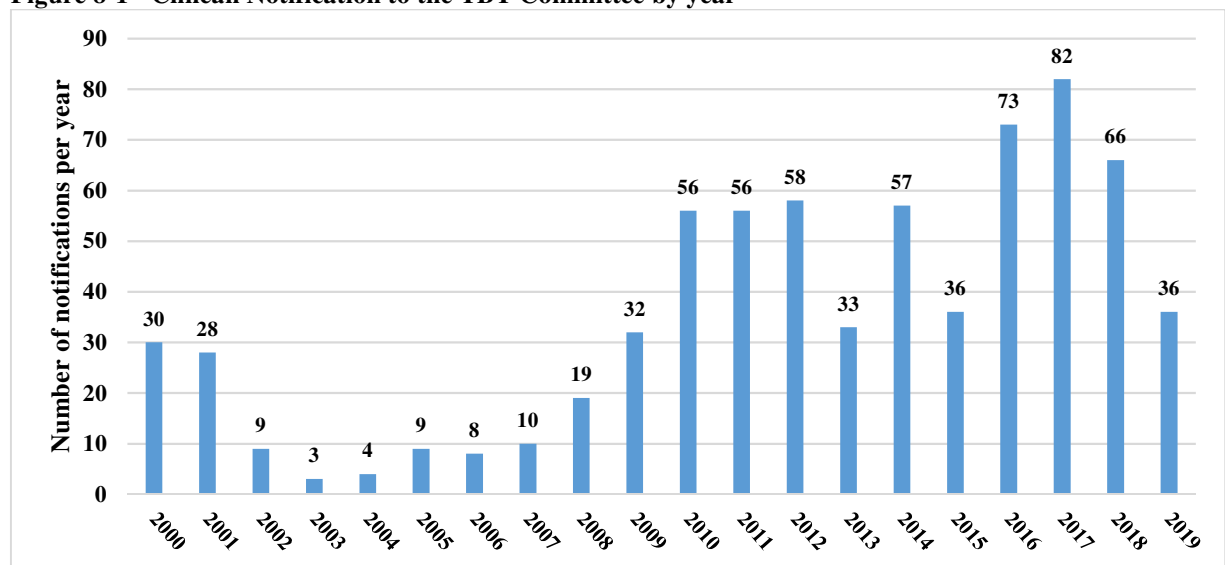
8.1. Regulatory Convergence in Chile

Convergence presupposes the existence of two or more distinct international regulatory systems and possibly divergent aspects. There are different ways of seeking convergence between systems, seeking mechanisms of cooperation endowed with formalization and variable effectiveness. From the perspective of international trade, three forms of instrumentalization of convergence are important: those adopted at the multilateral level, especially within the framework of the multilateral trading system, those formalized in preferential trade agreements and those established through agreements and arrangements between specialized subnational actors .

8.2. Multilateral Level

At the multilateral level, the investigation of the notifications made by Chile to the WTO TBT Committee provides an overview of the country's regulatory technical activity. Note that, in more recent years, coinciding with the period of deepening of regulatory reform in Chile, the number of notifications rises consistently. The year 2017 shows the highest number of notifications in the selected interval, as shown in the graph below.

Figure 8-1 - Chilean Notification to the TBT Committee by year

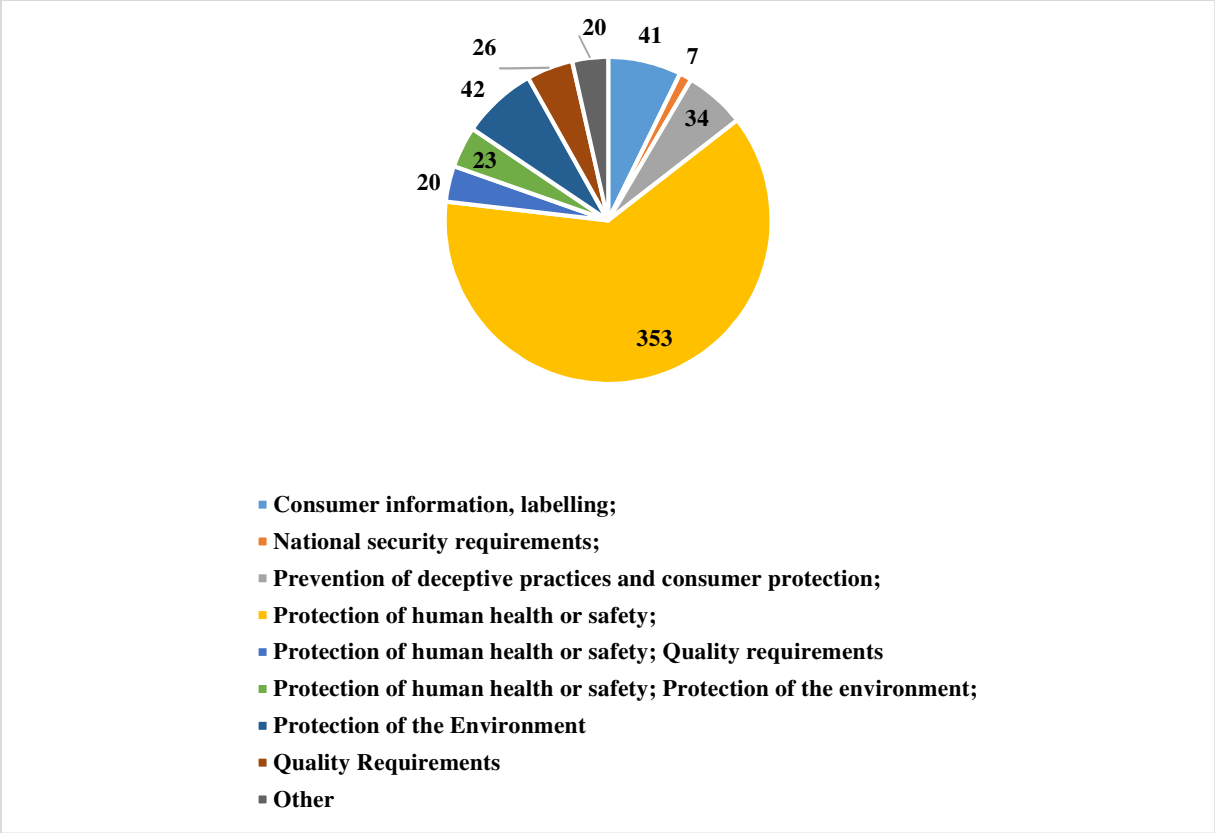


Source: TBT WTO. Elaborated by CCGI-EESP/FGV.

The number of notifications that Chile presented to the TBT Committee is presented in the Chart. As it can be seen through the numbers, there is a tendency towards increasing the number of notifications to the TBT Committee. The notifications have reached a peak in 2017 with 82 notifications in total. As of May of 2019, the Committee has already received 36 notifications.

In the beginning of the decade the numbers were lower in general, with only 3 notifications in 2003 and 4 notifications in 2004.

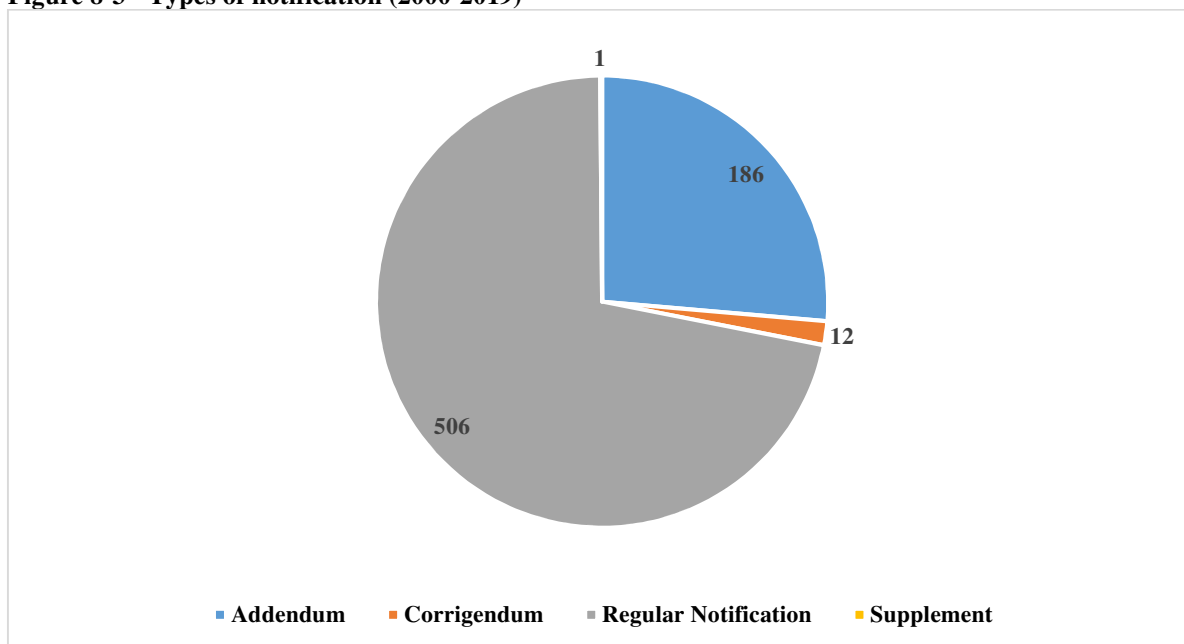
Figure 8-2 - Objectives of the notified measures (Chile: 2008-2019)



Source: TBT WTO. Elaborated by CCGI-EESP/FGV.

The distribution of the measures by their objectives is shown in the chart. As it can be seen, the main measures are those that concern Protection of Human Health or safety, accounting to the majority of the notifications in the referred period. Following are the measures that deal with the consumer, such as consumer labelling and consumer protection. There are also themes related to National security requirements and Quality requirements.

Figure 8-3 - Types of notification (2000-2019)



Source: TBT WTO. Elaborated by CCGI-EESP/FGV.

As it can be seen in the chart, the majority of the notifications made by Chile are Regular Notifications, followed by Addendums.

8.3. Preferential Trade Agreements

In total, Chile has twenty-seven international agreements on trade, mainly Free Trade Agreements (FTAs) (either bilateral or multilateral), six Economic Complementation Agreements (ACEs), three Economic Association Agreements and one partial reach Agreement. The following table identifies the TBT content in the agreements.

Table 8.1 - Technical Regulation in Trade Agreements (Chile)

Signatory Party	Type of Agreement	TBT Chapter	Overview of TBT Chapter
Australia	Free Trade Agreement	yes	Chapter 7 on technical regulations, norms and proceedings to evaluate the conformity; detailed 7 pages
Bolivia	Economic Complementation Agreement	no	Absent in the agreement, although present in article 19, item b) on economic cooperation on technical norms
Canada	Free Trade Agreement	no	Absent in the agreement
Central America	Free Trade Agreement	yes	Chapter 9 on normalization measures, metrology and authorization proceedings. Very detailed 9 pages.
China	Free Trade Agreement	yes	Chapter VIII on technical barriers to trade (TBT) detailed; 7 pages
Colombia	Free Trade Agreement	yes	Chapter XI, short 2 pages
South Korea	Free Trade Agreement	yes	Chapter IX, very detailed, 11 pages
Cuba	Economic Complementation Agreement	yes	Chapter V, short, not one page
Equador	Economic Complementation Agreement	yes	chapter 8, 7 pages, detailed description

EFTA (Iceland, Liechtenstein, Norway and Switzerland)	Free Trade Agreement	no	only specific article on the subject of technical regulations. Article 17
United States	Free Trade Agreement	yes	Chapter 7 on technical barriers to trade (TBT), detailed 6 pages
Hong Kong SAR	Free Trade Agreement	yes	Chapter 7 on technical obstacles to trade, 7 pages
India	Partial Reach Agreement	yes	Chapter XII, short
Japan	Economic Association Agreement	yes	Chapter 7: Technical Regulations, Standards and Procedures for the Evaluation of the Conformity. 4 pages.
Malaysia	Free Trade Agreement	yes	Chapter 7, detailed, 6 pages
MERCOSUR	Economic Complementation Agreement	no	Chapter on technical regulations is absent in this ACE
Mexico	Free Trade Agreement	yes	Chapter 8 on normalization measures. Chapter is long with 14 pages of detailed description
P4 (Chile, New Zealand, Singapore and Brunei)	Economic Association Agreement	yes	Chapter 8 on TBT; detailed 8 pages
Panama	Free Trade Agreement	yes	Chapter VII on TBT with 6 pages detailed.
Peru	Economic Complementation Agreement	yes	Chapter XI on measures regarding Metrology and Normalization, very short.
Turkey	Free Trade Agreement	yes	Chapter 2 about technical regulations, Norms and proceedings to evaluate the conformity; articles 24-32, 6 pages, detailed.
European Union	Economic Association Agreement	yes	Section 4 on norms, technical regulations and proceedings to evaluate the conformity. 7 pages.
Venezuela	Economic Complementation Agreement	yes	Chapter XI on technical norms, very short
Vietnam	Free Trade Agreement	yes	Chapter 7: Technical Regulations, Standards and Procedures for the Evaluation of the Conformity, 7 pages, detailed
Thailand	Free Trade Agreement	yes	Chapter 7 TBT. 5 pages
Alliance of the Pacific	Free Trade Agreement	yes	Chapter 7 on TBT with 9 pages, detailed
Uruguay	Free Trade Agreement	yes	Chapter 6 on TBT detailed with 8 pages

Source: Acuerdos Chile. Elaborated by CCGI-EESP/FGV.

There are seventeen FTAs and almost all of them have a chapter on technical barriers, although some are short such as in the Agreement with Colombia or with EFTA countries. The notable exception is the FTA signed in 1997 with Canada, where this issue is notably absent. In general, however the chapter on the subject has 5-7 pages as medium length with detailed description. Generally, the subject is addressed in chapters with one of the following items: Technical Barriers to Trade or Technical Regulations, Standards and Procedures for the Evaluation of Conformity. The free trade agreement with Mexico is the longest and most detailed with almost 14 pages addressing this issue, counting the annexes. A complete chapter usually brings some of the following items: definitions, scope of application, basic rights and obligations,

compatibility, evaluation of risk, proceedings to evaluate the conformity, authorization proceedings, notification, publication and transparency, technical cooperation, equivalence of technical regulations, conformity assessment, trade facilitation, affirmation of the TBT agreement, technical cooperation and the establishment of a technical barriers to trade committee. However, it is important to notice that each of the agreements have a certain logic and the subthemes vary depending on the signatory parties and the type of the Agreement.

The ACEs are established with countries part of the Latin American Integration Association (ALADI) such as Bolivia, Cuba, Ecuador, Venezuela¹⁴¹, Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela) and the Alliance of the Pacific (Colombia, Mexico and Peru). These agreements have among other objectives, to promote the maximum use of the factors of production, to stimulate economic complementation, to ensure equitable conditions of competition, to facilitate the concurrence of products to the international market and to promote the balanced and harmonious development of the member countries. However, on the issue of TBT, they are usually more concise and shorter and sometimes absent. The issue is notably absent in the agreement with Mercosur and present in ACEs with Venezuela, Cuba, Peru and Bolivia, although with only short references. Only the ACE with Ecuador presents a well detailed chapter on technical obstacles to trade.

Regarding Economic Association Agreements, there is one with the European Union, where the issue of TBT is raised on section 4 in a detailed manner. Economic Association Agreements are the generic name given to the contractual instruments used to establish in depth political and economic cooperation with third States or international organizations. An economic association agreement eliminates barriers to the free movement of goods, services and investment between countries. The materials they comprise are therefore quite comprehensive and their content varies according to the degree of cooperation sought¹⁴². This agreement can be considered an intermediate step between the free trade area and the single market in the process of economic integration, because it extends the areas of coverage. Chile has also economic association agreement with P4 countries (New Zealand, Singapore, Brunei) and Japan. In these agreements, the issue is also addressed in a detailed manner.

Lastly, there is a partial reach Agreement with India, where it can be found a short reference to technical barriers to trade. These types of agreements may be about trade, economic complementarity, agriculture, trade promotion, or the adoption of other modalities in accordance with Article 14 of the Treaty of Montevideo 1980 (ALADI).¹⁴³

It is necessary to point out that the older agreements have the tendency to underestimate the issues of TBT, because the theme has become more relevant to the international trade negotiations mainly during the last two decades, due to the significant reduction of tariffs in FTAs.

¹⁴¹ The Agreement with Venezuela is prior to the Agreement with Mercosur, when Venezuela was not part of it.

¹⁴²EU monitor. Available in <https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vh7dosdm4dzj>. Access in 22/05/2019.

¹⁴³ALADI. Available in <http://www.aladi.org>. Access in 22/05/2019.

SECTION III - REGULATION BY SECTORS

The aim of this section is to examine how regulation, technical standardization and conformity assessment procedures (quality infrastructure system) adopted by Chile, Mexico and Colombia can affect the international trade of these countries, especially in relation to Brazil and Argentina and also to Mercosur.

In the contemporary context of international trade, regulatory barriers are increasingly relevant. After successive multilateral negotiations and preferential trade agreements only tariff barriers were consistently reduced. This did not happen with regulatory barriers. The World Trade Organization, in particular the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS), together with international standards and regulatory bodies, prescribe the broader normative framework for regulatory, standardization and conformity assessment activities. Simply observing these international rules and recommendations, however, may be insufficient to eliminate barriers to trade. In this case, regulatory convergence initiatives among trading partners become necessary.

In view of the relevance of the regulatory theme for international trade, the scope of this research will include: the mapping of the regulatory policies and structures of regulation, standardization and conformity assessment in Chile, Mexico and Colombia, which are important trade partners of Brazil. The main purpose is to identify the difficulties these systems represent for trade between these Mercosur partners. The research will also investigate the possible solutions offered by those countries to mitigate or eliminate the non-tariff barriers through regulatory convergence initiatives.

Regulations, Standards and International Supporting Standards

In order to identify the degree of compatibility among Latin-America Countries, this Part of the Project will compare the Regulatory Policy of these countries related to Technical Regulations in 5 important sectors of their economies: automotive, electric products, pharmaceutical, food and oil and gas. This comparative examination will include, for each sector: the main regulators, the main technical regulations, their standards and conformity rules.

To compare the degree of compatibility of technical barriers among these countries, this research will identify the main international supporting standards followed by the national regulations and standards for each of the 5 sectors.

Two important concepts used in this project are international standards and global sectorial standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), Codex Alimentarius Commission, World Organization for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*.

International standards are generally produced in accordance with the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectorial standards are private standards developed by relevant standardizing bodies that are followed by producers and exporters around the World and are relevant to international trade. There are two main sources for these standards: the United States and the European Union.

The United States (US) produce important global sectorial standards, following the logic of a market oriented economy. There are around 300 Standards Bodies in the US. This model can be identified as a *bottom-up* approach. Some standards can be considered as global standards. They are: American Society for Testing and Materials (ASTM), American Petroleum Institute (API), American Society of Mechanical Engineers (ASME) and Underwriters Laboratories (UL). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

The EU produces another set of global standards, following the logic of an integrated or regional common market, produced and used not only regionally but also around the World. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI). They are produced under Directives established by the European Commission under what is called a *top down* approach. European standards are essential for the functioning of the EU integrated market and are widely used as the model influencing many standardization and regulatory work in several countries of the World.

For Latin-American countries, these global standards are important because they are used as supporting standards of technical regulations and technical standards. International and global standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies.

The objective of this Part III of the Project is to identify the degree of convergence of Mexico, Chile and Colombia with Brazil and Argentina through the use of these international and global supporting standard.

Considering the characteristics of the current trade and the existence of a legal framework for trade liberalization in Latin America (formalized in ALADI and its various EACs), trade between Brazil and the three selected countries could be substantially stimulated through regulatory convergence efforts, as tariffs between these trading partners are relatively low¹⁴⁴. The approximation of the regulatory, standardization and conformity assessment systems¹⁴⁵ of the countries could also strengthen regional industrial production chains as well as create new chains for dynamic and important industrial sectors in these countries.

¹⁴⁴ See tariffs of ALADI countries:

http://consultawebv2.aladi.org/sicoexV2/jsfAranceles/arancel_vigente_item_entrada.seam?cid=1373530

¹⁴⁵ There is important evidence that the countries analyzed have medium or high regulatory complexity. For international trade, this complexity may represent costs and barriers to the exchange of goods and services. See, for example, the indicators of regulatory complexity calculated by the OECD for Chile, Mexico and Brazil: <http://www.oecd.org/eco/reform/indicatorsofproductmarketregulationhomepage.htm>

In this context, a comparative analysis between the regulatory frameworks related to technical barriers to trade (TBT) in Mexico, Colombia and Chile can offer solutions to problems and impasses observed in Brazil and within Mercosur. As with bilateral trade with Argentina, the Brazilian trade pattern with the three countries is heavily concentrated in industrialized products with high added value. Considering the export difficulties of Brazilian industry, the study of these markets that demand Brazilian manufactured goods becomes even more relevant.

One of the main practical results of the research will be the strengthening of communication between business communities, industry associations and regulatory bodies, with the aim of promoting bilateral trade and investment, as well as cooperation in innovation, research and development. There is great potential to strengthen the economic relationship between Brazil and the three selected countries, through regulatory convergence based on mandated requirements and recommendations from international organizations.

This project, therefore, could provide subsidies for ambitious regulatory cooperation between Brazil and Argentina with Chile, Colombia and Mexico, raising some of the main obstacles in bilateral and regional trade. The initiatives adopted on the basis of this study could therefore result in greater economic integration and increased business competitiveness and growth in all countries involved.

8. Mexico

8.1. The automotive sector in Mexico

8.1.1. Overview

The trade balance between Brazil and Mexico in the area of automobiles shows that Mexico usually maintains substantive surpluses in the bilateral trade. The Mexican surplus reached US\$ 1,52 billion in 2014, US\$ 676 million in 2015, US\$ 240 million in 2016, US\$ 361 million in 2017 and US\$ 1,270 billion in 2018. The trade surplus favoring Mexico has fluctuated in the period, regaining momentum in 2018. The exports from Brazil reached a peak in 2017, surpassing US\$ 1 billion in the value exported but receded in the end of the period. The bilateral trade numbers indicate the great capacity of the automotive industrial complex in Mexico.

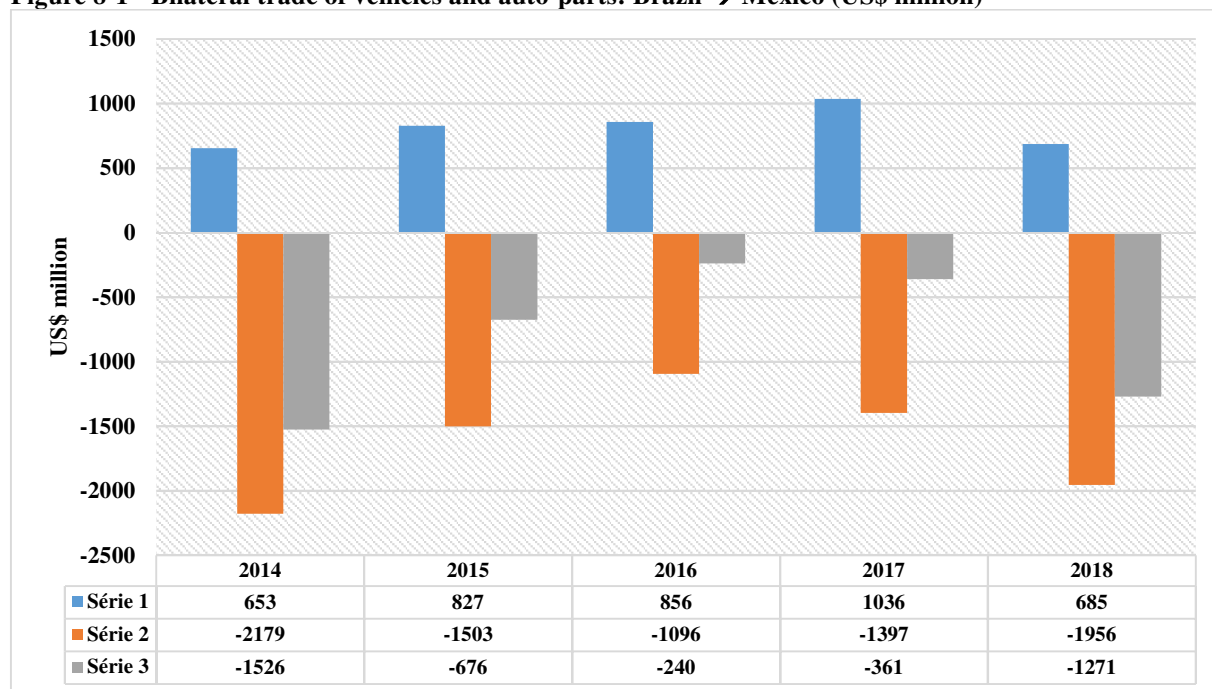
Table 8.1 - Auto trade between Brazil and Mexico (US\$)

Year	Total	
	Exports	Imports
2014	653.235.930	2.179.596.698
2015	827.451.391	1.503.921.749
2016	856.571.994	1.096.574.772
2017	1.036.397.830	1.397.290.286
2018	685.743.353	1.956.606.681

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In the figure 51 below, it can be observed the evolution of the bilateral trade relations between Mexico and Brazil:

Figure 8-1 - Bilateral trade of vehicles and auto-parts: Brazil → México (US\$ million)

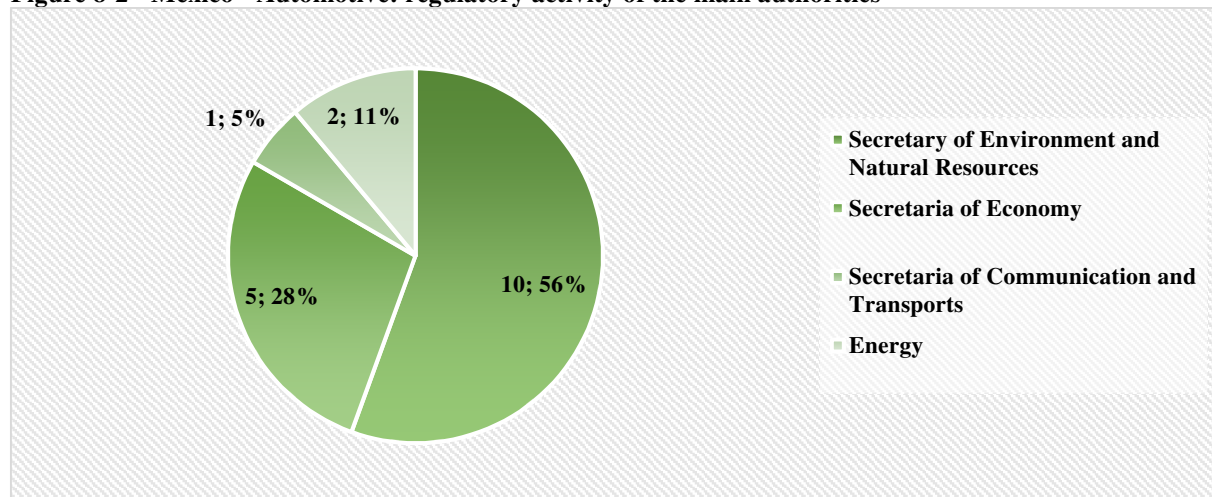


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

8.1.2. Main authorities

The main authorities that regulate the sector are the Secretary of Economics, Secretary of Communication and Transportation, Secretary of Energy, Secretary of Environment and Natural Resources. As it can be seen in the figure 52, the Secretary of Environment and Natural Resources corresponds to 56% of the regulatory activity in Mexico, whilst the Secretary of Economy corresponds to 28% of the regulatory activity. The Secretary of Energy represents 11% and the Secretary of Communication and Transports only 5% of the issued regulations.

Figure 8-2 - Mexico - Automotive: regulatory activity of the main authorities



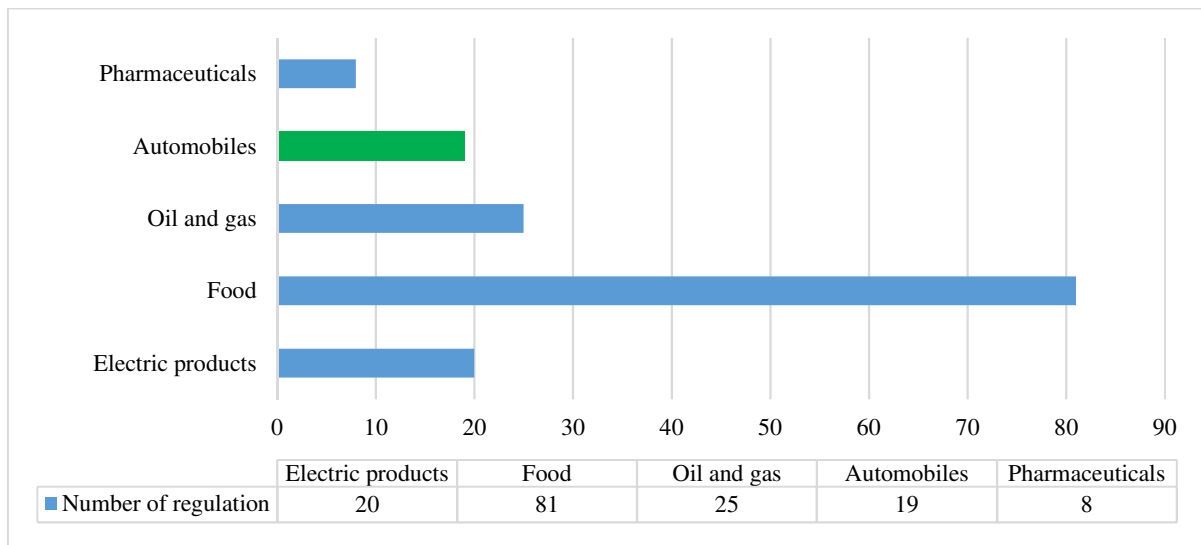
Source: ComexStat. Elaborated by CCGI-EESP/FGV.

Mexico has a very developed auto industry, with companies from diverse countries and a strong auto parts industry. The technical regulation of the sector is influenced by this central condition of the automobile industry in the Mexican economy. The Secretariat of Environment and Natural Resources is the body that most creates technical regulations, most of them related to the emission of polluting substances in the atmosphere. As Mexico is a major exporter of vehicles, an important part of production must meet the requirements imposed in other countries, such as the United States and Canada.

8.1.3. Technical regulations, standards and supporting standards

The researcher identified 19 regulations on vehicles and auto-parts. If the sector was compared with others, the intensity of regulatory activity would be moderate.

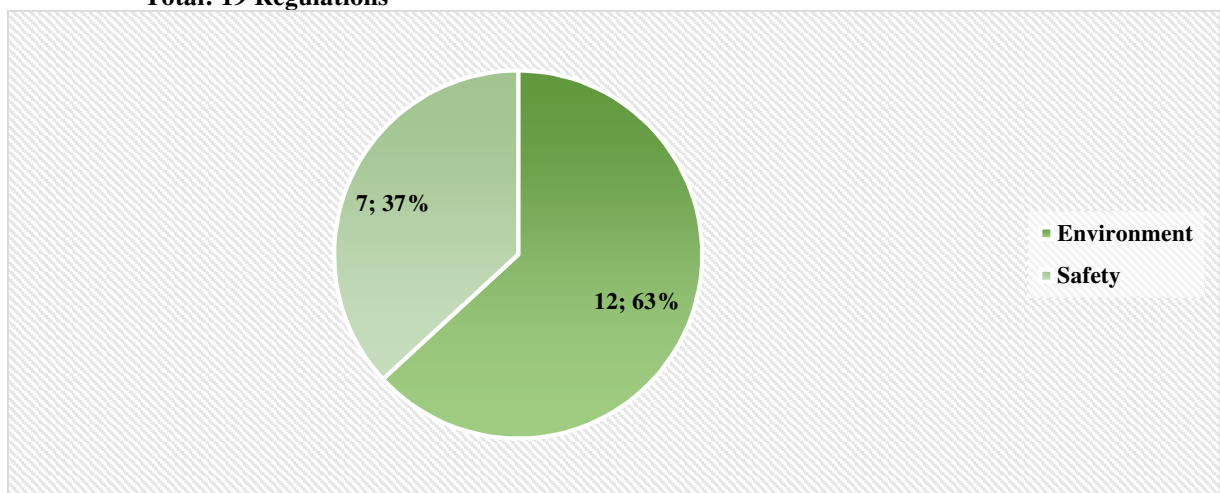
Figure 8-3 - Mexico - Automotive: regulatory activity - comparison among sectors



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

The main themes inserted on technical regulations of the auto sector are those related to safety of the vehicles. Regarding the Secretary of Environment and Natural Resources there are many regulations that take care of maximum permissible levels of the emission of pollutant gases.

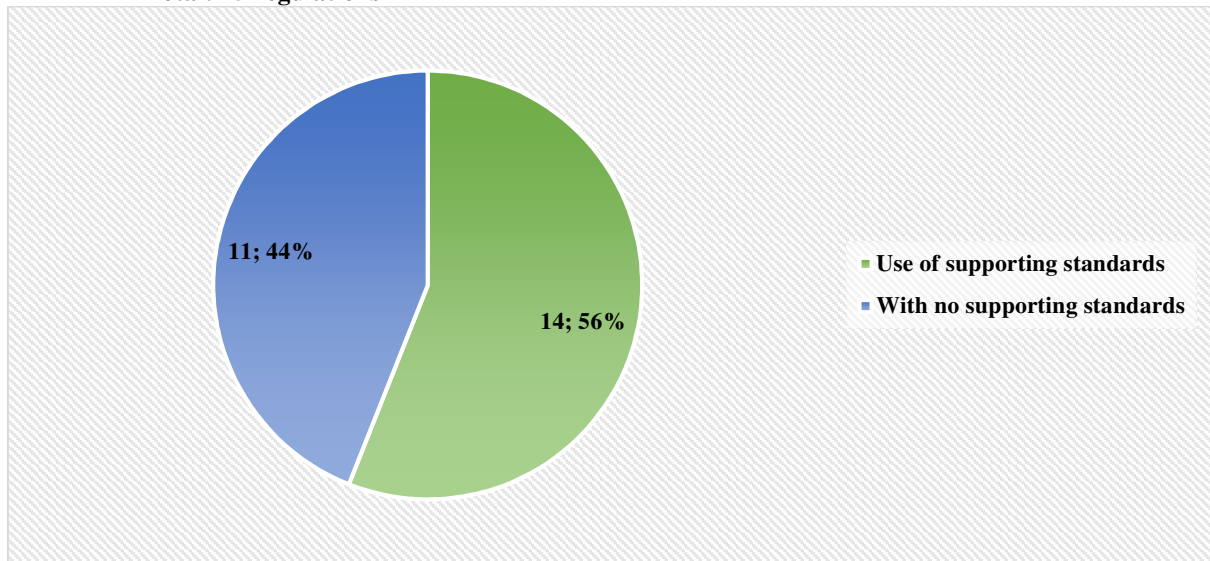
Figure 8-4 - Mexico - Automotive: object of technical regulation
Total: 19 Regulations



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

In general, these two themes, safety and the environment, are the two central objects of technical regulations for vehicles and auto parts. This feature is repeated in Mexico, with the greatest emphasis on environmental technical regulations, mainly aspects related to the emission of polluting substances in the atmosphere. This concern of the Mexican authorities to discipline, more rigorously and in detail, the emission of pollutants is in line with the various commitments made by Mexico in the international sphere, including in the framework of the free trade agreements signed by the country. The technical regulations on Environment represent 63% of the regulatory activity in the sector, whilst the regulations on safety represent 37%.

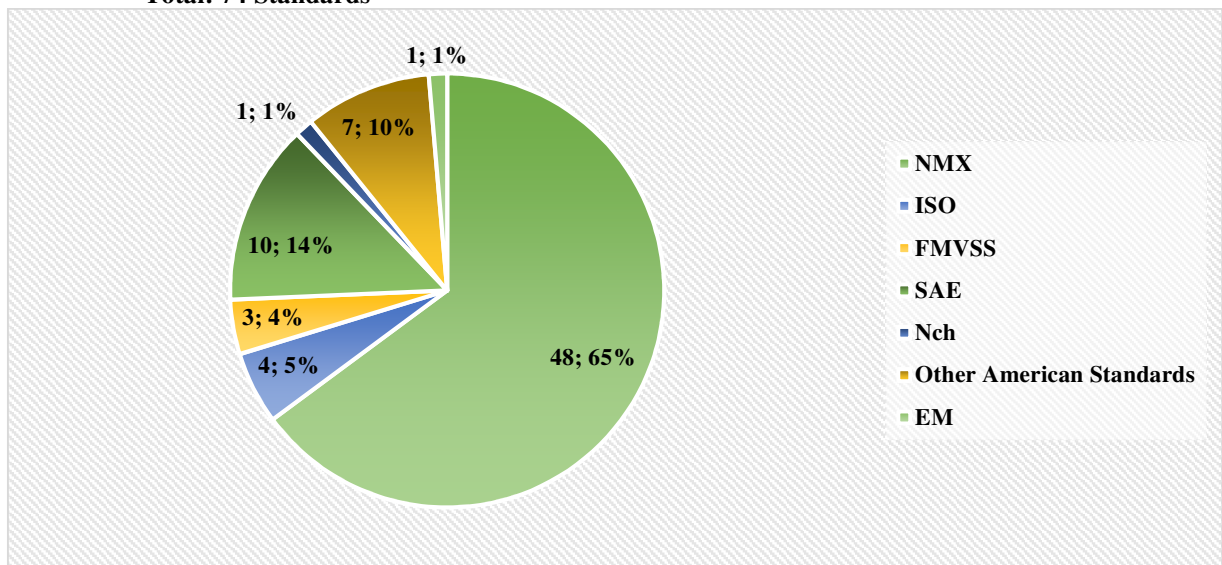
Figure 8-5 - Mexico - Automotive: use of supporting standards
Total: 25 regulations



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Most of the Mexican technical regulations for vehicles make use of international technical standards, a characteristic that indicates the concern of Mexican regulatory authorities to follow certain international standards. The greatest number of technical standards used, however, is of Mexican domestic origin, which may at first appear to contradict the idea of international insertion underlying Mexican regulatory policy. Other standards frequently used in Mexican technical regulations are US standards, with emphasis on the standards produced by Federal Motor Vehicle Safety Standards (FMVSS) and Society of Automotive Engineers (SAE), as well as other standards and prescriptive documents produced by US public and private bodies.

Figure 8-6 - Mexico - Automotive: types of supporting standards
Total: 74 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

As it can be seen in figure 55, Mexican norms NMX predominate and are present in 56% of the norms that use supporting standards whilst SAE norms are present in 14% of the norms with supporting standards. ISO norms are present in 5%, FMVSS in 4% and Nch norms are in 1%

of the norms that require supporting standards. American standards in general account for 10% of the norms that use supporting standards and EM standards account for 1%.¹⁴⁶

8.1.4. Conformity assessment and certification

The Federal Law on Metrology and Standardization establishes the possibility for private entities to carry out the function of assessing compliance with standards by means of ocular verification, sampling, measurement, laboratory tests or examination of documents.

8.1.5. Main government and private actors

Among the private actors that are involved in the process of issuing Technical Regulations there are entities like the *Asociación Mexicana de Distribuidores de Automotores (AMDA)*¹⁴⁷, *Asociación Mexicana de la Industria Automotriz Asociación de Familiares de Atropellados*¹⁴⁸, *Fundación para la prevención de accidentes por alcohol*, *Industria nacional de autopartes*, *Asociación Mexicana de la Industria Automotriz*, *Asociación Nacional de Productores de Autobuses, Camiones y Tractocamiones*, along with multinationals companies such as General Motors of Mexico, Mercedes Benz of Mexico and Volkswagen of Mexico.

8.2. Electric products in Mexico

8.2.1. Overview

The trade balance between Brazil and Mexico in the area of electric products shows that Mexico has kept substantial surpluses during the last five years. In the period, Mexico exports have fluctuated between US\$ 616 million and US\$ 656 million, an increase of 6,4% whilst Brazil exports started at US\$ 192 million in 2014 and finished at US\$ 183 million in 2018, a decrease of 4,7%. The trade surplus favoring Mexico is a constant in the period, going from US\$ 424 million in 2014 to almost US\$ 473 million in 2018, an increase of 11,55%.

Table 8.2 - Electric products trade between Brazil and Mexico (US\$)

Year	Total	
	Exports	Imports
2014	192.366.830	616.601.385
2015	237.888.968	638.603.727
2016	227.945.276	507.078.206
2017	191.071.476	667.270.347
2018	183.338.612	656.186.529

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

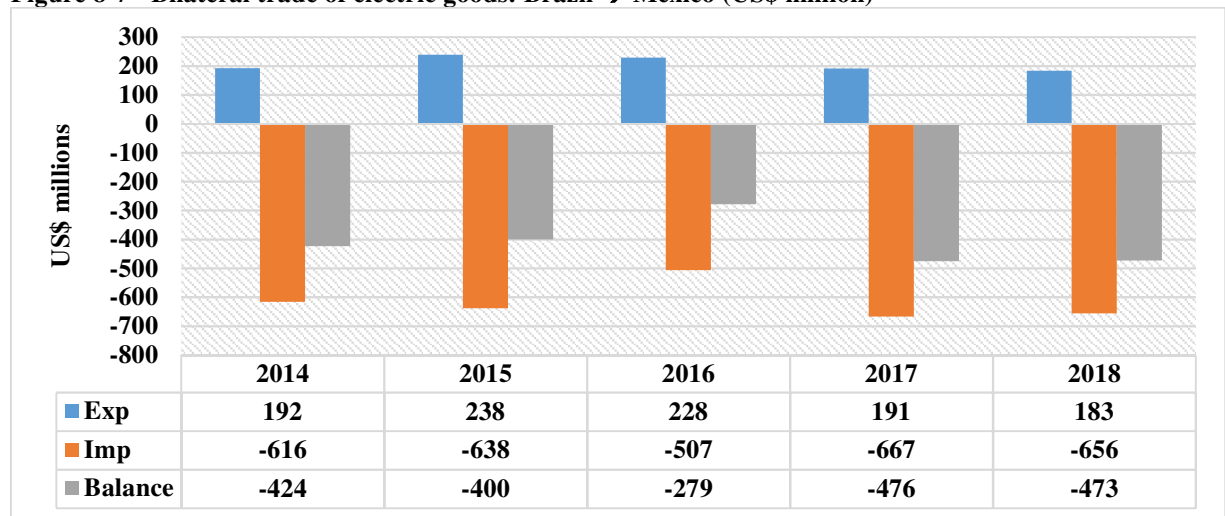
In figure 65, it is possible to observe the evolution of the trade during the last 5 years.

¹⁴⁶ The list of regulation is in [appendix 3.C](#).

¹⁴⁷ See: <https://www.amda.mx/>

¹⁴⁸ See: <http://www.amia.com.mx/descargarb.html>

Figure 8-7 - Bilateral trade of electric goods: Brazil → México (US\$ million)

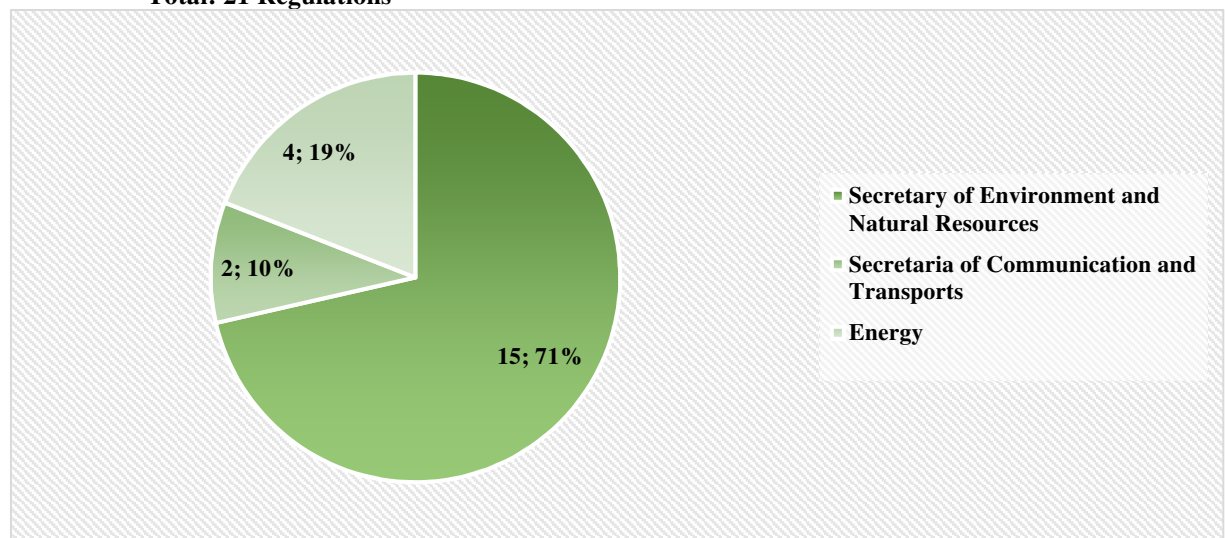


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

8.2.2. Main authorities

The main authorities that regulate the sector are the Secretary of Economics, Secretary of Communication and Transportation, Secretary of Energy.

Figure 8-8 - Mexico - Electrics: regulatory activity of the main authorities
Total: 21 Regulations



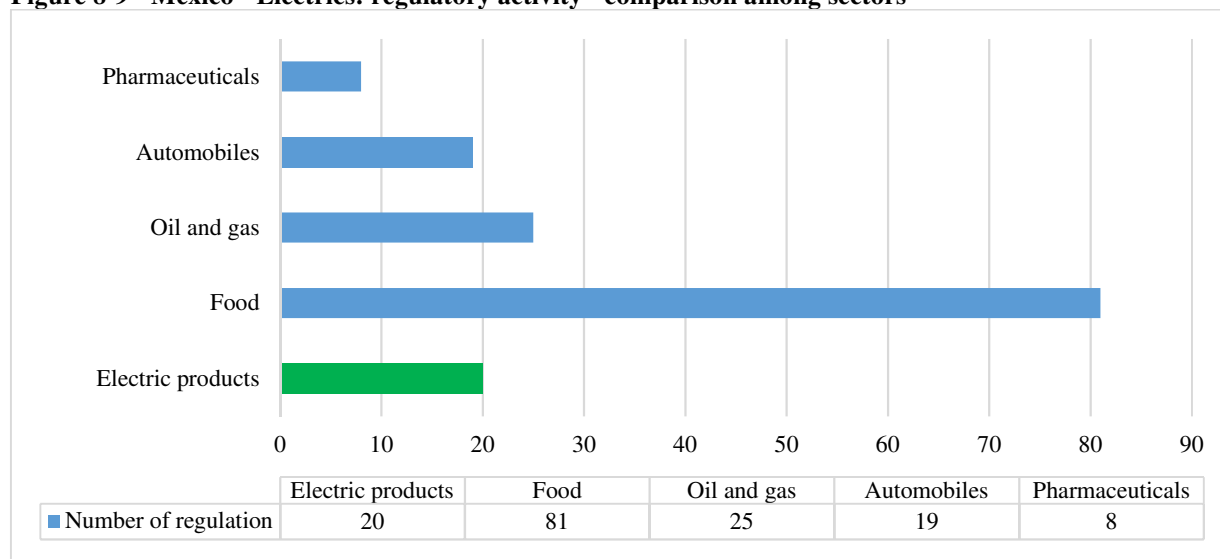
Source: ComexStat. Elaborated by CCGI-EESP/FGV.

The Secretariat of Economy is the most active in the technical regulation of electrical products. More than seventy percent of the technical rules for the sector are edited by the Secretariat of Economy of Mexico. Second is the Secretariat for the Environment and Natural Resources, which has issued almost twenty percent of the technical regulations for the sector, whilst the Secretary of Communication and Transports is responsible for ten percent of the regulatory activity in the sector.

8.2.3. Technical regulations, standards and supporting standards

In electric product sector, there 20 regulations in force in Mexico. Compared with other sectors, the products of oil and gas sector presents a moderate degree of regulatory intervention in Mexico.

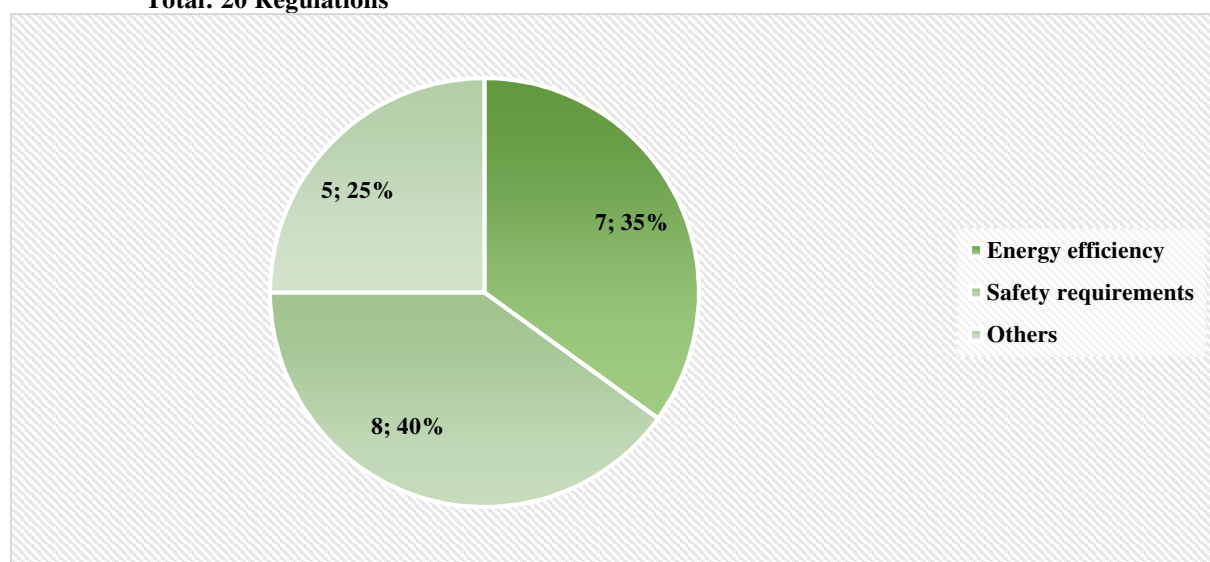
Figure 8-9 - Mexico - Electrics: regulatory activity - comparison among sectors



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

The main themes inserted on technical regulations of the electric products sector are safety specifications in the electric and electronic sector and requirements for energy efficiency.

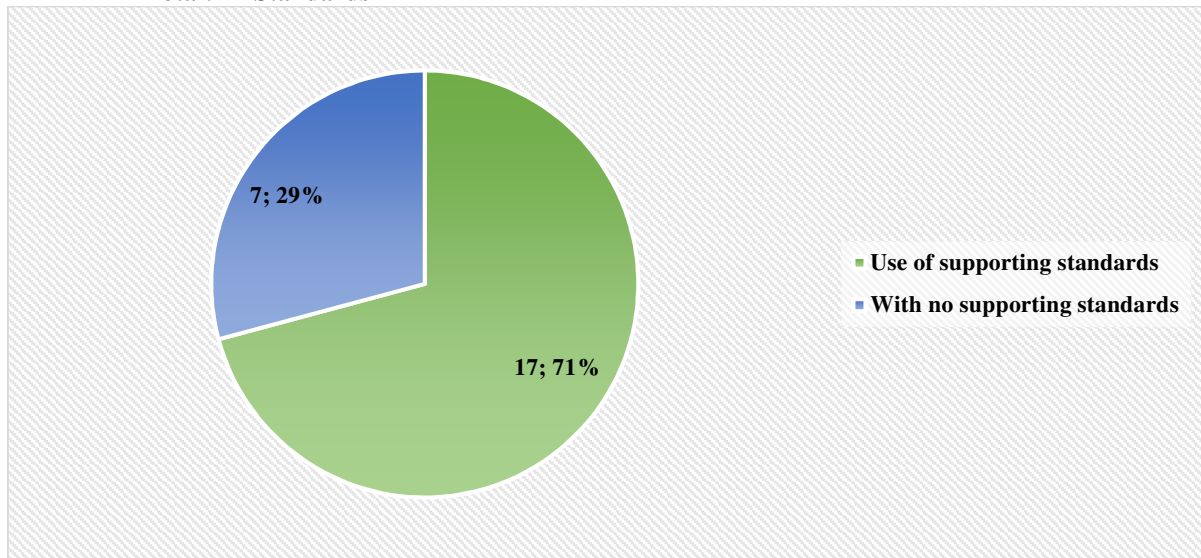
Figure 8-10 - Mexico - Electrics: object of technical regulation
Total: 20 Regulations



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

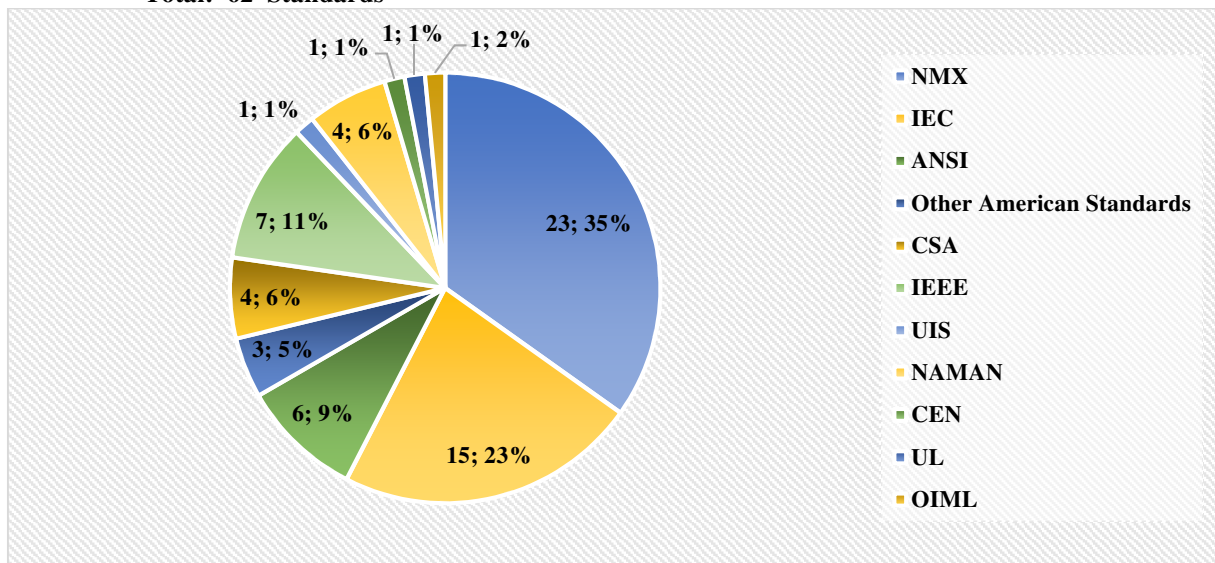
Regarding the use of supporting standards, as observed in figure 61 below, 71% of the technical regulations use supporting standards, while 29% do not use supporting standards, which indicates the tendency of basing the technical regulations on standards already existent.

Figure 8-11 - Mexico - Electrics: use of supporting standards
Total: 24 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Figure 8-12 - Mexico - Electrics: types of supporting standards
Total: 62 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Although Mexican standards (NMX) are the majority (35%), the use of other technical standards is quite varied. Of particular note is the use of standards produced by the IEC, which accounts for 23% of the norms that cite supporting standards, and also the standards produced by US standardization bodies, such as American National Standards Institute (ANSI), accounting for 9% and Institute of Electrical and Electronics Engineers (IEEE), present in 11% of the norms using supporting standards.¹⁴⁹

8.2.4. Conformity assessment and certification

The electrical and electronic products that are commercialized in Mexico must be certified in

¹⁴⁹ The list of regulation is in [appendix 3.C](#).

accordance with the Official Mexican Standards (NOM), which establish the minimum requirements of security that these products must meet. The legal framework applicable to these products is the Law Federal on Metrology and Normalization.

The Ministry of Economy (SE) delegated the services of conformity assessment, it is say tests, certification, calibration and inspection to the Mexican Accreditation Entity, A.C. (EMA) Most product categories require that certification and trials are carried out by organizations present in Mexico and that are accredited by the EMA and approved by the SE. In the event that there is no certification body, the General Directorate of Standards (DGN), an executing arm of the SE, issues certificates for the products. NOM certification is related to product safety.

The main bodies responsible for the conformity assessment and certification are the *Normalización y Certificación Electrónica* NYCE, UL de México, Centro de *Normalización y Certificación de Productos* (CNCPE), Factual Services, S.C, Intertek México.

8.2.5. Main government and private actors

There are many institutions and bodies that operate in the issuing of NOMs related to electric products such as the *Asesoría y pruebas a Equipo eléctrico y electrónico*, *Instituto de Investigaciones Eléctricas*, *Dirección General de Normas (DGN)*, *Asesoría y pruebas a equipo eléctrico y electrónico*, *Asociación de Normalización y certificación*, *Asociación nacional de fabricantes de la industria de la refrigeración*, *Procuraduría federal del consumidor*, *Asociación Nacional de Normalización y Certificación del Sector eléctrico*.

In the government sphere there is also the Comisión Federal de Electricidad (CFE). Currently, the Federal Electricity Commission (CFE) is a state company, exclusive property of the Federal Government, the main company in the electric sector in Mexico: *Asociación Mexicana de Distribuidores de Automotores (AMDA)* and *Asociación Mexicana de la Industria Automotriz*.

8.3. Food in Mexico

8.3.1. Overview

The trade balance between Brazil and Mexico in the food sector shows a substantial surplus in favor of Brazil in the last five years. As it can be seen in table 15, the Brazilian exports have increase during the period from almost US\$ 245 million in 2014 to US\$ 489 million in 2018, a substantial increase of 99,8%, almost doubling the exports in the sector. The cause of this substantial increase may be related to the devaluation of the Brazilian currency during the period, making Brazilian products much more competitive in the international market. The imports from Mexico were practically stable during the period, staying at around US\$ 69 million. The increase of the trade flow was significant and was derived from the increase in Brazilian exports.

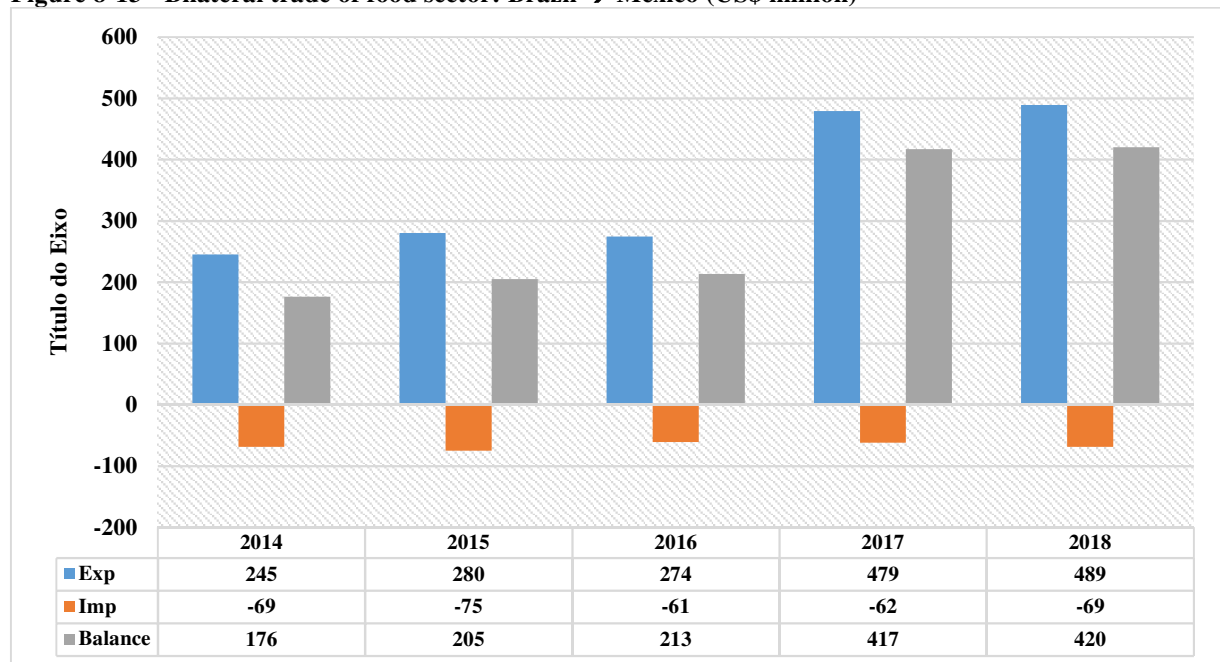
Table 8.3 - Food trade between Brazil and Mexico (US\$)

Year	Total	
	Exports	Imports
2014	244.921.769	69.339.061
2015	280.171.406	75.605.322
2016	273.877.359	61.250.957
2017	479.333.175	62.611.811
2018	489.292.346	69.661.478

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

The evolution of the trade between the two countries is shown in figure 71:

Figure 8-13 - Bilateral trade of food sector: Brazil → México (US\$ million)

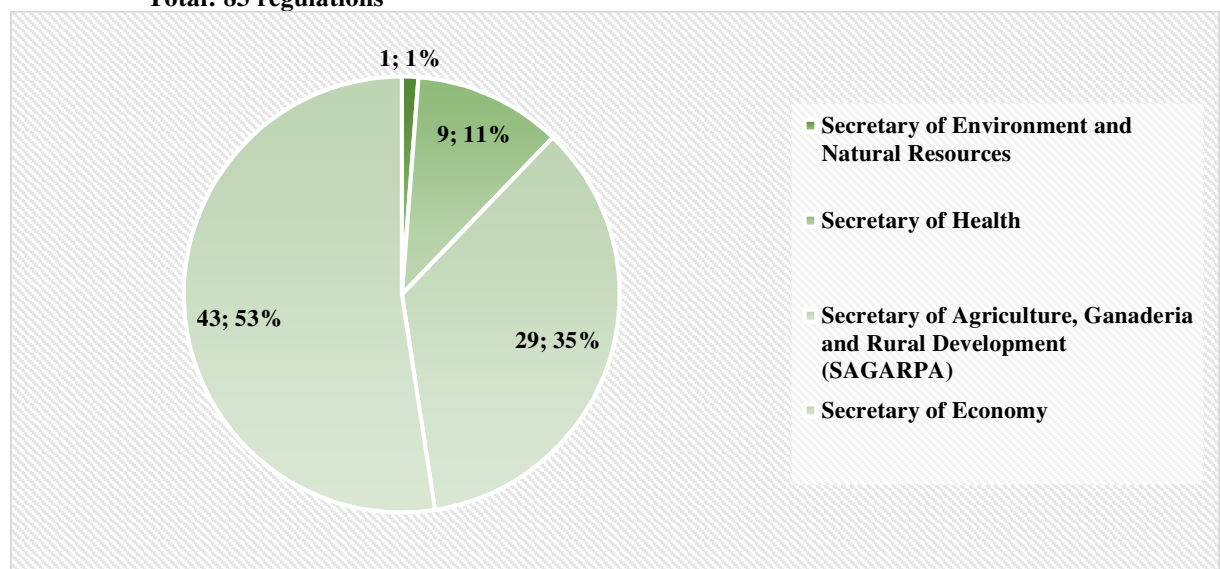


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

8.3.2. Main authorities

The main authorities that regulate the sector are the Secretary of Economics, Secretary of Health, Secretariat of Agriculture and Rural Development (SAGARPA), and the Secretary of Environment and Natural Resources.

Figure 8-14 - Mexico - Food: regulatory activity of the main authorities
Total: 83 regulations



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

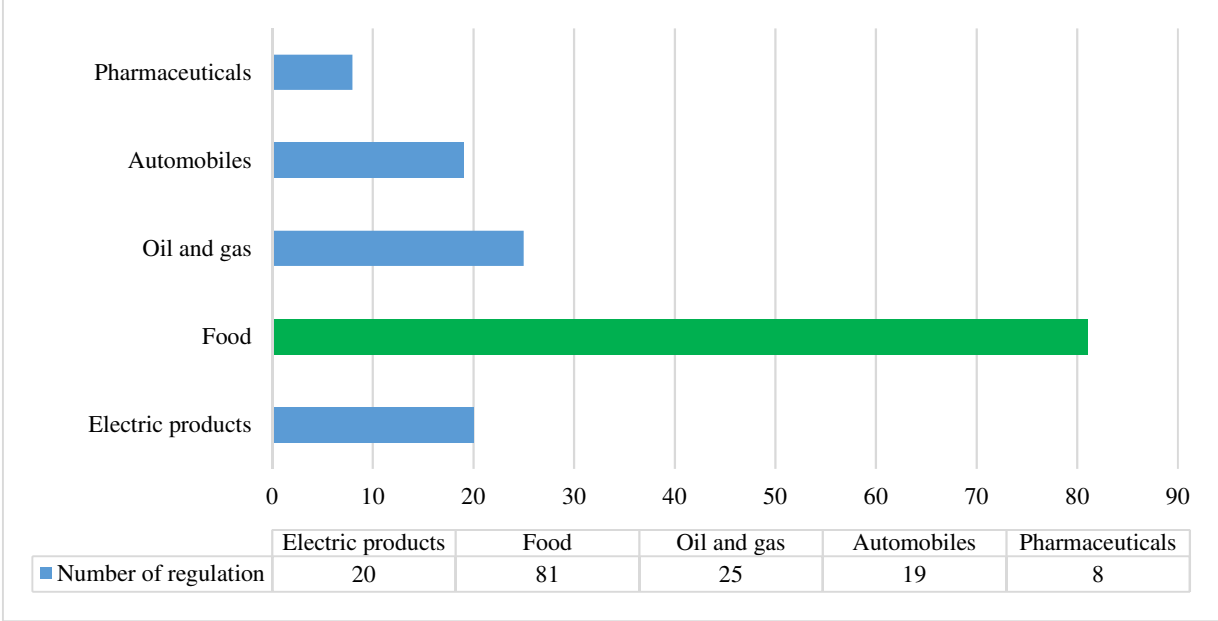
The Secretariat of the Economy, as in other sectors, plays a central role in the technical regulation of the food sector in Mexico. More than half (53%) of the technical regulations issued by Mexican authorities was designed by the Secretariat of Economy, which issued forty-three

technical regulations. Another important entity is SAGARPA, responsible for the edition of 35% of the Mexican technical regulations for the food industry. The secretary of Health is responsible for 11 % of the regulatory activity.

8.3.3. Technical regulations, standards and supporting standards

In food product sector, there eighty-one regulations in force in Mexico. Compared with other sectors, the products of food sector present high degree of regulatory intervention in Mexico.

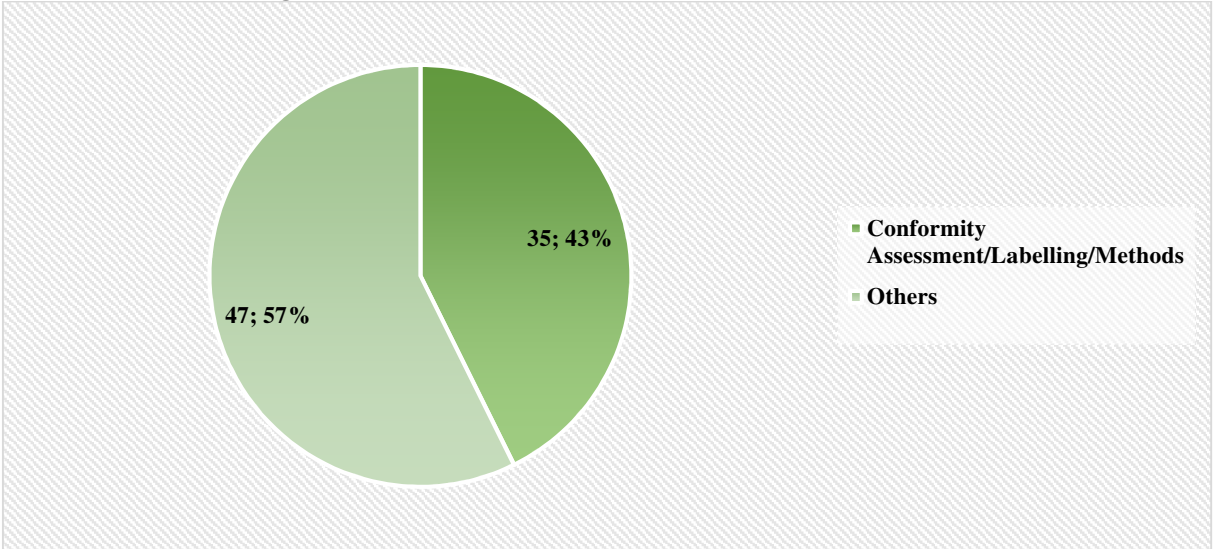
Figure 8-15 - Mexico - Foods: regulatory activity - comparison among sectors



Source: Secretaría da Economía. Elaborated by CCGI-EESP/FGV.

The main themes inserted on technical regulations of the food sector are alcoholic beverages, milk and dairy and issues related with fishing such as commercial and sanitary information and rules for responsible fishing.

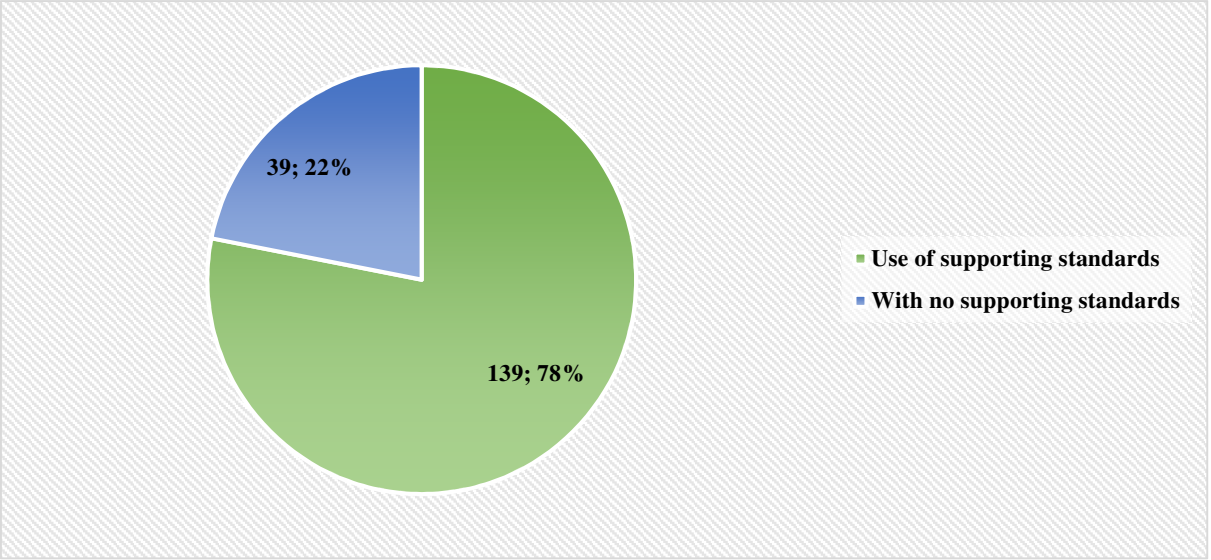
Figure 8-16 - Mexico - Food: object of technical regulation
Total: 82 Regulations



Source: Secretaría da Economía. Elaborated by CCGI-EESP/FGV.

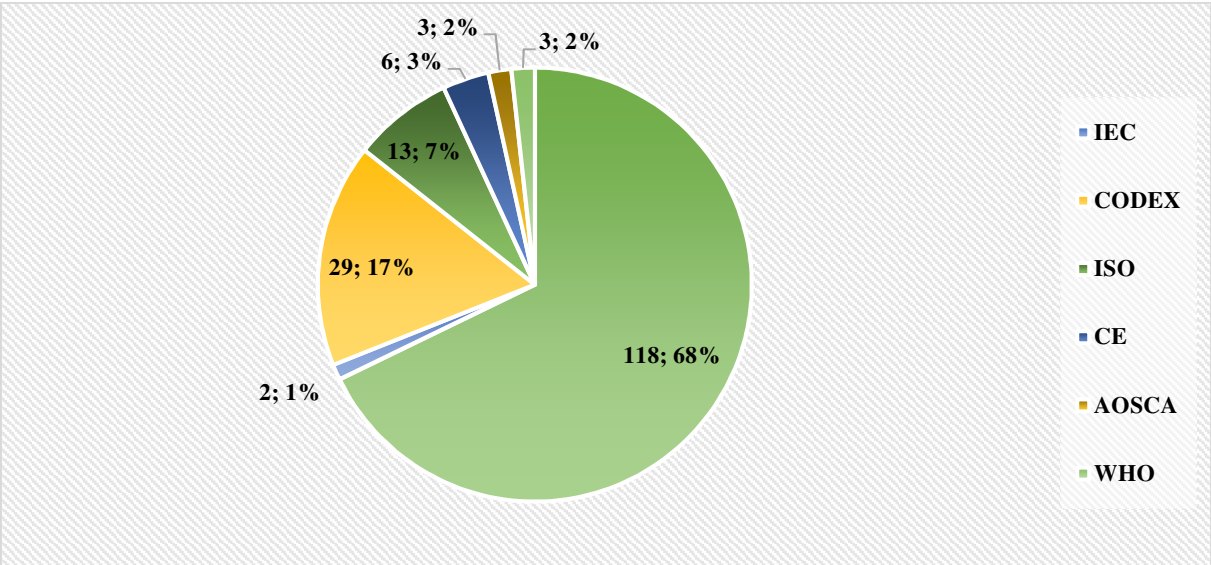
Unlike other sectors, most Mexican technical regulations make use of technical support standards. This characteristic confers greater flexibility to the country's technical rules, since the change of technical norms is usually faster than the change of technical regulations, which sometimes depends on the performance of government agencies and, sometimes, depends on parliamentary approval.

Figure 8-17 - Mexico - Food: use of supporting standards
Total: 158 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Figure 8-18 - Mexico - Food: types of supporting standards
Total: 154 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

There is a predominance of Mexican technical norms in the food sector. Other important standards used are international standards and prescriptive documents produced by

international bodies. In this sense, the standards produced by the *Codex Alimentarius* Commission and by the Food and Agriculture Organization stand out.¹⁵⁰

8.3.4. Conformity assessment and certification¹⁵¹

The Conformity Assessment is the determination of the degree of compliance with Mexican official standards or compliance with Mexican standards, international standards or other specifications, prescriptions or characteristics. It includes, among others, the sampling, testing, calibration, certification and verification procedures. All products, processes, methods, facilities, services or activities must comply with Mexican official standards. When a product or service must comply with a certain official Mexican standard, its similar to be imported must also meet the specifications established in that standard.

The Federal Law on Metrology and Standardization establishes the possibility for private entities to carry out the function of assessing compliance with standards by means of ocular verification, sampling, measurement, laboratory tests or examination of documents.

These conformity assessment agents, according to their activities and functions, are known as: a) Certification Bodies b) Test Laboratories c) Calibration Laboratories d) Verification Units for the Evaluation of the Conformity of the Official Mexican Standards, competence of the Ministry of Economy, the conformity assessment agents, must be Accredited and Approved.

Accreditation is the act by which an accreditation entity recognizes the technical competence and reliability of the certification bodies, test laboratories, calibration laboratories and verification units for the assessment of compliance. In compliance with art. 72 of the Law on Metrology and Standardization makes available the data of the National Accreditation Entity authorized by the Ministry of Economy.

8.3.5. Main government and private actors

The COFEPRIS (Federal Commission for the Protection against Sanitary Risk) is the competent authority for the exercise of the powers that correspond to the Ministry of Health in terms of regulation, control and health promotion of products and services, their import and export. In order to comply with this task, the Commission carries out actions for the control and sanitary surveillance of food and beverages, food supplements, raw materials and additives that are involved in its preparation, importation and exportation, as well as the establishments destined to the processing of said products.

The sanitary control actions of food for national consumption, are carried out in coordination with the State Health Authorities under a risk approach within the framework of the Food Program.

In support of exports, the Ministry of Health has competence to certify the processes or products referred to in article 194, section I of the General Health Law (LGS), or the establishments in which these processes are carried out, provided that they comply with the applicable provisions (Article 287, LGS). Processes, products or establishments can also be certified for purposes

¹⁵⁰ The full list of regulation is in [appendix 3.C](#).

¹⁵¹ Trade Policy Review. Mexico, 2017. Available in https://www.wto.org/english/tratop_e/tpr_e/s352_e.pdf. Access in 18/06/2018

other than export, as is intended for domestic or national consumption. The foregoing without prejudice to the powers of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), through the National Service of Health, Safety and Agri-Food Quality (SENASICA), in matters of control of safety during the primary production.

There are many public and private institutions that are involved in the process of issuing technical regulations in the area of foods and beverages. For example, the *Consejo para el Fomento de la Calidad de la Leche y sus derivados, A.C. (COFOCALEC)*¹⁵², the *Dirección General de Normalización Agroalimentaria*, many private distilleries, the *Camara nacional de la industria de conservas alimentarias (CANAINCA)*, the *Consejo Mexicano de la Carne, Sociedad Mexicana de Normalización y Certificación, s.c. (NORMEX)*¹⁵³, *Universidad Autónoma de Chihuahua*, *Universidad Autónoma de Guadalajara*, *Universidad Autónoma de Yucatán*, *Universidad Nacional Autónoma de México*, etc.

8.4. Oil and gas in Mexico

8.4.1. Overview

The trade balance between Brazil and Mexico in the area of oil and gas is shown below. It can be seen that Mexico has maintained a significant surplus with Brazil in the last four years in this sector. Mexico is an important producer and exporter of oil, and Brazil, in spite of its increasing production, is a traditional importer of oil and gas.

Figure 8-19 - Oil and gas trade between Brazil and Mexico (US\$)

Year	Total	
	Exports	Imports
2014	5.627.041	64.703.265
2015	1.140.203	174.797.583
2016	26.106.363	84.971.736
2017	1.355.446	83.508.752
2018	3.346.243	75.138.527

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

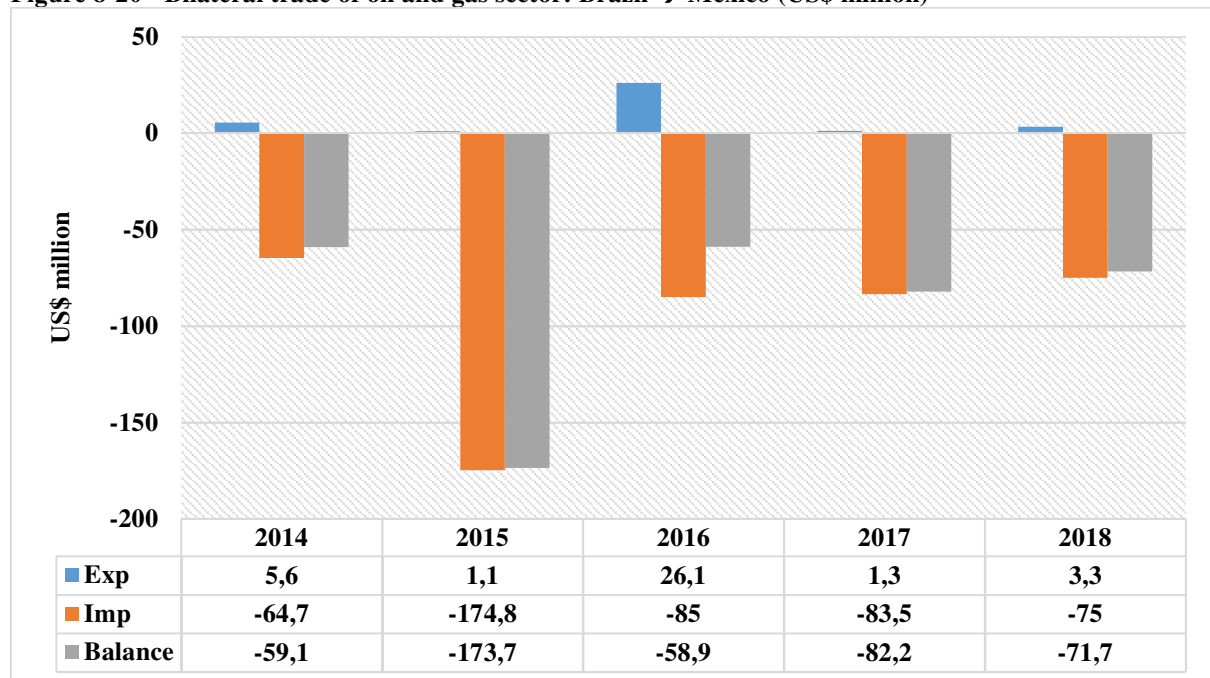
In 2014, Brazil exported just over US \$ 5 million and imported US \$ 64.7 million from Mexico. In the following year, the Brazilian deficit in the sector was even higher, totaling more than US \$ 170 million. The year of 2016 was the best performance of Brazilian oil and gas exports to Mexico (US \$ 26 million), but even so, there was a deficit of almost US \$ 60 million. In the years 2017 and 2018, Brazil had deficits of approximately US \$ 80 million and US \$ 70 million, respectively.

In figure 70, the evolution of the bilateral trade of oil and gas sector is shown. It can be observed the relevance of the imports in relation to the total trade flow, it is also possible to identify a peak in imports in 2015:

¹⁵² See: <https://www.cofocalec.org.mx/>

¹⁵³ See: <https://comecarne.org/>

Figure 8-20 - Bilateral trade of oil and gas sector: Brazil → México (US\$ million)

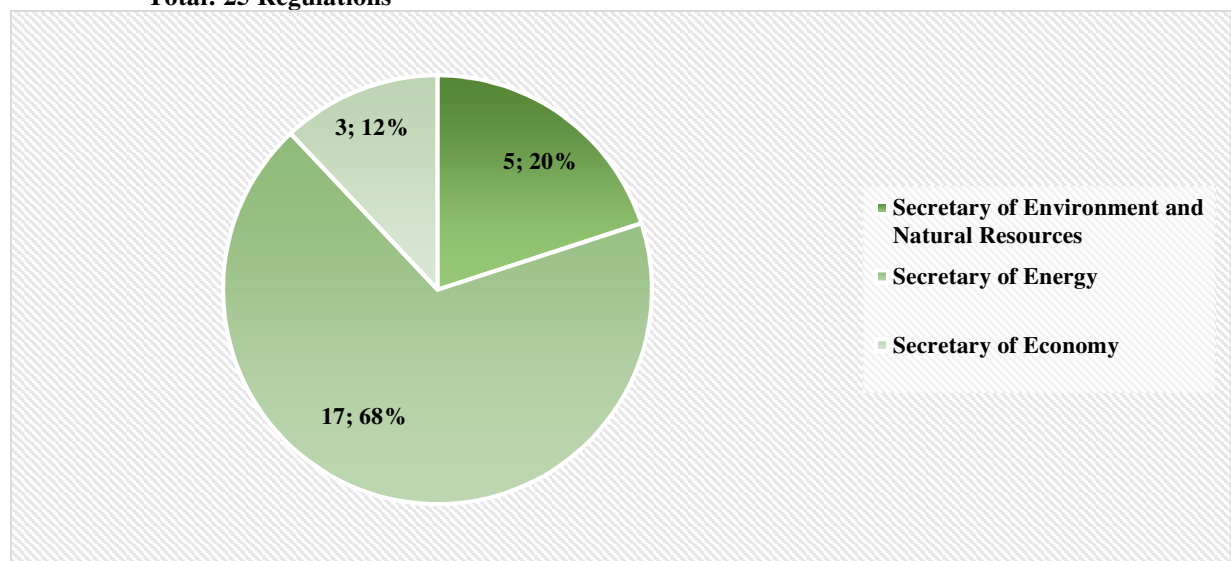


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

8.4.2. Main authorities

The main authorities that regulate the sector are the Secretariat of Economics, the Secretary of Energy and the Secretariat of Environment and Natural Resources. The Secretary of Energy is the main regulatory body of the sector, making a total of 68% of the technical regulations, the Secretary of Environment and Natural Resources is responsible for 20% of the regulations of the sector and the Secretary of the Economy is responsible for 12% of the regulatory activity.

Figure 8-21 - Mexico - Oil and Gas: regulatory activity of the main authorities
Total: 25 Regulations

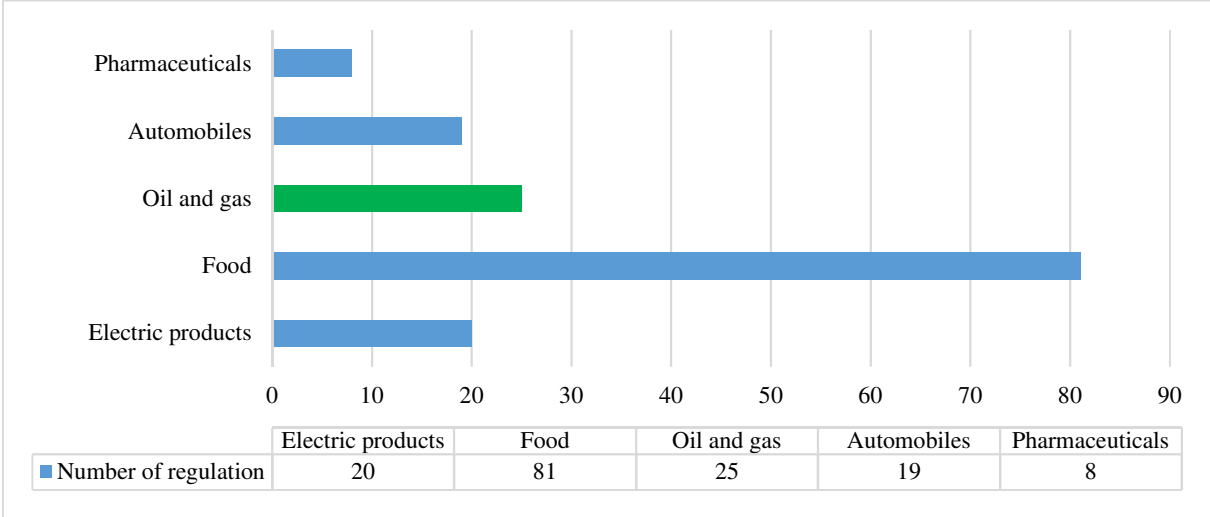


Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

8.4.3. Technical regulations, standards and supporting standards

In oil and gas product sector, there 20 regulations in force in Mexico. Compared with other sectors, the products of oil and gas sector presents high degree of regulatory intervention in Mexico.

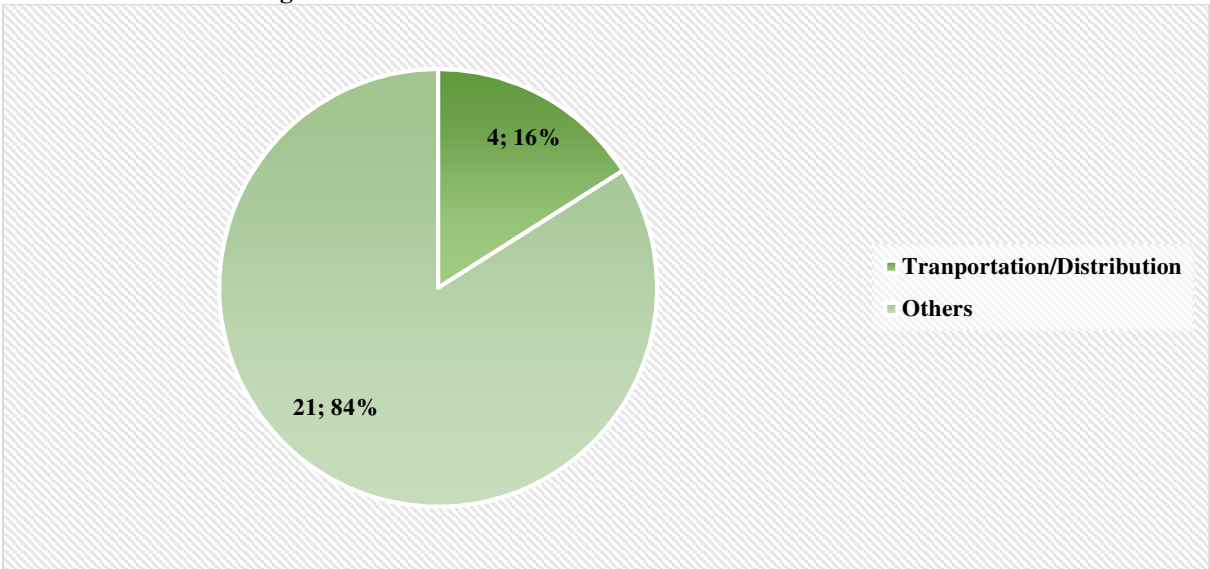
Figure 8-22 - Mexico - Oil and Gas: regulatory activity - comparison among sectors



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

The technical regulations on the area of oil and gas include themes such as: establishing maximum permissible levels of emission of unburned hydrocarbons, carbon monoxide and nitrogen oxides from the exhaust, using gasoline specifications of fossil fuels for environmental protection and issues related to the distribution of natural gas and liquefied petroleum gas by ducts.

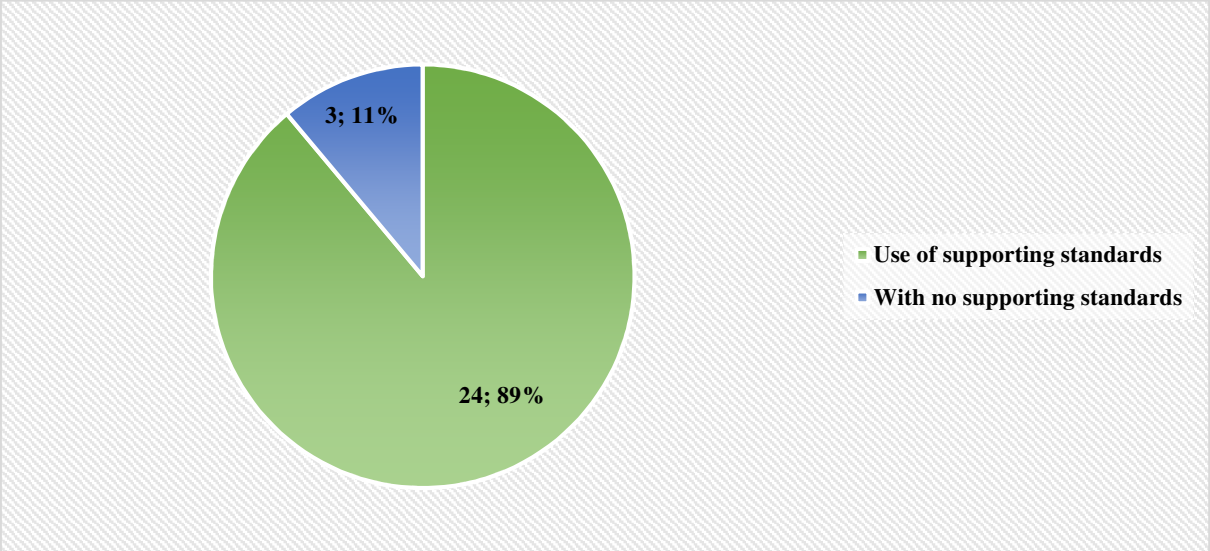
Figure 8-23 - Mexico - Oil and Gas: object of technical regulation
Total: 25 Regulations



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

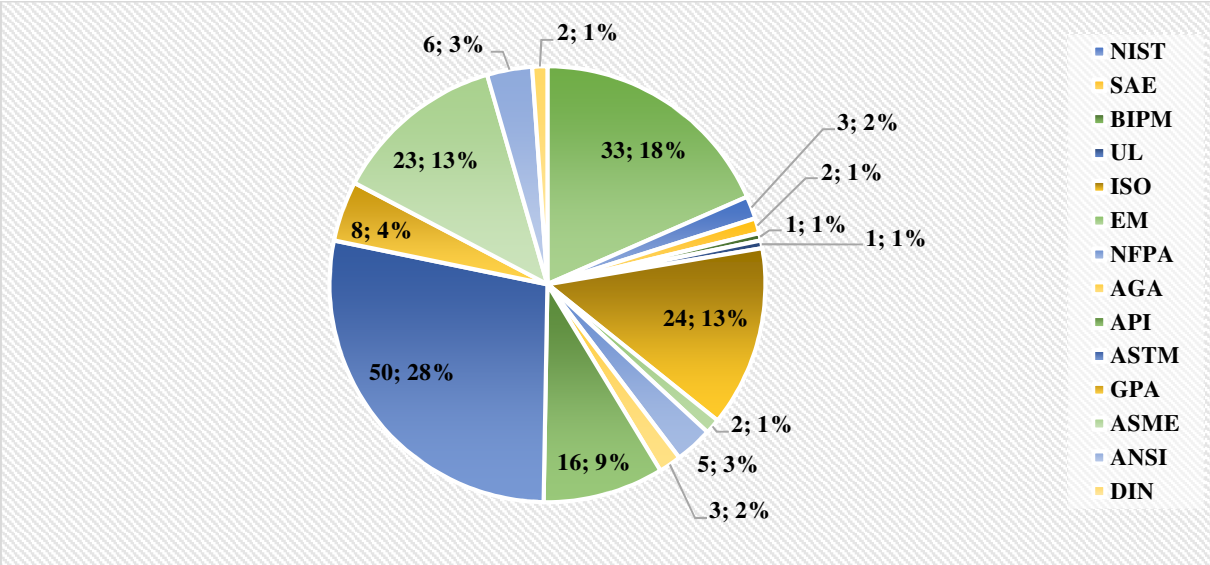
Concerning the use of supporting standards in the oil and gas sector of Mexico, it can be observed in figure 74 that the vast majority (89%) of the technical regulations use international supporting standards.

Figure 8-24 - Mexico - Oil and Gas: use of supporting standards
Total: 27 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Figure 8-25 - Mexico - Oil and Gas: types of supporting standards
Total: 186 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Mexican technical regulations on oil and gas mention a wide variety of technical standards. In this sector, the technical standards produced by American standards organizations, such as the American Society of Testing and Materials (ASTM), the American Society of Mechanical Engineers (ASME) and the Society of Automotive Engineers (SAE) stand out. ASTM are mentioned in 28% percent of the technical regulations that mention supporting standards, while

ISO norms are present in 13%, the same amount as the ASME norms. NMX norms are present in 18% of the technical regulations. API norms are present in 9% of the technical regulations.¹⁵⁴

8.4.4. Conformity assessment and certification

The Energy Regulatory Commission (CRE) is a dependency of the centralized Federal Public Administration, with the character of a Coordinated Regulatory Body in Energy Matters, as established in the eighth paragraph of Article 28 of the Political Constitution of the United Mexican States.

The CRE is an autonomous body of the Secretariat of Energy (SENER), and has technical, operational and management autonomy, and has its own legal personality. The technical regulations are issued in accordance with its requisites and recommendations.

8.4.5. Main government and private actors

There are many public and private institutions that are involved in the process of issuing technical regulations in the area of Oil and Gas such as: *Asociación Mexicana de la Industria Automotriz, Asociación Nacional de la Industria Química, Asociación Nacional de Productores de Autobuses, Camiones y Tractocamiones, Pemex refinación, Pemex Gas y Petroquímica Básica, Asociación de ingenieros petroleros de México, Instituto Mexicano del petróleo, Universidad Nacional Autónoma de México.*

8.5. Pharmaceuticals in Mexico

8.5.1. Overview

The trade balance between Brazil and Mexico in the area of pharmaceuticals shows a fluctuating relationship. Although there was a relevant surplus favoring Mexico in 2014, Brazil managed to keep surpluses during 2015, 2016, 2017, 2018. The exports from Brazil have fluctuated between US\$ 86 million and US\$ 96 million, while the imports from Mexico have fluctuated more in value, departing from around US\$ 117 million in 2014 and decreasing to around US\$ 66 million in 2018, a reduction of 44% percent in the imports, which may be also related to exchange rate variations during the period.

Table 8.4 - Pharmaceutical trade between Brazil and Mexico (US\$)

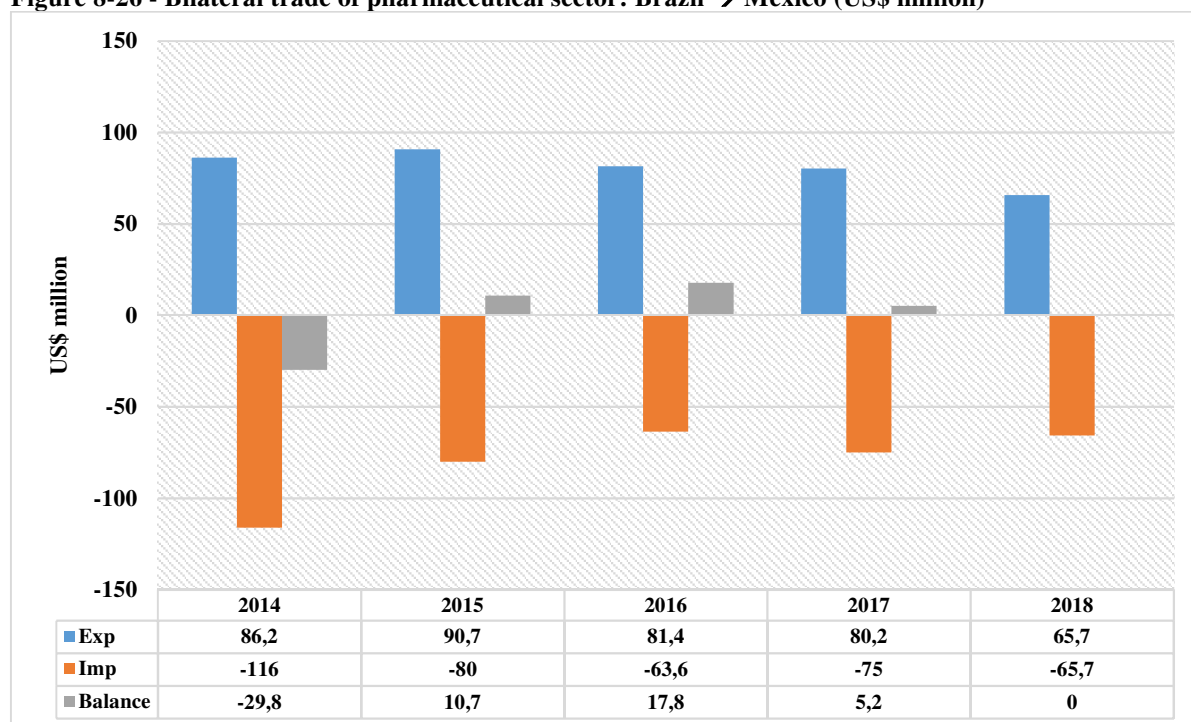
Year	Total	
	Exports	Imports
2014	86.218.329	116.640.700
2015	90.714.427	80.037.781
2016	81.430.814	63.585.041
2017	80.243.423	75.233.838
2018	95.875.095	65.729.594

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In figure 8-26, the evolution of the bilateral trade can be observed:

¹⁵⁴ The list of regulation is in [appendix 3.C](#).

Figure 8-26 - Bilateral trade of pharmaceutical sector: Brazil → México (US\$ million)



Source: ComexStat. Elaborated by CCGI-EESP/FGV.

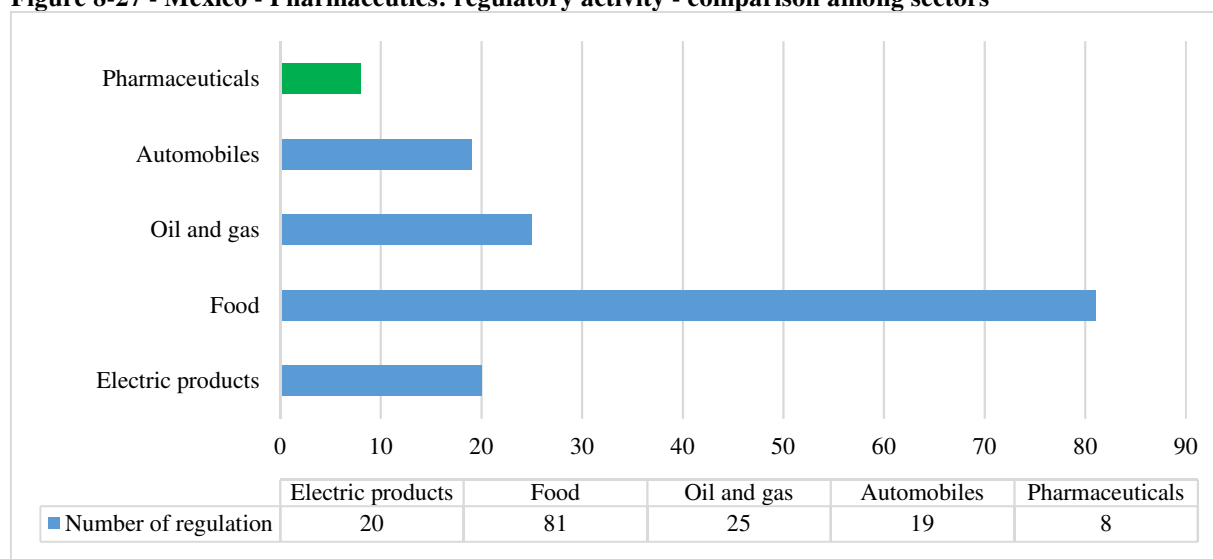
8.5.2. Main authorities

The main authorities in the public sphere that regulate the sector are in the Secretary of Health. All the technical regulations identified were issued by Secretary of Health.

8.5.3. Technical regulations, standards and supporting standards

In pharmaceutical products sector, there are 8 regulations in force in Mexico. Compared with other sectors, the pharmaceutical sector presents very low degree of regulatory intervention in Mexico.

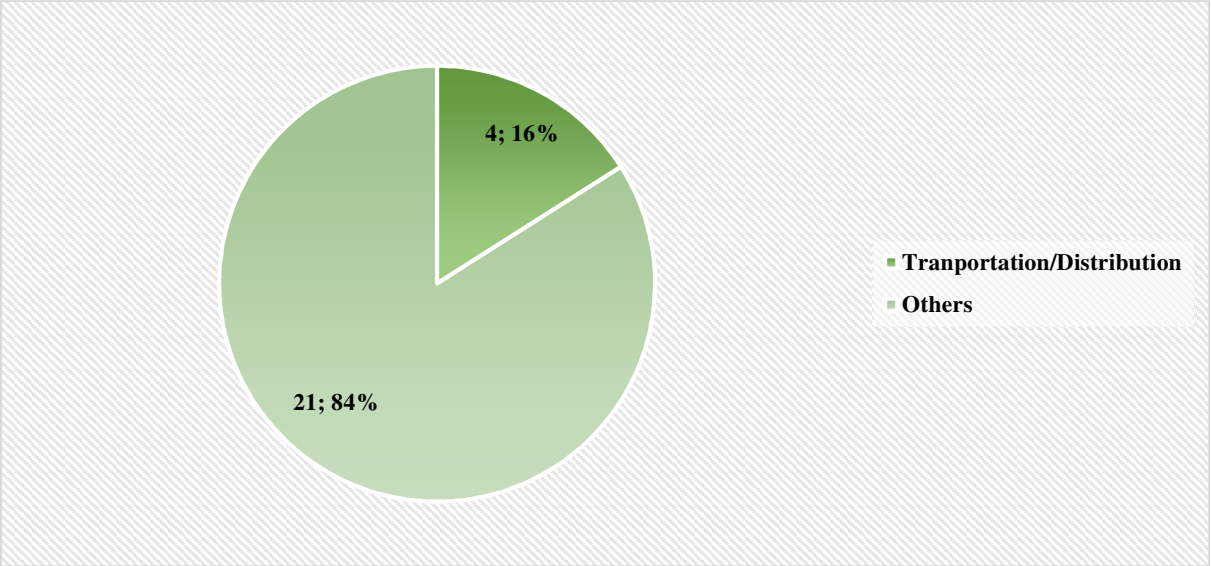
Figure 8-27 - Mexico - Pharmaceuticals: regulatory activity - comparison among sectors



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

The main themes inserted on technical regulations of the pharmaceutical sector are those related to the installation and operation of pharmacovigilance, good manufacturing practices of medicines, stability of drugs and medicines, as well as herbal remedies, labelling of medications and herbolarly remedies. In figure 78, the object of technical regulations can be observed. The theme of transportation and distribution is the most relevant and makes a total of 16% of the norms.

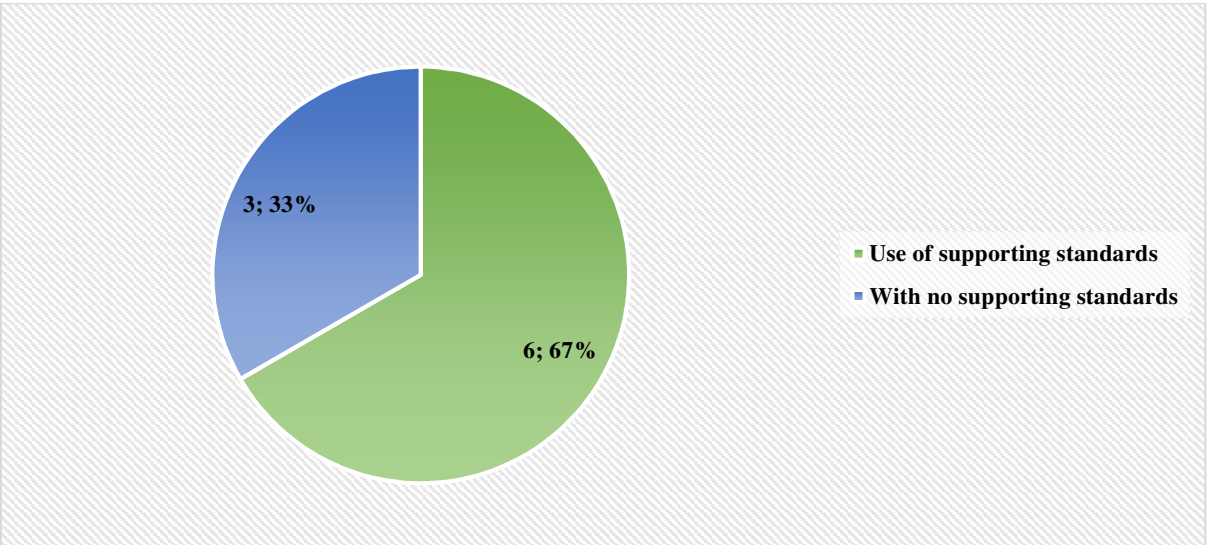
Figure 8-28 - Mexico - Pharmaceuticals: object of technical regulation (Mexico - pharmaceutical)
Total: 25 Regulations



Source: Secretaría da Economia. Elaborated by CCGI-EESP/FGV.

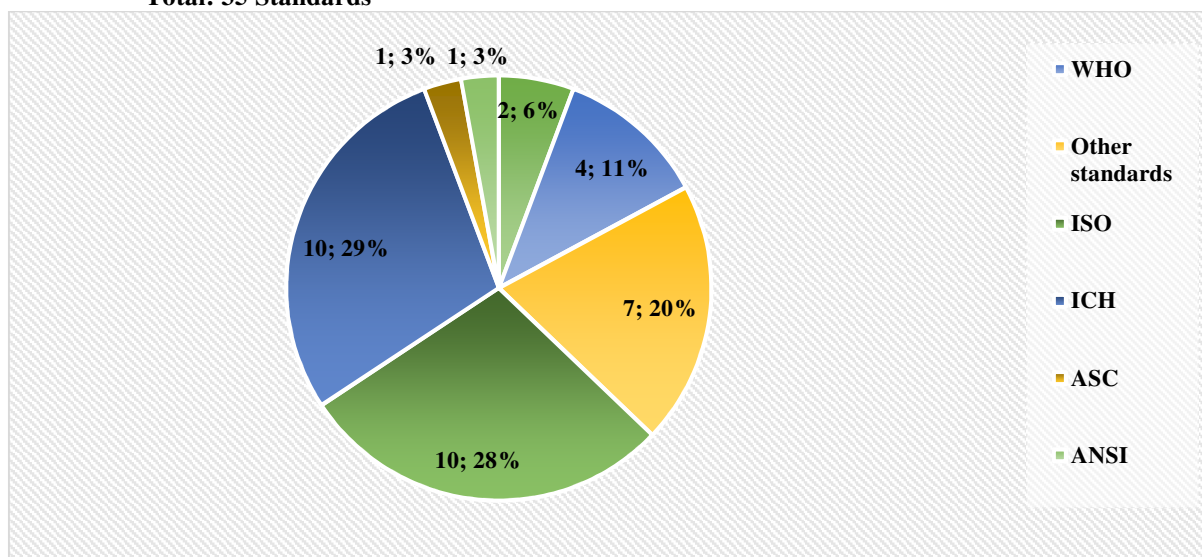
Regarding the use of supporting standards, it can be seen in figure 79 below that 67% of the technical regulations use supporting standards.

Figure 8-29 - Mexico - Pharmaceuticals: use of supporting standards
Total: 9 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Figure 8-30 - Mexico - Pharmaceuticals: types of supporting standards
Total: 35 Standards



Source: Secretaria da Economia. Elaborated by CCGI-EESP/FGV.

Mexican technical regulations on pharmacists refer predominantly to international standards. The standards and prescriptive documents produced by the International Organization for Standardization (ISO) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) stand out. ICH norms make a total of 29% of the technical regulations that use supporting standards, while ISSO norms make 28% and WHO norms are cited in 11% of the technical regulations that use supporting standards.¹⁵⁵

8.5.4. Conformity assessment and certification

The COFEPRIS (Federal Commission for the Protection against Sanitary Risk) is the competent authority for the exercise of the powers that correspond to the Ministry of Health in terms of regulation, control and health promotion of products and services. Their mission is to protect the population against health risks caused by the use and consumption of goods and services, health supplies, as well as exposure to environmental and labor factors, the occurrence of health emergencies and the provision of health services through regulation, control and prevention of health risks. The COFEPRIS will establish and implement policies, programs and projects at the level of the best international practice, in effective coordination with the different actors of the public, private and social sphere, to prevent and attend to health risks, thus contributing to the health of the population.

8.5.5. Main government and private actors

Beside the action of COFEPRIS, there are many private and public bodies involved in the issuing of technical regulations such as the: *Comisión Federal para la Protección contra Riesgos Sanitarios*, *Centro Nacional para la Salud de la Infancia y la Adolescencia*, the *Consejo de Salubridad General*, the *Instituto Nacional de Cancerología*, *Programa Institucional de Farmacovigilancia*, *Universidad Nacional Autónoma de México: Facultad de Química y Facultad de Medicina*, *Academia Nacional de Medicina de México*, *Asociación Farmacéutica Mexicana*, the *Asociación Mexicana de farmacovigilancia*, *Asociación Mexicana de Profesionales en Regulación Sanitaria*, *Asociación Nacional de Fabricantes de Medicamentos*, *Asociación mexicana de industrias de investigación farmacéutica*.

¹⁵⁵ The list of regulation is in [appendix 3.C](#).

9. Colombia

Section III of the project will analyze some important sectors of the Brazilian industry to verify the degree of convergence among the regulatory framework of these sectors and their similar in other South-American partners. Non-compatible rules among countries can represent important barriers to trade.

9.1. The automotive and auto-parts sector in Colombia

9.1.1. Overview

The trade of vehicles and auto parts is quite relevant in the commercial relations between Brazil and Colombia, although it presents a great imbalance in favor of Brazil. Colombia has a significant deficit both in the trade of whole vehicles and in the exchange of auto parts. This imbalance reflects the degree of development and diversification of the automobile industry in both countries. As it can be seen in table 4, the imports from Colombia in the automotive sector are practically negligible regarding the trade of vehicles and have little expression in the trade of auto parts. Brazil has a much more developed automotive complex and is able therefore to keep a huge surplus in the bilateral trade. The Brazilian exports, adding the trade of vehicles and auto parts, started at US\$ 292,3 million in 2014 and finished at US\$ 433,2 in 2018, which represents an increase of 48,2% during the period.

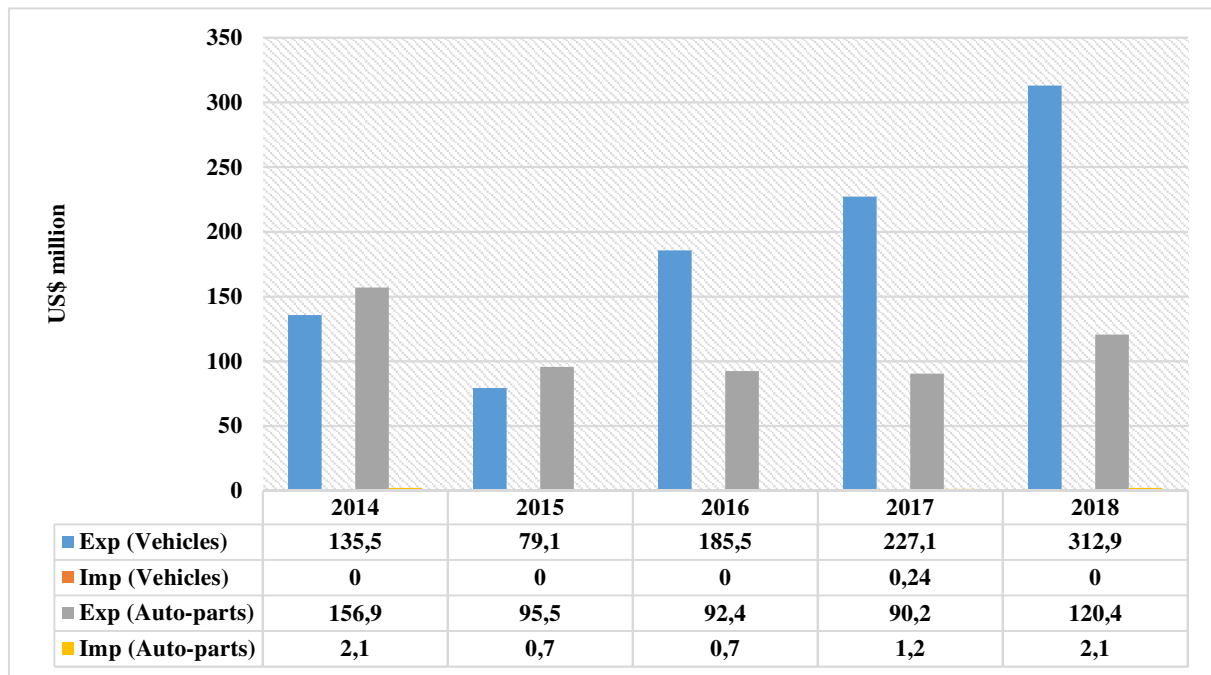
Table 9.1 - Automotive trade between Brazil and Colombia (US\$ million)

Year	Vehicles		Auto parts		Total	
	Exports	Imports	Exports	Imports	Exports	Imports
2014	135,5	0	156,9	2,1	292,3	2,1
2015	79,1	0	95,5	0,7	174,5	95,4
2016	185,5	0	92,4	0,7	277,9	0,6
2017	227,1	0,240	90,2	1,2	317,2	1,3
2018	312,9	0	120,4	2,1	433,2	2,1

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

As can be seen in the table below, Brazilian exports to the Colombian market far outweigh imports. In 2018, for example, Brazil exported more than US\$ 300 billion in whole vehicles and more than 120 million in auto parts for the neighboring country.

Figure 9-1 - Automotive Bilateral Trade (Brazil→Colombia) (US\$ million)



Source: ComexStat. Elaborated by CCGI-EESP/FGV.

9.1.2. Main regulatory authorities

At the present time, tariffs are not import barriers between Brazil and Colombia. The point in question is whether regulatory barriers are present in this market for Brazil.

In Colombia, the ministries that are competent to regulate the automotive sector are the Ministry of the Environment and Sustainable Development¹⁵⁶, the Ministry of Trade, Industry and Tourism¹⁵⁷ and the Ministry of Transport¹⁵⁸.

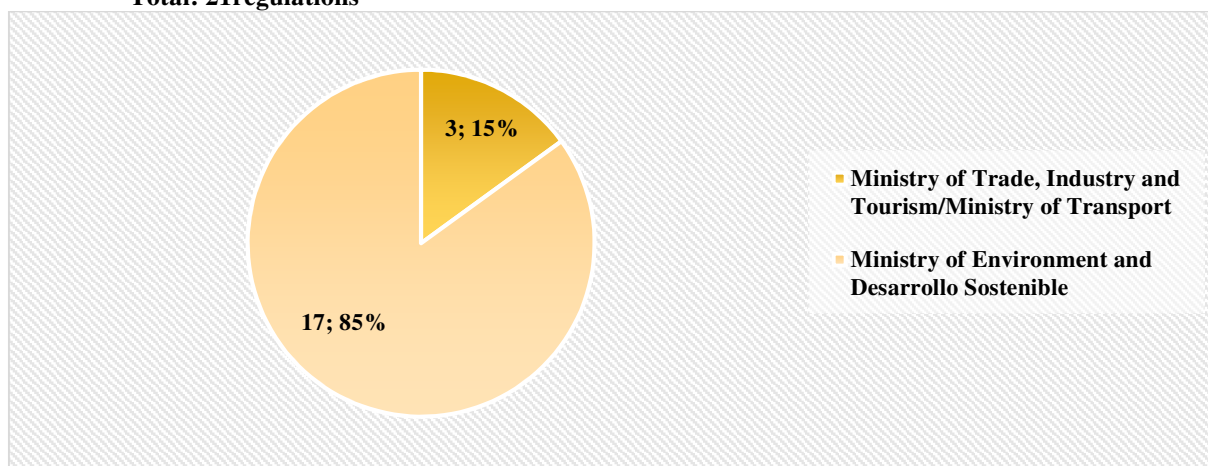
This research identified 21 important regulations related to the automotive sector in Colombia.

¹⁵⁶ See <http://www.minambiente.gov.co/>

¹⁵⁷ More details in <http://www.mincit.gov.co/>

¹⁵⁸ See: <https://www.mintransporte.gov.co/>

Figure 9-2 - Colombia Automotive Sector - Regulatory activity of the main authorities
Total: 21 regulations



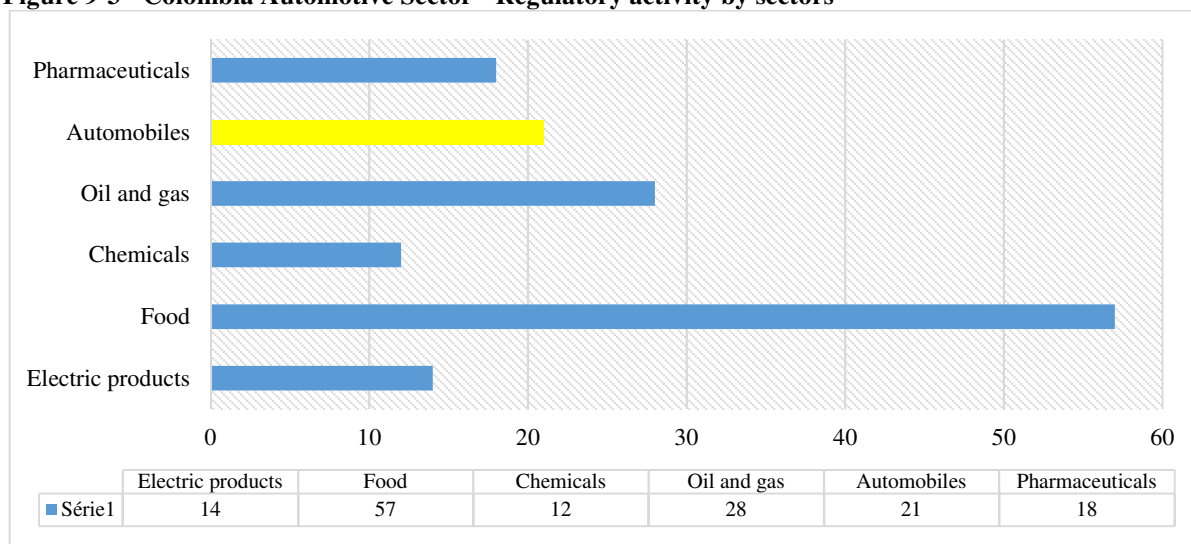
Source: ComexStat. Elaborated by CCGI-EESP/FGV.

As can be seen from the above graph, the Colombian technical regulations are edited through singular or joint action of the ministries. In the case of automobiles, the Ministry of the Environment and Sustainable Development (*Ministerio de Medio Ambiente y Desarrollo Sostenible*) is responsible for editing about 85% of the technical regulations, most of which are related to atmospheric pollutant emission levels.

9.1.3. Technical regulations, standards and supporting standards

For the automotive sector, 21 technical regulations in force in Colombia were identified. Compared with other sectors, the vehicles sector presents moderate degree of regulatory intervention in Colombia.

Figure 9-3 - Colombia Automotive Sector - Regulatory activity by sectors

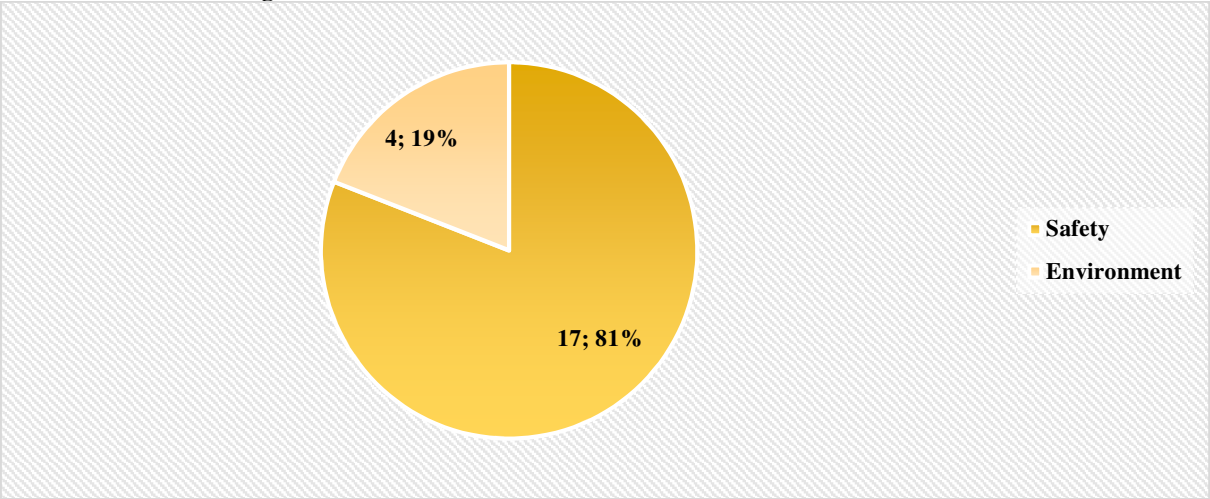


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The main themes inserted on technical regulations of the automotive sector are permissible levels of emission of pollutants, equipment and procedures for measuring said emissions retroreflective tapes for use in motor vehicles and their trailers, brake systems, safety belts and

security glazing resistant to bullets. If grouped into two major themes, environment and safety, the technical regulations have the following distribution:

Figure 9-4 - Colombia - Automotive Sector: object of technical regulation
Total: 21 regulations

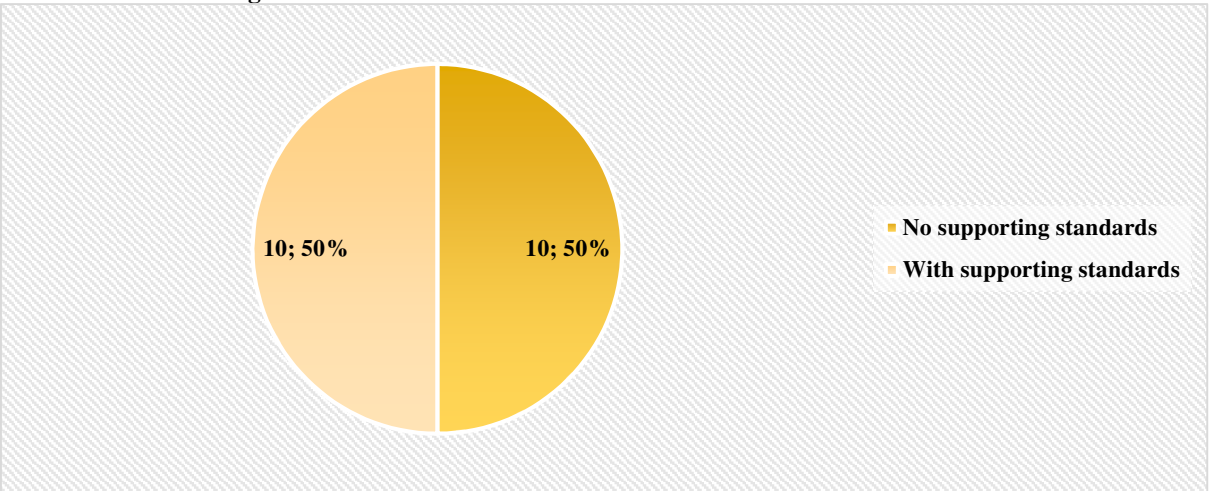


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

As it can be seen in figure 7 regarding the object of technical regulations, 81% of them are about safety and 19% of them are about environment.

Half of the Colombian technical regulations do not use international technical standards of support, a characteristic that makes it difficult to ascertain the compatibility of these rules with international standards. However, the low degree of regulatory intervention in the sector, evidenced by the small number of technical regulations, mitigates possible problems for international trade resulting from the country's regulatory activity.

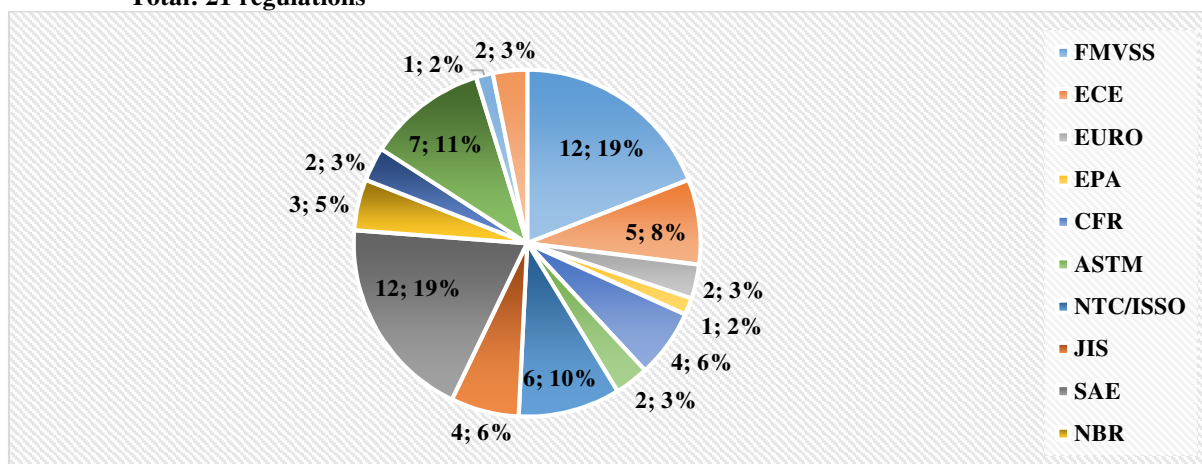
Figure 9-5 - Colombia - Automotive Sector: use of supporting standards
Total: 21 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The standards mentioned in the Colombian technical regulations of vehicles have quite varied origin. International standards are used alongside Colombian standards and foreign and sectoral standards.

Figure 9-6 - Colombia - Automotive Sector: types of supporting standards
Total: 21 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Despite this great variety of technical norms, there is the predominance of sectorial norms of North-American origin such as the norms of the Federal Motor Vehicle Safety Standards (FMVSS) and the Society of Automotive Engineers (SAE). The FMVSS are used in 19% of the regulations that use supporting standards, the same percentage as SAE norms. NTC/ISSO norms are present in 10 % of the technical regulations that require supporting standards, while UL norms are cited in 11% and NTC/ISO norms are present in 10% of the technical regulations that require supporting standards.¹⁵⁹

9.1.4. Conformity assessment and certification

The recent rise of the total number of vehicles, which generated a great demand for automotive services and considerable rise of the number of new drivers was one of the causes of the increase of conformity assessment bodies. The Supervisory Authority for Industry and Trade (SIC) is competent to monitor compliance with technical regulations in the following areas: reflective tape for motor vehicles and, in transport, products such as public service vehicles, safety belts, safety windows, braking systems and tires. The installation of components in vehicles converted to vehicular compressed natural gas (GNCV) is also certified according to MINCIT resolution 957/2012 and its modifying resolution 2881/2014. This certification aims to achieve the respective gas supply in different service stations and to guarantee that the facility complies minimum safety requisites. On a regional level, Colombian automotive associations integrate the Evaluation Program of New Vehicles for Latin America and the Caribbean (*Programa de Evaluación de Vehículos Nuevos para América Latina y el Caribe - Latin NCAP*)¹⁶⁰, a system that provides to consumers independent and transparent information about the safety levels offered by different models of vehicles in the market.

9.1.5. Main government and private actors

The main government actors are the aforementioned ministries and management entities. The main private actors are the National Association of Sustainable Mobility (*Asociación Nacional*

¹⁵⁹ The list of regulation is in [appendix 1](#).

¹⁶⁰ See: <https://www.latinncap.com/es/>

de Movilidad Sostenible - ANDEMOS)¹⁶¹ and the Automobile Club of Colombia (*Automóvil Club de Colombia* - ACC)¹⁶².

9.2. Electric products in Colombia

9.2.1. Overview

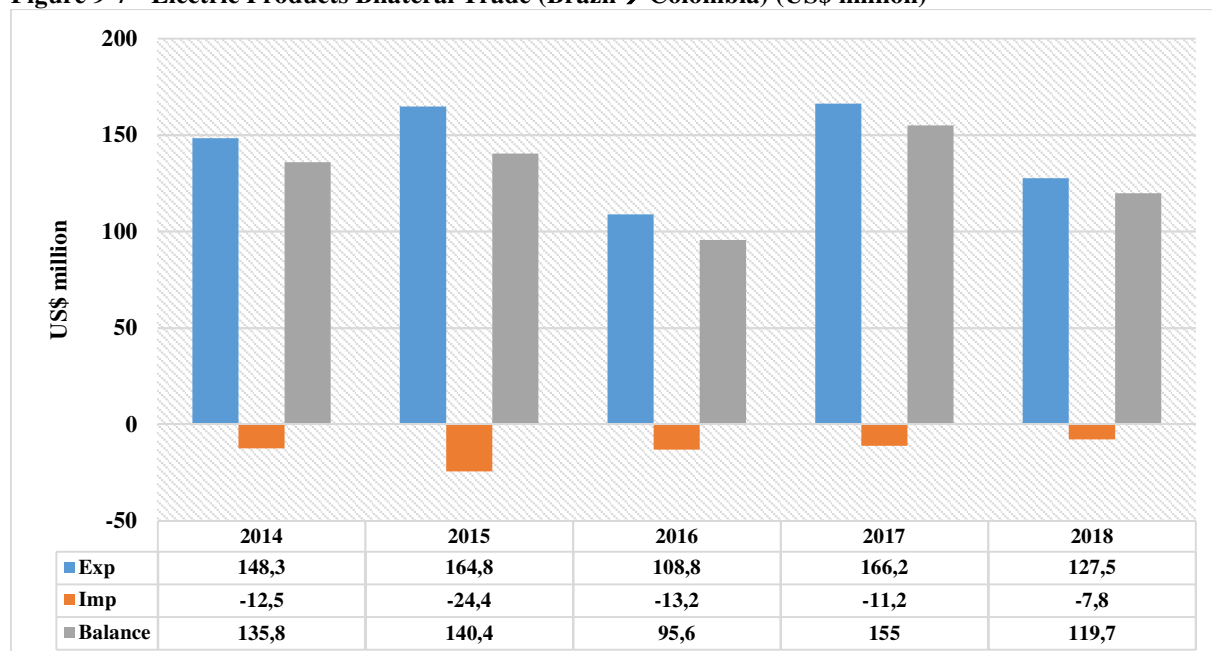
The trade balance between Brazil and Colombia reveals that the first country holds a significant surplus on the electric products' sector on the five years analyzed and that the total trade volume has oscillated from US\$ 122 million to US\$ 189 million on the period analyzed. The exports from Brazil were US\$ 148.3 million in 2014 and US\$ 127,5 million in 2018, which indicates a decrease of 14% in the value traded in the period. The imports from Colombia went from US\$ 12.5 million in 2014 to US\$ 7.8 million in 2018, which indicates a decrease of 37.6 %. The sector had overall a decrease of the trade flow going from around US\$ 161 million in 2014 to US\$ 135.3 million in 2018, a reduction of 16%.

Table 9.2 - Electric products trade between Brazil and Colombia (US\$ million)

Year	Total	
	Exports	Imports
2014	148.3	12.5
2015	164.8	24.4
2016	108.8	13.2
2017	166.2	11.2
2018	127.5	7.8

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

Figure 9-7 - Electric Products Bilateral Trade (Brazil→ Colombia) (US\$ million)



Source: ComexStat. Elaborated by CCGI-EESP/FGV.

¹⁶¹ See: <https://www.andemos.org/>

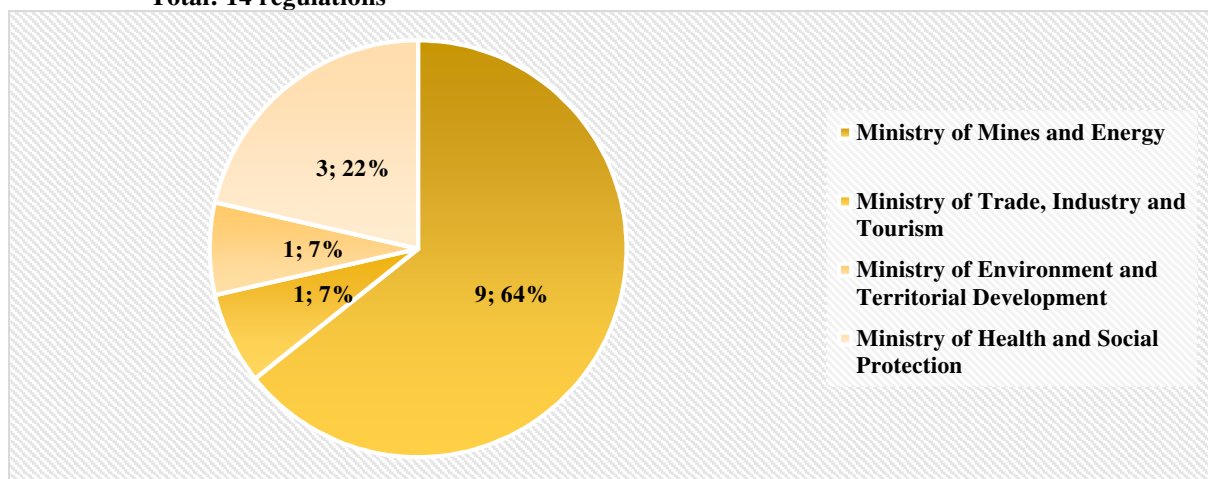
¹⁶² See <https://acc.com.co/p/quienes-somos>

9.2.2. Technical Regulation - Main authorities

At the present time, tariffs are not import barriers between Brazil and Colombia. The point in question is whether regulatory barriers are present in this market for Brazil. This research identified a total of 14 regulations related to the sector.

The most important authorities that regulate the sector are the Ministry of the Environment and Territorial Development; the Ministry of Health and Social Protection; the Ministry of Mines and Energy and the Ministry of Trade, Industry and Tourism. As it can be seen in figure 11, the Ministry of Mines and Energy corresponds to 64% of the technical regulations, while the Ministry of Health and Social protection issued 22% of the regulations and both the Ministry of Environment and Territorial development and the Ministry of Trade, Industry and Tourism issued 7% of the technical regulations.

Figure 9-8 - Colombia - Electric Products: Regulatory activity of the main authorities
Total: 14 regulations



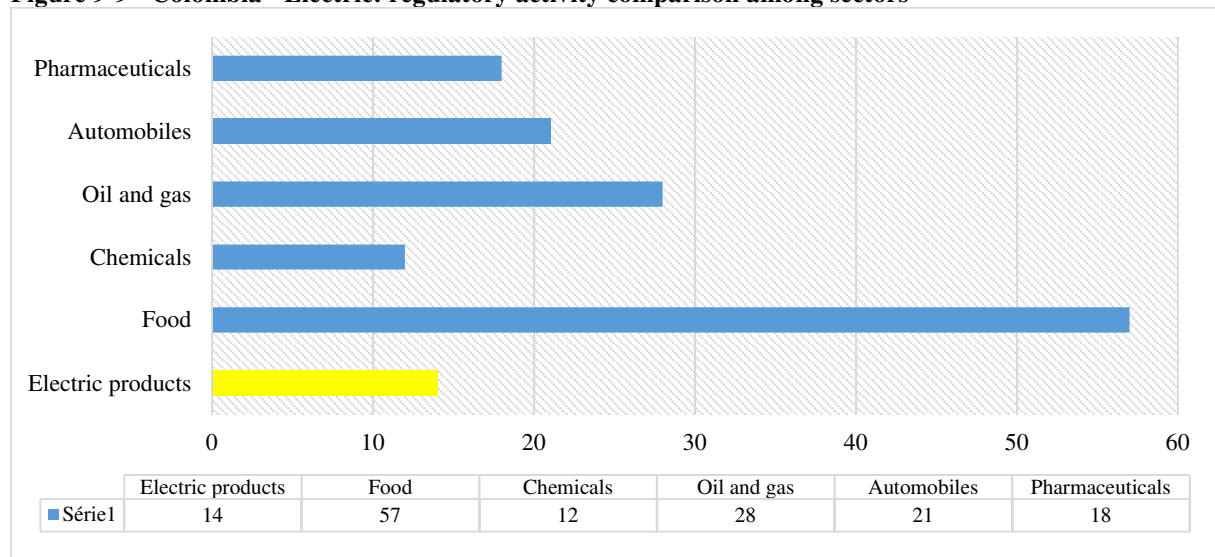
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

The Mines and Energy Ministry is the main regulatory authority in the electrical products and equities sector. Most technical regulations do not deal with products that are used directly by the consumer, but rather for business use.

9.2.3. Technical regulations, standards and supporting standards

For the electric products sector, there are 14 regulations in force in Colombia. Compared with other sectors, the electric products sector presents low degree of regulatory intervention in Colombia.

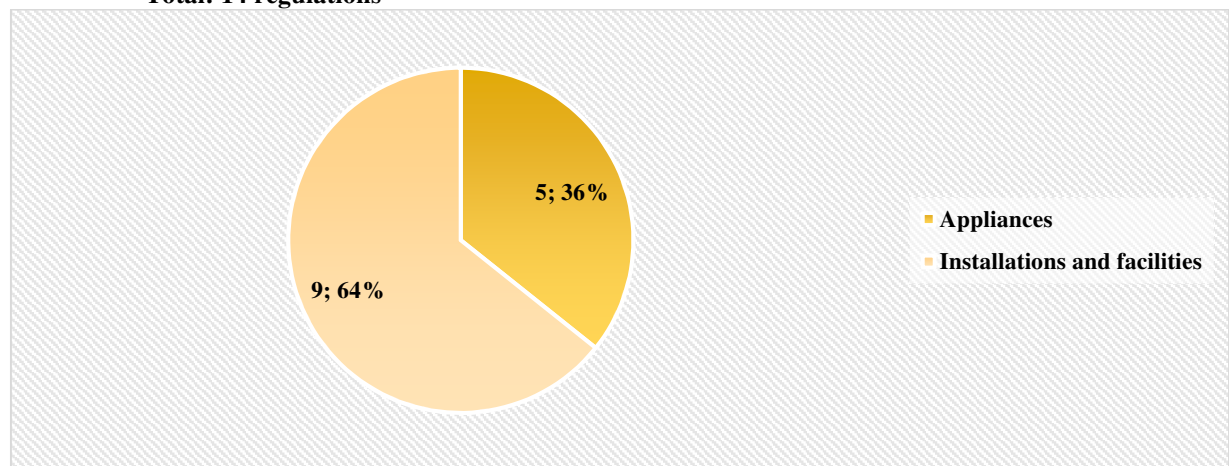
Figure 9-9 - Colombia - Electric: regulatory activity comparison among sectors



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

The main topics foreseen on technical regulations of the electric products sector are electrical facilities, refrigerators, freezers, refrigerator-freezer combinations, storage capacity requirements and/or conditioning for medical devices, sanitary registration or marketing permit of medical devices and electrical installations. If grouped into two major themes, appliances and installations, the technical regulations have the following distribution:

Figure 9-10 - Colombia - Electric Products: object of technical regulation
Total: 14 regulations

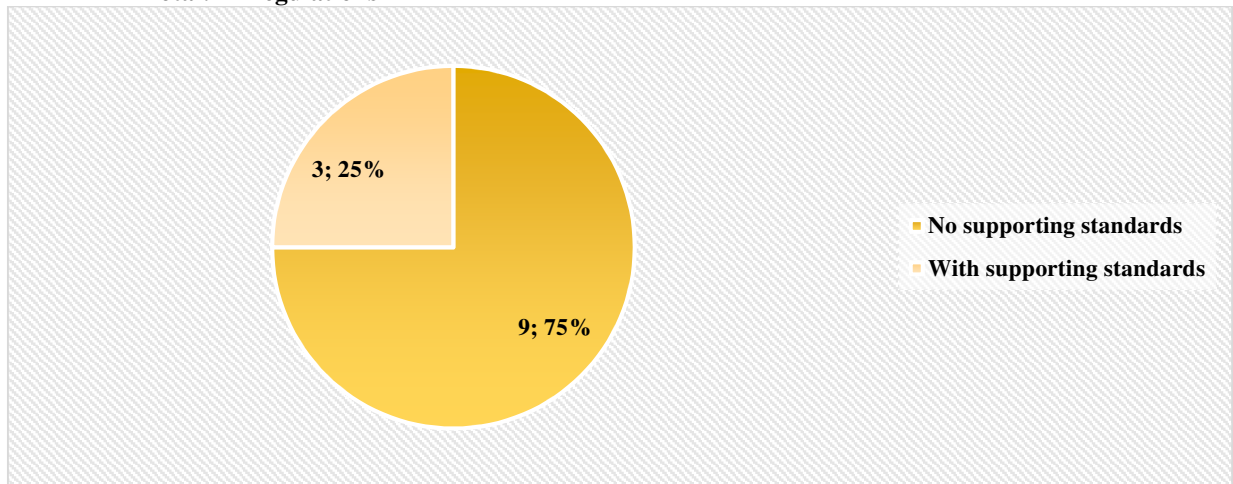


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

In figure 13, it can be seen that the theme of installations and facilities are present in 64 % of the regulations, while the theme of Appliances are present in 36% of the regulations.

Most of the technical regulations regarding electrical products do not mention technical support standards. In fact, if considered a set of regulations of the sector, it is verified that the sector is very little regulated in Colombia, mainly in what concerns to the dimension of equipment and electrical apparatuses. The use of international supporting standards is present in only 25% of the technical regulations.

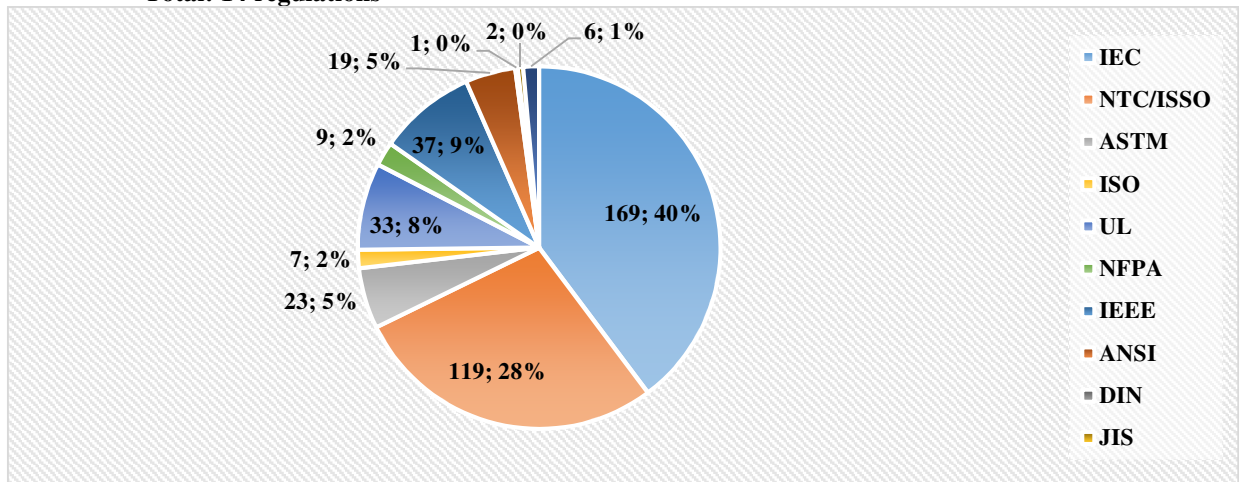
Figure 9-11 - Colombia - Electric Products: use of supporting standards
Total: 12 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The standards mentioned in the Colombian technical regulations of electrical products have quite varied origin. International standards are used alongside Colombian standards and foreign and sectoral standards, as showed in the following figure:

Figure 9-12 - Colombia - Electric products: types of supporting standards used in Colombia
Total: 14 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

A wide variety of technical standards are used in the Colombian technical regulations on electrical products. The most mentioned standards are IEC standards, followed by Colombian technical standards. The US industry standards, especially ASTM, UL and IEEE, are relevant, especially if taken together.¹⁶³

9.2.4. Conformity assessment and certification

In Colombia, Intertek performs certification of electrical installations to demonstrate their conformity. Through its accreditation for product certification granted by ONAC supports companies of the electric industry to demonstrate the conformity of their products according to

¹⁶³ The list of regulation of electric products is in [appendix 1](#).

the quality standards foreseen on resolution 180398/2004. The institution acts through laboratory tests, auditing and/or inspection of products. The General Society of Oversight (*Société Générale de Surveillance* - SGS) is also a certifier of the electrical security of a product. The approved candidates for the safety certification of products can use the SGS safety mark of a product, which demonstrates that the product complies with the relevant product safety requirements, applicable in the target market.

9.2.5. Main government and private actors

The main government actors for the sector are the aforementioned ministries. The main private actors for the sector are National of Electric (*Nacional de Eléctricos*) and Electric Networks (*Redes Eléctricas S.A.*).

9.3. Food sector in Colombia

9.3.1. Overview

The trade balance between Brazil and Colombia shows that the first country holds a surplus on the food sector on the five years analyzed and that the total trade volume has continuously increased on the period analyzed. The exports from Brazil went from around US\$ 130 million in 2014 to US\$ 223,8 million in 2018, indicating a substantial increase of 72%. The imports from Colombia also have grown substantially from US\$ 31,6 million in 2014 to US\$ 97,1 million in 2018, an increase of 207 %. Brazil managed to keep trade surpluses during the whole period, from US\$ 98,3 million in 2014 to US\$ 126,7 million in 2018, which indicates an increase of around 29% in the trade surplus favoring Brazil.

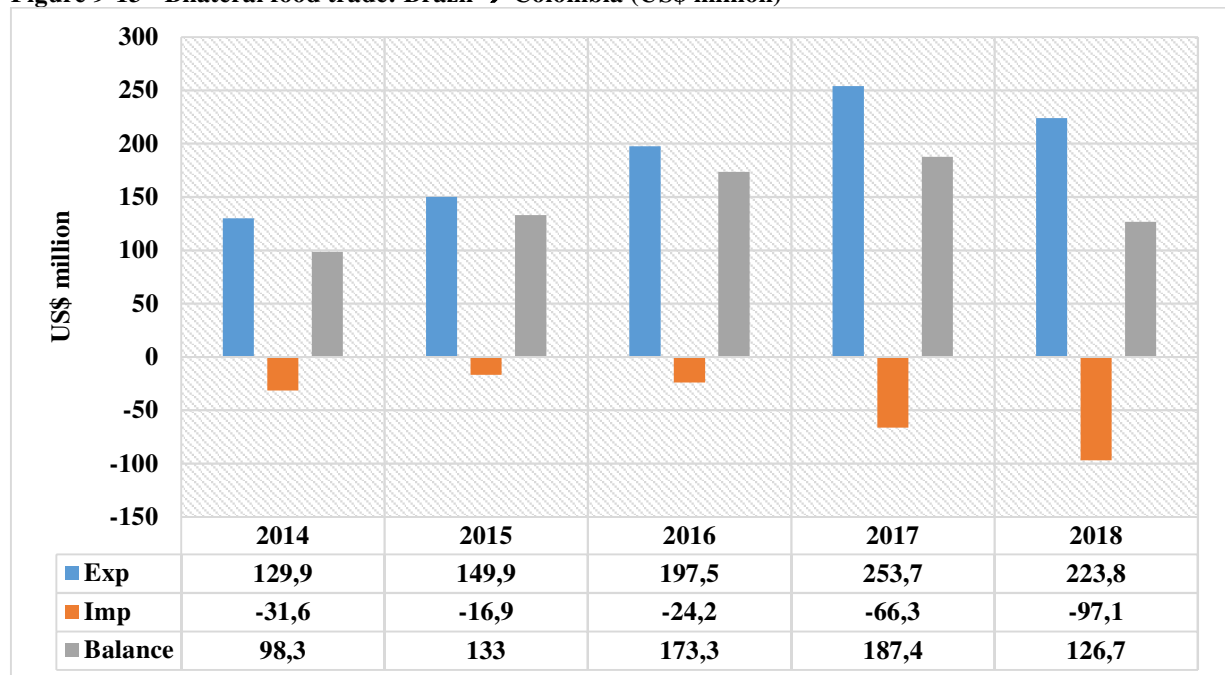
Table 9.3 - Food trade between Brazil and Colombia (US\$ million)

Year	Total	
	Exports	Imports
2014	129,9	31,6
2015	149,3	16,9
2016	197,5	24,2
2017	253,7	66,3
2018	223,8	97,1

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In figure 9-13, it is possible to observe the evolution of the bilateral trade:

Figure 9-13 - Bilateral food trade: Brazil → Colombia (US\$ million)

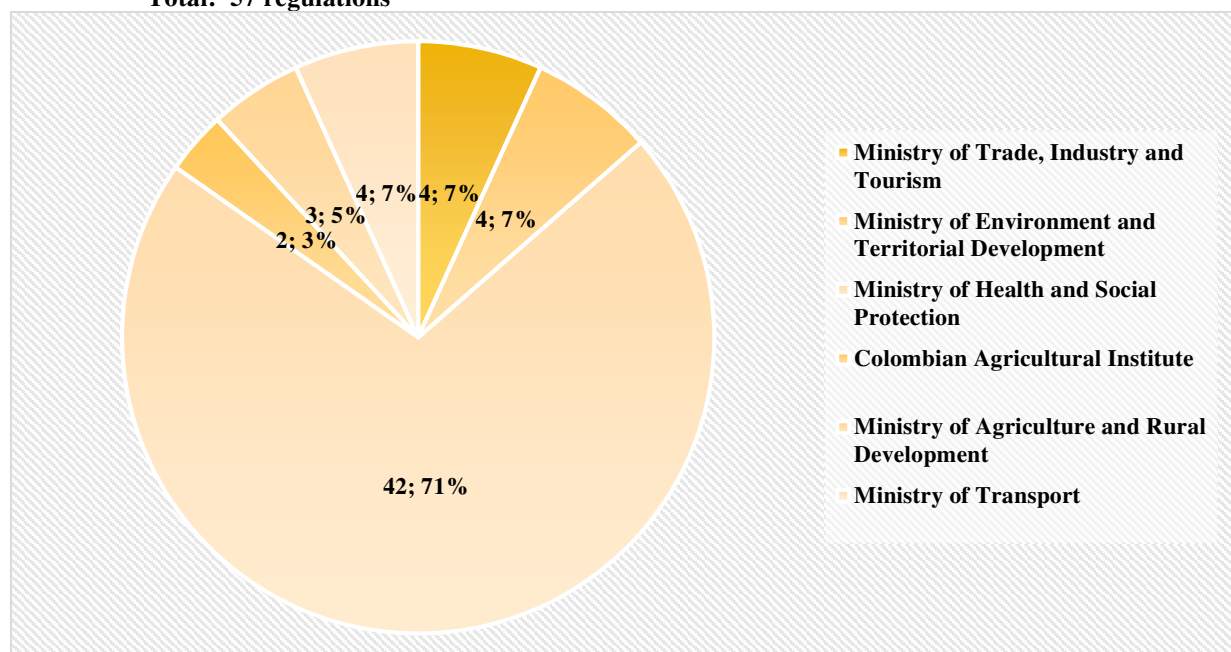


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

9.3.2. Technical Regulations: main authorities

This research identified 57 regulations related to the sector. The main authorities that regulate the sector are the Colombian Agricultural Institute, the Ministry of Agriculture and Rural Development, the Ministry of the Environment and Sustainable Development, the Ministry of Health and Social Protection, the Ministry of Trade, Industry and Tourism and the Ministry of Transport. Under the ministries, management entities (*direcciones*) are competent to lead the process of design of the bill.

Figure 9-14 - Colombia - Food: regulatory activity of the main authorities
Total: 57 regulations



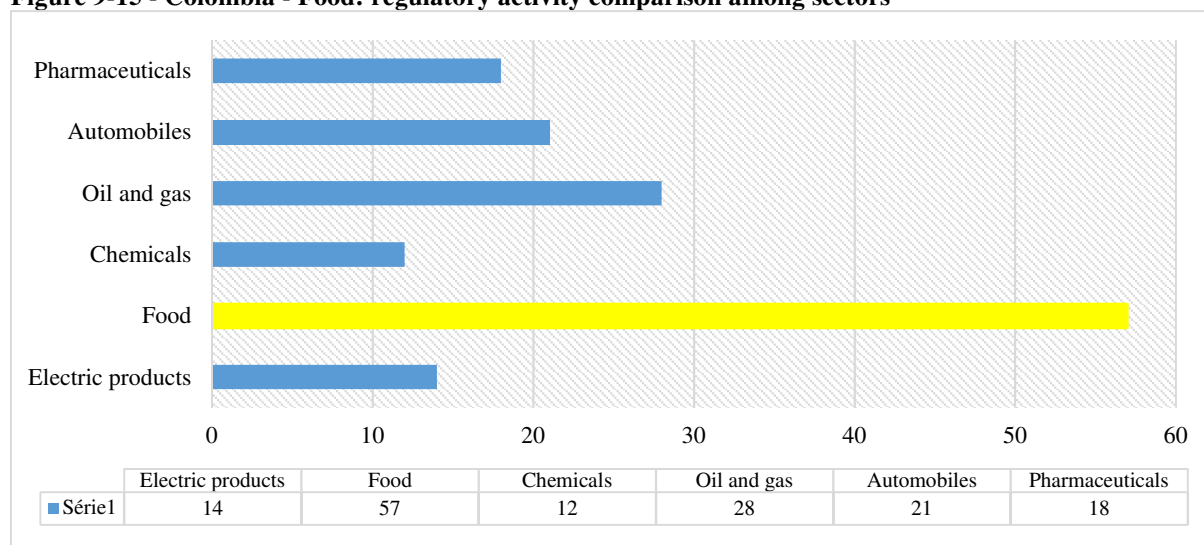
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP-FGV.

In the matter of food, several organs of the central administration and decentralized bodies have a regulatory function. The Ministry of Health and Social Protection is the body that edits the largest number of technical regulations, as observed in the chart above.

9.3.3. Technical regulations, standards and supporting standards

For the food sector, there are 57 regulations in force in Colombia. Compared with other sectors, the food products sector presents very high degree of regulatory intervention in Colombia.

Figure 9-15 - Colombia - Food: regulatory activity comparison among sectors

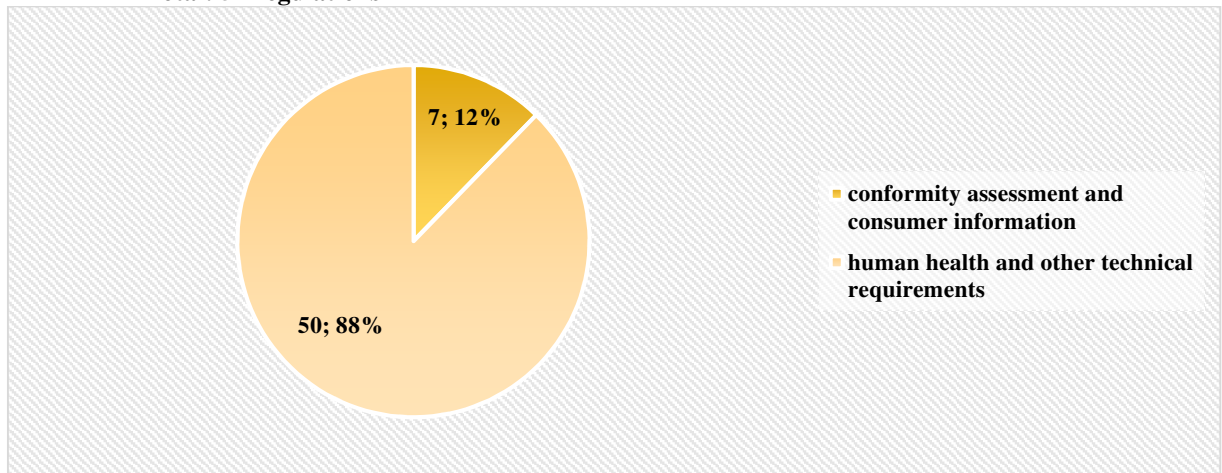


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

The main themes inserted on technical regulations of the food sector are production and processing of food and beverages; requirements to be met by certain food; inspection, surveillance and control procedures; manufacture, processing, packaging, labeling, stripping, storage, transport, sale, import and export of food; sanitary registration, sanitary requirements, quality control, sanitary surveillance and sanitary control of food and requirements to be met by materials in contact with food and beverages.

If grouped into two major themes - conformity assessment and consumer information (group 1), and human health and other technical requirements (group 2) - the technical regulations have the following distribution:

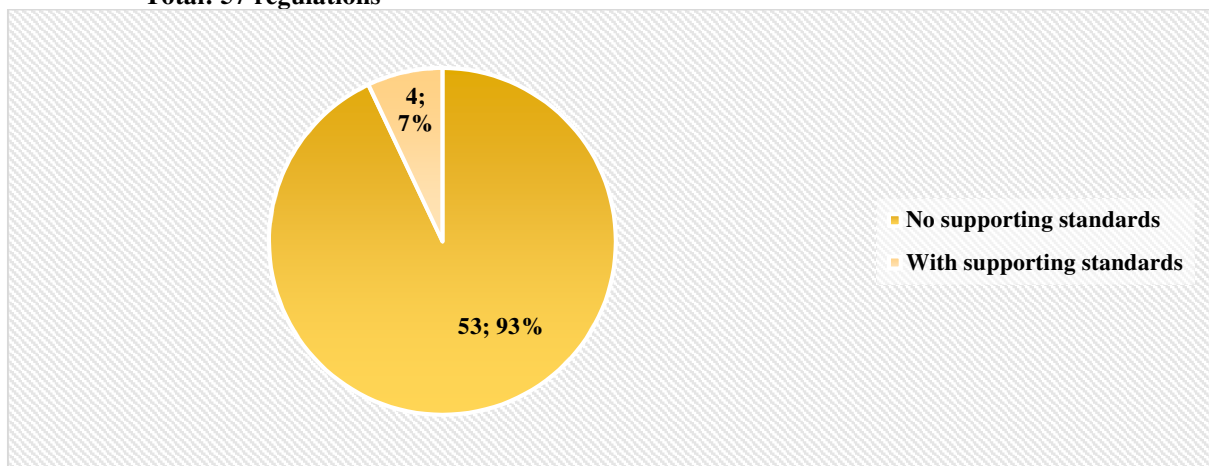
Figure 9-16 - Colombia - Food: object of technical regulation
Total: 57 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

Most of the technical regulations on food products deal with aspects related to human health, as observed in the figure above. This is generally a sensitive issue and requires mandatory rules issued by state authorities.

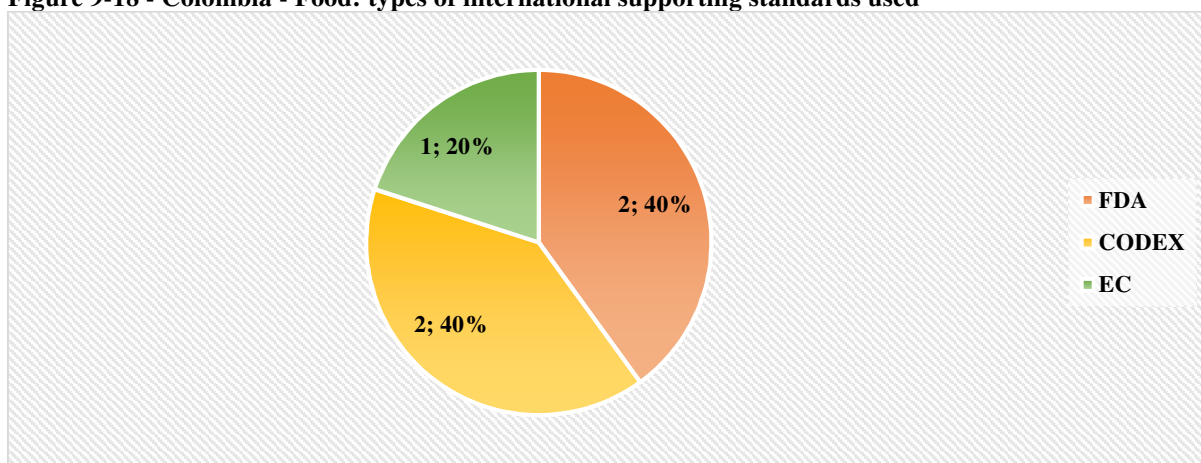
Figure 9-17 - Colombia - Food: use of supporting standards
Total: 57 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

It is not very frequent to mention international technical standards under Colombian technical regulations for food. Most of these rules are built without reference to international support standards. This characteristic, however, does not necessarily indicate a contradiction with some international norm, which, in the absence of support norms, would increase the international prescriptive mismatch and may represent regulatory barriers to trade.

Figure 9-18 - Colombia - Food: types of international supporting standards used



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The few technical standards referred to in the technical regulations are more phytosanitary standards than rules on technical barriers to trade. It is worth noting the Codex standards and those produced by the FDA, the US agency.¹⁶⁴

9.3.4. Conformity assessment and certification

Calibration is a conformity assessment procedure applied to food that consists on the establishment of a comparative relation, in specific conditions, between the values obtained and the corresponding values of the same magnitude indicated by standards. The General Society of Oversight (*Société Générale de Surveillance* - SGS), in a similar manner, performs the certification of food safety and quality. The main advantages arising from this certification are an independent standard to evaluate quality attributes of the product, a quality protection that is shown on products of certified quality centers and the application of the methodology Codex APPCC to identify and control dangers to food quality and safety. In its sphere of competence, the National Food and Drug Surveillance Institute (INVIMA) has accreditation powers.

9.3.5. Main government and private actors

The main government actors for the sector are the aforementioned ministries and the Colombian Agricultural Institute.

The main private actors for the sector are the Association of Food Banks of Colombia (*Asociación de Bancos de Alimentos de Colombia* - ABACO)¹⁶⁵ and the Colombian Association of Science and Technology of Food (*Asociación Colombiana de Ciencia y Tecnología de Alimentos* - ACTA)¹⁶⁶.

¹⁶⁴ The full list of regulation is in [appendix 1](#).

¹⁶⁵ See: <https://www.bancosdealimentosdecolombia.com/>

¹⁶⁶ See: <https://portal.acta.org.co/alimentos-acta/>

9.4. Oil and gas in Colombia

9.4.1. Overview

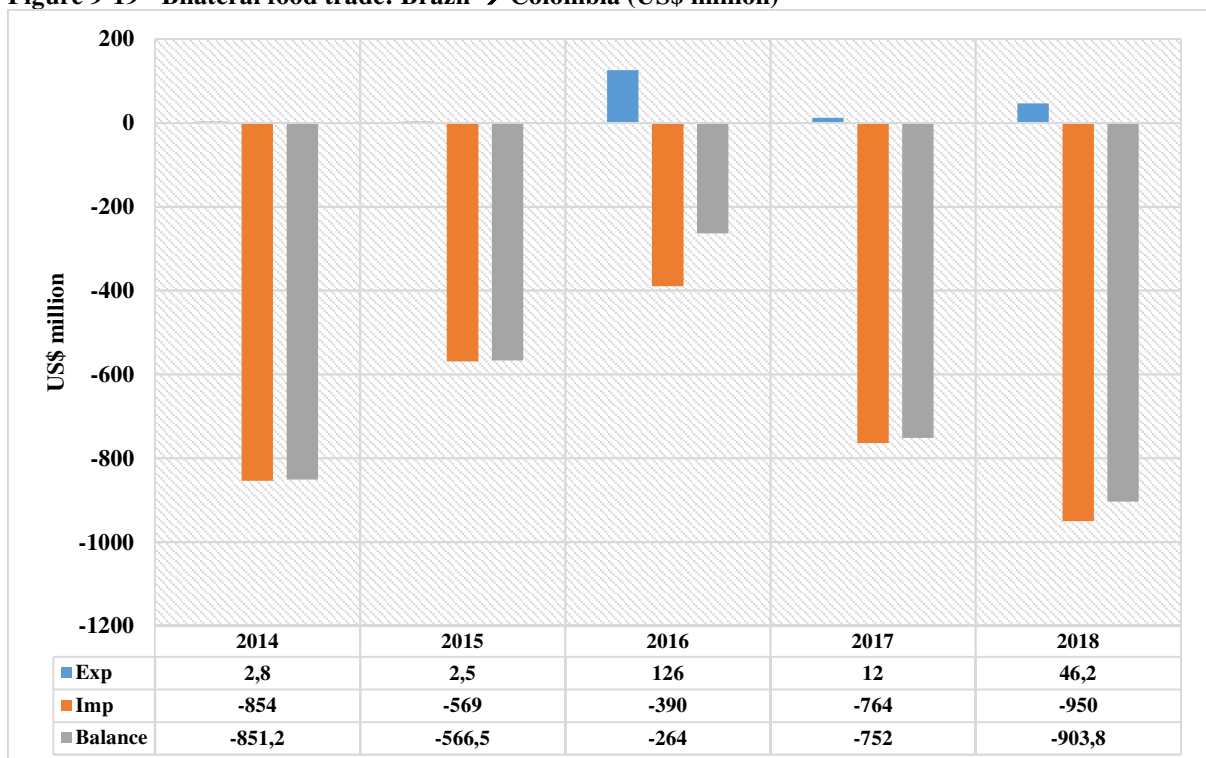
The trade balance between Brazil and Colombia reveals that the first country holds a deficit on oil and gas since 2017 and that the total trade volume has largely oscillated on the analyzed period from US\$ 2,2 million to US\$ 133 million. The Brazilian exports have fluctuated a lot during the period starting at US\$ 2,8 million in 2014, reaching a peak in 2016 of around US\$ 127 million and ending with US\$ 46 million in 2018. The imports from Colombia in this sector are much more significant in value, starting at 854 million in 2014 and ending with the value of 950 million, indicating an increase of approximately 11%.

Table 9.4 - Oil and gas trade between Brazil and Colombia (US\$)

Year	Total	
	Exports	Imports
2014	2.801.756	854.292.276
2015	2.555.358	569.047.534
2016	126.806.856	390.451.597
2017	12.181.619	764.668.320
2018	46.223.808	950.406.112

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

Figure 9-19 - Bilateral food trade: Brazil → Colombia (US\$ million)

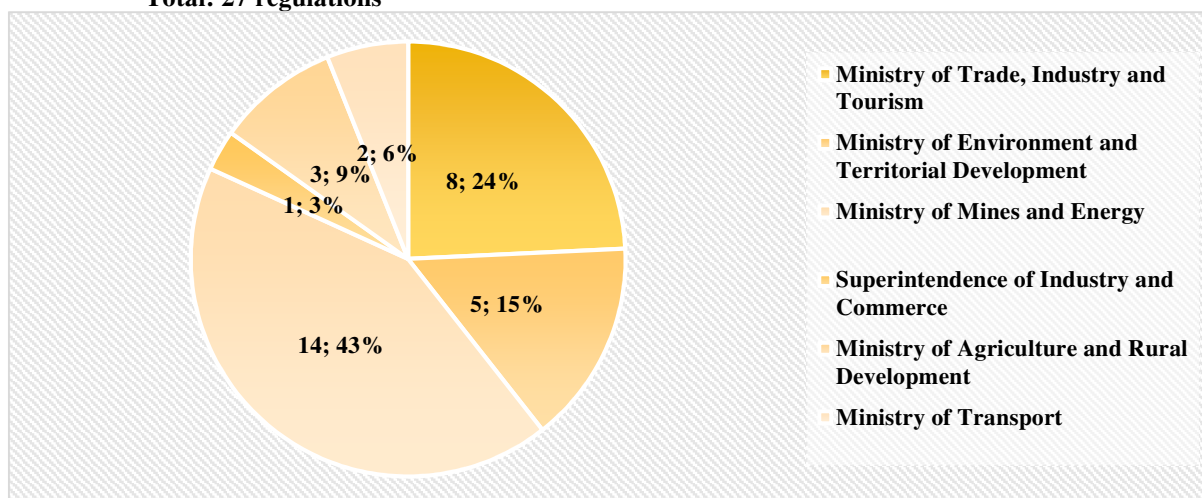


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

9.4.2. Main authorities

The main authorities that regulate the sector are the Ministry of the Environment and Sustainable Development; the Ministry of Mines and Energy; the Ministry of Trade, Industry and Tourism; the Ministry of Transport, ICONTEC and the Superintendence of Industry and Commerce (SIC).

Figure 9-20 - Colombia - Oil and Gas - Regulatory activity of the main authorities
Total: 27 regulations



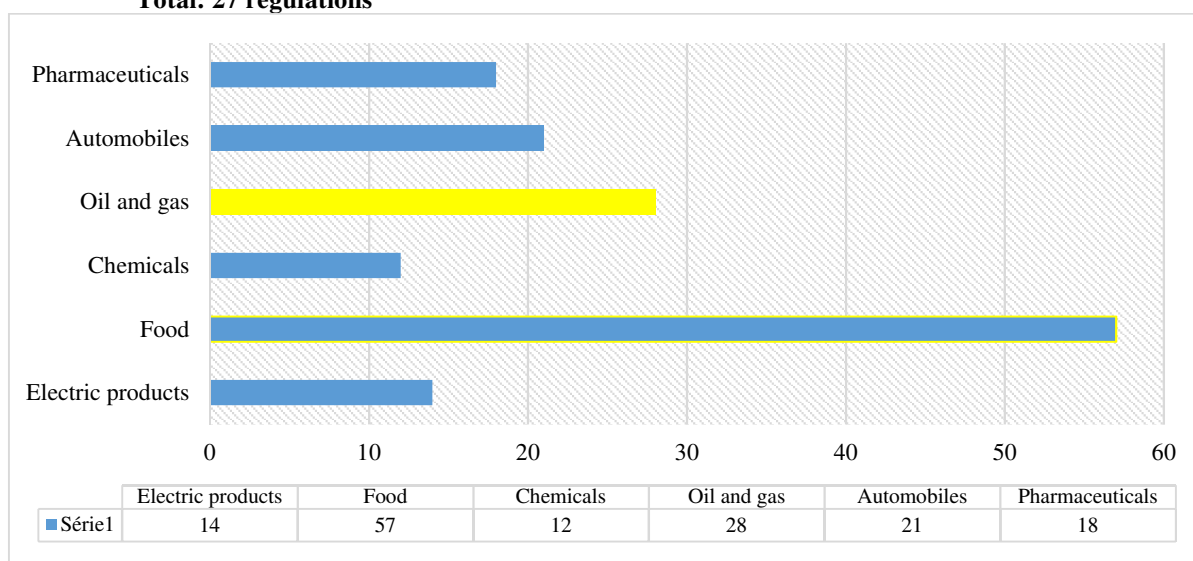
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP-FGV.

In the oil and gas sector, there is again a number of regulatory authorities. Certainly, the most relevant regulatory authority, a condition evidenced by the number of rules issued, is the Ministry of Mines and Energy.

9.4.3. Technical regulation, standards and supporting standards

In fuel and gas sector, there are 27 regulations in force in Colombia. Compared with other sectors, the products of gas and fuel sector presents high degree of regulatory intervention in Colombia.

Figure 9-21 - Colombia - Oil and Gas - Regulatory activity of the main authorities
Total: 27 regulations



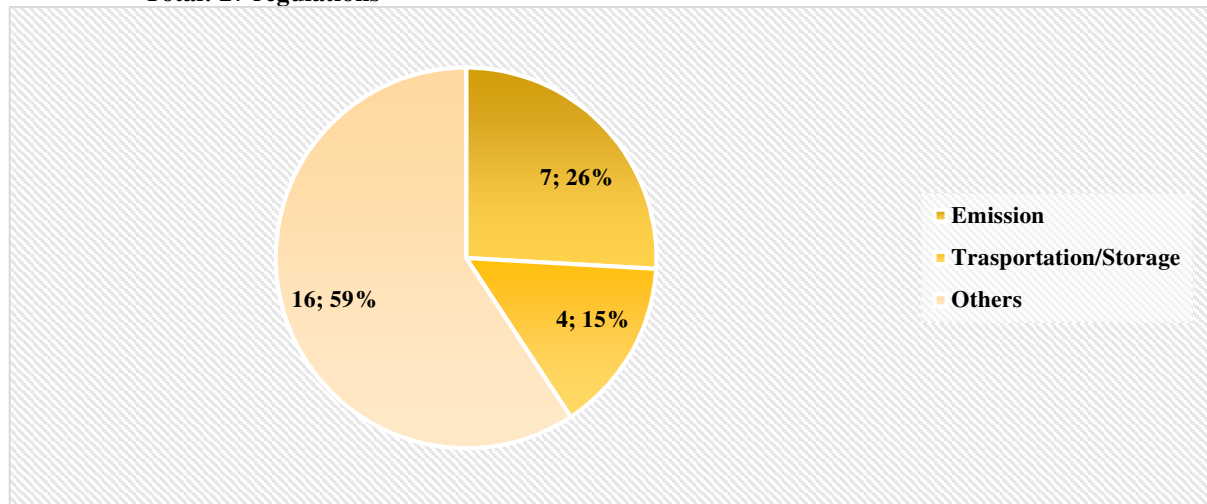
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

The main themes inserted on technical regulations of the oil and gas sector are gas-electrics, cylinders and stationary tanks, internal facilities of fuel gas, equipment and processes of

conversion by compressed natural gas, stations for the supply of compressed natural gas for vehicular use, stamp and labeling of transportable cylinders, hydrocarbons, gas appliances, emission of pollutants and equipment, procedures to measure said emissions and production, storage, transport, distribution and mixing points of fuel.

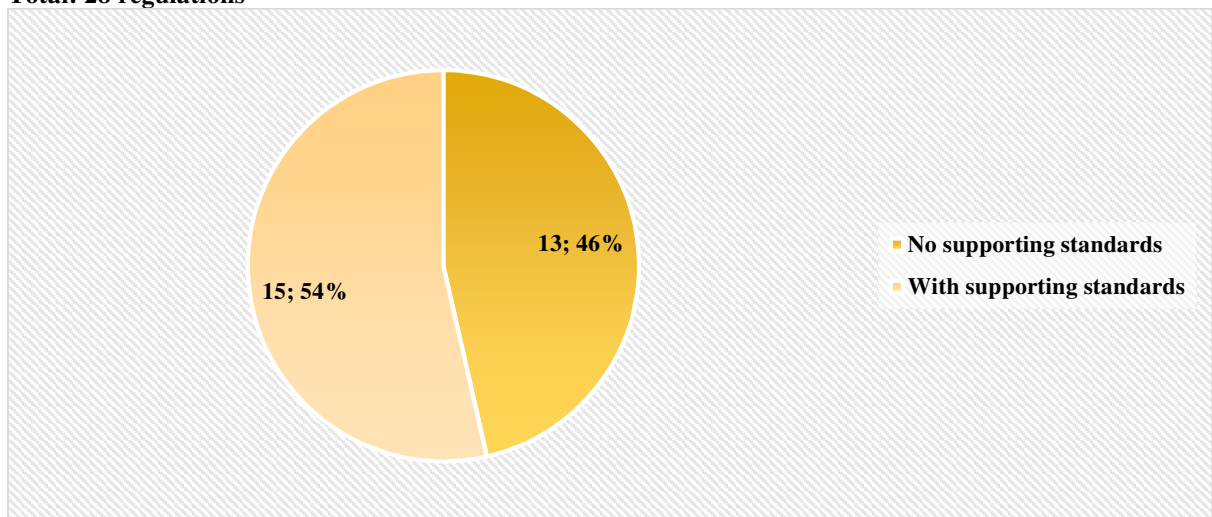
If grouped into three major themes - emission, transportation/storage, others - the technical regulations have the following distribution:

Figure 9-22 - Colombia - Oil and Gas: Object of technical regulation
Total: 27 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

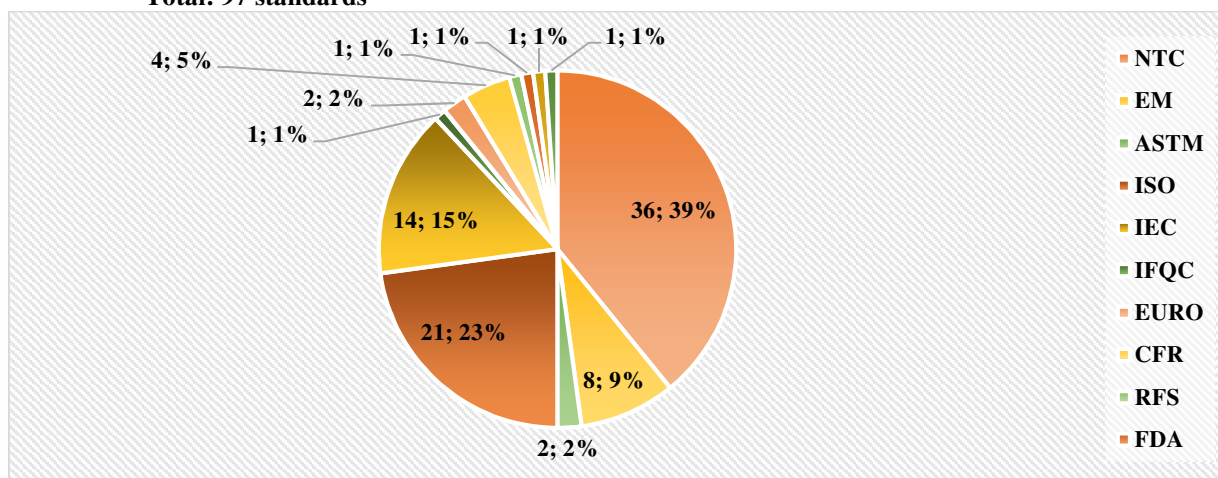
Figure 9-23 - Colombia - Oil and Gas: Use of supporting standards
Total: 28 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

It is relatively frequent to mention technical standards under Colombian technical regulations for oil and gas. The Colombian Technical regulations use a great variety of standards.

Figure 9-24 - Colombia - Oil and Gas: Types of supporting standards used
Total: 97 standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Although most of the technical standards used by the technical regulations of the sector are Colombian standards, there is a great variety of international standards - mainly ISO and IEC - and of sectoral standards of diverse origins should be highlighted.¹⁶⁷

9.4.4. Conformity assessment and certification

The main institution that performs conformity assessment activities on the sector are ICONTEC, SIC and the General Society of Oversight (*Société Générale de Surveillance* - SGS). ICONTEC certifies service stations that supply liquid fuels derived from oil through a procedure of evaluation of technical requisites foreseen on decree 1073/2015 of the Ministry of Mines and Energy. When the service station is in conformity with the technical requisites, it receives a conformity certificate that is valid for 3 years, during which there must be an annual follow-up and a renovation for more three years on the last year. SIC is responsible to monitor the compliance with technical regulations in the fields of vehicular natural gas (VNG) and household gas. SGS provides inspection, certification and verification of companies that participate on the exploration, extraction, refining, transport and trade of oil and gas.

9.4.5. Main government and private sectors

The main government actors for the sector are the ministries, the National Agency of Hydrocarbons (*Agencia Nacional de Hidrocarburos* - ANH)¹⁶⁸ and SIC.

The main private actor for the sector is the Colombian Association of Oil (*Asociación Colombiana del Petróleo* - ACP)¹⁶⁹ and ICONTEC.

¹⁶⁷ The full list of regulation is in [appendix 1](#).

¹⁶⁸ See: <http://www.anh.gov.co/Paginas/inicio/defaultANH.aspx>

¹⁶⁹ See: <https://acp.com.co/web2017/es/>

9.5. PHARMACEUTICALS IN COLOMBIA

9.5.1. Overview

In the last five years, the values of bilateral trade between Brazil and Colombia in pharmaceutical products oscillated between US\$ 75 million and US\$ 87 million. For Colombia, Brazil is a key origin of such products. The exports from Brazil have fluctuated starting at around US\$ 77 million in 2014 and ending at US\$ 70 million, which indicates a decrease in the total exported of approximately 10%. The imports from Colombia started at US\$ 9,4 million and ended at US\$ 5,3 million, indicating a decrease of 44% in the total imported value. Brazil has kept substantial trade surpluses during the period, from US\$ 68 million in 2014 to US\$ 64 million in 2018, a decrease of approximately 6%.

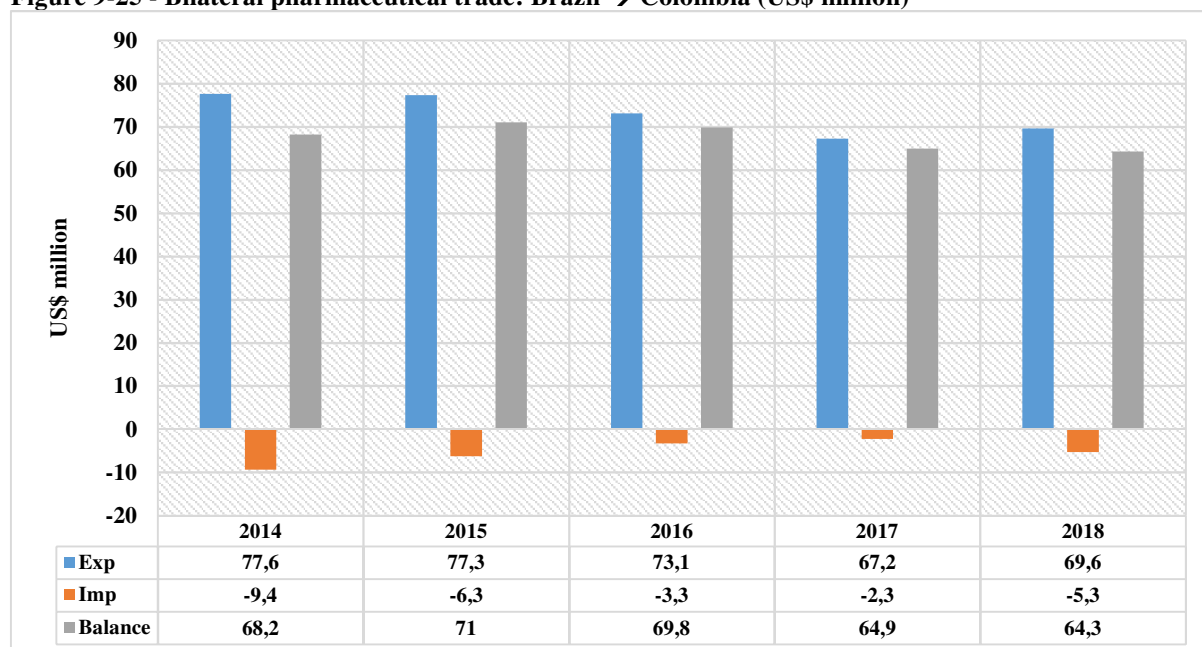
Table 9.5 - Pharmaceuticals trade between Brazil and Colombia (US\$)

Year	Total	
	Exports	Imports
2014	77.589.228	9.404.283
2015	77.284.800	6.326.290
2016	73.114.096	3.388.346
2017	67.211.143	2.371.176
2018	69.696.803	5.347.810

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In figure 26, it is possible to observe the evolution of the bilateral trade in the pharmaceutical sector. The Brazilian exports are responsible to the major part of the trade flow:

Figure 9-25 - Bilateral pharmaceutical trade: Brazil → Colombia (US\$ million)



Source: ComexStat. Elaborated by CCGI-EESP/FGV.

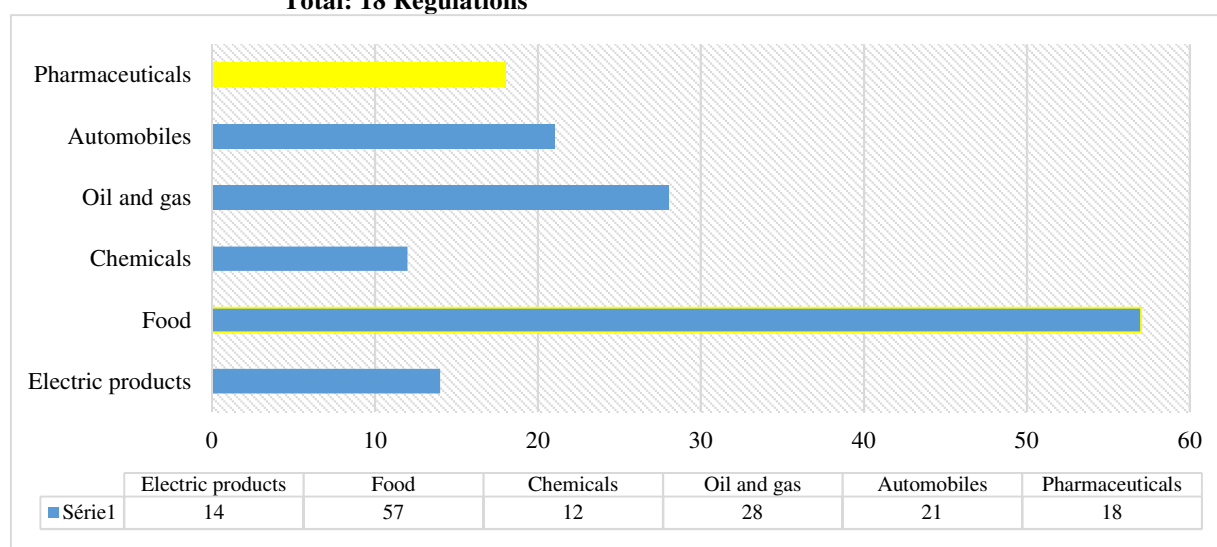
9.5.2. Main authorities

The main authority regulating the sector is the Ministry of Health and Social Protection. The eighteen technical regulations identified for the sector were issued by the Ministry of Health and Social Protection.

9.5.3. Technical regulation, standards and supporting standards

In the pharmaceutical sector, there are eighteen regulations in force in Colombia. Compared with other sectors, the pharmaceutical products sector presents moderate degree of regulatory intervention in Colombia.

Figure 9-26 - Colombia - Pharmaceuticals: Regulatory activity: comparison among sectors
Total: 18 Regulations

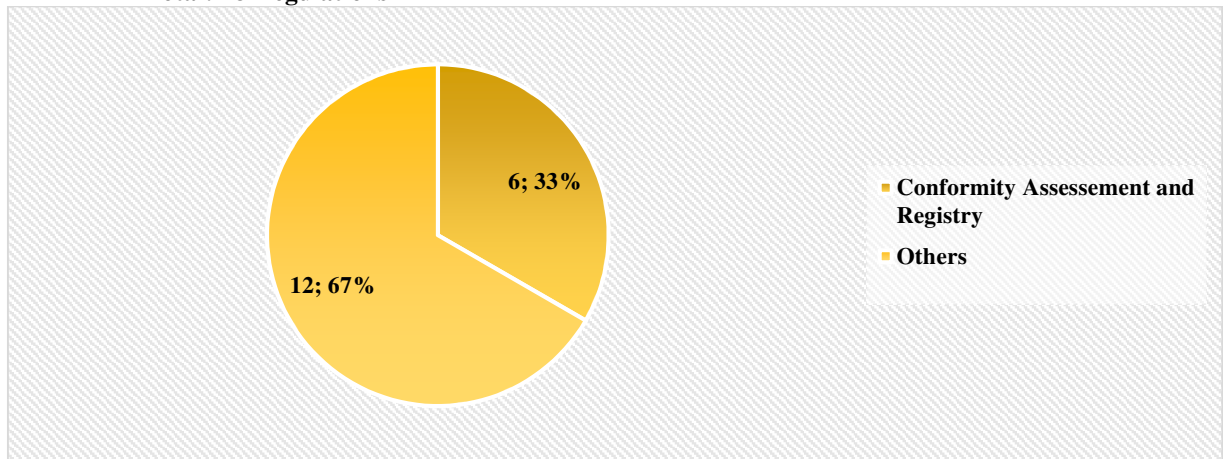


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

The main topics inserted on technical regulations in the sector are medicines, medical devices, phytotherapeutic products, homeopathic products, in vitro diagnostic reagents, sanitary registry, certification of good practices of laboratory of quality control of pharmaceutical products, immunogenicity of biological medicines, stability of biological medicines, manufacture of biological medicines, evaluation procedure of quality, safety and efficacy of biological medicines, vaccines, quality control laboratories of pharmaceutical products, medicinal gases, laboratories or pharmaceutical production establishments and drug manufacturing laboratories.

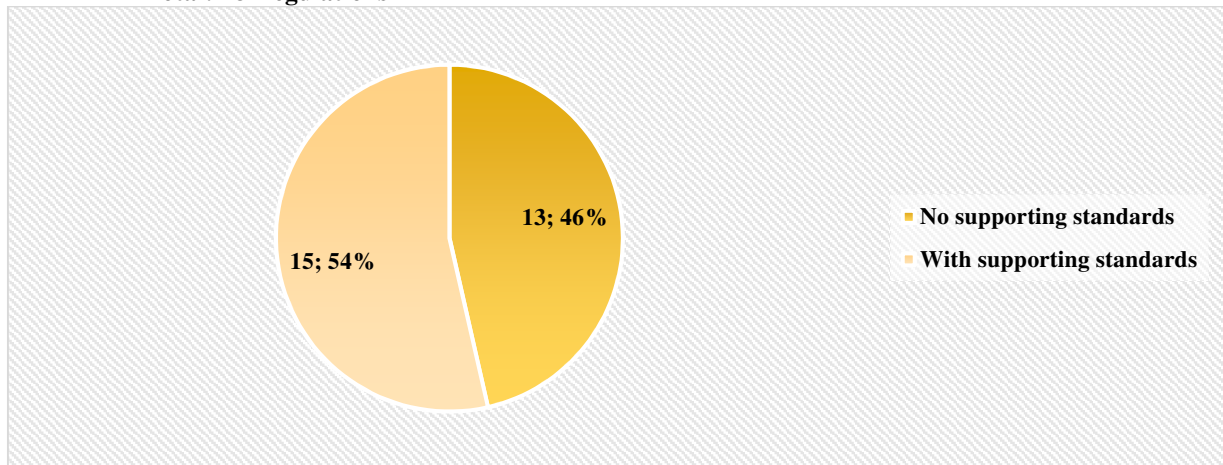
If grouped into three major themes - emission, transportation/storage, others - the technical regulations have the following distribution:

Figure 9-27 - Colombia - Pharmaceuticals: object of technical regulation
Total: 18 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

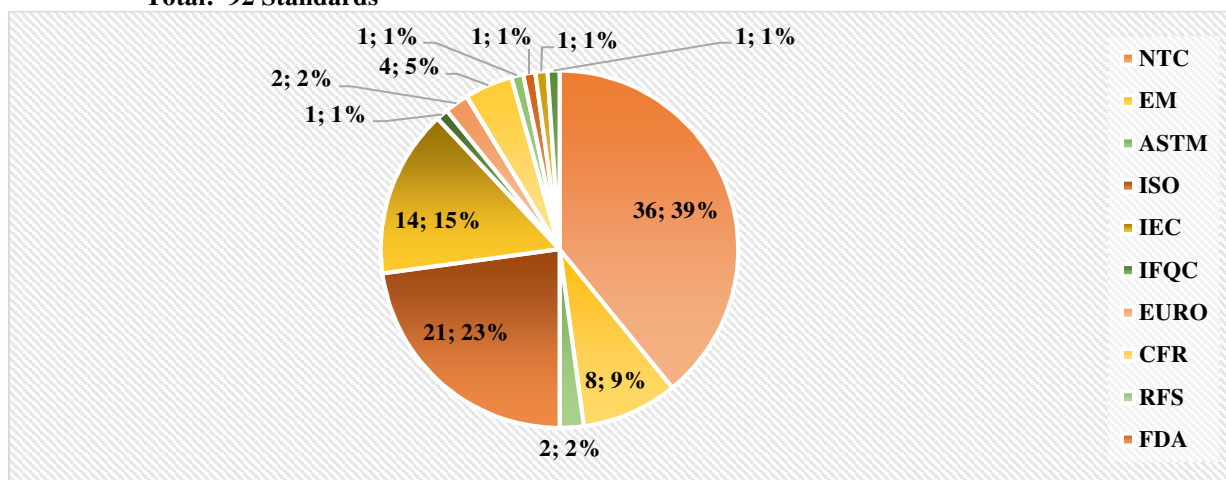
Figure 9-28 - Colombia - Pharmaceuticals: use of supporting standards
Total: 18 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

It is relatively frequent to mention technical standards under Colombian technical regulations for pharmaceuticals. The Colombian Technical regulations use a great variety of standards.

Figure 9-29 - Colombia - Pharmaceuticals: types of supporting standards used
Total: 92 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The full list of regulation is in [appendix 1](#).

9.5.4. Conformity assessment and certification

The conformity assessment in this sector is mainly done by private institutions. Altea Farmacéutica S.A. is a private entity that performs certification of good laboratory practices through physical analyses and physical-chemical analyses. The University Hospital of Medellín is another private institution that performs the certification of good practices of the following processes: repackaging and refilling of solid medicines, production of medicinal air by compressor and mixing and dose adjustment of oncological medicines. Finally, the good distribution practices (GDP) constitute a quality system for warehouses and distribution centers of medicines that guarantee the application of uniform quality management systems since the early supply of raw materials, passing through the manufacture plants and ending on the shipment of finished medicines to the end user.

9.5.5. Main government and private sectors

The main actor from the government is the Ministry of Health and Social Protection.

The main private actors for the sector are AbbVie and Altea Farmacéutica S.A.

10. Chile

10.1. The automotive and auto-parts sector in Chile

10.1.1. Overview

The trade balance between Brazil and Chile reveals that the first country holds a huge surplus on vehicles since 2014 and also a surplus on auto parts on the last five years. In total, Brazil has substantially increased the amount exported in the last five years starting at approximately US\$ 567 million in 2014 and reaching US\$ 1,231 billion in 2018, which represents an increase of approximately US\$ 665 million or 117% in the total value exported during the period. The increase was mainly due to the trade in vehicles, where Brazil increased the amount exported in 223%, from US\$ 288 million in 2014 to US\$ 929 million in 2018. In the trade of auto parts, the evolution is more stable during the period, although Brazil increased the surplus from US\$ 195 million in 2014 to US\$ 215 million in 2018. The imports from Chile are more expressive in the areas of auto parts, totaling more than US\$ 87 million in 2018, while the imports of vehicles are not very significant, amounting only US\$ 430.138 in 2018. The automotive sector is not an expressive sector in the Chilean economy, and the country depends heavily on imports.

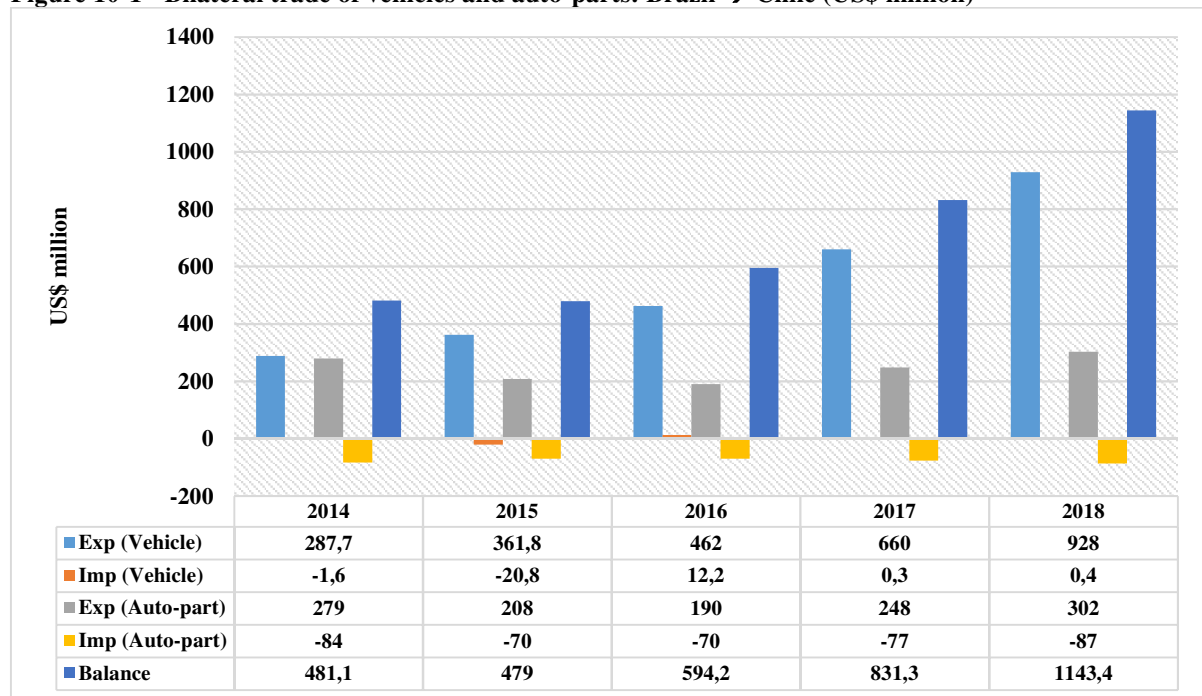
Table 10.1 - Bilateral trade of vehicles and auto-parts (Brazil → Chile) (US\$)

Year	Vehicles		Auto parts		Total	
	Exp.	Imp.	Exp.	Imp.	Exp.	Imp.
2014	287.712.230	1.589.683	279.410.154	84.427.616	567.122.384	86.017.299
2015	361.809.447	20.869.852	208.001.837	70.499.288	569.811.284	91.369.140
2016	462.072.692	12.207.882	190.293.617	69.611.423	652.366.309	81.819.305
2017	660.597.241	243.130	248.456.065	77.245.739	909.053.306	77.488.869
2018	928.969.070	430.138	302.861.767	87.678.039	1.231.830.837	88.108.177

Source: Comexstat. Elaborated by CCGI-EESP/FGV.

The growth in the exports of Brazilian exports in the automotive industry may be related to the devaluation of the Brazilian currency in the period, which turns the products of the Brazilian industry more competitive in the international trade by cheapening their prices in dollar. Moreover, the automotive industry in Chile is not an expressive sector of the economy, and that is also the reason the trade mostly favors Brazil. The following figure illustrates how the trade developed during the last 5 years.

Figure 10-1 - Bilateral trade of vehicles and auto-parts: Brazil → Chile (US\$ million)

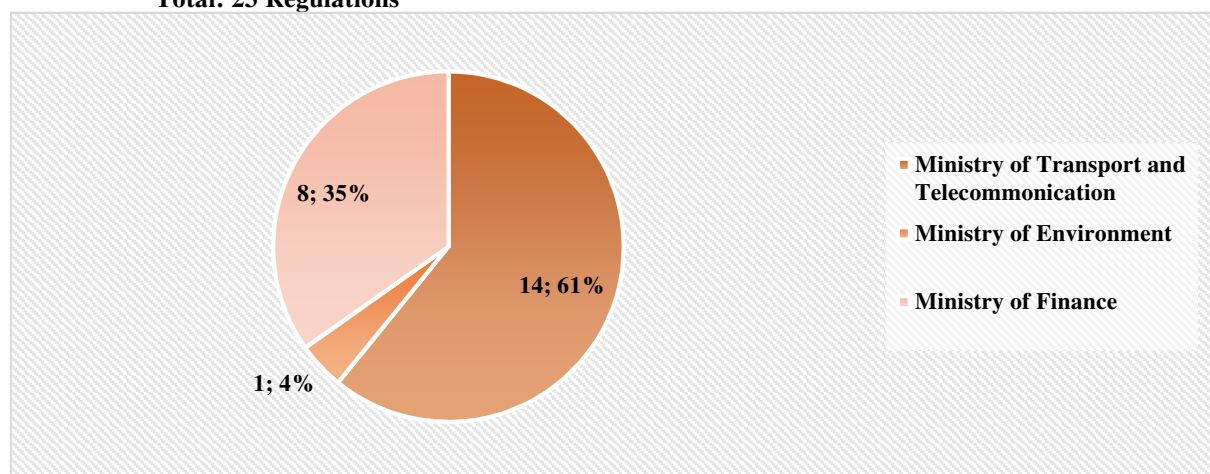


Source: Comexstat. Elaborated by CCGI-EESP/FGV.

10.1.2. Main authorities

The ministries that are regulating the sector are the Ministry of the Environment, the Ministry of Finance and the Ministry of Transport and Telecommunications. As it can be seen in the graphic below, the Ministry of Transport and Telecommunications is the most relevant of the regulatory bodies in the automotive sector. Its relevance is fundamentally due to the need to regulate the active and passive safety of vehicles, accounting for 61% of the regulatory activity, whilst the Ministry of Finance comes second accounting for 35% and the Ministry of Environment accounts for 4% of the regulations in the auto sector.

Figure 10-2 - Chile - Automotive: regulatory activity of the main authorities
Total: 23 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

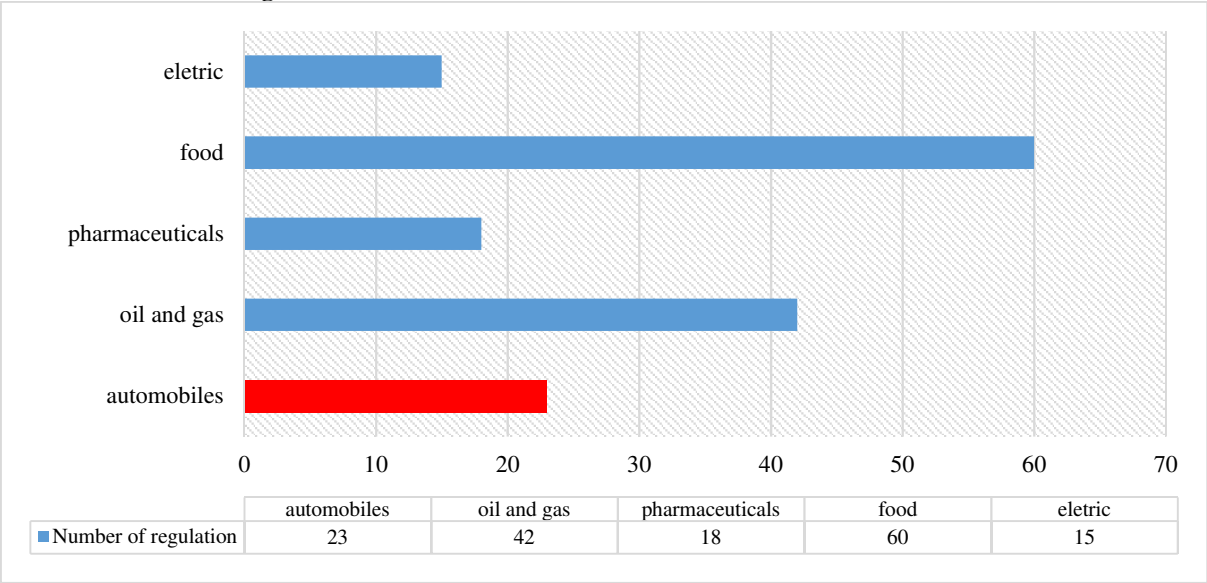
The Ministry of Transport and Telecommunications is the most relevant regulatory bodies in the automotive sector. Its relevance is fundamentally due to the need to regulate the active and

passive safety of vehicles. The Ministry of Transport and Telecommunications is responsible by more than sixty percent of the technical regulation on vehicles.

10.1.3. Technical regulations, standards and supporting standards

In vehicles sector, there are 23 regulations in force in Chile. Compared with other sectors, the products of vehicle sector presents very medium degree of regulatory intervention in Chile.

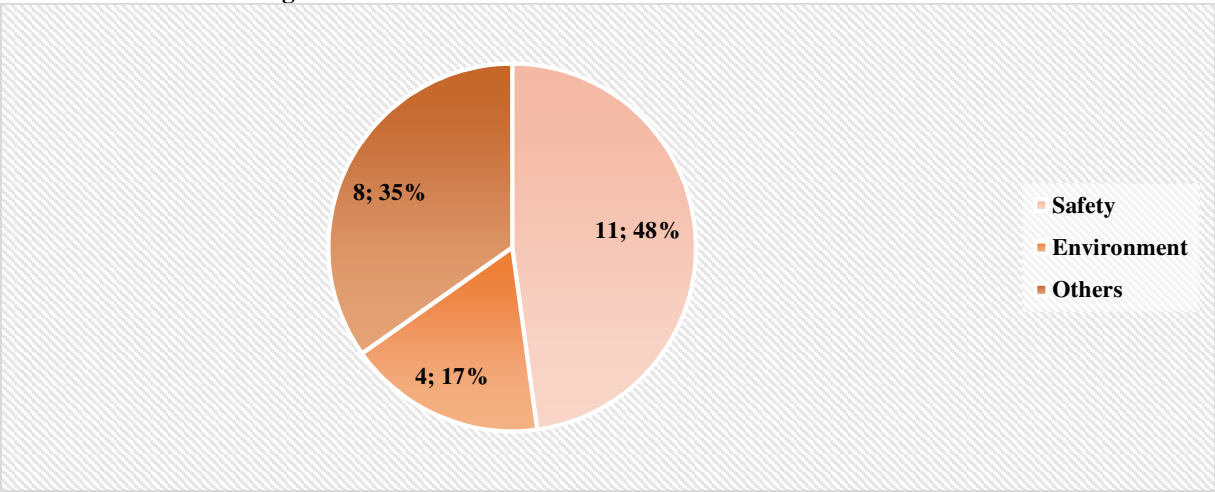
Figure 10-3 - Chile - Automotive: regulatory activity: comparison among sectors
Total: 23 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The main themes foreseen on technical regulations of the sector are vehicles fueled with natural gas, traffic law, noise emission, importation of vehicles, incident rights and taxes and internation of vehicles. If the vehicles regulation were organized in three groups (safety, environment and others), the distribution of themes would be the following:

Figure 10-4 - Chile - Automotive: object of technical regulation
Total: 23 Regulations

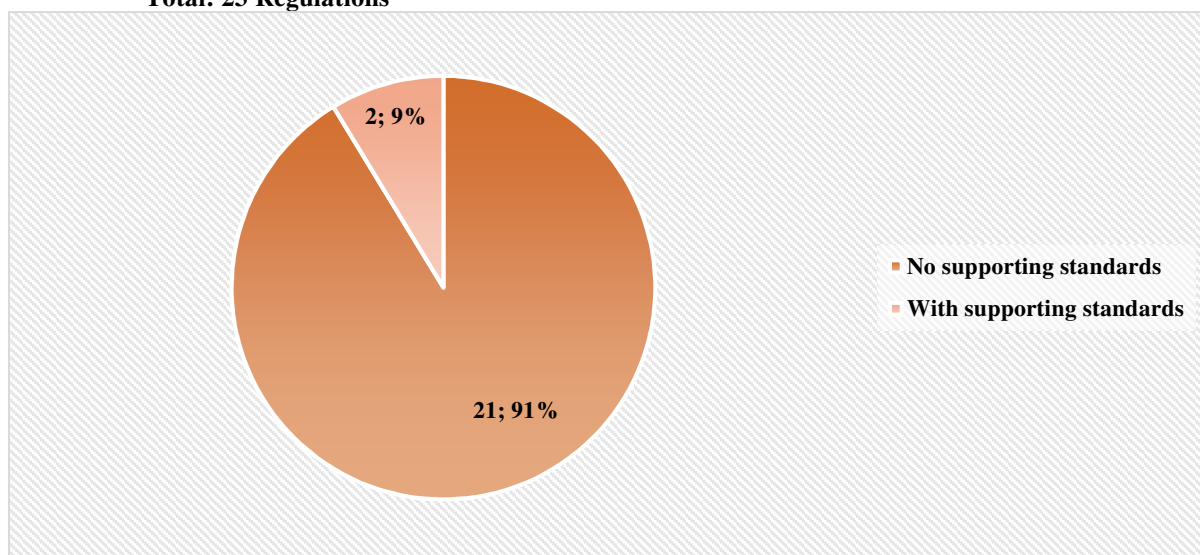


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The full list of regulation is in [appendix 2](#).

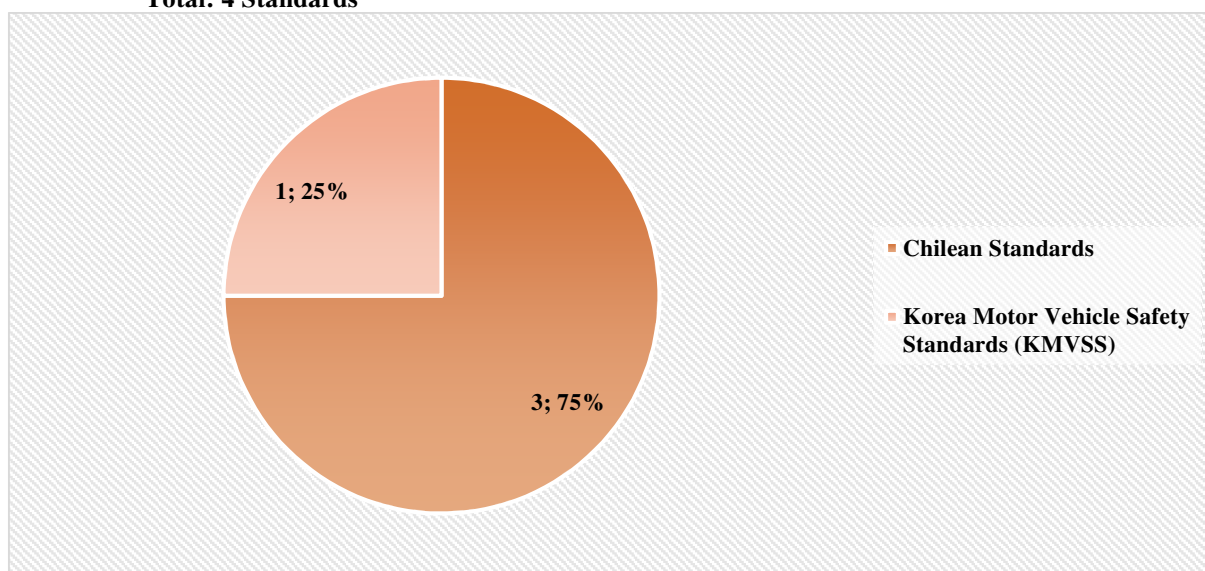
In this small number of Chilean technical regulations concerning vehicles and auto parts, the use of technical standards is infrequent and the use of international technical standards has not been identified. Only two of these regulations expressly mention technical standards, which are Chilean standards. It should be noted that the Chilean auto industry is practically non-existent, which indicates that Chile is only a consumer market.

Figure 10-5 - Chile - Automotive: use of supporting standards
Total: 23 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

Figure 10-6 - Chile - Automotive: types of Supporting Standards
Total: 4 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

Thus, technical regulation and technical standards for vehicle and auto parts sector presents some important characteristics in Chile: low state regulatory intervention, expressed in the small number of technical regulations, and low use of international supporting standards (most

of them Chilean Standards¹⁷⁰). The first characteristic, which is the most important aspect, has the potential to facilitate the importation of products from abroad, regardless of the origin of the manufacture, since it does not create compulsory requirements for importers. This feature is consistent with Chile's liberal trade policy, formalized in the various free trade agreements signed by the country. The fact that technical standards are not used under technical regulations does not distort this characteristic of the sector in Chile.

10.1.4. Conformity assessment and certification

The Ministry of Transport and Telecommunications is a key player on conformity assessment procedures. During the process, the Ministry firstly selects randomly vehicles of departures of models or families of engines of individual vehicles of already approved models, which are marketed in the country. The Ministry then proceeds to the conformity assessment procedure performed on the Center of Control and Vehicle Certification (3CV). On the inspection, it is verified if the vehicles comply with national norms of emissions and are operating technically with the equipment and motor regulation indicated in the background that the manufacturer or ship owner or its legal representative in Chile, distributor or importer had to demonstrate to the 3CV to attest the conformity of the information that it keeps. The selected vehicle must be in functioning conditions according to the description foreseen on the aforementioned background, without change of parts and components. When the results of the measurements, for each pollutant, are according to the existing rules, the conformity will be attributed to the model or family of engines. Examples of vehicles and vehicles' parts that undergo conformity assessment procedures are new buses, catalytic converters, emission after-treatment system and emission control devices.

10.1.5. Main governmental and private actors

The main government actors are the aforementioned ministries.

The main private actors are the National Automotive Association of Chile (*Asociación Nacional Automotriz de Chile* - ANAC)¹⁷¹, the Guild Association of Electric Vehicles of Chile (*Asociación Gremial de Vehículos Eléctricos de Chile* - AVEC)¹⁷², the National Chamber of Automotive Trade of Chile (*Cámara Nacional de Comercio Automotriz de Chile* - CAVEM)¹⁷³ and Automobile Club (*Automóvil Club*).

10.2. Electric products in Chile

10.2.1. Introduction

The trade balance between Brazil and Chile shows that the first country holds a large surplus on the last five years. In 2014, the exports from Brazil amounted for US\$ 131 million while the imports accounted for almost US\$ 3 million, which represents a surplus in favor of Brazil equal to around US\$ 128 million. In 2015, the Brazilian surplus was equal to US\$ 128 million and subsequently in 2016, 2017 and 2018 the surplus was approximately: US\$ 136 million, US\$ 183 million, US\$ 193 million, which indicates that the surplus favoring Brazil has increased

¹⁷⁰ The following Chilean standards were identified: NCh 2102, NCh 2109

¹⁷¹ See: <https://www.anac.cl/>

¹⁷² See: <https://www.avec.cl/nosotros/>

¹⁷³ See: <https://www.cavem.cl/>

approximately 51% in the period. As with the trade in the automotive sector, the growth in the Brazilian surplus may be related to the expressive devaluation of the currency in the period, which cheapens the Brazilian products. The trade volume increased exponentially since 2017, reaching US\$ 188 million against US\$ 143 million in 2016.

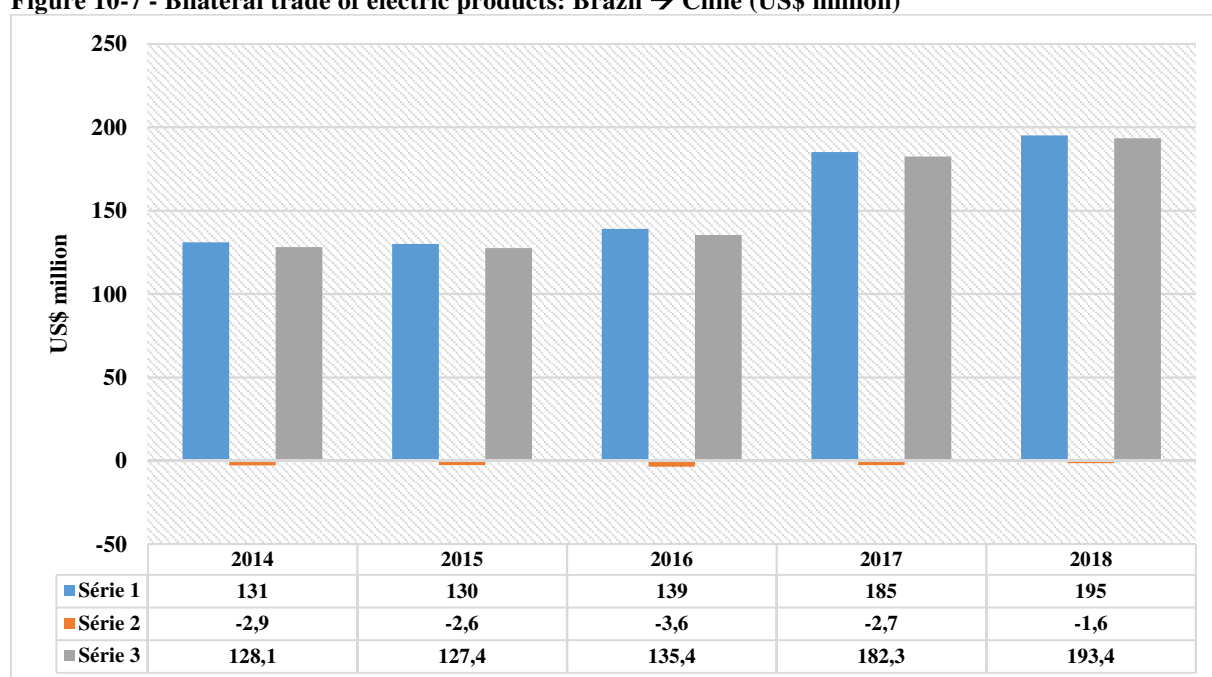
Table 10.2 - Electric products trade balance between Brazil and Chile (US\$)

Year	Total	
	Exports	Imports
2014	131.086.324	2.949.646
2015	130.859.802	2.608.038
2016	139.987.614	3.659.382
2017	185.386.936	2.742.419
2018	195.082.227	1.678.734

Source: Comexstat. Elaborated by CCGI-EESP/FGV.

Since 2016, Brazilian commercial output has consistently increased in the balance of trade in electric products. It should be highlighted the year 2018, when Brazil exported almost US \$ 200 million to Chile and imported only US \$ 1.6 million from the Andean country. As it can be seen in the chart, the Brazilian export is almost entirely responsible for the trade flow between the two countries.

Figure 10-7 - Bilateral trade of electric products: Brazil → Chile (US\$ million)

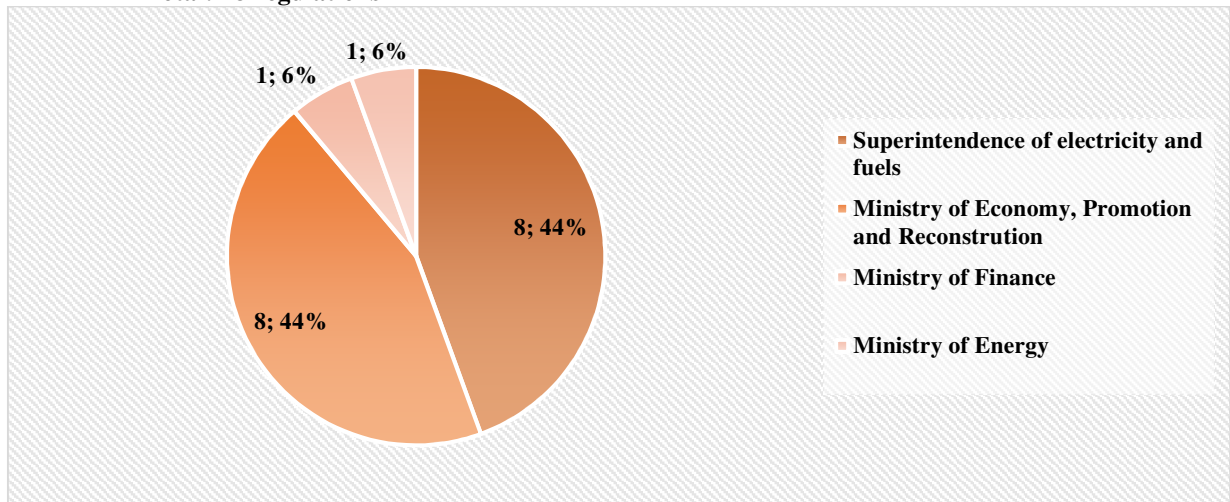


Source: Comexstat. Elaborated by CCGI-EESP/FGV.

10.2.2. Main authorities

The main authorities that regulate the sector are the Ministry of Economy, Promotion and Reconstruction and the Superintendence of Electricity and Fuels. As it can be seen in figure 29, the Superintendence of electricity and Fuels and the Ministry of Economy, Promotion and Reconstruction are the most relevant bodies when issuing the technical regulations, each one responsible for 44% of the regulatory activity. The Ministry of Finance and the Ministry of Energy are each responsible for 6% of the technical regulations.

Figure 10-8 - Chile - Electrics: Regulatory activity of the main authorities
Total: 18 regulations



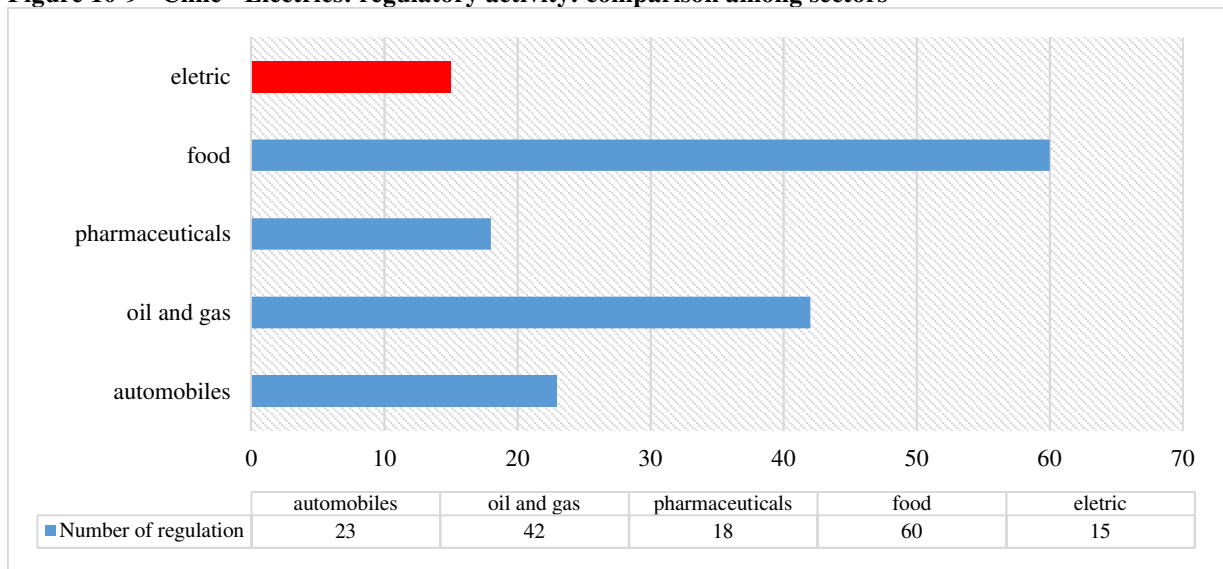
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Of the current set of technical regulations, are mainly the Superintendence of Electricity and Commerce and the Ministry of Economy. Both bodies, together, are responsible for producing almost 90% of the technical regulations.

10.2.3. Technical regulations, standards and supporting standards

In electric products sector, there 15 regulations in force in Chile. Compared with other sectors, the products of electric sector presents very low degree of regulatory intervention in Chile.

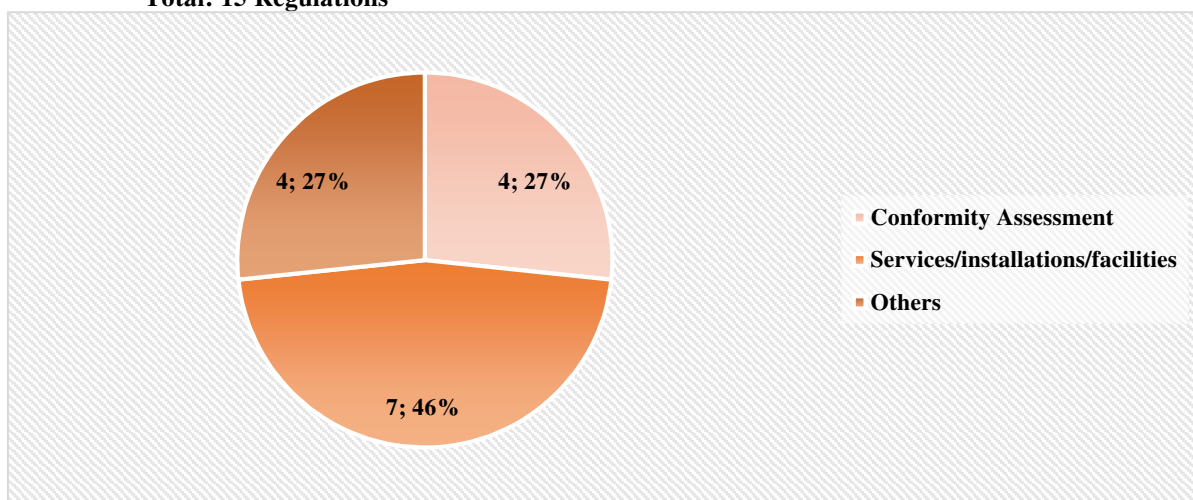
Figure 10-9 - Chile - Electrics: regulatory activity: comparison among sectors



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

The most relevant themes foreseen on the technical regulations of the sector are certification of electric products and fuels, sanctions to electric products that do not bear the respective certificate of approval, functioning of electric fences, labeling of electric products, certification of electric product, approval certificate of electric products and bodies that perform evaluations or calibrations of electric power meters.

Figure 10-10 - Chile - Electrics: object of technical regulation
Total: 15 Regulations

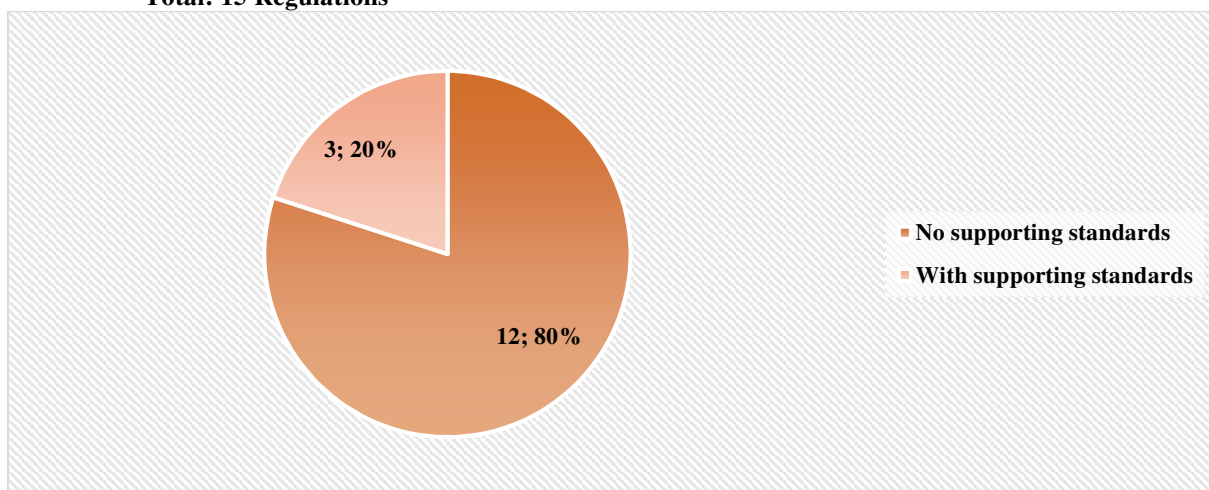


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

The list of regulation is in [appendix 2](#).

As observed in the automotive sector, the electrical products sector is also very little regulated in Chile. Of the small set of 15 technical regulations, only three refer to technical standards.

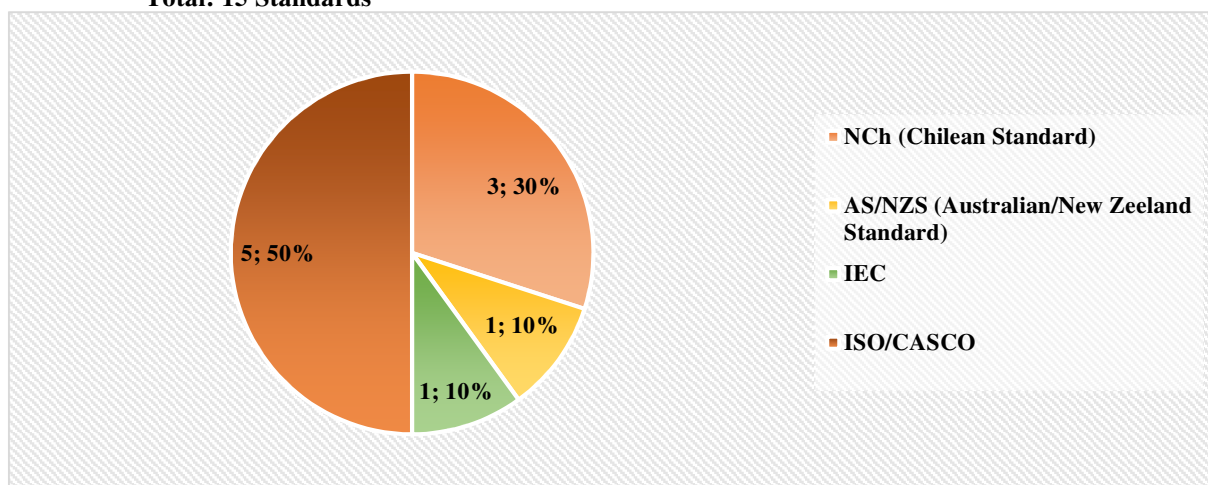
Figure 10-11 - Chile - Electrics: use of supporting standards
Total: 15 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The set of Chilean technical regulations that make reference to some international support technical standard adopts standards from diverse origins, as verified in the graph below:

Figure 10-12 - Chile - Electrics: types of supporting standards used in Chile
Total: 15 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The figure above shows the types of supporting standards used in Chile. The norms ISO/CASCO are used in 50% of the cases, whilst the Chilean Standard NCh is used in 30% of the cases and the AS/NZS (Australian/ New Zealand Standard) are used both in 10% of the cases.

In addition to the Chilean standards, it is important to emphasize the use of Australian / New Zealand standards and standards of international standardization bodies, which are predominant.

Thus, similarly to autos sector, technical regulation and technical standards for electric products sector presents some important characteristics in Chile: low state regulatory intervention, expressed in the small number of technical regulations, and low use of supporting standards. The first characteristic, which is the most important aspect, has the potential to facilitate the importation of products from abroad, regardless of the origin of the manufacture, since it does not create compulsory requirements for importers. This feature is consistent with Chile's liberal trade policy, materialized in the various free trade agreements signed by the country. The fact that technical standards are not so frequent in technical regulations does not distort this characteristic of the sector in Chile.

10.2.4. Conformity assessment and certification

The certification of electric products is regulated on law 18410, on the article 60 of the law 18681 and on supreme decree 399/85 of the Ministry of Economy, Promotion and Reconstruction. Electric products are subject to mandatory certification before their trade on the country and their use is subject to an assessment of the compliance of minimum safety requisites. The certification of electric products subject to mandatory certification is performed by testing laboratories. The Superintendence of Electricity and Fuels acts in parallel to these laboratories through the analysis and proposal of products that must undergo mandatory certification on the country and the approval or creation of technical protocols for their certification.

The certification activities performed are different tests. The type test consists on a set of tests carried out on the sample of a product, done according to an established method. The production control is a control based on tests carried out on samples taken at the factory, in the finished product stage, in order to verify that the production carried out following that correspondingly applied to the type sample, remains in compliance. The batch test constitutes a certification system according to which the batch of a product is submitted to a sampling to be performed on the obtained sample, the tests from which a judgment on the conformity of the lot with respect to a given specification can be provided. Examples of electric products that must undergo certification are household electrical appliances, installation accessories, connection devices and lighting, measuring instruments, cables and cords.

10.2.5. Main governmental and private actors

The main governmental actors are the aforementioned authorities.

The main private actors are the Association of the Electric and Electronic Industry (AIE) and Electric Products (*Electro Productos*).

10.3. Food sector in Chile

10.3.1. Overview

The trade balance between Brazil and Chile reveals that the second country holds a surplus on the last five years. It is also noteworthy that the trade volume between both countries has increased continuously since 2016. The exports from Brazil have increased during the period from US\$ 616 million in 2014 to 933 million in 2018, which represents an increase of 51,4 %. The imports from Chile have remained roughly stable during the period fluctuating between US\$ 883 million and US\$ 1 billion. It is noteworthy that the trade deficit favoring Chile has been reduced in the period, from around US\$ 412 million in 2014 to around US\$ 99 million in 2018. In the food sector, unlike the other sectors, Brazil has had significant deficits in recent years.

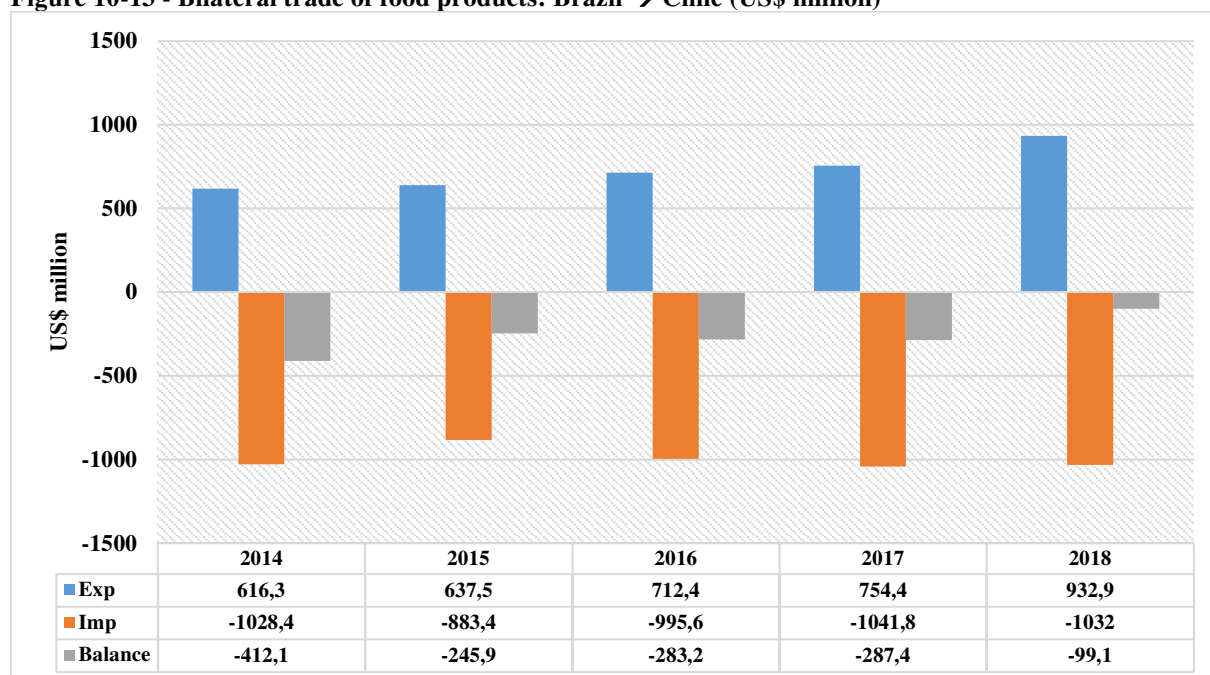
Table 10.3 - Food trade between Brazil and Chile (US\$)

Year	Total	
	Exp.	Imp.
2014	616.302.538	1.028.405.402
2015	637.480.040	883.417.827
2016	712.358.720	995.652.558
2017	754.387.576	1.041.802.662
2018	932.988.868	1.032.252.384

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In the food sector, unlike others, Brazil has had significant deficits with Chile in recent years. If it is considered a broader time series, it could be seen that surpluses in bilateral trade are alternated between Brazil and Chile. In the last five years, Brazil presented a surplus in the years 2014 and 2015 and presented deficits in the following three years.

Figure 10-13 - Bilateral trade of food products: Brazil → Chile (US\$ million)



Source: ComexStat. Elaborated by CCGI-EESP/FGV.

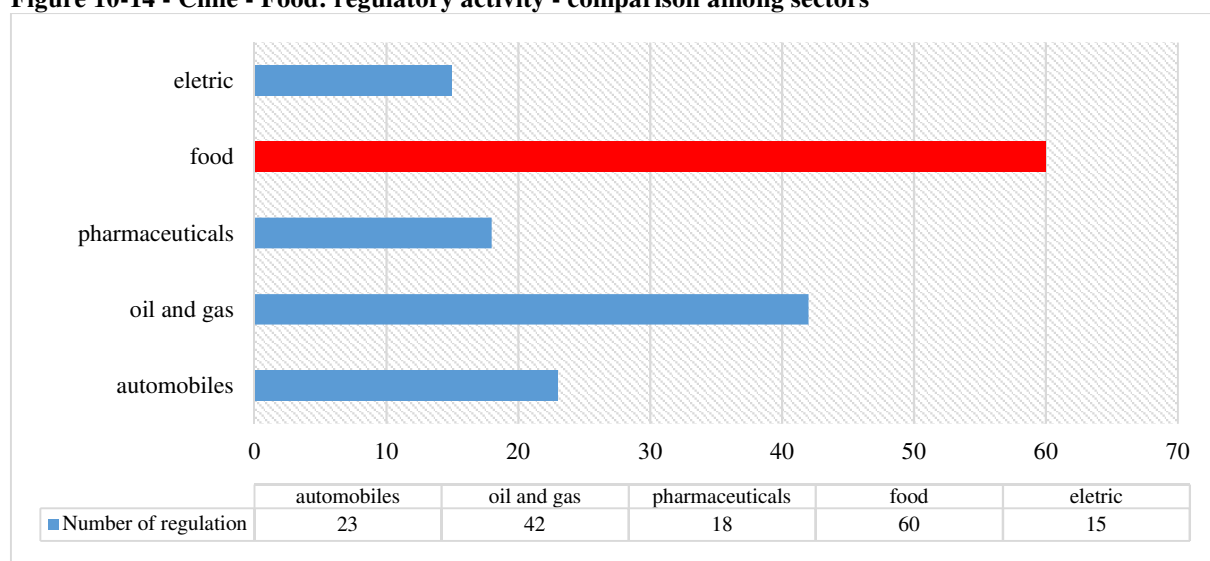
10.3.2. Main authorities

The main authority that regulates the sector are the Ministry of Agriculture and the Ministry of Health.

10.3.3. Technical regulations, standards and supporting standards

In food sector, there are sixty regulations in force in Chile. Compared with other sectors, the products of food sector presents very high degree of regulatory intervention in Chile.

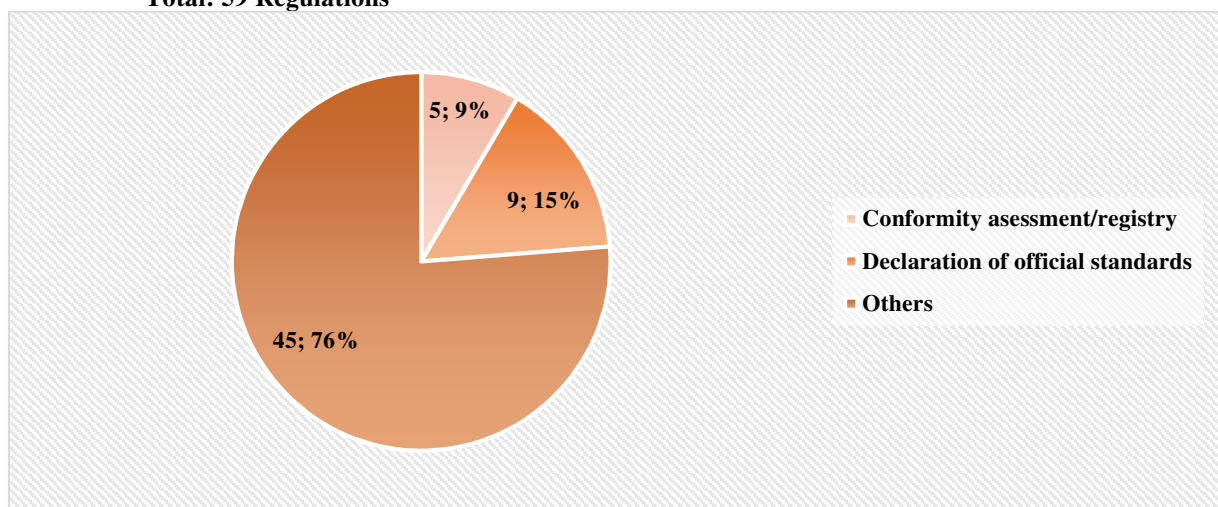
Figure 10-14 - Chile - Food: regulatory activity - comparison among sectors



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

The main topics foreseen on the technical regulations of the sector are certification of agricultural organic products; vineyard grape; importation of vegetables, animals, products and sub-products and agricultural and livestock supplies; incentives for the agro-environmental sustainability of the agricultural soils; regulation of corn; viticulture zoning; commercial transactions of agricultural products; agricultural contracts; regulation of wheat; food industry; slaughter houses, refrigeration establishments, refrigeration chambers and peel plants; livestock classification; livestock protection; production, preparation and trade of ethyl alcohols, alcoholic beverages and vinegars; traceability system for livestock and meat; specification of standards; creation of institutions for the Chilean food industry and typification and nomenclature of meat.

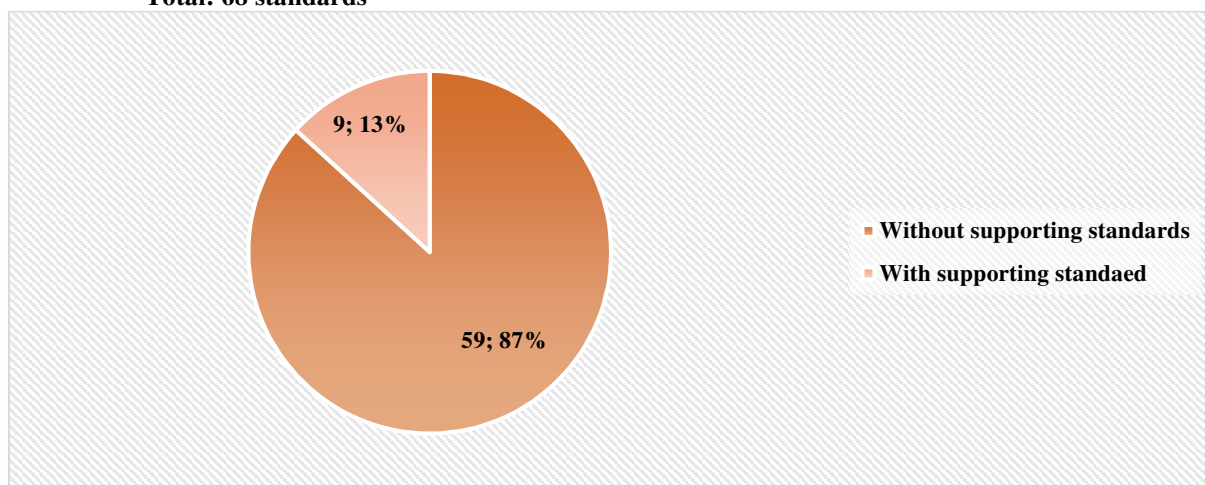
Figure 10-15 - Chile - Food: object of technical regulation
Total: 59 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

If it is compared with previous sectors, the food sector has a much higher number of technical regulations. In fact, among the sectors selected, it is the food sector that has the largest number of technical regulations (59). There are two possible explanations for the greatest number of technical regulations for the characteristic of this sector in Chile. The first hypothesis is that this sector, due to its direct relationship with human health, demands a greater degree of regulatory intervention by the state. Another hypothesis is that, unlike the situation observed in the case of electric products and automobiles, Chile is an important exporter of food (and not an importer). This indicates that the regulatory activity of a country may vary depending on the role of the sector in the national economy.

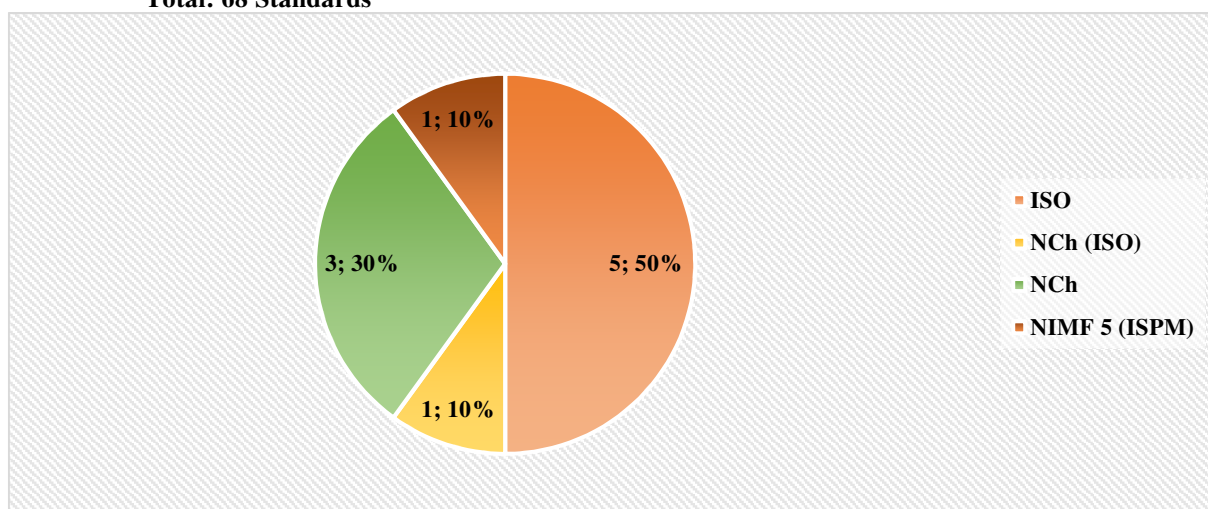
Figure 10-16 - Chile - Food: use of supporting standards
Total: 68 standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Chilean technical regulations that mention technical standards make use of national and international standards, in particular ISO standards, as shown below:

Figure 10-17 - Chile - Food: types of supporting standards
Total: 68 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Unlike the sectors analyzed above, the food sector presents a high level of regulatory intervention in Chile, especially if it is considered the model of little intervention state adopted by the country. The nature of the sector and the importance of food production are likely to influence regulatory dynamics in Chile.

The list of regulation is in [appendix 2](#).

10.3.4. Conformity assessment and certification

The national system of certification of agricultural organic products constitutes one pillar of the sectorial conformity assessment. The system aims to guarantee and certify that organic products are produced, created, packaged and handled according to the rules of law 20089/2006. The

system is of voluntary assignment for all those who participate in the internal and external market of organic products. Inside the system, the traders can have their own and alternative certification systems, once the traceability of the product and the free access to the production places are guaranteed to the consumers and to the supervising body. The certification is done by accredited entities on certification of products. The Agriculture and Livestock Service is the competent authority to oversee the compliance of the law, to impose sanctions on possible infringements and to control the registry of certifiers and the use of the distinctive official label of agricultural organic products.

Public and private entities also perform food certification. The Institute of Nutrition and Food Technology (INTA), inside the University of Chile, certifies food and its certification attests that one food and/or food supplement complies with what is declared on the nutritional composition foreseen on the label and implies a periodical control of the product on time. Intertek, a private entity, provides innovative services on food certification systems according to international standards. A group of auditors is competent to certify food in Chile.

10.3.5. Main governmental and private actors

The main government actors are the aforementioned ministries.

The main private actors are the Association of Food Companies of Chile (Chilealimentos) and Food and Beverages of Chile A.G. (AB Chile).

10.4. Oil and gas in Chile

10.4.1. Overview

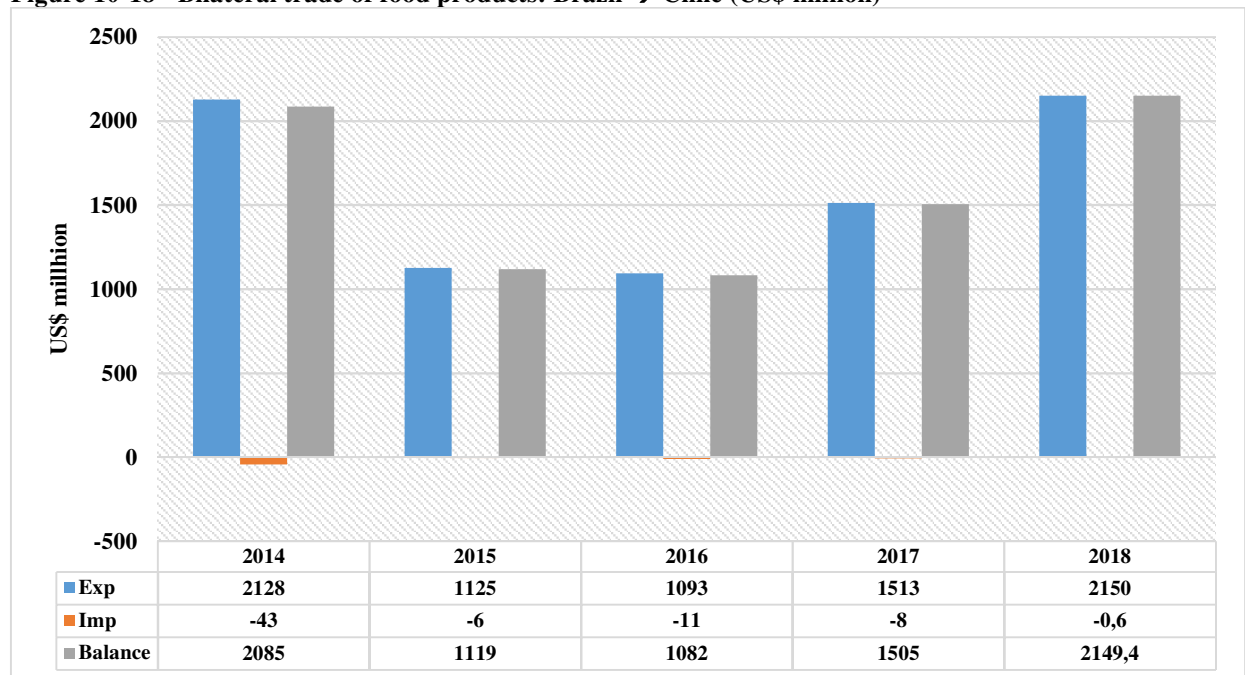
The trade balance between Brazil and Chile is largely favorable to the first country on the last five years. The trade volume, on its turn, has oscillated significantly between US\$ 1 billion and US\$ 2,2 billion. The trade relations are very asymmetric, as it can be observed in table. Brazil is responsible for the greatest part of the trade flow and holds a huge surplus. The Brazilian exports have considerably fluctuated during the period starting at US\$ 2,13 billion in 2014, going down to US\$ 1,125 billion in 2015, US\$ 1 billion in 2016, US\$ 1,5 billion, and going up again to US\$ 2,1590 billion in 2018. The Chilean oil and gas sector is pretty much inexpressive and that is why the imports are in small quantity.

Table 10.4 - Oil and gas trade between Brazil and Chile (US\$)

Year	Total	
	Exp.	Imp.
2014	2.128.400.771	43.758.670
2015	1.125.396.071	6.288.318
2016	1.093.837.779	11.368.758
2017	1.513.861.495	8.987.624
2018	2.150.148.649	600.143

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

Figure 10-18 - Bilateral trade of food products: Brazil → Chile (US\$ million)



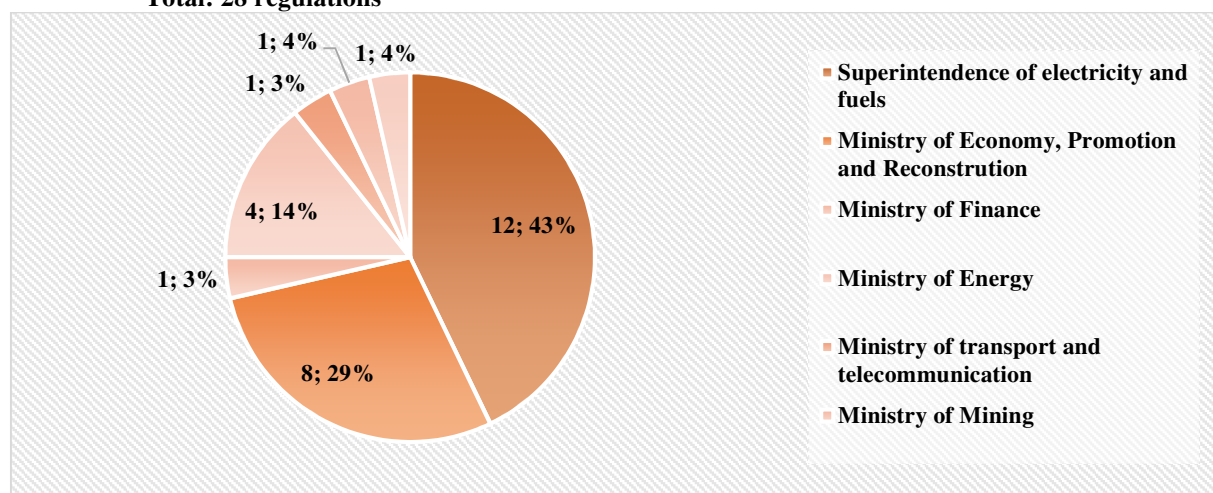
Source: ComexStat. Elaborated by CCGI-EESP/FGV.

10.4.2. Main authorities

The ministries that regulate the sector are the Ministry of Economy, Promotion and Reconstruction, the Ministry of Energy, the Ministry of Finance, the Ministry of Interior, the Ministry of Mining and the Ministry of Transport and Telecommunications. Another key player is the Superintendence of Electricity and Fuels.

Figure 10-19 - Chile - Oil and Gas: regulatory activity of the main authorities

Total: 28 regulations

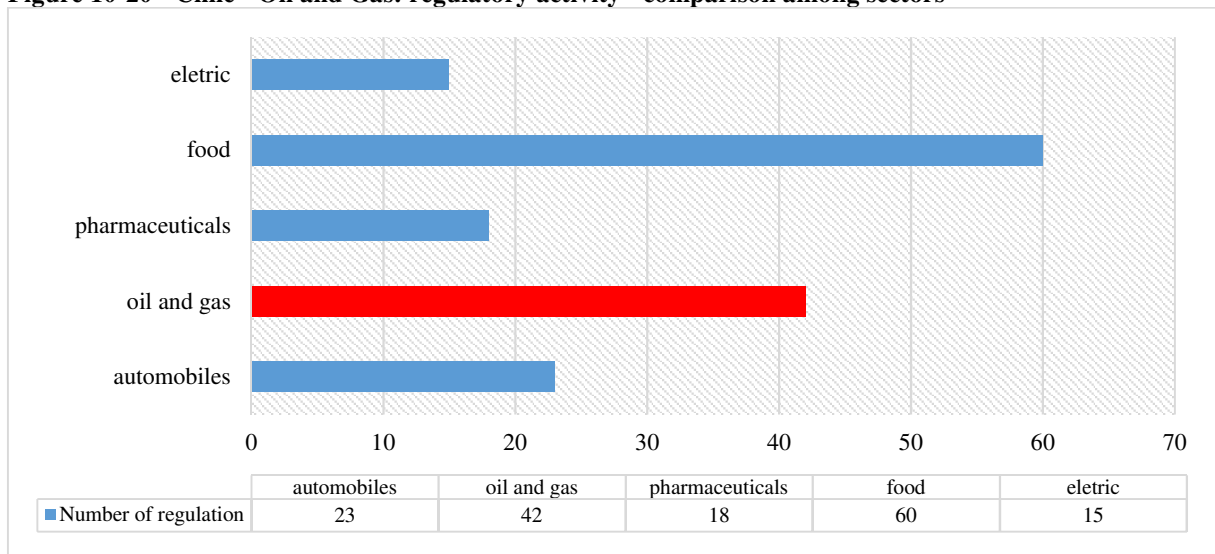


Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

10.4.3. Technical regulations, standards and supporting standards

In oil and gas sector, there are 42 regulations in force in Chile. Compared with other sectors, the products of oil and gas sector presents high degree of regulatory intervention in Chile.

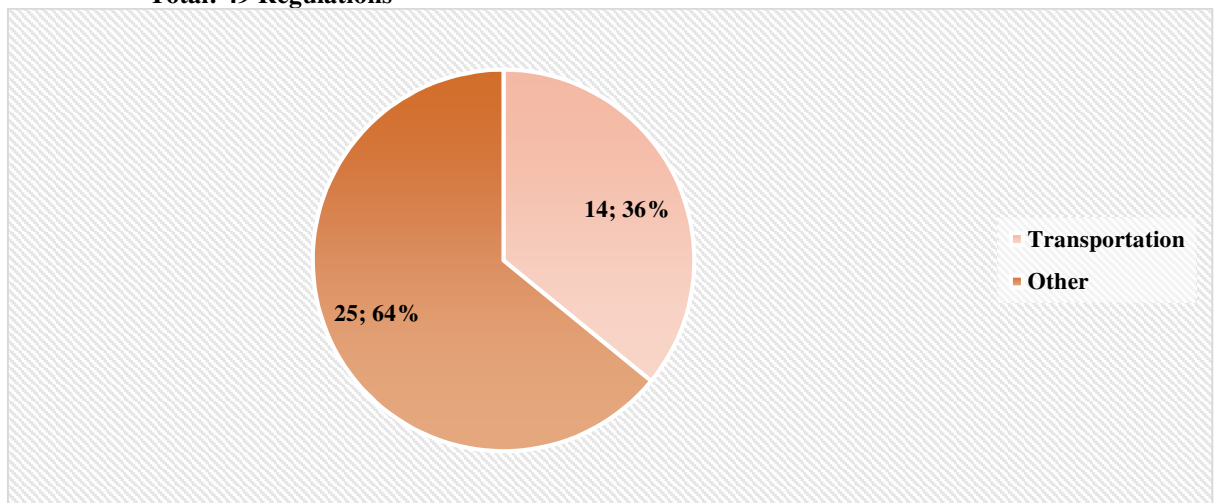
Figure 10-20 - Chile - Oil and Gas: regulatory activity - comparison among sectors



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

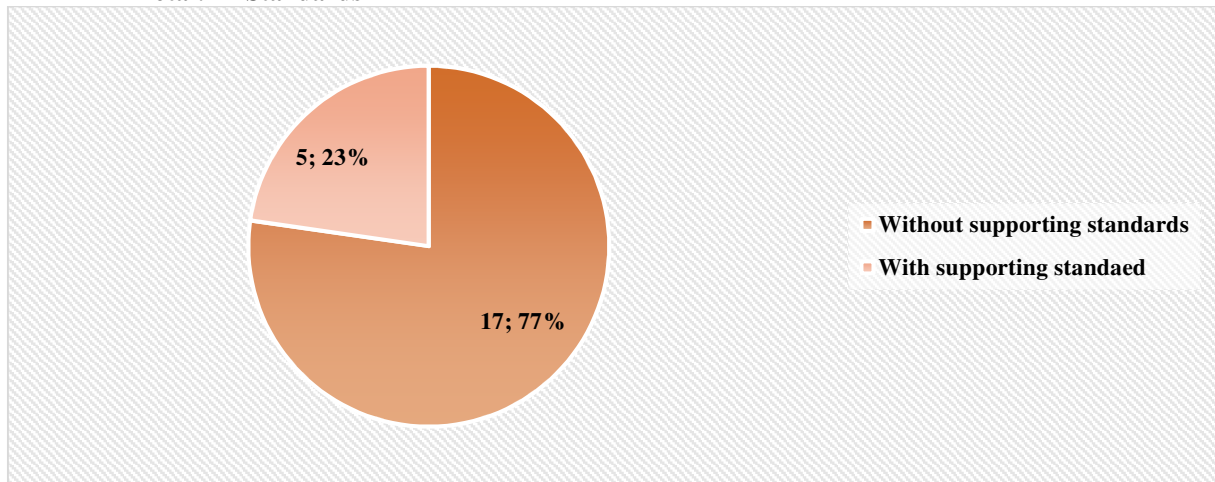
The most frequent themes inserted on technical regulations of the sector are production, refinement, storage, transportation, distribution and supply of liquefied petroleum gas; transportation of liquefied natural gas; safety of facilities, plants and gas meters; certification, periodic inspection and verification of conversion of interior gas installations; certificates of fuel products; authorization and control of certification entities of internal gas installations; authorization of testing laboratories, inspection bodies, certification bodies and the Liquefied Natural Gas Plant certification system; test protocols; devices and systems for the evacuation of gases produced by combustion; quality specifications of fuels; network gas service; sanctions on fuels and technical, quality and development standards control procedure.

Figure 10-21 - Chile - Oil and Gas: object of technical regulation
Total: 49 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

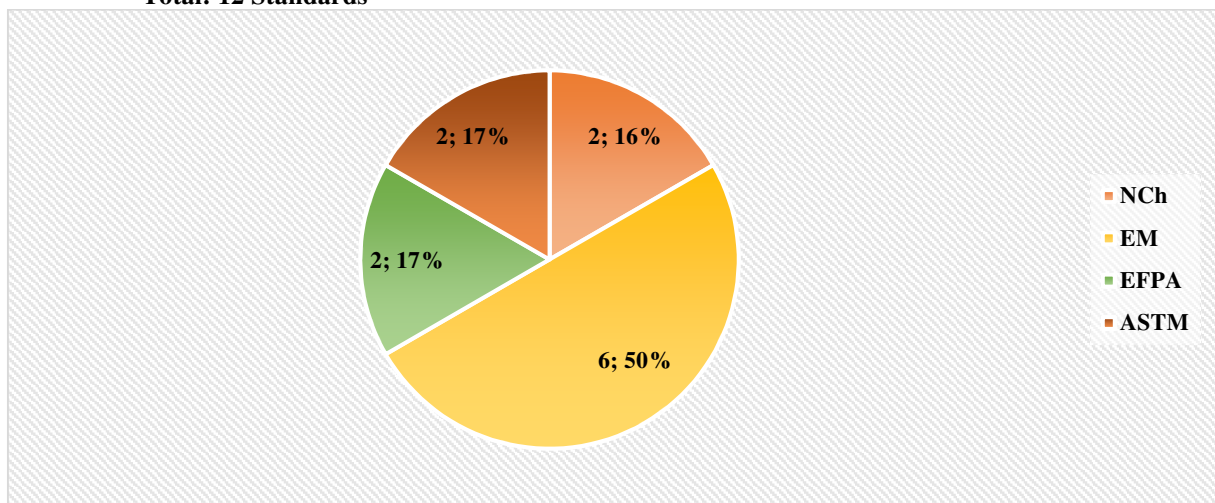
Figure 10-22 - Chile - Oil and Gas: use of supporting standards
Total: 22 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Chilean technical regulations that mention technical standards make use of national and international standards, as shown below:

Figure 10-23 - Chile - Oil and Gas: types of supporting standards
Total: 12 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

The list of regulation is in [appendix 2](#).

10.4.4. Conformity assessment and certification

The Superintendence of Electricity and Fuels is a key entity on the certification of oil and gas. It acts through the approval of protocols to the conformity assessment of interior gas facilities, the establishment of conformity assessment procedures, the establishment of requirements for the authorization of conformity assessment bodies and the establishment of electronic certification procedures. The General Society of Oversight (SGS) also acts on the sector through the certification of a unique product that can be extended to a series of products when the same commodities and the same management system are applied and the basic figure is not significantly changed and a restriction of dangerous substances (RoHS) that facilitates the access of products on any part of the world is used.

10.4.5. Main governmental and private actors

The main governmental actors are the aforementioned ministries.

The main private actors are the Superintendence of Electricity and Fuels, the General Society of Oversight, the Chilean Institute of Oil (ICHP) and the National Company of Oil (ENAP).

10.5. Pharmaceuticals in Chile

10.5.1. Overview

On the trade balance between Brazil and Chile, the first country holds a large surplus from 2014 to 2018. In this period, the trade volume oscillated between US\$ 53 million and US\$ 61 million. The exports from Brazil have fluctuated around US\$ 50 to US\$ 60 million dollars, while the imports from Chile are much less significant, reaching the approximate value of US\$ 500.000 in 2018. The trade relations between the two countries in this sector is not overall very expressive, if compared with the other sectors.

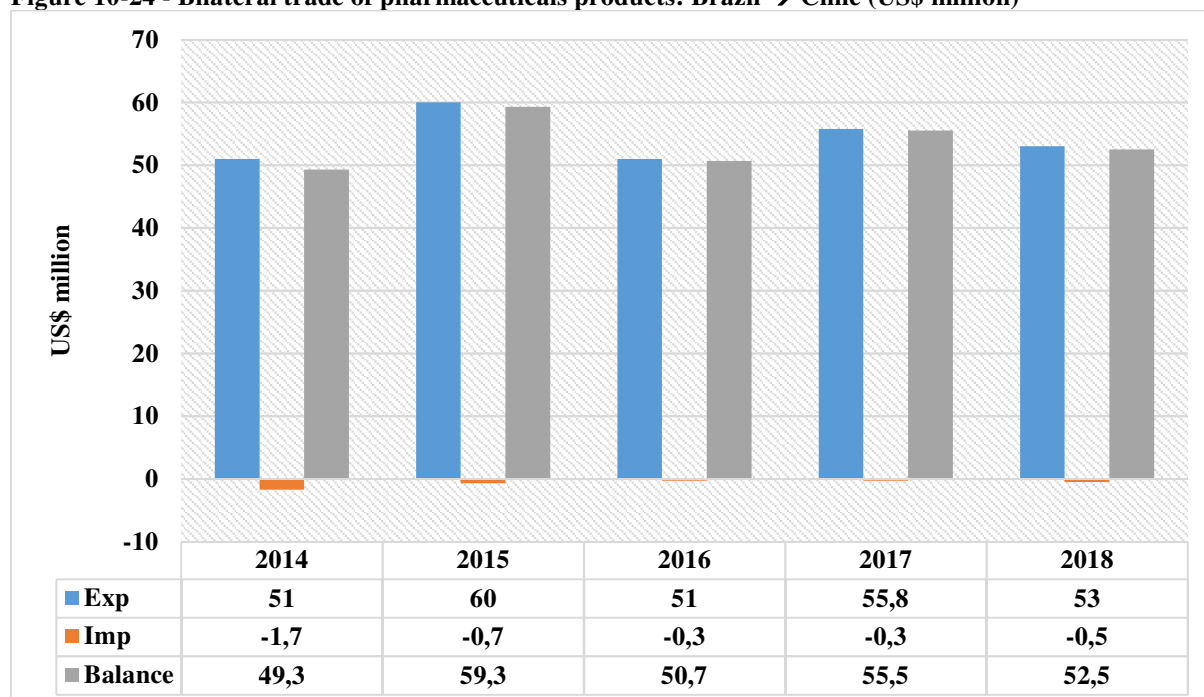
Table 10.5 - Pharmaceutical trade between Brazil and Chile (US\$)

Year	Total	
	Exp.	Imp.
2014	51.132.882	1.728.418
2015	60.299.202	672.914
2016	51.329.252	306.905
2017	55.868.719	294.762
2018	53.164.728	500.688

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

In following picture, it is possible to observe how the evolution of the bilateral trade: Brazil has large surpluses in the sector and accounts for almost all of the trade flow. The trade is practically unilateral, with little expression of the Chilean production in the sector.

Figure 10-24 - Bilateral trade of pharmaceuticals products: Brazil → Chile (US\$ million)

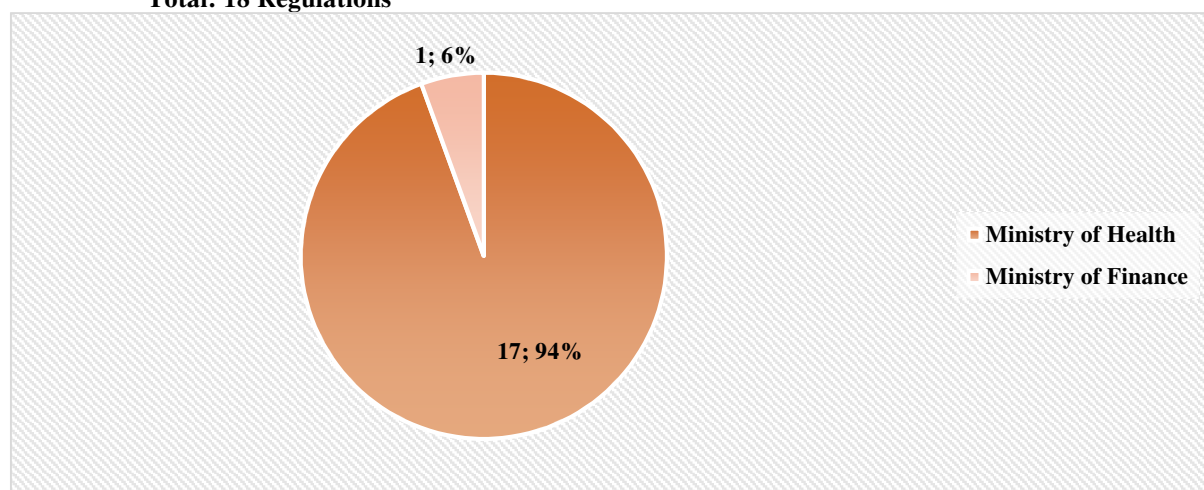


Source: ComexStat. Elaborated by CCGI-EESP/FGV.

10.5.2. Main authorities

The authorities that regulate the sector are the Ministry of Health and the Ministry of Finance.

Figure 10-25 - Chile - Pharmaceuticals: regulatory activity of the main authorities
Total: 18 Regulations



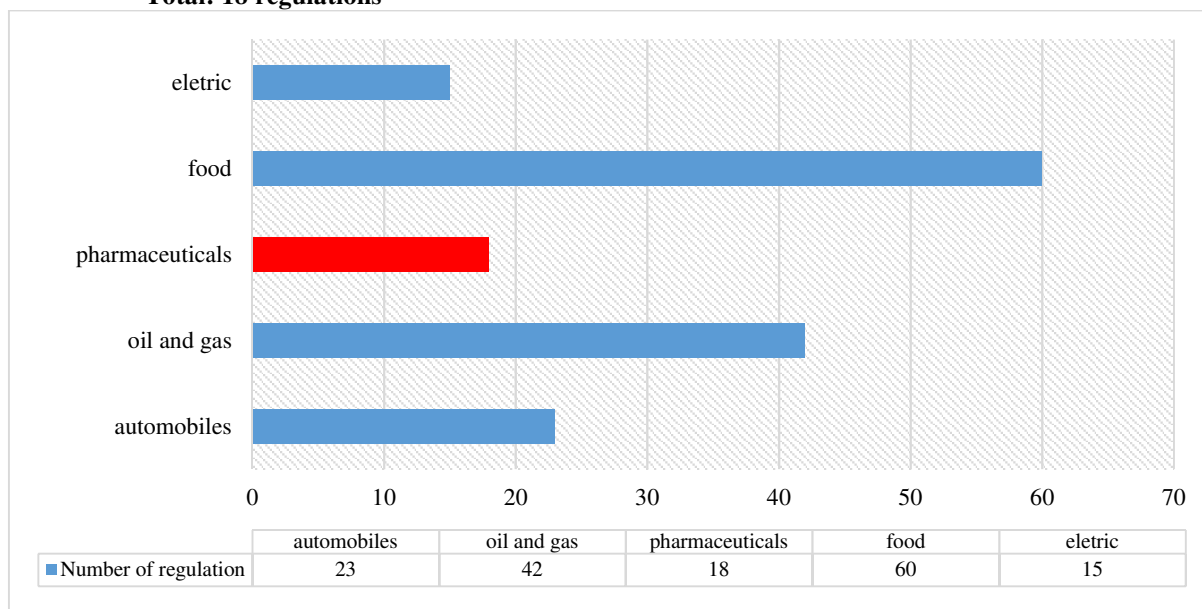
Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

As shown in the above chart, the Ministry of Health is the main regulator of the sector, with more than 90% of the regulation published in Chile.

10.5.3. Technical regulations, standards and supporting standards

In pharmaceutical sector, there are eighteen regulations in force in Chile. Compared with other sectors, the pharmaceutical products present low degree of regulatory intervention in Chile.

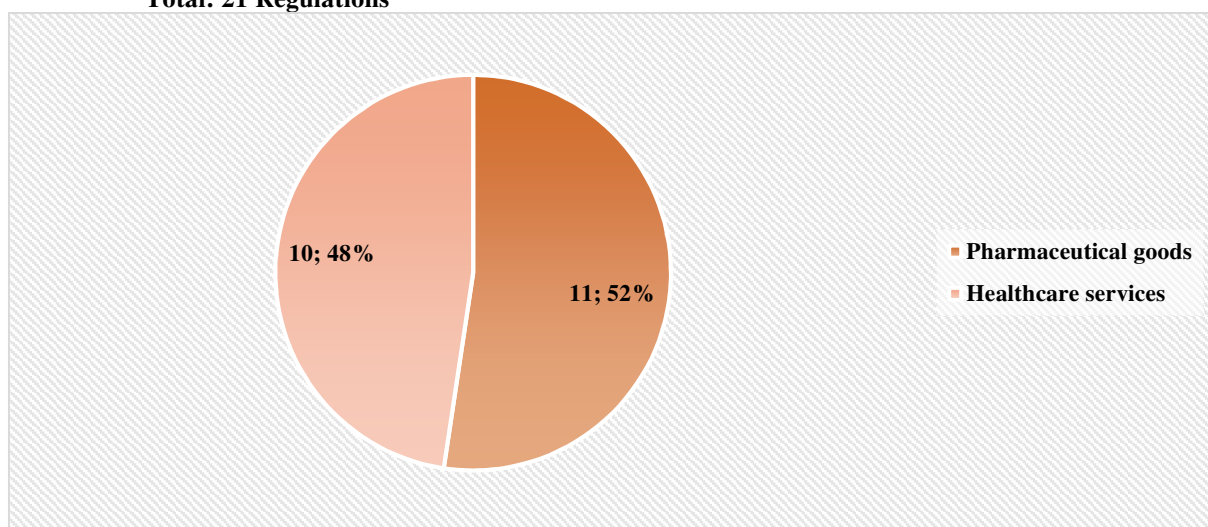
Figure 10-26 - Chile - Pharmaceuticals regulatory activity - comparison among sectors
Total: 18 regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

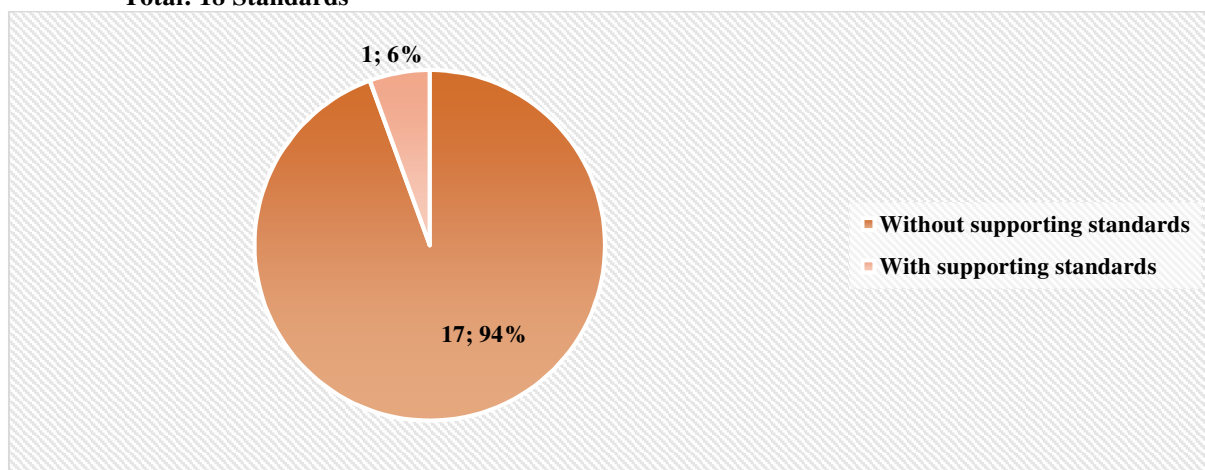
The themes inserted on technical regulations are diagnostics; high costs treatments; narcotics and psychotropic regulation; bioequivalent medicines on the primary level of health; pharmacies, drugstores, pharmaceutical stores, pharmaceutical warehouses, first aid and deposits; pharmaceutical products for human use; authorization, control and sanitary audit of establishments and pharmaceutical products; health care; preparation of pharmaceutical preparations; drug policy and hospital and clinical regulation.

Figure 10-27 - Chile - Pharmaceuticals: object of technical regulation (Chile - pharmaceutical)
Total: 21 Regulations



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPGV.

Figure 10-28 - Chile - Pharmaceuticals: use of supporting standards
Total: 18 Standards



Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Chilean technical regulations that mention technical standards make use of national standards. The Chilean standards used are the following: Chilean Standard 136/2012 and Chilean Standard 131/2012.

The list of regulation is in [appendix 2](#).

10.5.4. Conformity assessment and certification

The Institute of Public Health is the sanitary authority competent to oversee the quality of pharmaceutical products. Its activities consist on inspective actions and shelf control on manufacturing, importers, conditioners, distributors, vending machines and assistance establishments. Any failure of quality of pharmaceuticals or claim about it should be notified to the Institute, which shall evaluate them and determine the actions that are appropriate in each case. When a verification on foreign laboratories is needed, the Institute can contract advisory services and foreign services or subscribe covenants with national or foreign entities that are necessary to its performance according to the required quality standards. The institute can also accept the international certification of pharmaceutical species, to the extent that production and quality control standards applied by the sanitary authority of the manufacturing country or of the country recognized as accreditor have been declared homologous by a resolution of the Ministry of Health or by an international treaty.

10.5.5. Main governmental and private actors

The main governmental actors are the Ministry of Health and the entities inside it as the Institute of Public Health and the National Agency of Medicines and the Ministry of Finance.

The main private actors are the Industrial Association of Pharmaceutical Laboratories (Asilfa), the Chamber of Pharmaceutical Innovation of Chile (CIF), the Pharmacological Society of Chile (SOFARCHI) and the Chamber of Direct Sales of Medicines (CAMEVED).

11. Conclusion

The aim of this Part of the research is to examine how technical regulation, standardization and conformity assessment procedures (quality infrastructure systems) adopted by Chile, Mexico and Colombia and analyze how these systems could affect the international trade flows of these countries, especially in relation to Mercosur and the Pacific Alliance.

In the contemporary context of international trade, regulatory barriers are increasingly relevant. After successive multilateral negotiations and preferential trade agreements tariff barriers were consistently reduced. This did not happen with regulatory barriers. The World Trade Organization, in particular the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS), together with international standards and regulatory bodies, prescribe a broader normative framework for regulations, standardization and conformity assessment activities connected to international trade. Simply observing these international rules and recommendations, however, may be insufficient to eliminate barriers to trade. In this case, regulatory convergence initiatives among trading partners become necessary.

In view of the relevance of the regulatory theme for international trade, the scope of this research included: the mapping of the regulatory policies and structures for regulations, standardization and conformity assessment in Chile, Mexico and Colombia, which are important trade partners in Latin America. The main purpose is to identify the degree of convergence of regulatory policies. The research also investigated the possible solutions offered by those countries to mitigate or eliminate the non-tariff barriers through regulatory convergence initiatives.

Regulations, Standards and International Supporting Standards

In order to identify the degree of compatibility among these Latin American Countries, this Part of the Project compared the Regulatory Policy of these three countries related to technical regulations for five different sectors of their economies: automotive, electric products, pharmaceutical, food and oil and gas. This comparative examination will include, for each sector: the main regulators, the main technical regulations, their standards and conformity rules.

To make the comparison of technical barriers among these countries, Colombia, Chile and Mexico with Brazil and Argentina, this research identifies the main international supporting standards followed by the national regulators and standardization bodies for each of the sectors.

Some important concepts used in this project are related to the most important standardization models around the world: the international model, the US model and the EU model. As a consequence, it is possible to identify: international standards and sectoral global standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), *Codex Alimentarius Commission*, World Organization for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*. International standards are generally produced in accordance with

the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectoral standards are private standards developed by relevant standardizing bodies and are followed by producers and exporters around the world and are relevant to international trade. There are two main sources for these standards: the United States and the European Union.

The United States produce important sectoral global standards, following the logic of a market oriented economy. There are around 300 Standards Bodies in the US. This model can be identified as a *bottom-up* approach. Some standards can be considered as global standards. They are: American Society for Testing and Materials (ASTM), American Petroleum Institute (API), American Society of Mechanical Engineers (ASME), Underwriters Laboratories (UL), Institute of Electrical and Electronics Engineers (IEEE), Society of Automotive Engineers (SAE). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

The EU produces another set of global standards, following the logic of an integrated or common market, produced and used not only regionally but also around the world. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI). They are produced following Directives established by the European Commission under what is called a *top down* approach. European standards are essential for the functioning of the EU integrated market and are widely used as a model influencing many standardization and regulatory work in several countries around the world.

For Latin-American countries, these global standards are important because they are used as supporting standards for technical regulations and technical standards. International and global standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies.

In the case of Mexico, Colombia and Chile, the regulatory system for the technical regulations, the process of standardization and the conformity assessment systems of these selected countries present some important common characteristics. The fact that the three countries underwent similar liberal administrative reforms, signed a major set of international trade agreements and adopted many of the good regulatory practices advocated by the Organization for Economic Cooperation and Development (OECD), probably approached the systems of these three countries, despite important differences in their production systems and in the development stage of their industries.

In the specific topic of technical regulation, it was clear that the three countries adopt low-intensity regulatory practices, a characteristic that is evident in the relatively small regulatory stock of the three countries. However, the standardization activity appears to be less complementary to the technical regulation of what is observed in the two Mercosur countries - Brazil and Argentina. This can be verified in the few references to the technical standards in

the text of the technical regulations of Chile, Colombia and Mexico. Because of the small number of compulsory rules, this lack of support standards in technical regulations is unlikely to create technical barriers to international trade.

Regarding the choice of the technical standards used by the regulatory authorities, it can be noted, alongside domestic and international standards, the strong presence of global sectorial technical standards, with emphasis on standards produced by US entities (SAE, ASTM, UL, IEEE, for example). The presence of these sectorial standards reveals, possibly, the strong economic bond of these countries with the United States, a characteristic that was also among the hypotheses initially proposed in the research.

The main conclusions of this research is the evidence of two regulatory trends in Latin American countries: Pacific countries seem to be progressively moving closer to the US model, with the adoption of supporting technical standards produced by US sectorial organizations, while Mercosur countries have a strong presence of indigenous technical standards and European standards.

The Pacific countries of Latin America are clearly under a strong influence of the US, not only because they have preferential trade agreements with the US, but also because the US is their most important trade partner.

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13. Appendices

13.1. Appendix 1 – STCs raised against Mexico, Colombia, and Chile

A. Mexico

Table 13.1 - STCs raised against Mexico

IMS ID	TITLE	MEMBER(S) SUBJECT TO STC	MEMBER(S) RAISING STC	FIRST DATE RAISED	LAST DATE RAISED	NUMBER OF TIMES SUBSEQUENTLY RAISED
522	Mexico - Official Standard PROY-NOM-199-SCFI-2015: Alcoholic beverages - Designations, physicochemical specifications, commercial information and test methods (ID 522)	Mexico	European Union	10/11/2016		0
462	Mexico -Standard on non-alcoholic and soft drinks (ID 462)	Mexico	El Salvador	18/03/2015		0
445	Mexico -Draft Mexican Official Standard PROY NOM 142 SSA1/SCFI 2013: Alcoholic beverages. Health specifications. Health and commercial labelling (ID 445)	Mexico	Chile; United States of America; European Union	05/11/2014		0
406	Mexico - Draft Mexican Official Standard PROY-NOM-032-ENER-2013: Maximum electrical power limits for equipment and appliances requiring standby power. Test methods and labelling (ID 406)	Mexico	Korea, Republic of; United States of America	30/10/2013	19/03/2014	1
330	Mexico - Refusal of the National Water Commission to re-certify HDPE pipe products meeting quality/safety standards for piping set out in NOM 001 and NMX 241 (ID 330)	Mexico	United States of America	10/11/2011	30/10/2013	3
314	Mexico - Energy Labelling Measures (Law for Sustainable Use of Energy, 28 November 2008; Regulation of the Law for Sustainable Use of Energy, 11 September 2009; National Program for Sustainable Use of Energy 2009-2012, 27 November 2009; and Catalogue of equipment and appliances used by manufacturers, importers, distributors and marketers that require mandatory inclusion of energy consumption information, 10 September 2010) (ID 314)	Mexico	Argentina; Japan; Korea, Republic of; United States of America; European Union	15/06/2011	20/03/2012	2
319	Mexico - Draft Decree Amending Provisions for Drinks with Caffeine (ID 319)	Mexico	United States of America; European Union	10/11/2011	20/03/2012	1
275	Mexico - Mexican Official Standard PROY NOM 051 SCFI/SSA1 2009: General specifications for the labelling of pre packaged food and non alcoholic beverages - Commercial and health information (ID 275)	Mexico	United States of America	03/11/2010		0

109	Mexico - Standard for Glazed Pottery Ware, Glazed Ceramic Ware and Porcelain Ware (ID 109)	Mexico	European Union	01/07/2004	22/03/2005	2
115	Mexico Pre-packaged products (ID 115)	Mexico	European Union	04/11/2004	22/03/2005	1
34	Mexico-Standard on the Use of Chlorofluorocarbon (ID 34)	Mexico	United States of America	20/11/1998		0
20	Mexico Labelling of Spirits (ID 20)	Mexico	European Union	18/11/1997	27/03/1998	1
21	Mexico-Standards on Labelling of Industrial Products (ID 21)	Mexico	European Union	18/11/1997	27/03/1998	1
24	Mexico-Labelling of Leather Products (ID 24)	Mexico	European Union	27/03/1998		0
3	Mexico - Labelling Regulation on Meat (ID 3)	Mexico	New Zealand	21/04/1995		0

Table 13.2 - STCs raised by Mexico

IMS ID	TITLE	MEMBER(S) SUBJECT TO STC	MEMBER(S) RAISING STC	FIRST DATE RAISED	LAST DATE RAISED	NUMBER OF TIMES SUBSEQUENTLY RAISED
328	Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety (ID 328)	Indonesia	Canada; Japan; Mexico; United States of America; European Union	10/11/2011	14/11/2018	20
332	Russian Federation -- Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011) (ID 332)	Russian Federation	Argentina; Australia; Guatemala; Mexico; New Zealand; South Africa; Ukraine; United States of America; European Union	20/03/2012	14/11/2018	20
393	European Union --- Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment (ID 393)	European Union	Argentina; Australia; Brazil; Canada; Chile; Colombia; Guatemala; Mexico; New Zealand; South Africa; Thailand; Egypt; United States of America; Ecuador; Uruguay; Costa Rica; Panama; Israel; India; Paraguay	17/06/2013	14/11/2018	16
427	Thailand -- Draft Notification of the Alcoholic Beverages Control, Re: Rules, Procedure and condition for Labels of Alcoholic Beverages, issued under B.E. (ID 427)	Thailand	Australia; Canada; Chile; Guatemala; Japan; Mexico; New Zealand; South Africa; United States of America; European Union; Argentina	18/06/2014	14/11/2018	13
489	China - Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation (ID 489)	China	Australia; Canada; Japan; Mexico; United States of America; European Union	04/11/2015	14/11/2018	9
494	India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015 (ID 494)	India	Australia; Canada; Chile; Guatemala; Japan; Mexico; New Zealand; South Africa; Switzerland;	09/03/2016	14/11/2018	8

			United States of America; European Union			
497	Russian Federation - Rules of cement certification (ID 497)	Russian Federation	Mexico; Ukraine; European Union	09/03/2016	14/11/2018	8
516	Ireland — Public Health (Alcohol) Bill 2015 (ID 516)	Ireland; European Union	Guatemala; Mexico; Argentina; United States of America; Chile; New Zealand; Australia	10/11/2016	14/11/2018	6
530	Italy - Labelling requirements of the origin of grains used in the preparation of dried pasta (ID 530)	Italy; European Union	Mexico; United States of America; Canada; Brazil; Argentina	29/03/2017	14/11/2018	4
532	Viet Nam - Alcoholic Beverages (ID 532)	Viet Nam	Mexico	29/03/2017	14/11/2018	2
546	India — Amended regulation on toy imports (ID 546)	India	European Union; China; United States of America; Mexico; Canada; Hong Kong, China	08/11/2017	14/11/2018	3
547	China — Certification requirements for processed foods (ID 547)	China	European Union; United States of America; Guatemala; Singapore; Chinese Taipei; Japan; Korea, Republic of; Switzerland; Mexico	08/11/2017	14/11/2018	3
549	Viet Nam: Decree on the regulation on conditions for automobiles manufacturing, assembling importing and automotive warranty & maintenance services (ID 549)	Viet Nam	Japan; United States of America; Thailand; European Union; Canada; Russian Federation; Mexico	08/11/2017	14/11/2018	3
556	Thailand - New certification requirements under the Thai Ministry of Finance's Ministerial Notification on Importation of Spirits into the Kingdom of Thailand (B.E 2560) (ID 556)	Thailand	Australia; United States of America; Japan; European Union; New Zealand; Mexico; Canada; Chile	21/03/2018	14/11/2018	2
569	Dominican Republic - Regulation on Cosmetic and Hygiene Products (ID 569)	Dominican Republic	Mexico; United States of America	14/11/2018		0
570	Chile - Regulations on the classification, labelling and notification of chemical substances and mixtures (ID 570)	Chile	Mexico	14/11/2018		0
561	Indonesia - Regulation of the Chairman of NADFC RI No.14 of 2016 on The Safety and Quality Standard of Alcoholic Beverages (ID 561)	Indonesia	Mexico	20/06/2018		0
562	Colombia - Technical Regulation applicable to zinc-carbon and alkaline cells and batteries imported into or manufactured in Colombia (ID 562)	Colombia	Mexico; United States of America	20/06/2018		0
563	Ecuador - RTE INEN 088 (1R) Surface tension agents (ID 563)	Ecuador	Mexico	20/06/2018		0
518	Korea — Amendment of the Notifications on Warning Messages on	Korea, Republic of	Australia; Canada; Japan; Mexico; New Zealand; United States of	10/11/2016	21/03/2018	4

	Smoking and Drinking (ID 518)		America; European Union; Chile			
383	Peru — Act to Promote Healthy Eating Among Children and Adolescents (ID 383)	Peru	Argentina; Brazil; Canada; Colombia; Costa Rica; Guatemala; Mexico; Switzerland; United States of America; European Union	17/06/2013	08/11/2017	13
411	Ecuador -- Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products (ID 411)	Ecuador	Brazil; Canada; Chile; Colombia; Costa Rica; Guatemala; Mexico; Peru; Switzerland; United States of America; European Union	19/03/2014	08/11/2017	11
517	Bolivia — Technical regulations on the labelling of foods and products destined for human consumption that consist of, contain or derive from genetically modified organisms (ID 517)	Bolivia, Plurinational State of	Guatemala; Mexico	10/11/2016	08/11/2017	1
88	European Communities - Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (ID 88)	European Union	Argentina; Australia; Botswana; Brazil; Canada; Chile; China; Chinese Taipei; Colombia; Costa Rica; Cuba; Dominican Republic; Ecuador; El Salvador; India; Indonesia; Israel; Japan; Korea, Republic of; Kuwait, the State of; Malaysia; Mexico; Pakistan; Philippines; Qatar; Russian Federation; Saudi Arabia, Kingdom of; Singapore; South Africa; Switzerland; Thailand; Egypt; United States of America; Uruguay	20/03/2003	29/03/2017	37
409	Ecuador - Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034) (ID 409)	Ecuador	Brazil; Canada; Japan; Mexico; United States of America; European Union	19/03/2014	29/03/2017	7
479	Colombia - Testing Requirements to be met by Toys and their Components and Accessories (ID 479)	Colombia	Canada; United States of America; Mexico	04/11/2015	29/03/2017	3
523	European Union -- Country of Origin Labelling (ID 523)	European Union	New Zealand; United States of America; Brazil; Indonesia; Canada; Australia; Mexico; Uruguay	10/11/2016	29/03/2017	1
370	Chile - Proposed amendment to the Food Health Regulations,	Chile	Argentina; Australia; Brazil; Canada; Colombia; Costa	06/03/2013	10/11/2016	11

	Supreme Decree No. 977/96 (ID 370)		Rica; Guatemala; Mexico; Peru; Switzerland; United States of America; European Union			
389	Indonesia - Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods (ID 389)	Indonesia	Australia; Brazil; Canada; Guatemala; Mexico; Switzerland; United States of America; European Union	17/06/2013	10/11/2016	10
392	Peru — Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops (ID 392)	Peru	Mexico; United States of America	17/06/2013	10/11/2016	6
443	Brazil - Draft Technical Resolution nº 69, 9 September 2014, Regarding the Requirement of Describing the Chemical Composition, in Portuguese, in the Label of Personal Hygiene Products, Cosmetics and Perfumes (ID 443)	Brazil	Canada; Mexico; European Union	05/11/2014	10/11/2016	6
506	Colombia - Draft Resolution of the Ministry of Health and Social Welfare and the Ministry of the Environment and Sustainable Development "adopting the Technical Regulation establishing the maximum levels of phosphorus and the biodegradability of surfactants in detergents and soaps, and introducing other provisions" (ID 506)	Colombia	Mexico	15/06/2016	10/11/2016	1
433	Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: "Labelling of alcoholic beverages" (ID 433)	Ecuador	Canada; Chile; Mexico; United States of America; European Union	18/06/2014	15/06/2016	6
432	Colombia - Draft Ministry of Commerce, Industry and Tourism Decree "Restructuring the National Quality Subsystem and amending Decree No. 2269 of 1993" (ID 432)	Colombia	Japan; Mexico; United States of America; European Union	18/06/2014	09/03/2016	2
455	Ecuador - (PRTE INEN) No. 111: Energy efficiency. Clothes dryers. Labelling (ID 455)	Ecuador	Mexico; United States of America	05/11/2014	09/03/2016	4
458	Ecuador - Emergency Technical Regulation (RTE) No. 088: "Surface tension agents", of the Ecuadorian Standardization Institute (INEN) G/TBT/N/ECU/117 (ID 458)	Ecuador	Mexico	18/03/2015	09/03/2016	3
417	Ecuador - Cosmetic products (ID 417)	Ecuador	Brazil; Chile; Korea, Republic of; Mexico; European Union	19/03/2014	04/11/2015	3
420	France - Recycling Triman Mark: "Draft Decree on a common set of symbols	France; European Union	Canada; Mexico; New Zealand;	19/03/2014	18/03/2015	3

	informing the consumer about recyclable products subject to a system of extended producer responsibility associated with waste sorting instructions" (ID 420)		United States of America			
453	Ecuador - Equivalence Agreement N° 14.241 with the European Union regulations (ID 453)	Ecuador	Brazil; Mexico; United States of America	05/11/2014	18/03/2015	1
454	Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (RTE INEN) No. 047: "Metal cable tray, electrical conduit and trunking systems") (ID 454)	Ecuador	Mexico	05/11/2014	18/03/2015	1
304	Australia - Tobacco Plain Packaging Bill 2011 (ID 304)	Australia	Chile; China; Colombia; Cuba; Dominican Republic; El Salvador; Guatemala; Honduras; Hong Kong, China; Indonesia; Japan; Mexico; Nicaragua; Nigeria; Philippines; Russian Federation; Zimbabwe; Switzerland; Turkey; Ukraine; Zambia; European Union	15/06/2011	05/11/2014	4
394	Ecuador - Resolution No. SENAE-DGN-2013-0300-RE relating to post entry control of imported alcoholic beverages (ID 394)	Ecuador	Canada; Mexico; United States of America; European Union	30/10/2013	18/06/2014	2
311	Kenya - Alcohol Labelling: The Alcoholic Drinks Control (Licensing) Regulations, 2010: Legal Notice No. 206: 2010 (ID 311)	Kenya	Mexico; United States of America; European Union	15/06/2011	19/03/2014	5
361	New Zealand - Proposal to introduce plain packaging of tobacco products in New Zealand (ID 361)	New Zealand	Cuba; Dominican Republic; Guatemala; Honduras; Indonesia; Malawi; Mexico; Nicaragua; Nigeria; Zimbabwe; Ukraine; Zambia	27/11/2012	19/03/2014	3
377	European Union - Tobacco products, nicotine containing products and herbal products for smoking. Packaging for retail sale of any of the aforementioned products (ID 377)	European Union	Cuba; Dominican Republic; Guatemala; Honduras; Indonesia; Malawi; Mexico; Mozambique; Nicaragua; Nigeria; Philippines; Zimbabwe; Ukraine; Zambia	06/03/2013	19/03/2014	3
407	Turkey - Draft Communiqué on Warning Messages Placed on Containers of Alcoholic	Turkey	Canada; Mexico; United States of America; European Union	30/10/2013	19/03/2014	1

	Beverages; and, Draft Regulation Amending the Regulation on Procedures and Principles Concerning Domestic and Foreign Trading of Alcohol and Alcoholic Beverages (ID 407)					
224	India - Mandatory Certification for Steel Products (ID 224)	India	China; Japan; Korea, Republic of; Mexico; European Union	18/03/2009	30/10/2013	12
233	Brazil - Health Products (ID 233)	Brazil	Canada; Mexico; Singapore; Switzerland; United States of America; European Union	25/06/2009	30/10/2013	10
320	Peru - Draft Supreme Decree Approving the Regulations Governing the Labelling of Genetically Modified Foods (ID 320)	Peru	Argentina; Brazil; Canada; Chile; Colombia; Mexico; United States of America	10/11/2011	30/10/2013	5
364	Israel - Warning regulations on alcoholic beverages (ID 364)	Israel	Argentina; Mexico; United States of America; European Union	27/11/2012	30/10/2013	3
318	Colombia - Commercial Truck Diesel Emissions Regulation (Resolution 2604, 24 December 2009) (ID 318)	Colombia	Canada; Mexico; United States of America	15/06/2011	17/06/2013	5
322	European Union - Issue with respect of honey containing pollen from genetically modified maize MON810, Ruling from ECJ (ID 322)	European Union	Argentina; Brazil; Canada; El Salvador; Mexico; United States of America; Uruguay	10/11/2011	06/03/2013	2
39	European Communities - Regulation on Certain Wine Sector Products (ID 39)	European Union	Argentina; Australia; Bolivia, Plurinational State of; Brazil; Canada; Chile; Mexico; New Zealand; Paraguay; Peru; South Africa; United States of America; Uruguay	01/10/1999	27/11/2012	28
349	Viet Nam - Regulations relating to liquor production and trading (ID 349)	Viet Nam	Australia; Canada; Chile; Mexico; New Zealand; South Africa; United States of America; European Union	13/06/2012	27/11/2012	1
288	Brazil - Draft Resolution No. 112, 29 November 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (ID 288)	Brazil	Chile; Colombia; Cuba; Dominican Republic; Ecuador; Guatemala; Honduras; Indonesia; Jordan; Kenya; Malawi; Mexico; Mozambique; Nicaragua; Nigeria; Philippines; Russian Federation; Zimbabwe; Turkey; North Macedonia; Tanzania; Zambia; European Union	24/03/2011	13/06/2012	4

350	Indonesia - Draft modification to the technical regulation HK.00.05.52.4040 on food categories, published on 9 October 2006 (ID 350)	Indonesia	Mexico; South Africa	13/06/2012		0
35	European Communities - Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (ID 35)	European Union	Australia; Canada; China; Israel; Japan; Jordan; Korea, Republic of; Malaysia; Mexico; Thailand; Egypt; United States of America; Venezuela, Bolivarian Republic of	31/03/1999	20/03/2012	27
216	Colombia - Draft Decree Establishing Provisions to Promote the Use of Biofuels (ID 216)	Colombia	Argentina; Mexico; European Union	18/03/2009	20/03/2012	9
259	Thailand - Health warnings for alcoholic beverages (ID 259)	Thailand	Argentina; Australia; Canada; Chile; Mexico; New Zealand; Switzerland; United States of America; European Union	24/03/2010	20/03/2012	6
331	El Salvador - Law on hygienic production of milk and milk products and the regulation of their sale (ID 331)	El Salvador	Mexico	10/11/2011	20/03/2012	1
333	Dominican Republic - Draft of the Technical Regulation "Categorization of Alcoholic Beverages" (ID 333)	Dominican Republic	Mexico; European Union	20/03/2012		0
263	Brazil - Alcoholic Beverages (ID 263)	Brazil	Mexico; United States of America; European Union	24/03/2010	10/11/2011	5
285	European Union - Proposal for a Council Regulation on the Indication of the Country of Origin of Certain Products Imported from Third Countries (SEC(2005)1657) (ID 285)	European Union	Mexico; United States of America	03/11/2010	15/06/2011	2
249	Canada - Bill C-32 amendment to Tobacco Act (ID 249)	Canada	Argentina; Brazil; Burundi; Chile; Colombia; Croatia; Cuba; Dominican Republic; Ecuador; Guatemala; Honduras; Indonesia; Japan; Jordan; Kenya; Malawi; Mexico; Mozambique; Philippines; Zimbabwe; Switzerland; Turkey; Uganda; North Macedonia; Egypt; Tanzania; United States of America; Zambia; European Union	05/11/2009	24/03/2011	4
299	Brazil - Disposition (Portaria) n° 371, December 29th 2009 and Annex; INMETRO approves Conformity Assessment	Brazil	Mexico	24/03/2011		0

	Requirements for Security of Electronic Appliances (ID 299)					
300	United States - Food Safety Modernization (FSMA) Public Law 111-353 (ID 300)	United States of America	Mexico	24/03/2011		0
245	Korea - Regulation for Food Industry Promotion Act (ID 245)	Korea, Republic of	Australia; Canada; Chile; Mexico; New Zealand; Switzerland; United States of America; European Union	25/06/2009	03/11/2010	4
267	Viet Nam - Alcoholic Beverages (ID 267)	Viet Nam	Australia; Chile; Mexico; United States of America; European Union	23/06/2010	03/11/2010	1
277	United States - Foreign Manufacturers Legal Accountability Act (ID 277)	United States of America	Australia; Hong Kong, China; Mexico	03/11/2010		0
260	Brazil - Food registration and notification procedures (ID 260)	Brazil	Mexico	24/03/2010		0
91	United States - Country of Origin Labelling (ID 91)	United States of America	Argentina; Australia; Brazil; Canada; China; Mexico; New Zealand	21/06/2002	05/11/2009	8
258	United States - Country of Origin Labeling for Dairy (ID 258)	United States of America	Mexico	05/11/2009		0
131	European Communities - Fire Performance of Construction Products (ID 131)	European Union	Brazil; Colombia; Japan; Korea, Republic of; Mexico; Philippines; Thailand; United States of America	15/03/2006	25/06/2009	6
136	Saudi Arabia - International Conformity Certification Programme (ICCP) (ID 136)	Saudi Arabia, Kingdom of	Japan; Korea, Republic of; Mexico; United States of America	15/03/2006	25/06/2009	6
219	European Communities - Green Paper on Agricultural Product Quality Policy (ID 219)	European Union	Mexico; United States of America	18/03/2009	25/06/2009	1
247	United States - Food and Drugs Cosmetic Act (ID 247)	United States of America	Mexico	25/06/2009		0
193	Brazil - Regulation on Identification and Quality Standards of Ethyl Alcohol and other Spirits (ID 193)	Brazil	Mexico; United States of America; European Union	01/07/2008	18/03/2009	2
205	European Communities - Novel foods (ID 205)	European Union	Bolivia, Plurinational State of; Brazil; Colombia; Costa Rica; Cuba; Ecuador; Mexico; Peru; Venezuela, Bolivarian Republic of	05/11/2008	18/03/2009	1
211	United States - Requirements to combat illegal logging (ID 211)	United States of America	Argentina; Canada; Japan; Mexico; Switzerland; European Union	05/11/2008	18/03/2009	1
218	Ecuador - Test report and certificate of conformity for industrial products including tyres, steel products and automobile components (ID 218)	Ecuador	Chile; Colombia; Korea, Republic of; Mexico; United States of America; European Union	18/03/2009		0
228	Korea - Beef (ID 228)	Korea, Republic of	Australia; Canada; Mexico; New	18/03/2009		0

			Zealand; United States of America			
200	Korea - Country of Origin Labelling Requirements for Certain Imported Fruit (ID 200)	Korea, Republic of	Mexico; United States of America	01/07/2008		0
103	China - Wireless Local Area Network Products with WAPI functions (ID 103)	China	Canada; Japan; Mexico; United States of America; European Union	23/03/2004	09/11/2006	3
41	European Communities - Restrictions on the Use of Certain Phthalates in Toys (ID 41)	European Union	Brazil; Canada; China; Hong Kong, China; Japan; Mexico; Egypt; United States of America	25/02/2000	16/06/2005	3
107	Argentina - MERCOSUR Regulation on Definitions Relating to Alcoholic Beverages other than Fermented (ID 107)	Argentina	Barbados; Cuba; Dominican Republic; Jamaica; Mexico; Trinidad and Tobago; United States of America; European Union	01/07/2004	04/11/2004	1
87	European Communities - Amendment to Regulation on Sardines (ID 87)	European Union	Canada; Chile; Ecuador; Mexico; Norway; Peru; United States of America; Venezuela, Bolivarian Republic of	20/03/2003	02/07/2003	1
90	United States - Bioterrorism Act (ID 90)	United States of America	Argentina; Australia; Brazil; China; Ecuador; Indonesia; Malaysia; Mexico; Switzerland; European Union	20/03/2003	02/07/2003	1
86	Venezuela - Register of Domestic Manufactures and Importers of Textile Clothing (ID 86)	Venezuela, Bolivarian Republic of	Mexico	17/10/2002	20/03/2003	1
53	Belgium - Draft Law aiming at Promoting Socially Responsible Production (ID 53)	European Union; Belgium	Argentina; Brazil; Canada; Cuba; Hong Kong, China; India; Malaysia; Mexico; Pakistan; Thailand; Egypt; United States of America	30/03/2001	15/03/2002	3
42	United States - Dolphin-Safe Tuna Labelling Requirement (ID 42)	United States of America	Brazil; Mexico; Egypt	25/02/2000	10/11/2000	4
12	France - Regulation on Asbestos (ID 12)	France; European Union	Canada; Colombia; Mexico; South Africa	14/02/1997	20/06/1997	1

Fonte: OMC. Elaborado por CCGI-EESP/FGV.

B. Colombia

Table 13.3 - STC raised against Colombia

IMS ID	Title	Member(s) subject to STC	Member(s) raising STC	First date raised	Last date raised	Number of times subsequently raised
562	Colombia - Technical Regulation applicable to zinc-carbon and alkaline cells and batteries imported into or manufactured in Colombia (ID 562)	Colombia	Mexico; United States of America	20/06/2018		0
479	Colombia - Testing Requirements to be met by Toys and their Components and Accessories (ID 479)	Colombia	Canada; United States of America; Mexico	04/11/2015	29/03/2017	3
506	Colombia - Draft Resolution of the Ministry of Health and Social Welfare and the Ministry of the Environment and Sustainable Development "adopting the Technical Regulation establishing the maximum levels of phosphorus and the biodegradability of surfactants in detergents and soaps, and introducing other provisions" (ID 506)	Colombia	Mexico	15/06/2016	10/11/2016	1
432	Colombia - Draft Ministry of Commerce, Industry and Tourism Decree "Restructuring the National Quality Subsystem and amending Decree No. 2269 of 1993" (ID 432)	Colombia	Japan; Mexico; United States of America; European Union	18/06/2014	09/03/2016	2
422	Colombia - Steel (ID 422)	Colombia	Turkey	19/03/2014		0
318	Colombia - Commercial Truck Diesel Emissions Regulation (Resolution 2604, 24 December 2009) (ID 318)	Colombia	Canada; Mexico; United States of America	15/06/2011	17/06/2013	5
291	Colombia - Alcoholic beverages (ID 291)	Colombia	United States of America; European Union	24/03/2011	13/06/2012	4

343	Colombia - Draft Resolution of the Ministry of Transport Issuing the Technical Regulation for public transport (ID 343)	Colombia	Korea, Republic of	20/03/2012	13/06/2012	1
216	Colombia - Draft Decree Establishing Provisions to Promote the Use of Biofuels (ID 216)	Colombia	Argentina; Mexico; European Union	18/03/2009	20/03/2012	9
269	Colombia - Shelf life Requirements for Milk Powder (ID 269)	Colombia	European Union	23/06/2010	20/03/2012	5
217	Colombia - Quality and Identity Requirements for Distilled Spirits (ID 217)	Colombia	United States of America; European Union	18/03/2009	05/11/2009	2
196	Colombia - Regulation on Wine labelling (ID 196)	Colombia	Chile	01/07/2008		0
125	Colombia - Labelling of Footwear (ID 125)	Colombia	European Union	22/12/2005		0
64	Colombia - Recognition and Acceptance of Certificates for Products Sold in the Andean Community (ID 64)	Colombia	Switzerland	09/10/2001	15/03/2002	1

Table 13.4 - STCs raised by Colombia

IMS ID	Title	Member(s) subject to STC	Member(s) raising STC	First date raised	Last date raised	Number of times subsequently raised
579	European Union - Chlorothalonil (pesticide active substance) (ID 579)	European Union	Colombia; Guatemala; United States of America; Brazil; Panama; Paraguay; Canada; Ecuador; Costa Rica; Honduras	06/03/2019		0
580	European Union - Transitional periods for MRLs and international consultations (ID 580)	European Union	Colombia; Guatemala; United States of America; Paraguay; Brazil; Ecuador; Costa Rica; Panama	06/03/2019		0
393	European Union - — Hazard-based approach to plant protection products and setting of import	European Union	Argentina; Australia; Brazil; Canada; Chile; Colombia; Guatemala;	17/06/2013	14/11/2018	16

	tolerances (ID 393)		Mexico; New Zealand; South Africa; Thailand; Egypt; United States of America; Ecuador; Uruguay; Costa Rica; Panama; Israel; India; Paraguay			
553	European Union — Amendments to the Directive 2009/28/EC, Renewable Energy Directive (ID 553)	European Union	Malaysia; Thailand; Indonesia; Colombia; Costa Rica; Guatemala; Nigeria; Honduras; Ecuador; Argentina	21/03/2018	14/11/2018	2
555	European Union — Application of Regulation No. 1169/2011 and Regulation (EC) No. 1924/2006 as regards the labelling of food products, in not prohibiting or examining the use of "palm oil free" labels (ID 555)	European Union	Colombia; Indonesia; Costa Rica; Guatemala; Thailand; Malaysia; Ecuador; Honduras	21/03/2018	14/11/2018	2
548	Ecuador - Household refrigerating appliances (RTE INEN No. 009) (ID 548)	Ecuador	Colombia	08/11/2017	21/03/2018	1
383	Peru — Act to Promote Healthy Eating Among Children and Adolescents (ID 383)	Peru	Argentina; Brazil; Canada; Colombia; Costa Rica; Guatemala; Mexico; Switzerland; United States of America; European Union	17/06/2013	08/11/2017	13
411	Ecuador -- Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical	Ecuador	Brazil; Canada; Chile; Colombia; Costa Rica; Guatemala; Mexico; Peru; Switzerland; United States of	19/03/2014	08/11/2017	11

	Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products (ID 411)		America; European Union			
88	European Communities - Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (ID 88)	European Union	Argentina; Australia; Botswana; Brazil; Canada; Chile; China; Chinese Taipei; Colombia; Costa Rica; Cuba; Dominican Republic; Ecuador; El Salvador; India; Indonesia; Israel; Japan; Korea, Republic of; Kuwait, the State of; Malaysia; Mexico; Pakistan; Philippines; Qatar; Russian Federation; Saudi Arabia, Kingdom of; Singapore; South Africa; Switzerland; Thailand; Egypt; United States of America; Uruguay	20/03/2003	29/03/2017	37
370	Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96 (ID 370)	Chile	Argentina; Australia; Brazil; Canada; Colombia; Costa Rica; Guatemala; Mexico; Peru; Switzerland; United States of America; European Union	06/03/2013	10/11/2016	11

398	Ecuador - Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations (ID 398)	Ecuador	Brazil; Canada; Chile; Colombia; Costa Rica; Peru; Switzerland; United States of America; European Union	30/10/2013	17/06/2015	5
304	Australia - Tobacco Plain Packaging Bill 2011 (ID 304)	Australia	Chile; China; Colombia; Cuba; Dominican Republic; El Salvador; Guatemala; Honduras; Hong Kong, China; Indonesia; Japan; Mexico; Nicaragua; Nigeria; Philippines; Russian Federation; Zimbabwe; Switzerland; Turkey; Ukraine; Zambia; European Union	15/06/2011	05/11/2014	4
320	Peru - Draft Supreme Decree Approving the Regulations Governing the Labelling of Genetically Modified Foods (ID 320)	Peru	Argentina; Brazil; Canada; Chile; Colombia; Mexico; United States of America	10/11/2011	30/10/2013	5
378	Ecuador - Draft Technical Regulation of the Ecuadorian	Ecuador	Colombia	06/03/2013		0

	Standardization Institute (PRTE INEN) No. 080: "Labelling of footwear" (ID 378)					
379	Ecuador - Labelling of articles of apparel, household linen and clothing accessories (ID 379)	Ecuador	Colombia	06/03/2013		0
288	Brazil - Draft Resolution No. 112, 29 November 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (ID 288)	Brazil	Chile; Colombia; Cuba; Dominican Republic; Ecuador; Guatemala; Honduras; Indonesia; Jordan; Kenya; Malawi; Mexico; Mozambique; Nicaragua; Nigeria; Philippines; Russian Federation; Zimbabwe; Turkey; North Macedonia; Tanzania; Zambia; European Union	24/03/2011	13/06/2012	4
165	European Communities - Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) (ID 165)	European Union	Argentina; Australia; Botswana; Brazil; Canada; Chile; China; Colombia; Cuba; Dominican Republic; Ecuador; India; Indonesia; Japan; Korea, Republic of; Malaysia; Mauritius; Philippines; Russian Federation; Saudi Arabia, Kingdom of; South Africa; Zimbabwe;	05/07/2007	15/06/2011	12

			Thailand; Turkey; United States of America; Venezuela, Bolivarian Republic of			
249	Canada - Bill C-32 amendment to Tobacco Act (ID 249)	Canada	Argentina; Brazil; Burundi; Chile; Colombia; Croatia; Cuba; Dominican Republic; Ecuador; Guatemala; Honduras; Indonesia; Japan; Jordan; Kenya; Malawi; Mexico; Mozambique; Philippines; Zimbabwe; Switzerland; Turkey; Uganda; North Macedonia; Egypt; Tanzania; United States of America; Zambia; European Union	05/11/2009	24/03/2011	4
131	European Communities - Fire Performance of Construction Products (ID 131)	European Union	Brazil; Colombia; Japan; Korea, Republic of; Mexico; Philippines; Thailand; United States of America	15/03/2006	25/06/2009	6
174	Argentina - Measures affecting market access for pharmaceutical products (ID 174)	Argentina	Chile; Colombia; Paraguay	09/11/2007	25/06/2009	5
205	European Communities - Novel foods (ID 205)	European Union	Bolivia, Plurinational State of; Brazil; Colombia; Costa Rica; Cuba; Ecuador; Mexico; Peru; Venezuela, Bolivarian Republic of	05/11/2008	18/03/2009	1

218	Ecuador - Test report and certificate of conformity for industrial products including tyres, steel products and automobile components (ID 218)	Ecuador	Chile; Colombia; Korea, Republic of; Mexico; United States of America; European Union	18/03/2009		0
12	France - Regulation on Asbestos (ID 12)	France; European Union	Canada; Colombia; Mexico; South Africa	14/02/1997	20/06/1997	1

Source: WTO. Elaborated by CCGI.

C. Chile

Table 13.5 - STCs raised by Chile

IMS ID	Title	Member(s) subject to STC	Member(s) raising STC	First date raised	Last date raised	Number of times subsequently raised
566	Chile - Public Consultation for draft legislation setting out rules on the preparation, description and labelling of milk products deriving from milk (ID 566)	Chile	European Union; United States of America	14/11/2018		0
570	Chile - Regulations on the classification, labelling and notification of chemical substances and mixtures (ID 570)	Chile	Mexico	14/11/2018		0
370	Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96 (ID 370)	Chile	Argentina; Australia; Brazil; Canada; Colombia; Costa Rica; Guatemala; Mexico; Peru; Switzerland; United States of America; European Union	06/03/2013	10/11/2016	11
403	Chile - Safety for Printers and Energy Efficiency for Printers (ID 403)	Chile	United States of America	30/10/2013	19/03/2014	1
213	Chile Cosmetics (ID 213)	Chile	European Union	18/03/2009	24/03/2010	3
63	Chile Labelling System for Transgenic Foods (ID 63)	Chile	Canada	09/10/2001		0

Source: WTO. Elaborated by CCGI-EESP/FGV.

Table 13.6 - STCs raised against Chile

IMS ID	Title	Member(s) subject to STC	Member(s) raising STC	First time raised	Last time raised	Number of times raised
<u>566</u>	Chile - Public Consultation for draft legislation setting out rules on the preparation, description and labelling of milk products deriving from milk (ID 566)	Chile	European Union; United States of America; New Zealand	14/11/2018	06/03/2019	1
<u>570</u>	Chile - Regulations on the classification, labelling and notification of chemical substances and mixtures (ID 570)	Chile	Mexico	14/11/2018		0
<u>370</u>	Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96 (ID 370)	Chile	Argentina; Australia; Brazil; Canada; Colombia; Costa Rica; Guatemala; Mexico; Peru; Switzerland; United States of America; European Union	06/03/2013	10/11/2016	11
<u>403</u>	Chile - Safety for Printers and Energy Efficiency for Printers (ID 403)	Chile	United States of America	30/10/2013	19/03/2014	1
<u>213</u>	Chile - Cosmetics (ID 213)	Chile	European Union	18/03/2009	24/03/2010	3

63	Chile - Labelling System for Transgenic Foods (ID 63)	Chile	Canada	09/10/2001		0

Source: WTO. Elaborated by CCGI-EESP/FGV.

13.2. Appendix 2 – Technical Standards: Mexico, Colombia, and Chile

A. Mexico

Table 13.7 - Technical Standards on Quality

Standard	Description
NMX-CC-023-IMNC-2008 IWA 2:2007	Diretrizes para a aplicação da norma NMX-CC9001-IMNC-2000 em educação
NMX-CC-025-IMNC-2010 IWA 4: 2009	Diretrizes para a aplicação da norma NMX-CC9001-IMNC-2008 no governo local
NMX-CC-027-IMNC-2009	Guia de interpretação para o NMX-CC-9001-IMNC2008 na indústria da construção
NMX-CC-040-IMNC-2017	Sistemas de gestão da qualidade - Requisitos particulares para a aplicação da Norma Mexicana NMX-CC-9001-IMNC-2015 para lavagem e sanitização de têxteis reutilizável por lavanderias industriais para o setor saúde
NMX-CC-10001-IMNC-2012 ISO 10001:2007	Satisfação do cliente - Diretrizes para códigos de conduta das organizações
NMX-CC-10002-IMNC-2005 ISO 10002:2004 COPANT/ISO 10002:2004	Satisfação do cliente - Diretrizes para tratamento de reclamações nas organizações
NMX-CC-10003-IMNC-2012 ISO 10003:2007	Satisfação do cliente - Diretrizes para a resolução de conflitos externos às organizações
NMX-CC-10004-IMNC-2017 ISO 10004:2012	Gestão da qualidade - satisfação do cliente - Diretrizes para monitoramento e medição
NMX-CC-10005-IMNC-2006 ISO 10005:2005	Diretrizes para planos de qualidade
NMX-CC-10006-IMNC-2005 ISO 10006:2003 COPANT/ISO 10006:2003	Diretrizes para a gestão da qualidade em projetos
NMX-CC-10007-IMNC-2006 ISO 10007:2003	Diretrizes para gerenciamento de configuração
NMX-CC-10012-IMNC-2004 ISO 10012:2003 COPANT/ISO 10012:2003	Sistemas de gerenciamento de medição - Requisitos para processos e equipamentos de medição
NMX-CC-10013-IMNC-2002 ISO/TR 10013:2001 COPANT/ISO 10013:2002	Diretrizes para a documentação de sistemas de gestão de qualidade
NMX-CC-10017-IMNC-2006 ISO/TR 10017:2003	Orientação sobre técnicas estatísticas para o padrão NMX-CC-9001-IMNC-2000
NMX-CC-10019-IMNC-2008 ISO 10019:2005	Diretrizes para a seleção de consultores de sistemas de gestão da qualidade e o uso de seus serviços
NMX-CC-13485-IMNC-2017 ISO 13485:2016	Dispositivos médicos - Sistemas de gestão de qualidade - Requisitos para fins regulatórios
NMX-CC-16949-IMNC-2010 ISO/TS 16949:2009	Requisitos particulares para a aplicação da norma NMXCC-9001-IMNC-2008 para produção em série e peças de reposição na indústria automotiva
NMX-CC-29001-IMNC-2009 ISO 29001:2007	Sistema de gestão da qualidade no campo da indústria de petróleo, petroquímica e gás natural - Requisitos para organizações provedoras de produto e serviços
NMX-CC-9001-IMNC-2015 ISO 9001:2015	Sistemas de Gestão da Qualidade - Requisitos
NMX-CC-9000-IMNC-2015 ISO 9000:2015	Sistemas de gestão de qualidade - Fundamentos e Vocabulário
NMX-CC-9002-IMNC-2017 ISO/TS 9002:2016	Sistemas de gestão da qualidade - Diretrizes para a aplicação do padrão mexicano NMX-CC-9001- IMNC-2015
NMX-CC-9004-IMNC-2009 ISO 9004:2009 COPANT/ISO 9004:2009	Gestão para o sucesso sustentado de uma organização - Abordagem para a gestão da qualidade
NMX-CC-19011-IMNC-2012 ISO 19011:2011	Diretrizes para a auditoria de sistemas de gerência
NMX-CC-19600-IMNC-2017 ISO 19600:2014	Sistema de gerenciamento de conformidade - Diretrizes
PROY-NMX-CC-024-IMNC-2005 IWA 1:2005	Diretrizes para melhorias de processo em organizações de serviços de saúde
PROY-NMX-CC-026-IMNC-2008	Guia de interpretação do padrão NMX-CC-9001- IMNC-2000 em serviços de saúde

Fonte: IMNC

Table 13.8 - Mexican Standards on Food

Standard	Description
NMX-F-CC-22000-NORMEXIMNC-2007 ISO 22000:2005	Sistemas de gestão de segurança alimentar - Requisitos para qualquer organização na cadeia alimentar
NMX-F-CC-22002-1-NORMEXIMNC-2013 ISO/TS 22002-1:2009	Programas de pré-requisitos em matéria de segurança alimentar - Parte 1: Produção de alimentos
NMX-F-CC-22003-NORMEXIMNC-2008 ISO/TS 22003:2007	Sistemas de gestão de segurança alimentar - Requisitos para agências que realizam auditoria e certificação de sistemas de gestão de segurança alimentar
NMX-F-CC-22004-NORMEXIMNC-2007 ISO/TS 22004:2005	Sistemas de gestão de segurança alimentar - Guias de aplicação do NMX-F-CC-22000-NORMEX-IMNC-2007
NMX-F-CC-22005-NORMEXIMNC-2008 ISO/TS 22005:2007	Rastreabilidade da cadeia alimentar - Princípios gerais e requisitos fundamentais para o projeto e a implementação do sistema

NMX-CC-15161-IMNC-2007 ISO 15161:2001	Orientações para a aplicação da norma NMXCC-9001-IMNC-2000 nas indústrias alimentar e de bebidas

Fonte: IMNC. Elaboração: CCGI-EESP/FGV.

Table 13.9 - Mexican Standard on Environment

Standard	Description
NMX-SAA-064-IMNC-2010 ISO GUIDE 64:2008	Guia para lidar com questões ambientais em padrões de produto
NMX-SAA-14001-IMNC-2015 ISO 14001:2015	Sistema de gestão ambiental - Requisitos com orientação para seu uso
NMX-SAA-14004-IMNC-2004 ISO 14004:2004 COPANT-ISO 14004:2004	Sistema de gestão ambiental - Diretrizes gerais sobre princípios, sistemas e técnicas de apoio
NMX-SAA-14005-IMNC-2016 ISO 14004:2004 COPANT-ISO 14004:2004	Sistemas de gestão ambiental - Guia para a implementação de um sistema de gestão ambiental por etapas, incluindo emprego de avaliação de desempenho ambiental
NMX-SAA-14015-IMNC-2006 ISO 14015:2001 COPANT - ISO 14015:2007	Gestão ambiental - Avaliação ambiental de espaços e organizações (EASO)
NMX-SAA-14020-IMNC-2004 ISO 14020:2000 COPANT - ISO 14020:2007	Rótulos e declarações ambientais - Princípios gerais
NMX-SAA-14024-IMNC-2004 ISO 14024:1999 COPANT - ISO 14024:2007	Rótulos e declarações ambientais - Rotulagem ambiental Tipo I - Princípios e procedimentos
NMX-SAA-14025-IMNC-2008 ISO 14025:2006	Gestão ambiental - rótulos e declarações ambientais - Declarações Ambientais Tipo III - Princípios e procedimentos
NMX-SAA-14031-IMNC-2017 ISO 14031:2013	Gestão ambiental - Avaliação de desempenho ambiental - Diretrizes
NMX-SAA-14033-IMNC-2016 ISO/TS 14033:2012	Gestão ambiental - Informação ambiental quantitativa - Diretrizes e exemplos
NMX-SAA-14040-IMNC-2008 ISO 14040:2006	Gestão ambiental - Análise do ciclo de vida - Princípios e ponto de referência
NMX-SAA-14044-IMNC-2008 ISO 14044:2006	Gestão ambiental - Análise do ciclo de vida - Requisitos e diretrizes
NMX-SAA-14045-IMNC-2016 ISO 14045:2012	Gestão Ambiental - Avaliação da ecoeficiência do sistema produto - Princípios, requisitos e diretrizes
NMX-SAA-14046-IMNC-2017 ISO 14046:2014	Gestão ambiental - Pegada hídrica - Princípios, requisitos e diretrizes
NMX-SAA-14050-IMNC-2009 ISO 14050:2009	Gestão Ambiental - Vocabulário
NMX-SAA-14051-IMNC-2016 ISO 14051:2011	Gestão ambiental - Contabilidade de custos para o fluxo de materiais - Referencial geral
NMX-SAA-14062-IMNC-2010 ISO/TR 14062:2002	Gestão ambiental - Integração dos aspectos ambientais no design e no desenvolvimento de produtos
NMX-SAA-14063-IMNC-2007 ISO 14063:2006	Gestão ambiental - Comunicação ambiental - Diretrizes e exemplos
NMX-SAA-14064-1-IMNC-2007 ISO 14064-1:2006	Gases com efeito de estufa - Parte 1: Especificação com orientação, no nível das organizações, para a quantificação e o relatório de emissões e remoções de gases estufa
NMX-SAA-14064-2-IMNC-2007 ISO 14064-2:2006	Gases com efeito de estufa - Parte 2: Especificação com orientação, no nível do projeto, para quantificação, a monitorização e comunicação de reduções de emissões ou aumento de remoções de gases de efeito estufa
NMX-SAA-14064-3-IMNC-2007 ISO 14064-3:2006	Gases com efeito de estufa - Parte 3: Especificação com orientação para a validação e verificação de declarações sobre gases de efeito estufa
NMX-SAA-14065-IMNC-2008 ISO 14065:2007	Gases com efeito de estufa - Requisitos para agências que realizam a validação e verificação de gases de efeito estufa, uso em acreditação ou outras formas de reconhecimento
NMX-SAA-14066-IMNC-2015 ISO 14066:2011	Gases com efeito de estufa - requisitos de competição para equipes de validação e verificação de gases de efeito estufa
NMX-SAA-14069-IMNC-2017 ISO/TR 14069:2016	Gases com efeito de estufa - Quantificação e relatório de emissões de gases com efeito de estufa para organizações - Orientação para a aplicação de os padrões NMX-SAA-14064-1-IMNC
PROY-NMX-SAA-14055-1-IMNC-2018 ISO 14055-1: 2017	Diretrizes de gestão ambiental para o estabelecimento de boas práticas para combater a degradação do solo e desertificação - parte 1: estrutura de boas práticas

Source: IMNC.

Table 13.10 - Mexican Standards on Vehicles and Autoparts

Standard	Description
NMX-D-225-IMNC-2017	Segurança - Fitas reflexivas para veículos automotores - Especificações e métodos de teste e instalação
NMX-D-233-IMNC-2016	Produtos para uso no transporte automotivo - luzes exteriores
NMX-D-300-IMNC-2017	Filtros para óleo para carros e caminhões - Especificações e métodos de teste
NMX-D-301-IMNC-2006	Autopeças - Conjuntos de cabos de ignição
NMX-D-302-IMNC-2007	Indústria automotiva - Tanques de combustível diesel - Especificações e métodos de teste
NMX-D-303-IMNC-2009	Autopeças - Elaboração de materiais comprimidos sem amianto para produção de juntas de motor
NMX-D-304-IMNC-2006	Autopeças - Discos e tambores para freios de carros e caminhões leves - Especificações de segurança e métodos de testes
NMX-D-305-IMNC-2009	Transporte automotivo - Molas de suspensão para veículos automotivos - Especificações de segurança e métodos de testes

NMX-D-306-IMNC-2017	Filtros para carros e caminhões a gasolina e diesel - Especificações e métodos de teste
NMX-D-307-IMNC-2017	Indústria automotiva - Filtros para ar de tipo seco de uso em automóveis e caminhões, especificações e métodos de teste
NMX-D-308-IMNC-2010	Transporte automotivo - Molas de suspensão para veículos automotores - Especificações de segurança e métodos de teste
NMX-D-313-IMNC-2015	Sistemas de freios de ar
NMX-D-314-IMNC-2014	Transporte terrestre - serviços de transporte automotivo público federal de carga e transporte privado - especificações de segurança para a sujeição da carga que devem cumprir os veículos de transporte privado que transitam pelas estradas e pontes de jurisdição federal
NMX-D-315-IMNC-2015	Material de atrito para o sistema de freios
NMX-D-316-IMNC-2016	Motores a diesel - agente de redução de Nox
NMX-D-317-IMNC-2018	Transporte de passageiros, características, especificações técnicas e de segurança para unidades de transporte urbano de passageiros
NMX-D-318-IMNC-2017	Veículos (Autopeças) - Dispositivos de proteção lateral - Especificações
PROY-NMX-D-319-IMNC-2017	Veículos (Autopeças) - Cadeia de montagem de segurança para conversores
PROY-NMX-D-320-IMNC-2018	Veículos (Autopeças) - montagem de fita técnica a ser utilizada em sistemas de fixação de carga
PROY-NMX-D-313-2-IMNC-2017	Sistemas de freio a ar - Parte 2: Sistema para veículos das categorias M2, M3, N e O
PROY-NMX-D-9227-IMNC-2018	Testes de corrosão em atmosferas artificiais - Testes de pulverização de sal
PROY-NMX-D-13216-1-IMNC-2018	Veículos a motor - Âncoras em veículos e conexões para as âncoras nos sistemas restrição para crianças - Parte 1: Âncoras e conexões de encosto
PROY-NMX-D-9819-IMNC-2018	Veículos a motor - tabelas comparativas de regulamentos sobre requisitos fotométricos de dispositivos de sinalização luminosa

Source: IMNC.

Table 13.11 - Mexican Standards on Metrology

Standard	Description
NMX-CH-002-IMNC-2004	Instrumentos de medição dimensional - Calibradores tipo vernier e medidores de profundidade - Design e requisitos
NMX-CH-010-IMNC-1999	Instrumentos de medição, instrumentos de pesagem de operação não automática - Formatos padronizados para avaliação de modelos
NMX-CH-012-1-IMNC-2007 ISO 9044:1999	Especificações Geométricas do Produto (GPS) - Malha tecida para telas ou peneiras - Parte 1: Especificações, verificação e calibração de malhas de metal
NMX-CH-047-1996-IMNC	Instrumentos de medição - Balanças de braços iguais - Método de calibração
NMX-CH-049-IMNC-2006	Instrumentos de medição - Medições volumétricas metálicas de pescoço graduado para líquidos - Método de calibração
NMX-CH-059-1996 IMNC	Instrumentos de medição - Balança de um só braço - Método de calibração
NMX-CH-060-IMNC-2006	Medições de pressão - Vocabulário
NMX-CH-062-IMNC-2004	Instrumentos de medição - Quadrados de aço - Especificações
NMX-CH-064-IMNC-2006	Medições de temperatura - Vocabulário
NMX-CH-068-IMNC-2015	Materiais de referência - Preparação de soluções de trabalho de pH
NMX-CH-092-IMNC-2005	Especificações Geométricas do Produto (GPS) - Instrumentos de medição dimensional - Micrômetros para interiores com três superfícies de medição
NMX-CH-093-IMNC-2005	Especificações Geométricas do Produto (GPS) - Instrumentos de medição dimensional - Micrômetros para interiores com duas superfícies de medição
NMX-CH-099-IMNC-2005 ISO 3611:1978	Especificações Geométricas do Produto (GPS) - Instrumentos de medição dimensional - Micrômetros para medição ao ar livre
NMX-CH-100-IMNC-2005 ISO 1:2002	Especificações Geométricas do Produto (GPS) - Temperatura de referência padrão para especificações e verificações geométricas dos produtos
NMX-CH-10360-1-IMNC-2004 ISO 10360-1:2000	Especificações Geométricas do Produto (GPS) - Testes de aceitação e verificação periódica para máquinas de medição por coordenadas (CMM) - Parte 1: Vocabulário
NMX-CH-10360-2-IMNC-2008 ISO 10360-2:2001	Especificações Geométricas do Produto (GPS) - Testes de aceitação e verificação periódica para máquinas de medição por coordenadas (MMC) - Parte 2: MMCs usadas para medição de tamanho
NMX-CH-10576-1-IMNC-2007 ISO 10576-1:2003	Métodos Estatísticos - Diretrizes para avaliação de conformidade com os requisitos especificados - Parte 1: Princípios gerais
NMX-CH-10989-IMNC-2012 ISO/TR 10989:2009	Materiais de referência - Orientação e palavras chave usada para a categorização de MR
NMX-CH-1101-IMNC-2008 ISO 1101:2004	Especificações Geométricas do Produto (GPS) - Tolerâncias geométricas - Tolerâncias de forma, orientação, localização e campo
NMX-CH-11095-IMNC-2007 ISO 11095:1996	Calibração linear usando materiais de referência
NMX-CH-1119-IMNC-2005 ISO 1119:1998	Especificações Geométricas do Produto (GPS) - Série de ângulos de cone e de conicidades
NMX-CH-11453-IMNC-2008 ISO 11453:1999	Interpretação estatística dos dados - Intervalos de confiança e evidências relacionadas a proporções
NMX-CH-11462-1-IMNC-2007 ISO 11462-1:2001	Diretrizes para a implementação do Controle Estatístico do Processo (CEP) - Parte 1: Elementos do CEP
NMX-CH-117-IMNC-2009	Materiais de referência - escala de pH para soluções aquosas

NMX-CH-11843-1-IMNC-2007 ISO 11843-1:1997	Capacidade de detecção - Parte 1: Termos e Definições
NMX-CH-11843-2-IMNC-2007 ISO 11843-2:2000	Capacidade de detecção Parte 2: Metodologia no caso de calibração linear
NMX-CH-11843-3-IMNC-2007 ISO 11843-3:2003	Capacidade de detecção - Parte 3: Metodologia para a determinação do valor crítico para a variável de resposta quando os dados de calibração não são usados
NMX-CH-11843-4-IMNC-2007 ISO 11843-4:2003	Capacidade de detecção - Parte 4: Metodologia para comparar o valor mínimo detectável com um valor dado
NMX-CH-11843-5-IMNC-2009 ISO 11843-5:2008	Capacidade de detecção - Parte 5: Metodologia no casos de calibração linear e não linear
NMX-CH-118-IMNC-2009	Materiais de referência - soluções padrão que reproduzem a condutividade do eletrólito
NMX-CH-129-1-IMNC-2010 ISO 129-1:2004	Desenho técnico - Indicação das dimensões e tolerâncias - Parte 1: Princípios gerais
NMX-CH-12179-IMNC-2015 ISO 12179:2000	Especificações Geométricas do Produto (GPS) - Textura da superfície: Método de perfil - Calibração de rugosímetros com sonda
NMX-CH-1302-IMNC-2008 ISO 1302:2002	Especificações Geométricas do Produto (GPS) - Indicação do acabamento superficial na documentação técnica do produto
NMX-CH-13528-IMNC-2007 ISO 13528:2005	Métodos estatísticos para uso em testes de adequação por comparações interlaboratoriais
NMX-CH-140-IMNC-2002 GUM-ISO/IEC Guide 98:1995	Guia para a expressão da incerteza em medições
NMX-CH-141-IMNC-2005	Especificações Geométricas do Produto (GPS) - Instrumentos de medição dimensional - Medidores de Alturas - Requisitos de design e metrológicos
NMX-CH-14253-1-IMNC-2008 ISO 14253-1:1998	Inspeção de especificações geométricas do produto (GPS) por medição de peças de trabalho e equipamentos de medição - Parte 1: Regras de decisão para verificar a conformidade ou não conformidade com as especificações
NMX-CH-14253-2-IMNC-2005 ISO/TS 14253-2:1999	Especificações Geométricas do Produto (GPS) - Inspeção por medição de peças e equipamentos de medição - Parte 2: Guia para estimar a incerteza na medição do GPS, em calibração de equipamentos de medição e na verificação do produto
NMX-CH-14253-3-IMNC-2008 ISO/TS 14253-3:2002	Especificações Geométricas do Produto (GPS) - Inspeção por medição de peças e equipamentos de medição - Parte 3: Diretrizes para chegar a acordos sobre declarações de incerteza de medição
NMX-CH-146-IMNC-2008	Metrologia - Tanques automáticos e carros-tanque - Classificação, características, verificação e métodos de calibração
NMX-CH-147-IMNC-1999	Métodos de calibração - Calibração de tanques automáticos por gravimetria
NMX-CH-148-IMNC-2004	Instrumentos de medição dimensional - Regras graduadas para uso industrial - Design e requisitos metrológicos
NMX-CH-148-3-IMNC-2013	Materiais metálicos - Teste de impacto Charpy por pêndulo - Parte 3: Preparação e caracterização de peças de teste Charpy V-notch para verificação indireta de máquinas de impacto por pêndulo
NMX-CH-149-IMNC-2005	Especificações geométricas do produto (GPS) - Instrumentos de medição dimensional - Indicadores de cobertura tipo alavanca - Design e especificações metrológicas
NMX-CH-14978-IMNC-2014	Especificações geométricas do produto (GPS) - Conceitos gerais e requisitos para equipamentos de medição GPS
NMX-CH-150-IMNC-1999 ISO 8601:1998	Elementos de informação e troca de formatos - Intercâmbio de informações - Representação de datas e horas
NMX-CH-151-IMNC-2005	Especificações Geométricas do Produto (GPS) - Instrumentos de medição dimensional - Goniômetro portátil (transferidor)
NMX-CH-152-IMNC-2005	Metrologia em química - Vocabulário
NMX-CH-16015-IMNC-2005 ISO 16015:2003	Especificações geométricas do produto (GPS) - Erros sistemáticos e contribuições para incerteza de medição das medições de comprimento devido a influências térmicas
NMX-CH-160-IMNC-2018 ISO/Guide 30:2015	Materiais de referência - Termos e definições
NMX-CH-161-IMNC-2006 ISO/Guide 31:2000	Materiais de referência - Conteúdo dos certificados e rótulos
NMX-CH-16269-6-IMNC-2008 ISO 16269-6:2005	Interpretação estatística dos dados - Parte 6: Determinação de intervalos de tolerância estatística
NMX-CH-16269-7-IMNC-2008 ISO 16269-7:2001	Interpretação estatística dos dados - Parte 7: Mediana - Estimação e intervalos de confiança
NMX-CH-16269-8-IMNC-2010 ISO 16269-8:2004	Interpretação estatística dos dados Parte 8: Determinação de intervalos de previsão
NMX-CH-162-IMNC-2006 ISO/Guide 32:1997	Materiais de referência -Calibração em química analítica e o uso de materiais de referência certificados
NMX-CH-163-IMNC-2018 ISO/Guide 33:2015	Materiais de referência - Boas práticas no uso de materiais de referência
NMX-CH-164-IMNC-2012 ISO Guide 34:2009	Materiais de referência - Requisitos gerais para a concorrência de produtores de materiais referência
NMX-CH-165-IMNC-2008 ISO Guide 35:2006	Materiais de referência - Princípios gerais e estatísticas para certificação
NMX-CH-166-IMNC-2010	Rastreabilidade e estimativa da incerteza da medição de pH - Medidores de pH calibrados em dois pontos usando materiais de referência certificados
NMX-CH-1660-IMNC-2009 ISO 1660:1987	Especificações Geométricas do Produto (GPS) - Desenho técnico - Aplicação de dimensões e tolerâncias aos perfis
NMX-CH-17450-1-IMNC-2011 ISO/TS 17450-1:2005	Especificações Geométricas do Produto (GPS) - Conceitos Gerais - Parte 1: Modelo para verificação e especificação geométrica

NMX-CH-18414-IMNC-2009 ISO 18424:2006	Procedimentos de amostragem de aceitação por atributos - Sistema de amostragem de aceitação zero com base no princípio do crédito para controlar a qualidade de saída
NMX-CH-20461-IMNC-2005 ISO/TR 20461:2000	Diretrizes para determinar a incerteza para medições de volume usando o método gravimétrico
NMX-CH-21747-IMNC-2008 ISO 21747:2006	Métodos estatísticos - Estatísticas de capacidade e desempenho do processo para características de medidas de qualidade
NMX-CH-21748-IMNC-2007 ISO 21748:2004	Guia para o uso de estimativas de repetibilidade, reprodutibilidade e precisão na estimativa da incerteza da medição
NMX-CH-21749-IMNC-2008 ISO/TS 21749:2005	Medição de incerteza para aplicações metrológicas - Medições repetidas e experimentos aninhados
NMX-CH-219-IMNC-2016	Instrumentos de medição - Carpintaria - Suportes
NMX-CH-22971-IMNC-2008 ISO/TR 22971:2005	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Guia prático para o uso do padrão mexicano NMX-CH-5725-2-IMNC-2006 no desenho, na implementação e na análise estatística de resultados de repetibilidade e reprodutibilidade interlaboratoriais
NMX-CH-23165-IMNC-2009 ISO 23165:2006	Especificações Geométricas do Produto (GPS) - Guia para a avaliação da incerteza de teste em máquinas de medição de coordenadas (CMM)
NMX-CH-2538-IMNC-2006 ISO 2538:1998	Especificações Geométricas do Produto (GPS) - Série de ângulos e inclinações em cunhas e prismas
NMX-CH-2602-IMNC-2008 ISO 2602:1980	Interpretação estatística dos resultados dos testes - Estimativa da média - Intervalo de confiança
NMX-CH-2692-IMNC-2009 ISO 2692:2006	Especificações Geométricas do Produto (GPS) - Tolerâncias geométricas - Requisito de material máximo (MMR), requisito mínimo de material (MRL) e exigência de reciprocidade (RPR)
NMX-CH-2768-1-IMNC-2016 ISO 2768-1:1989	Tolerâncias gerais - Parte 1: Tolerâncias para dimensões lineares e angulares sem tolerância individual indicada
NMX-CH-2854-IMNC-2016 ISO 2854:1976	Interpretação estatística de dados - Técnicas de estimativas e testes relacionados com meios e variações
NMX-CH-286-1-IMNC-2007 ISO 286-1:1998	Especificações Geométricas do Produto (GPS) - Sistema internacional de limites e ajustes - Parte 1: Base de tolerâncias, desvios e ajustes
NMX-CH-286-2-IMNC-2007 ISO 286-2:1998 ISO 286-2:1998/Cor 1:2006	Especificações Geométricas do Produto (GPS) - Sistema internacional de limites e ajustes - Parte 2: Tabelas de graus de tolerância normalizados e desvios limites para furos e eixos
NMX-CH-3301-IMNC-2009 ISO 3301:1975	Interpretação estatística dos dados - Comparação de duas médias no caso de observações por pares
NMX-CH-3534-1-IMNC-2008 ISO 3534-1:2006	Estatística - Vocabulário e símbolos - Parte 1: Termos estatísticos gerais e termos utilizados no cálculo de probabilidades
NMX-CH-3650-IMNC-2004 ISO 3650:1998	Especificações Geométricas do Produto (GPS) - Padrões de comprimento - Blocos padrão
NMX-CH-376-IMNC-2008 ISO ISO 376:2004	Instrumentos de medição - Calibração de instrumentos de medição de força para a verificação de máquinas de teste uniaxial
NMX-CH-4006-IMNC-2009 ISO 4006:1991	Medição do fluxo de fluido em dutos fechados - Vocabulário e símbolos
NMX-CH 4064-3-IMNC-2011	Medição de vazão em dutos de pressão fechados - Medidores de água potável fria e água quente - Parte 3: Métodos e equipamentos de teste
NMX-CH-4287-IMNC-2007 ISO 4287:1997	Especificações Geométricas do Produto (GPS) - Acabamento superficial: Método de perfil - Termos, definições e parâmetros de acabamento superficial
NMX-CH-463-IMNC-2008 ISO 463:2006	Especificações Geométricas do Produto (GPS) - Equipamento de medição dimensional - Características de design e metrológicas dos indicadores de mostrador mecânico
NMX-CH-4787-IMNC-2010 ISO 4787:2010	Vidraria de laboratório - Instrumentos volumétricos - Métodos para a calibração de sua capacidade e uso
NMX-CH-5167-1-IMNC-2009 ISO 5167-1:2003	Medição do fluxo de fluidos por meio de dispositivos de pressão diferencial inserida na seção transversal circular em oleodutos completos - Parte 1: Princípios gerais e requisitos
NMX-CH-5167-2-IMNC-2010 ISO 5167-2:2003	Medição do fluxo de fluidos por meio de dispositivos de pressão diferencial inseridos na seção transversal circular de dutos preenchidos - parte 2: placas de orifício
NMX-CH-5479-IMNC-2008 ISO 5479:1997	Interpretação estatística de dados - Testes para determinar o desvio da distribuição normal
NMX-CH-5725-1-IMNC-2006 ISO 5725-1:1994	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 1: Princípios gerais e definições
NMX-CH-5725-2-IMNC-2006 ISO 5725-2:1994 ISO 5725-2:1994/Cor 1:2002	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 2: Método básico para a determinação da repetibilidade e da reprodutibilidade de um método de medição padronizado
NMX-CH-5725-3-IMNC-2006 ISO 5725-3:1994 ISO 5725-3:1994/Cor 1:2001	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 3: Medidas intermediárias da precisão de um método de medição padronizado
NMX-CH-5725-4-IMNC-2006 ISO 5725-4:1994 ISO 5725-4:1994/Cor 1:2001	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 4: Método básico para a determinação da veracidade de um método de medição padronizado
NMX-CH-5725-5-IMNC-2006 ISO 5725-5:1998 ISO 5725-5:1998/Cor 1:2005	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 5: Métodos alternativos para a determinação da precisão de um método de medição normalizado

NMX-CH-5725-6-IMNC-2006 ISO 5725-6:1994 ISO 5725-6:1994/Cor 1:2001	Exatidão (veracidade e precisão) dos resultados e métodos de medição - Parte 6: Uso na prática dos valores de precisão
NMX-CH-6141-IMNC-2007 ISO 6141:2000	Materiais de referência - Análise de gás - Requisitos dos certificados de gases de calibração e misturas de gases
NMX-CH-6142-IMNC-2009 ISO 6142:2001	Materiais de referência - Análise de gases - Preparação de misturas de gases de calibração - Método gravimétrico
NMX-CH-6143-IMNC-2008 ISO 6143:2001	Materiais de referência - Análise de gases - Métodos de comparação para determinar e verificar a composição de misturas gasosas de calibração - análise de gases
NMX-CH-6145-1-IMNC-2013 ISO 6145-1:2003	Análise de gases - Preparação de misturas gasosas de calibração usando métodos volumétricos dinâmicos - Parte 1: métodos de calibração
NMX-CH-6145-2-IMNC-2013 ISO 6145-2:2013	Análise de gases - Preparação de misturas gasosas de calibração usando métodos volumétricos dinâmicos - Parte 2: bombas volumétricas
NMX-CH-6145-9-IMNC-2015 ISO 6145-9:2009	Análise de gases - Preparação de misturas gasosas de calibração usando métodos volumétricos dinâmicos - parte 9: método de saturação
NMX-CH-6789-IMNC-2006 ISO 6789:2003	Ferramentas de montagem para parafusos e porcas - Ferramentas manuais de par torcional - Requisitos e métodos de teste para verificação de conformidade no desenho, comprovação de conformidade na qualidade e no procedimento de calibração
NMX-CH-7500-1-IMNC-2008 ISO 7500-1:2004	Verificação de máquinas uniaxiais para testes - Máquinas para ensaios de tração ou compressão - Verificação e calibração do sistema de medição de força
NMX-CH-7504-IMNC-2006 ISO 7504:2001	Materiais de referência - Análise de gás - Vocabulário
NMX-CH-7863-IMNC-2008 ISO 7863:1984	Especificações Geométricas do Produto (GPS)
NMX-CH-7870-1-IMNC-2008 ISO 7870-1:2007	Gráficos de controle - Parte 1: diretrizes gerais
NMX-CH-7873-IMNC-2008 ISO 7873:1993	Cartas de controle para média aritmética com limites de aviso
NMX-CH-8258-IMNC-2008 ISO 8258:1991	Gráficos de controle de Shewhart
NMX-CH-8512-2-IMNC-2005 ISO 8512-2:1990	Especificações Geométricas do Produto (GPS) - Mesas de nivelamento - Parte 2: Materiais pedregosos - Granitos
NMX-CH-8550-1-IMNC-2009 ISO/TR 8550-1: 2007	Diretriz para a seleção e uso de sistemas de inspeção de aceitação para a inspeção de elementos discretos em lotes - Parte 1: Amostragem de aceitação
NMX-CH-8550-2-IMNC-2010 ISO/TR 8550-2:2007	Diretriz para a seleção e uso de sistemas de inspeção de aceitação para a inspeção de elementos discretos em lotes -Parte 2: Amostragem por atributos
PROY-NMX-CH-10790-IMNC-2010	Medição do fluxo de fluido em dutos fechados - Guia para a seleção, instalação e uso de medidores de massa tipo Coriolis (medições de vazão de massa, densidade e fluxo de volume) incluindo a guia para medição de gás. Teste para a verificação de conformidade na concepção, verificação da conformidade na qualidade e procedimento de calibração
PROY-NMX-CH-1404-IMNC-2008	Sistemas de medição - mesas paralelepípedicas
PROY-NMX-CH-14660-2-IMNC-2009 ISO 14660-2:1999	Especificações Geométricas do Produto (GPS) - Elementos geométricos - Parte 2: linha média extraída de um cilindro e um cone, superfície média extraída, tamanho local de um item extraído
PROY-NMX-CH-148-2-IMNC-2013	Materiais metálicos - Teste de impacto por pêndulo Charpy - Parte 2 - Verificação de máquinas de teste
PROY-NMX-CH-157-IMNC-2009	Calibração de dispositivos de medição de torque torcional estático
PROY-NMX-CH-201-IMNC-2008	Instrumentos de medição - manômetros, indicadores de vácuo, mono-indicadores de vácuo e gravadores com elementos elásticos (instrumentos ordinários)
PROY-NMX-CH-20461-IMNC-2010	Diretrizes para determinar a incerteza para medições de volume usando o método gravimétrico
PROY-NMX-CH-207-IMNC-2008	Sistemas terminais aplicados como elementos primários de medição
PROY-NMX-CH-210-IMNC-2008	Guia para o uso de números normais e das séries de números normais
PROY-NMX-CH-213-IMNC-2008	Termostatos da sala de ação proporcional com faixa de 12 ° C a 28 ° C, para sistemas de ar condicionado
PROY-NMX-CH-215-IMNC-2008	Funcionamento para pressostatos
PROY-NMX-CH-232-IMNC-2008	Indústria óptica oftalmológica - Aparelhos de diagnóstico - Classificação e definições
PROY-NMX-CH-250-IMNC-2008	Métodos de medição - Determinação da densidade de líquidos - Princípio de Arquimedes
PROY-NMX-CH-258-IMNC-2008	Instrumentos de medição - Manômetros com elementos elásticos - Método de calibração com contrapeso de peso morto
PROY-NMX-CH-270-IMNC-2008	Instrumentos de medição - Termômetros de seletor bimetalicos
PROY-NMX-CH-286-2-IMNC-2009 ISO 286-2:1998 ISO 286-2:1988/Amd 1	Especificações Geométricas do Produto (GPS) - Sistema internacional de limites e ajustes - Parte 2: Tabelas de graus de tolerância normalizados e desvios limite para furos e eixos
PROY-NMX-CH-309-IMNC-2008	Instrumentos de medição - Instrumentos de pesagem de operação não automática - Métodos de teste
PROY-NMX-CH-313-IMNC-2008	Materiais de referência - Ferro fundido branco - Método de determinação do cromo
PROY-NMX-CH-319-IMNC-2008	Materiais de referência - Terminologia analítica da espectrometria atômica
PROY-NMX-CH-328-IMNC-2008	Microscópios ópticos
PROY-NMX-CH-331-1-IMNC-2008	Instrumentos de medição - Instrumentos de indicação digital para grandezas elétricas - Termos e definições
PROY-NMX-CH-331-2-IMNC-2008	Instrumentos de medição - Instrumentos de indicação digital para grandezas elétricas - Especificações e métodos de teste

PROY-NMX-CH-391-IMNC-2008	Materiais de referência - Ferro fundido branco - Método para a determinação do manganês
PROY-NMX-CH-4064-2-IMNC-2008 ISO 4064-11-1978	Medição do fluxo de água em condutas fechadas de sistemas hidráulicos - Medidores para água potável fria - Parte 2: Requisitos de instalação
PROY-NMX-CH-4064-4-IMNC-2008	Medição do fluxo de água em condutas fechadas de sistemas hidráulicos - Medidores para água potável fria -Parte 4: Evidência de influência no campo magnético
PROY-NMX-CH-414-IMNC-2008	Desempenho de qualidade de parâmetros industriais
PROY-NMX-CH-434-IMNC-2008	Instrumentos de medição - Dispositivos de pesagem - Terminologia geral básica
PROY-NMX-CH-435-IMNC-2008	Instrumentos de medição - Dispositivos de pesagem - Classificação e suas definições
PROY-NMX-CH-497-IMNC-2008	Guia para o uso de séries de números normais contendo valores mais arredondados
PROY-NMX-CH-5168-IMNC-2010 ISO 5168:2005	Medição do fluxo de fluido - Procedimentos para avaliação de incertezas
PROY-NMX-CH-7500-2-IMNC-2009 ISO 7500-2:2006	Verificação de máquinas uniaxiais para testes - Parte 2: Máquinas para teste de tração para o rendimento - Verificação da força aplicada
NMX-Z-055-IMNC-2009 ISO/IEC Guide 99:2007	Vocabulário Internacional de Metrologia - Conceitos fundamentais e gerais e termos associados (VIM)
PROY-NMX-Z-109-IMNC-1998	Padronização e atividades relacionadas - Vocabulário geral

Source: IMNC. Elaboration: CCGI-EESP/FGV.

Table 13.12 - Official mexican Standards (Vehicles and Autoparts)

<i>Clave</i>	<i>Fecha</i>	<i>Descripción</i>
<u>NOM-001-SSP-2008</u>	2010-01-13	Para la determinación, asignación e instalación del número de identificación vehicular.
<u>NOM-005-SESH-2010</u>	2010-11-26	Equipos de carburación de gas l.p. En motores de combustión interna. Instalación y mantenimiento.
<u>NOM-007-SESH-2010</u>	2011-07-11	Vehículos para el transporte y distribución de gas l.p.- condiciones de seguridad, operación y mantenimiento.
<u>NOM-142-SCFI-2000</u>	2001-02-02	Niveles de protección de materiales para blindajes resistentes a impactos balísticos-especificaciones de seguridad y métodos de prueba..(para saber la fecha de vigencia,favor de consultar el texto de la nom)(cancela a la nom-142-scfi-2000, publicada el
<u>NOM-194-SCFI-2015</u>	2016-05-09	Dispositivos de seguridad esenciales en vehículos nuevos-especificaciones de seguridad.
<u>PROY-NOM-014-SCT2-1993</u>	1994-01-25	Características y especificaciones técnicas y de seguridad para los vehículos automotores de más de 9 personas.
<u>PROY-NOM-150-SCFI-2002</u>	2002-11-15	Autotransporte-rines para llantas de automóviles y camiones ligeros-especificaciones de seguridad y métodos de prueba.
<u>NOM-012-SCT-2-2017</u>	2017-12-26	Sobre el peso y dimensiones máximas con los que pueden circular los vehículos de autotransporte que transitan en las vías generales de comunicación de jurisdicción federal.
<u>NOM-068-SCT-2-2014</u>	2015-01-19	Transporte terrestre-servicio de autotransporte federal de pasaje, turismo, carga, sus servicios auxiliares y transporte privado-condiciones físico-mecánica y de seguridad para la operación en vías generales de comunicación de jurisdicción federal.
<u>PROY-NOM-012-SCT-2-2017</u>	2017-06-07	Sobre el peso y dimensiones máximas con los que pueden circular los vehículos de autotransporte que transitan en las vías generales de comunicación de jurisdicción federal.

Table 13.13 - Normas Oficiais Mexicanas (Eletric Products)

<i>Clave</i>	<i>Fecha</i>	<i>Descripción</i>
<u>NOM-001-SCFI-1993</u>	1993-10-13	Aparatos electrónicos de uso doméstico alimentados por diferentes fuentes de energía eléctrica-requisitos de seguridad y métodos de prueba para la aprobación de tipo.
<u>NOM-016-SCFI-1993</u>	1993-10-14	Aparatos electrónicos de uso en oficina y alimentados por diferentes fuentes de energía eléctrica - requisitos de seguridad y métodos de prueba. (se ratifica por cinco años según resolución publicada en el d. O. F. El 29/06/2005)
<u>PROY-NOM-001-SCFI-2017</u>	2017-12-19	Aparatos electrónicos-requisitos de seguridad y métodos de prueba (cancelará a la nom-001-scfi-1993).
<u>NOM-014-ENER-2004</u>	2005-04-19	Eficiencia energética de motores eléctricos de corriente alterna, monofásicos, de inducción, tipo jaula de ardilla, enfriados con aire, en potencia nominal de 0,180 kw a 1,500 kw. Límites, método de prueba y marcado.
<u>NOM-016-ENER-2016</u>	2016-11-15	Eficiencia energética de motores de corriente alterna, trifásicos, de inducción, tipo jaula de ardilla, en potencia nominal de 0,746 kw a 373 kw. Límites, método de prueba y marcado.
<u>NOM-001-SEDE-2012</u>	2012-11-29	Instalaciones eléctricas (utilización)
<u>NOM-029-ENER-2017</u>	2017-10-27	Eficiencia energética de fuentes de alimentación externa. Límites, métodos de prueba, marcado y etiquetado.

NOM-032-ENER-2013	2014-01-23	Límites máximos de potencia eléctrica para equipos y aparatos que demandan energía en espera. Métodos de prueba y etiquetado.
NOM-063-SCFI-2001	2002-02-22	Productos eléctricos-conductores-requisitos de seguridad.
NOM-053-SCFI-2000	2001-04-04	Elevadores eléctricos de tracción para pasajeros y carga-especificaciones de seguridad y métodos de prueba para equipos nuevos.
NOM-031-ENER-2012	2012-11-06	Eficiencia energética para luminarios con diodos emisores de luz (leds) destinados a vialidades y áreas exteriores públicas. Especificaciones y métodos de prueba.

Table 13.14 - Official Mexican Standards (Food)

<i>Clave</i>	<i>Fecha</i>	<i>Descripción</i>
<i>NOM-010-SESH-2012</i>	2013-05-29	Aparatos domésticos para cocinar alimentos que utilizan gas l.p. O gas natural. Especificaciones y métodos de prueba.
<i>PROY-NOM-201-SCFI-2015</i>	2016-12-14	Aparatos portátiles para cocinar alimentos que utilizan como combustible gas l.p. U otros petrolíferos almacenados en recipientes desechables y/o recipientes portátiles. Especificaciones y métodos de prueba.
<i>NOM-130-SSA1-1995</i>	1997-11-21	Bienes y servicios. Alimentos envasados en recipientes de cierre hermético y sometidos a tratamiento térmico. Disposiciones y especificaciones sanitarias.
<i>NOM-086-SSA1-1994</i>	1996-06-26	Bienes y servicios. Alimentos y bebidas no alcohólicas con modificaciones en su composición. Especificaciones nutrimentales.
<i>NOM-116-SSA1-1994</i>	1995-08-10	Bienes y servicios. Determinación de humedad en alimentos por tratamiento térmico. Método por arena o gasa.
<i>NOM-117-SSA1-1994</i>	1995-08-16	Bienes y servicios. Método de prueba para la determinación de cadmio, arsénico, plomo, estaño, cobre, fierro, zinc y mercurio en alimentos, agua potable y agua purificada por espectrometría de absorción atómica.
<i>NOM-111-SSA1-1994</i>	1995-09-13	Bienes y servicios. Método para la cuenta de mohos y levaduras en alimentos.
<i>NOM-110-SSA1-1994</i>	1995-10-16	Bienes y servicios. Preparación y dilución de muestras de alimentos para su análisis microbiológico.
<i>PROY-NOM-109-SSA1-1994</i>	1994-11-04	Bienes y servicios. Procedimientos para la toma manejo y transporte de muestras de alimentos para su análisis microbiológico.
<i>NOM-025-ENER-2013</i>	2013-06-17	Eficiencia térmica de aparatos domésticos para cocción de alimentos que usan gas l.p. O gas natural. Límites, métodos de prueba y etiquetado
<i>NOM-051-SCFI/SSA1-2010</i>	2010-04-05	Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-información comercial y sanitaria.
<i>NOM-247-SSA1-2008</i>	2009-07-27	Productos y servicios. Cereales y sus productos. Cereales, harinas de cereales, sémolas o semolinas. Alimentos a base de: cereales, semillas comestibles, de harinas, sémolas o semolinas o sus mezclas. Productos de panificación. Disposiciones y especifica
<i>NOM-131-SSA1-2012</i>	2012-09-10	Productos y servicios. Fórmulas para lactantes, de continuación y para necesidades especiales de nutrición. Alimentos y bebidas no alcohólicas para lactantes y niños de corta edad. Disposiciones y especificaciones sanitarias y nutrimentales. Etiquetado y
<i>NOM-251-SSA1-2009</i>	2010-03-01	Prácticas de higiene para el proceso de alimentos, bebidas o suplementos alimenticios.
<i>PROY-NOM-211-SSA1-2002</i>	2003-08-14	Productos y servicios. Métodos de prueba fisicoquímicos. Determinación de humedad y sólidos totales en alimentos por secado en estufa. Determinación de arsénico, cadmio, cobre, cromo, estaño, hierro, mercurio, níquel, plata, plomo, selenio y zinc en alime
<i>PROY-NOM-021-PESC-1994</i>	1995-01-20	Que regula los alimentos balanceados, los ingredientes para su elaboración y los productos alimenticios no convencionales, utilizados en la acuicultura y el ornato, importados y nacionales, para su comercialización y consumo en la república mexicana.
<i>NOM-002-SSA1-1993</i>	1994-11-14	Salud ambiental. Bienes y servicios. Envases metálicos para alimentos y bebidas. Especificaciones de la costura. Requisitos sanitarios.

Source: Secretaria da Economia

Table 13.15 - Normas oficiais mexicanas (Secretaria da Economia)

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-SCFI-1993	1993-10-13	Aparatos electrónicos de uso doméstico alimentados por diferentes fuentes de energía eléctrica-Requisitos de seguridad y métodos de prueba para la aprobación de tipo.
NOM-002-SCFI-2011	2012-08-10	Productos preenvasados-contenido neto-tolerancias y métodos de verificación.
NOM-003-SCFI-2014	2015-05-28	Productos eléctricos-especificaciones de seguridad.
NOM-004-SCFI-2006	2006-06-21	Información comercial-etiquetado de productos textiles, prendas de vestir, sus accesorios y ropa de casa.

<u>NOM-005-SCFI-2011</u>	2012-03-30	Instrumentos de medición-sistema para medición y despacho de gasolina y otros combustibles líquidos-especificaciones, métodos de prueba y de verificación.
<u>NOM-006-SCFI-2012</u>	2012-12-13	Bebidas alcohólicas-tequila-especificaciones. (contiene la modificación publicada el 13/12/2012)
<u>NOM-007-SCFI-2003</u>	2003-07-08	Instrumentos de medición-taxímetros.
<u>NOM-008-SCFI-2002</u>	2002-11-27	Sistema general de unidades de medida.
<u>NOM-008-SESH/SCFI-2010</u>	2010-12-21	Recipientes transportables para contener gas l.p. Especificaciones de fabricación, materiales y métodos de prueba.
<u>NOM-009-SCFI-1993</u>	1993-10-13	Instrumentos de medición-esfigmomanómetros de columna de mercurio y de elemento sensor elástico para medir la presión sanguínea del cuerpo humano.
<u>NOM-010-SCFI-1994</u>	1999-06-09	Instrumentos de medición-instrumentos para pesar de funcionamiento no automático-requisitos técnicos y metrologicos (esta norma cancela la nom-010-scfi-1993).
<u>NOM-011-SCFI-2004</u>	2004-10-15	Instrumentos de medición-termómetros de líquido en vidrio para uso general-especificaciones y métodos de prueba.
<u>NOM-012-SCFI-1994</u>	1997-10-29	Medición de flujo de agua en conductos cerrados de sistemas hidráulicos-medidores para agua potable fría-especificaciones.
<u>NOM-013-SCFI-2004</u>	2005-01-18	Instrumentos de medición-manómetros con elemento elástico-especificaciones y métodos de prueba.
<u>NOM-014-SCFI-1997</u>	1998-10-23	Medidores de desplazamiento positivo tipo diafragma para gas natural o l.p. Con capacidad máxima de 16 m3/h con caída de presión máxima de 200 pa (20,40 mm de columna de agua) (esta norma cancela a la nom-014-scfi-1993)
<u>NOM-015-SCFI-2007</u>	2008-04-17	Información comercial-etiquetado para juguetes.
<u>NOM-016-SCFI-1993</u>	1993-10-14	Aparatos electrónicos de uso en oficina y alimentados por diferentes fuentes de energía eléctrica - Requisitos de seguridad y métodos de prueba. (Se ratifica por cinco años según resolución publicada en el D. O. F. el 29/06/2005)
<u>NOM-017-ENER/SCFI-2012</u>	2013-01-09	Eficiencia energética y requisitos de seguridad de lámparas fluorescentes compactas autobalastadas. Límites y métodos de prueba.
<u>NOM-017-SCFI-1993</u>	1993-10-29	Información comercial-etiquetado de artículos reconstruidos, usados o de segunda mano, de segunda línea, discontinuados y fuera de especificaciones.
<u>NOM-019-SCFI-1998</u>	1998-12-11	Seguridad de equipo de procesamiento de datos.(cancela a la nom-019-scfi-1994) (se ratifica por cinco años según resolución publicada en el d. O. F. El 29/06/2005)
<u>NOM-020-SCFI-1997</u>	1998-04-27	Información comercial- etiquetado de cueros y pieles curtidas naturales y materiales sintéticos o artificiales con esa apariencia,calzado, marroquinería así como los productos elaborados con dichos materiales.
<u>NOM-021-ENER/SCFI-2017</u>	2017-07-07	Eficiencia energética y requisitos de seguridad al usuario en acondicionadores de aire tipo cuarto. Límites, métodos de prueba y etiquetado.
<u>NOM-022-ENER/SCFI-2014</u>	2014-11-27	Eficiencia energética y requisitos de seguridad al usuario para aparatos de refrigeración comercial autocontenidos. Límites, métodos de prueba y etiquetado.
<u>NOM-024-SCFI-2013</u>	2013-08-12	Información comercial para empaques, instructivos y garantías de los productos electrónicos, eléctricos y electrodomésticos.
<u>NOM-028-SCFI-2007</u>	2007-11-01	Prácticas comerciales-elementos de información en las promociones coleccionables y/o promociones por medio de sorteos y concursos.
<u>NOM-029-SCFI-2010</u>	2010-05-17	Prácticas comerciales-requisitos informativos para la prestación del servicio de tiempo compartido.(contiene modificaciones publicadas el 15/072010 y 13/01/211)
<u>NOM-030-SCFI-2006</u>	2006-11-06	Información comercial-declaración de cantidad en la etiqueta-especificaciones.
<u>NOM-033-SCFI-1994</u>	1995-12-21	Información comercial-alhajas o artículos de oro, plata, platino y paladio.
<u>NOM-035-SCFI-2003</u>	2003-10-20	Prácticas comerciales-criterios de información para los sistemas de ventas a domicilio (cancela a la norma oficial mexicana nom-035-scfi-1994, publicada el 1 de julio de 1994).
<u>NOM-036-SCFI-2016</u>	2017-01-05	Prácticas comerciales, requisitos de información y disposiciones generales en la prestación de servicios funerarios.
<u>NOM-038-SCFI-2000</u>	2001-02-26	Pesas de clases de exactitud e1, e2, f1, f2, m1, m2 y m3 (esta norma cancela el proy-nom-039-scfi-1994).
<u>NOM-040-SCFI-1994</u>	1997-11-06	Instrumentos de medición-instrumentos rígidos reglas graduadas para medir longitud- uso comercial.
<u>NOM-041-SCFI-1997</u>	1998-12-09	Instrumentos de medición-medidas volumétricas metálicas cilíndricas para líquidos de 25 ml hasta 10 l (esta norma cancela la nmx-ch-45- 1983).
<u>NOM-042-SCFI-1997</u>	1998-12-09	Instrumentos de medición-medidas volumétricas metálicas con cuello graduado para líquidos con capacidades de 5 l, 10 l y 20 l.
<u>NOM-044-SCFI-2008</u>	2009-01-13	Wathorímetros electromecánicos-definiciones, características y métodos de prueba.
<u>NOM-045-SCFI-2000</u>	2001-02-23	Instrumentos de medición-manómetros para extintores..(para saber la fecha de vigencia, favor de consultar el texto de la nom)
<u>NOM-046-SCFI-1999</u>	1999-08-24	Instrumentos de medicion-cintas métricas de acero y flexómetros (esta norma cancela a la norma oficial mexicana nom-046-scfi-1999, instrumentos de medicion-cintas métricas de acero y flexómetros, y su aclaracion, publicadas los días 26 de julio y 9 d

<u>NOM-048-SCFI-1997</u>	1998-11-30	Instrumentos de medición-relojes registradores de tiempo-alimentados con diferentes fuentes de energía (esta norma cancela la nmx-j-382-1980).
<u>NOM-050-SCFI-2004</u>	2004-06-01	Información comercial-etiquetado general de productos.
<u>NOM-050-SCT2-2017</u>	2017-07-11	Disposición para la señalización de cruces a nivel de caminos y calles con vías férreas.
<u>NOM-051-SCFI/SSA1-2010</u>	2010-04-05	Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-información comercial y sanitaria.
<u>NOM-053-SCFI-2000</u>	2001-04-04	Elevadores eléctricos de tracción para pasajeros y carga-especificaciones de seguridad y métodos de prueba para equipos nuevos.
<u>NOM-054-SCFI-1998</u>	1998-09-04	Utensilios domésticos- ollas a presión- seguridad (cancela a la nom-054-scfi-1994)
<u>NOM-055-SCFI-1994</u>	1994-12-08	Información comercial-materiales retardantes y/o inhibidores de flama y/o ignífugos-etiquetado.
<u>NOM-058-SCFI-2017</u>	2017-08-15	Controladores para fuentes luminosas artificiales, con propósitos de iluminación en general-especificaciones de seguridad y métodos de prueba (cancela a la nom-058-scfi-1999)
<u>NOM-063-SCFI-2001</u>	2002-02-22	Productos eléctricos-conductores-requisitos de seguridad.
<u>NOM-064-SCFI-2000</u>	2000-05-22	Productos eléctricos-luminarios para uso en interiores y exteriores-especificaciones de seguridad y métodos de prueba.
<u>NOM-067-SCT-2/SECOFI-1999</u>	1999-11-01	Transporte terrestre-servicio de autotransporte económico y mixto-midibús-características y especificaciones técnicas y de seguridad.
<u>NOM-070-SCFI-2016</u>	2017-02-23	Bebidas alcohólicas-mezcal-especificaciones.
<u>NOM-071-SCFI-2008</u>	2008-12-10	Prácticas comerciales-atención médica por cobro directo.
<u>NOM-080-SCFI-2016</u>	2017-01-25	Arroz del estado de morelos.
<u>NOM-084-SCFI-1994</u>	1995-09-22	Información comercial-especificaciones de información comercial y sanitaria para productos de atún y bonita preenvasados.
<u>NOM-086-SCFI-2010</u>	2010-08-12	Industria hulera-llantas nuevas de construcción radial que son empleadas para cualquier vehículo con un peso bruto vehicular igual o menor a 4 536 kg (10 000 lb)-especificaciones de seguridad y métodos de prueba.
<u>NOM-086-SEMAR-SENER-SCFI-2005</u>	2006-01-30	Especificaciones de los combustibles fósiles para la protección ambiental.
<u>NOM-086/1-SCFI-2011</u>	2011-04-19	Industria hulera-llantas nuevas, de construcción radial que son empleadas en vehículos con un peso bruto vehicular superior a 4 536 kg (10 000 lb) y llantas de construcción diagonal de cualquier capacidad de carga-especific. De seg. Y método de prueba
<u>NOM-090-SCFI-2014</u>	2014-07-01	Encendedores portátiles, desechables y recargables-especificaciones de seguridad.
<u>NOM-093-SCFI-1994</u>	1997-12-08	Válvulas de relevo de presión (Seguridad, seguridad-Alivio y alivio) operadas por resorte y piloto; fabricadas de acero y bronce.
<u>NOM-106-SCFI-2017</u>	2017-09-08	Características de diseño y condiciones de uso de la contraseña oficial.
<u>NOM-113-SCFI-1995</u>	1998-01-28	Líquido para frenos hidráulicos empleado en vehículos automotores-especificaciones de seguridad y métodos de prueba.(contiene modifíc. A numerales)
<u>NOM-114-SCFI-2016</u>	2017-01-24	Gatos hidráulicos tipo botella-especificaciones de seguridad y métodos de prueba (cancela a la nom-114-scfi-2006).
<u>NOM-116-SCFI-1997</u>	1998-05-04	Industria automotriz - aceites lubricantes para motores a gasolina o a diesel - información comercial.
<u>NOM-117-SCFI-2005</u>	2006-01-17	Prácticas comerciales-elementos normativos para la comercialización de muebles de línea y sobre medida.
<u>NOM-118-SCFI-2004</u>	2004-05-07	Industria cerillera-cerillos y fósforos-especificaciones de seguridad (contiene la modificación publicada el 29 de sept. De 2009 en el d. O. F.)
<u>NOM-119-SCFI-2000</u>	2000-04-03	Industria automotriz-vehículos automotores-cinturones de seguridad-especificaciones de seguridad y métodos de prueba.
<u>NOM-120-SCFI-1996</u>	1996-11-22	Información comercial-etiquetado de productos agrícolas-uva de mesa.
<u>NOM-121-SCFI-2004</u>	2004-06-04	Industria hulera-cámaras para llantas neumáticas de vehículos automotores y bicicleta-especificaciones de seguridad y métodos de prueba (cancela a la norma oficial mexicana nom-121-scfi-1996, industria hulera-cámaras para llantas neumáticas de vehículo
<u>NOM-122-SCFI-2010</u>	2010-05-03	Prácticas comerciales-elementos normativos para la comercialización y/o consignación de vehículos usados.
<u>NOM-127-SCFI-1999</u>	1999-12-08	Instrumentos de medición-Medidores multifunción para sistemas eléctricos-Especificaciones y métodos de prueba..(Para saber la fecha de vigencia, favor de consultar el texto de la NOM)
<u>NOM-128-SCFI-1998</u>	1998-08-31	Información Comercial-Etiquetado de productos agrícolas-Aguacate.
<u>NOM-129-SCFI-1998</u>	1998-08-31	Información Comercial-Etiquetado de productos Agrícolas-Mango.
<u>NOM-132-SCFI-1998</u>	1998-11-25	Talavera- especificaciones.(para saber la fecha de vigencia, favor de consultar el texto de la nom)
<u>NOM-133/1-SCFI-1999</u>	1999-10-20	Productos infantiles-funcionamiento de andaderas para la seguridad del infante-especificaciones y métodos de prueba.(el texto incluye la resolución de modificación a la nom. De fecha 11/09/2000)
<u>NOM-133/2-SCFI-1999</u>	1999-10-15	Productos infantiles-funcionamiento de carriolas para la seguridad del infante-especificaciones y métodos de prueba.
<u>NOM-133/3-SCFI-1999</u>	1999-10-18	Productos infantiles-funcionamiento de corrales y encierros-especificaciones y métodos de prueba.
<u>NOM-134-SCFI-1999</u>	1999-11-29	Válvulas para cámara y válvulas para rines utilizados para llantas tipo sin cámara-especificaciones de seguridad y métodos de prueba

<u>NOM-135-SCFI-2006</u>	2006-06-28	Prácticas comerciales-Requisitos de información en la venta de materiales para construcción.
<u>NOM-139-SCFI-2012</u>	2012-07-10	Información comercial-etiquetado de extracto natural de vainilla (vainilla spp), derivados y sustitutos.
<u>NOM-140-SCFI-2017</u>	2018-01-03	Artículos escolares-tijeras-especificaciones y métodos de prueba (cancela a la nom-140-scfi-1999, artículos escolares-tijeras-especificaciones y métodos de prueba, publicada el 6 de marzo de 2000 y su modificación el 26 de julio de 2001).
<u>NOM-141-SSA1/SCFI-2012</u>	2012-09-19	Etiquetado para productos cosméticos preenvasados. Etiquetado sanitario y comercial.
<u>NOM-142-SCFI-2000</u>	2001-02-02	Niveles de protección de materiales para blindajes resistentes a impactos balísticos-especificaciones de seguridad y métodos de prueba..(para saber la fecha de vigencia,favor de consultar el texto de la nom)(cancela a la nom-142-scfi-2000, publicada el
<u>NOM-142-SSA1/SCFI-2014</u>	2015-03-23	Bebidas alcohólicas. Especificaciones sanitarias. Etiquetado sanitario y comercial.
<u>NOM-144-SCFI-2000</u>	2001-02-14	Bebidas alcohólicas-charanda-especificaciones.
<u>NOM-145-SCFI-2001</u>	2001-04-23	Información comercial-etiquetado de miel en sus diferentes presentaciones.
<u>NOM-146-SCFI-2016</u>	2017-02-03	Productos de vidrio-vidrio de seguridad usado en la construcción-especificaciones y métodos de prueba (cancela a la nom-146-scfi-2001).
<u>NOM-148-SCFI-2008</u>	2008-08-13	Prácticas comerciales-comercialización de animales de compañía o de servicio, y prestación de servicios para su cuidado y adiestramiento.
<u>NOM-149-SCFI-2001</u>	2002-01-07	Café veracruz-especificaciones y métodos de prueba.
<u>NOM-151-SCFI-2016</u>	2017-03-30	Requisitos que deben observarse para la conservación de mensajes de datos y digitalización de documentos (cancela la nom-151-scfi-2002).
<u>NOM-152-SCFI-2003</u>	2003-08-25	Ambar de chiapas-especificaciones y métodos de prueba
<u>NOM-153/I-SCFI-2003</u>	2003-05-30	Guillotinas o cizallas manuales-requisitos técnicos de seguridad y métodos de prueba.
<u>NOM-154-SCFI-2005</u>	2005-12-26	Equipos contra incendio-extintores-servicio de mantenimiento y recarga.
<u>NOM-155-SCFI-2012</u>	2012-05-03	Leche-denominaciones, especificaciones fisicoquímicas, información comercial y métodos de prueba.
<u>NOM-157-SCFI-2005</u>	2005-10-21	Equipo de protección contra incendio-extintores como dispositivo de seguridad de uso en vehículos de autotransporte particular, público y de carga en general- especificaciones y métodos de prueba.
<u>NOM-158-SCFI-2003</u>	2003-08-14	Jamón-denominación y clasificación comercial, especificaciones fisicoquímicas, microbiológicas, organolépticas, información comercial y métodos de prueba.
<u>NOM-159-SCFI-2004</u>	2004-06-16	Bebidas alcohólicas-sotol-especificaciones y métodos de prueba.
<u>NOM-160-SCFI-2014</u>	2014-09-02	Prácticas comerciales-elementos normativos para la comercialización de vehículos nuevos.
<u>NOM-161-SCFI-2003</u>	2003-10-20	Seguridad al usuario-juguetes-réplicas de armas de fuego- especificaciones de seguridad y métodos de prueba
<u>NOM-162-SCFI-2004</u>	2004-06-01	Electrónica-audio y video-discos compactos grabados con audio, video, datos y/o videojuegos-información comercial e identificación del fabricante.
<u>NOM-163-SEMARNAT-ENER-SCF-2013</u>	2013-06-21	Emisiones de bióxido de carbono (co2) provenientes del escape y su equivalencia en términos de rendimiento de combustible, aplicable a vehículos automotores nuevos de peso bruto vehicular de hasta 3 857 kilogramos.
<u>NOM-166-SCFI-2005</u>	2005-05-23	Seguridad al usuario-chalecos antibalas-especificaciones y métodos de prueba.(para saber la fecha de vigencia, favor de consultar el texto de la nom)
<u>NOM-168-SCFI-2004</u>	2005-12-14	Bebidas alcohólicas-bacanora-especificaciones de elaboración, envasado y etiquetado.
<u>NOM-169-SCFI-2007</u>	2007-03-26	Café chiapas-especificaciones y métodos de prueba.
<u>NOM-173-SCFI-2009</u>	2009-08-28	Jugos de frutas preenvasados-denominaciones, especificaciones fisicoquímicas, información comercial y métodos de prueba.
<u>NOM-174-SCFI-2007</u>	2007-11-01	Prácticas comerciales-elementos de información para la prestación de servicios en general.
<u>NOM-179-SCFI-2007</u>	2007-11-01	Servicios de mutuo con interés y garantía prendaria.
<u>NOM-179-SCFI-2016</u>	2017-08-08	Servicios de mutuo con interés y garantía prendaria (cancela la nom-179-scfi-2007, servicios de mutuo con interés y garantía prendaria).
<u>NOM-181-SCFI-2010</u>	2010-11-16	Yogurt-denominación, especificaciones fisicoquímicas y microbiológicas, información comercial y métodos de prueba.(contiene tres modificaciones la última del 14/11/2012 en la opción archivo texto de modificaciones)
<u>NOM-182-SCFI-2011</u>	2011-08-18	Vainilla de papantla, extractos y derivados-especificaciones, información comercial y métodos de ensayo (prueba).
<u>NOM-183-SCFI-2012</u>	2012-05-03	Producto lácteo y producto lácteo combinado-denominaciones, especificaciones fisicoquímicas, información comercial y métodos de prueba.
<u>NOM-184-SCFI-2012</u>	2012-08-24	Prácticas comerciales-elementos normativos para la comercialización y/o prestación de los servicios de telecomunicaciones cuando utilicen una red pública de telecomunicaciones.
<u>NOM-185-SCFI-2012</u>	2012-08-27	Programas informáticos y sistemas electrónicos que controlan el funcionamiento de los sistemas para medición y despacho de gasolina y otros combustibles líquidos-especificaciones, métodos de prueba y de verificación.

NOM-186-SSA1/SCFI-2013	2014-03-28	Cacao, chocolate y productos similares, y derivados del cacao. Especificaciones sanitarias. Denominación comercial. Métodos de prueba.
NOM-187-SSA1/SCFI-2002	2003-08-18	Productos y servicios. Masa, tortillas, tostadas y harinas preparadas para su elaboración y establecimientos donde se procesan. Especificaciones sanitarias. Información comercial. Métodos de prueba.
NOM-188-SCFI-2012	2012-11-29	Mango ataulfo del soconusco, chiapas (mangifera caesia jack ex wall)-especificaciones y métodos de prueba.
NOM-189-SCFI-2012	2012-11-30	Chile habanero de la península de yucatán (capsicum chinense jacq.)-especificaciones y métodos de prueba.
NOM-189-SCFI-2017	2018-02-21	Chile habanero de la península de yucatán (capsicum chinense jacq.)Especificaciones y métodos de prueba.
NOM-189-SSA1/SCFI-2002	2002-12-02	Productos y servicios. Etiquetado y envasado para productos de aseo de uso doméstico.
NOM-190-SCFI-2012	2012-08-31	Mezcla de leche con grasa vegetal-denominaciones, especificaciones fisicoquímicas, información comercial y métodos de prueba.
NOM-192-SCFI/SCFI-2013	2013-10-14	Telecomunicaciones-aparatos de televisión y decodificadores-especificaciones.
NOM-193-SCFI-2014	2015-01-05	Crema-denominaciones, especificaciones, información comercial y métodos de prueba.
NOM-194-SCFI-2015	2016-05-09	Dispositivos de seguridad esenciales en vehículos nuevos-especificaciones de seguridad.
NOM-196-SCFI-2016	2016-11-07	Productos. Equipos terminales que se conecten o interconecten a través de un acceso alámbrico a una red pública de telecomunicaciones.
NOM-199-SCFI-2017	2017-10-30	Bebidas alcohólicas-denominación, especificaciones fisicoquímicas, información comercial y métodos de prueba.
NOM-208-SCFI-2016	2017-02-07	Productos. Sistemas de radiocomunicación que emplean la técnica de espectro disperso-equipos de radiocomunicación por salto de frecuencia y por modulación digital a operar en las bandas 902 mhz-928 mhz, 2400 mhz-2483.5 mhz y 5725 mhz-5850 mhz-especificac
NOM-218-SCFI-2017	2018-02-15	Interfaz digital a redes públicas (interfaz digital a 2 048 kbit s y a 34

Table 13.16 - Normas oficiales mexicanas (Secretaría de Turismo)

CLAVE	FECHA	DESCRIPCIÓN
NOM-010-TUR-2001	2002-01-02	De los requisitos que deben contener los contratos que celebren los prestadores de servicios turísticos con los usuarios-turistas. (cancela la norma oficial mexicana nom-010-tur-1999).
NOM-011-TUR-2001	2002-07-22	Requisitos de seguridad, información y operación que deben cumplir los prestadores de servicios turísticos de turismo de aventura.
NOM-012-TUR-2016	2016-09-02	Para la prestación de servicios turísticos de buceo.
NOM-06-TUR-2009	2010-09-06	Requisitos mínimos de información, higiene y seguridad que deben cumplir los prestadores de servicios turísticos de campamentos.
NOM-07-TUR-2002	2003-02-26	De los elementos normativos del seguro de responsabilidad civil que deben contratar los prestadores de servicios turísticos de hospedaje para la protección y seguridad de los turistas o usuarios.
NOM-08-TUR-2002	2003-03-05	Que establece los elementos a que deben sujetarse los guías generales y especializados en temas o localidades específicas de carácter cultural.
NOM-09-TUR-2002	2003-09-26	Que establece los elementos a que deben sujetarse los guías especializados en actividades específicas. (cancela a la norma oficial mexicana nom-09-tur-1997).
PROY-NOM-011-TUR-2018	2018-05-04	Proyecto de modificación de la norma oficial mexicana nom-011-tur-2001, requisitos de seguridad, información y operación que deben cumplir los prestadores de servicios turísticos de turismo de aventura para quedar como proyecto de norma oficial mexicana

Table 13.17 - Normas oficiales mexicanas (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca)

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-FITO-2001	2002-02-08	por la que se establece la campaña contra el carbón parcial del trigo.
NOM-001-SAG/BIO-2014	2014-12-30	especificaciones generales de etiquetado de organismos genéticamente modificados que sean semillas o material vegetativo destinados a siembra, cultivo y producción agrícola.
NOM-001-SAG/FITO-2013	2014-05-30	por la que se establecen los criterios, procedimientos y especificaciones para la elaboración de guías para la descripción varietal y reglas para determinar la calidad de las semillas para siembra.
NOM-001-SAG/GAN-2015	2015-05-29	sistema nacional de identificación animal para bovinos y colmenas.(obligatoria a partir del 01/02/2017 según acuerdo publicado el 01/12/2016 en el dof)
NOM-001-SAG/PESC-2013	2014-01-16	pescas responsable de tñidos. especificaciones para las operaciones de pesca con red de cerco.
NOM-001-SAGARPA/SCFI-2016	2017-11-16	prácticas comerciales-especificaciones sobre el almacenamiento, guarda, conservación, manejo y control de bienes o mercancías bajo custodia de los almacenes generales de depósito. incluyendo productos agropecuarios y pesqueros.
NOM-001-ZOO-1994	1994-04-28	campaña nacional contra la varroasis de las abejas.

<u>NOM-002-FITO-2000</u>	2001-04-18	por la que se establece la campaña contra la broca del café.
<u>NOM-002-SAG/FITO-2015</u>	2015-12-01	por la que se establecen las características y especificaciones que deben reunir las etiquetas de certificación de la calidad de las semillas para siembra.
<u>NOM-002-SAG/GAN-2016</u>	2016-10-05	actividades técnicas y operativas aplicables al programa nacional para el control de la abeja africana.
<u>NOM-002-SAG/PESC-2013</u>	2013-07-11	para ordenar el aprovechamiento de las especies de camarón en aguas de jurisdicción federal de los estados unidos mexicanos.
<u>NOM-002-SAGARPA-2016</u>	2016-12-02	relativa a las características de sanidad, calidad agroalimentaria, autenticidad, etiquetado y evaluación de la conformidad de los fructanos de agave.
<u>NOM-003-PESC-1993</u>	1993-12-31	para regular el aprovechamiento de las especies de sardina monterrey, piña, crinuda, bocona, japonesa y de las especies anchoveta y macarela, con embarcacione de cerco, en aguas de jurisdicción federal del océano pacífico, incluyendo el golfo de califo
<u>NOM-003-SAG/FITO-2015</u>	2015-12-02	por la que establecen las especificaciones a cumplir por las personas morales para poder ser aprobadas como organismos de certificación de semillas.
<u>NOM-003-SAG/GAN-2017</u>	2017-10-06	propóleos, producción y especificaciones para su procesamiento.
<u>NOM-003-SAGARPA-2016</u>	2016-11-18	relativa a las características de sanidad, calidad agroalimentaria, autenticidad, etiquetado y evaluación de la conformidad del jarabe de agave.
<u>NOM-004-SAG/PESC-2015</u>	2015-10-06	especificaciones para el aprovechamiento de la almeja catarina (argopecten circularis) en aguas de jurisdicción federal de los estados unidos mexicanos.
<u>NOM-005-FITO-1995</u>	1996-07-04	por la que se establece la cuarentena exterior para prevenir la introducción del gorgojo khapra.(contiene cuatro modificaciones)
<u>NOM-005-PESC-1993</u>	1993-12-21	para regular el aprovechamiento de las poblaciones de las distintas especies de abulón en aguas de jurisdicción federal de la península de baja california.
<u>NOM-006-SAG/PESC-2016</u>	2016-09-07	para regular el aprovechamiento de todas las especies de langosta en las aguas de jurisdicción federal del golfo de méxico y mar caribe, así como del océano pacífico incluyendo el golfo de california.
<u>NOM-006-ZOO-1993</u>	1994-09-21	requisitos de efectividad biológica para los ixodicidas de uso en bovinos y método de prueba.
<u>NOM-007-SAG/PESC-2015</u>	2015-06-24	para regular el aprovechamiento de las poblaciones de erizo rojo y morado en aguas de jurisdicción federal del océano pacífico de la costa oeste de baja california.
<u>NOM-008-PESC-1993</u>	1993-12-21	para ordenar el aprovechamiento de las especies de pulpo en las aguas de jurisdicción federal del golfo de méxico y mar caribe.
<u>NOM-008-ZOO-1994</u>	1994-11-16	especificaciones zoosanitarias para la construcción y equipamiento de establecimientos para el sacrificio de animales y los dedicados a la industrialización de productos cárnicos.(modificada)
<u>NOM-009-SAG/PESC-2015</u>	2016-02-12	que establece el procedimiento para determinar las épocas y zonas de veda para la captura de las diferentes especies de la flora y fauna acuáticas, en aguas de jurisdicción federal de los estados unidos mexicanos.
<u>NOM-009-ZOO-1994</u>	1994-11-16	proceso sanitario de la carne.
<u>NOM-010-FITO-1995</u>	1996-11-18	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del plátano.
<u>NOM-011-FITO-1995</u>	1996-09-24	por la que se establece la cuarentena exterior para prevenir la introducción de plagas de los cítricos.
<u>NOM-011-PESC-1993</u>	1994-08-16	para regular la aplicación de cuarentenas, a efecto de prevenir la introducción y dispersión de enfermedades certificables y notificables, en la importación de organismos acuáticos vivos en cualesquiera de sus fases de desarrollo, destinados a la acuac
<u>NOM-012-SAG/PESC-2014</u>	2014-12-26	, para regular el aprovechamiento de los recursos pesqueros en el embalse de la presa el cuchillo-solidaridad, ubicada en el municipio de china, n.l.
<u>NOM-012-ZOO-1993</u>	2004-01-27	especificaciones para la regulación de productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos. (contiene dos modificaciones 03/06/1998 y 27/01/2004)
<u>NOM-013-FITO-1995</u>	1996-12-02	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del arroz.(contiene modificación y aclaración),
<u>NOM-013-SAG/PESC-2016</u>	2016-08-19	para regular el aprovechamiento de las especies de caracol en aguas de jurisdicción federal del golfo de méxico y mar caribe.
<u>NOM-014-FITO-1995</u>	1996-12-20	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del algodónero.
<u>NOM-014-SAG/PESC-2015</u>	2015-06-25	especificaciones para regular el aprovechamiento de almeja generosa (panopea generosa y panopea globosa) en aguas de jurisdicción federal del litoral del océano pacífico y golfo de california.
<u>NOM-015-FITO-1995</u>	1997-04-22	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del cocotero.
<u>NOM-015-SAG/PESC-2016</u>	2016-08-17	para regular el aprovechamiento de ostión (crassostrea virginica) en los sistemas lagunarios estuarinos del estado de tabasco.
<u>NOM-015-SEMARNAT/SAGARPA-2007</u>	2009-01-16	que establece las especificaciones técnicas de métodos de uso del fuego en los terrenos forestales y en los terrenos de uso agropecuario.
<u>NOM-016-FITO-1995</u>	1996-12-02	por la que se establece la cuarentena exterior para prevenir la introducción de plagas de la caña del azúcar.
<u>NOM-016-SAG/PESC-2014</u>	2015-07-29	para regular la pesca de lisa y liseta o lebrancha en aguas de jurisdicción federal del golfo de méxico y mar caribe, así como del océano pacífico, incluyendo el golfo de california.

NOM-017-FITO-1995	1996-12-05	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del trigo.
NOM-017-PESC-1994	1995-05-09	para regular las actividades de pesca deportivo recreativa en las aguas de jurisdicción federal de los estados unidos mexicanos.
NOM-018-FITO-1995	1996-12-10	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del maíz.
NOM-019-FITO-1995	1996-12-10	por la que se establece la cuarentena exterior para prevenir la introducción de plagas del café.
NOM-022-FITO-1995	1997-01-02	por la que se establecen las características y especificaciones para el aviso de inicio de funcionamiento y certificación que deben cumplir las personas morales interesadas en prestar los servicios de tratamientos fitosanitarios a vegetales, sus produc
NOM-022-SAG/PESC-2015	2015-06-12	para regular el aprovechamiento de las especies de tñidos con embarcaciones vareras en aguas de jurisdicción federal de los estados unidos mexicanos.
NOM-022-ZOO-1995	1996-01-31	características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que comercializan productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos.
NOM-023-FITO-1995	1999-02-11	por la que se establece la campaña nacional contra moscas de la fruta.
NOM-023-SAG/PESC-2014	2014-04-16	que regula el aprovechamiento de las especies de tñidos con embarcaciones palangreras en aguas de jurisdicción federal del golfo de méxico y mar caribe.
NOM-023-ZOO-1995	1995-09-14	identificación de especie animal en músculo de bovinos, ovinos, equinos, porcinos y aves, por la prueba de inmunodifusión en gel.
NOM-024-ZOO-1995	1995-10-16	especificaciones y características zoosanitarias para el transporte de animales, sus productos y subproductos, productos químicos, farmacéuticos biológicos y alimenticios para uso en animales o consumo por éstos.
NOM-025-FITO-2000	2000-06-12	para el establecimiento de zonas bajo protección y zonas libres de plagas cuarentenarias de la papa.
NOM-025-ZOO-1995	1995-10-16	características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos alimenticios para uso en animales o consumo por éstos.
NOM-026-FITO-1995	1997-09-10	por la que se establece el control de plagas del algodón.
NOM-026-SAG/PESC-2016	2016-09-06	que establece regulaciones para el aprovechamiento de los recursos pesqueros en el embalse de la presa aguamilpa, ubicado en el estado de nayarit.
NOM-026-ZOO-1994	1995-11-27	características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos químicos, farmacéuticos y biológicos para uso en animales.
NOM-027-ZOO-1995	1996-01-11	proceso zoosanitario del semen de animales domésticos.
NOM-028-SAG/PESC-2016	2016-09-23	pesca responsable en la presa ing. fernando hiriart balderrama (zimapan), en hidalgo y querétaro. especificaciones para el aprovechamiento de los recursos pesqueros.
NOM-029-PESC-2006	2007-02-14	pesca responsable de tiburones y rayas. especificaciones para su aprovechamiento.
NOM-030-PESC-2000	2002-01-23	que establece los requisitos para determinar la presencia de enfermedades virales de crustáceos acuáticos vivos, muertos, sus productos o subproductos en cualquier presentación y artemia (artemia spp.), para su introducción al territorio nacional y mo
NOM-030-ZOO-1995	1996-04-17	especificaciones y procedimientos para la verificación de carne, canales, vísceras y despojos de importación en puntos de verificación zoosanitaria.
NOM-031-FITO-2000	2001-08-10	por la que se establece la campaña contra el virus tristeza de los cítricos.
NOM-031-ZOO-1995	1996-03-08	campaña nacional contra la tuberculosis bovina (mycobacterium bovis).
NOM-032-SAG/FITO-2014	2015-08-11	por la que se establecen los requisitos y especificaciones fitosanitarios para la realización de estudios de efectividad biológica de plaguicidas agrícolas y su dictamen técnico.
NOM-032-SAG/PESC-2015	2015-06-19	pesca responsable en el lago de chapala, ubicado en los estados de jalisco y michoacán. especificaciones para el aprovechamiento de los recursos pesqueros.
NOM-033-FITO-1995	1996-06-24	por la que se establecen los requisitos y especificaciones fitosanitarias para aviso de inicio de funcionamiento que deberán cumplir las personas físicas o morales interesadas en comercializar plaguicidas agrícolas.
NOM-033-SAG/PESC-2014	2014-12-23	pesca responsable en el sistema lagunar champayán y río tamesí, incluyendo las lagunas chairel y la escondida, ubicados en el estado de tamaulipas. especificaciones para el aprovechamiento de los recursos pesqueros.
NOM-033-SAG/ZOO-2014	2015-08-26	métodos para dar muerte a los animales domésticos y silvestres.
NOM-034-FITO-1995	1996-06-24	por la que se establecen los requisitos y especificaciones fitosanitarias para el aviso de inicio de funcionamiento que deberán cumplir las personas físicas o morales interesadas en la fabricación, formulación, formulación por maquila, formulación y/o
NOM-034-SAG/PESC-2014	2014-12-10	pesca responsable en el embalse de la presa emilio portes gil (san lorenzo), ubicada en el estado de tamaulipas. especificaciones para el aprovechamiento de los recursos pesqueros.

<u>NOM-035-SAG/PESC-2014</u>	2014-12-26	pesca responsable en el embalse de la presa José S. Noriega (vaquerías o mimbrés), ubicada en el estado de Nuevo León. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-036-SAG/PESC-2015</u>	2015-06-11	pesca responsable en el lago de Pátzcuaro ubicado en el estado de Michoacán. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-037-PESC-2004</u>	2007-03-21	pesca responsable en el sistema lagunar formado por los humedales del Usamacinta, en los municipios de Catazajá, Palenque y la Libertad en el estado de Chiapas, Jonutá, Emiliano Zapata y Balancán en el estado de Tabasco, Ciudad del Carmen y Palizadas en
<u>NOM-039-PESC-2003</u>	2006-07-26	pesca responsable de Jaiba en aguas de jurisdicción federal del litoral del océano Pacífico. especificaciones para su aprovechamiento.
<u>NOM-040-FITO-2002</u>	2003-02-21	requisitos y especificaciones para la producción y movilización nacional de papa comercial.
<u>NOM-040-ZOO-1995</u>	1996-10-04	especificaciones para la comercialización de sales puras antimicrobianas para uso en animales o consumo por éstos.
<u>NOM-041-FITO-2002</u>	2003-03-04	requisitos y especificaciones fitosanitarias para la producción de material propagativo asexual de papa.
<u>NOM-041-PESC-2004</u>	2007-03-15	pesca responsable en el lago de Catemaco, ubicado en el estado de Veracruz. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-041-ZOO-1995</u>	1996-08-20	campaña nacional contra la brucelosis en los animales.
<u>NOM-042-PESC-2003</u>	2006-07-19	pesca responsable en el embalse de la presa Falcón en el estado de Tamaulipas. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-043-FITO-1999</u>	2000-03-01	especificaciones para prevenir la introducción de malezas cuarentenarias a México.
<u>NOM-043-PESC-2003</u>	2006-07-20	pesca responsable en el embalse de la presa Marte R. Gómez en el estado de Tamaulipas. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-044-PESC-2004</u>	2006-09-11	pesca responsable en el embalse de la presa la Boquilla en el estado de Chihuahua. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-045-SAG/PESC-2015</u>	2016-02-15	especificaciones para regular el aprovechamiento de la especie de cangrejo moro (menippe mercenaria), en las aguas de jurisdicción federal del estado de Campeche.
<u>NOM-045-ZOO-1995</u>	1996-08-05	características zoonosanitarias para la operación de establecimientos donde se concentren animales para ferias, exposiciones, subastas, tianguis y eventos similares.
<u>NOM-046-PESC-2005</u>	2006-07-21	pesca responsable en el embalse de la presa la Amistad en el estado de Coahuila. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-046-ZOO-1995</u>	1997-02-19	sistema nacional de vigilancia epizootiológica.
<u>NOM-047-SAG/PESC-2014</u>	2014-04-15	para la identificación del origen de camarones cultivados, de aguas marinas y de esteros, marismas y bahías.
<u>NOM-049-SAG/PESC-2014</u>	2014-04-14	que determina el procedimiento para establecer zonas de refugio para los recursos pesqueros en aguas de jurisdicción federal de los Estados Unidos Mexicanos.
<u>NOM-050-PESC--2004</u>	2006-08-14	pesca responsable en el embalse del lago de Tecocomulco en el estado de Hidalgo. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-051-ZOO-1995</u>	1998-03-23	trato humanitario en la movilización de animales.
<u>NOM-052-FITO-1995</u>	1997-06-10	por la que se establecen los requisitos y especificaciones fitosanitarias para presentar el aviso de inicio de funcionamiento por las personas físicas o morales que se dedican a la aplicación aérea de plaguicidas agrícolas.
<u>NOM-054-ZOO-1996</u>	1998-06-08	establecimiento de cuarentenas para animales y sus productos.
<u>NOM-056-ZOO-1995</u>	1999-02-22	especificaciones técnicas para las pruebas diagnósticas que realicen los laboratorios de pruebas aprobados en materia zoonosanitaria.
<u>NOM-057-FITO-1995</u>	1996-07-30	por la que se establecen los requisitos y especificaciones fitosanitarias para emitir el dictamen de análisis de residuos de plaguicidas.
<u>NOM-057-ZOO-1997</u>	1998-06-08	método de prueba para la evaluación de efectividad en acaricidas para el control de la Varroa.
<u>NOM-058-SAG/PESC/SEMARNAT-2013</u>	2013-12-23	para regular el cultivo de las ostras perleras: madreperla (pinctada mazatlanica), concha nacar (Pteria sterna), madreperla del Atlántico (pinctada imbricata) y la ostra perlera alada del Atlántico (Pteria colymbus) en aguas marinas de jurisdicción federal
<u>NOM-059-ZOO-1997</u>	2000-03-01	salud animal. especificaciones de productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos. manejo técnico del material publicitario.
<u>NOM-060-SAG/PESC-2016</u>	2016-09-19	pesca responsable en cuerpos de aguas continentales dulceacuícolas de jurisdicción federal de los Estados Unidos Mexicanos. especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-060-ZOO-1999</u>	2001-06-28	especificaciones zoonosanitarias para la transformación de despojos animales y su empleo en la alimentación animal.
<u>NOM-061-SAG-PESC/SEMARNAT-2016</u>	2016-12-13	especificaciones técnicas de los excluidores de tortugas marinas utilizados por la flota de arrastre camarонера en aguas de jurisdicción federal de los Estados Unidos Mexicanos.

NOM-061-ZOO-1999	2000-10-11	especificaciones zoosanitarias de los productos alimenticios para consumo animal.
NOM-062-SAG/PESC-2014	2015-07-03	para la utilización del sistema de localización y monitoreo satelital de embarcaciones pesqueras.
NOM-062-ZOO-1999	2001-08-22	especificaciones técnicas para la producción, cuidado y uso de los animales de laboratorio.
NOM-063-PESC-2005	2007-08-16	pescas responsable de curvina golfin (cynoscion othonopterus) en aguas de jurisdicción federal del alto golfo de california y delta del río colorado.
NOM-064-SAG/PESC/SEMARN-2013	2015-01-21	especificaciones para su aprovechamiento.
NOM-064-ZOO-2000	2003-01-27	sobre sistemas, métodos y técnicas de captura prohibidos en la pesca en aguas de jurisdicción federal de los estados unidos mexicanos.
NOM-065-SAG/PESC-2014	2015-07-03	lineamientos para la clasificación y prescripción de productos farmacéuticos veterinarios por el nivel de riesgo de sus ingredientes activos. (el 12/07/2004 se publico en el dof la clasificación y prescripción de los productos farmacéuticos)
NOM-066-FITO-2002.	2005-05-18	para regular el aprovechamiento de las especies de mero y especies asociadas, en aguas de jurisdicción federal del litoral del golfo de méxico y mar caribe.
NOM-067-ZOO-2007	2011-05-20	especificaciones para el manejo fitosanitario y movilización del aguacate.
NOM-068-SAG/FITO-2015	2015-08-19	campaña nacional para la prevención y control de la rabia en bovinos y especies ganaderas.
NOM-069-FITO-1995	1998-11-18	por la que se establecen las medidas fitosanitarias para combatir el moko del plátano y prevenir su dispersión.
NOM-070-SAG/PESC-2014	2014-12-09	para el establecimiento y reconocimiento de zonas libres de plagas.
NOM-074-SAG/PESC-2014	2014-04-28	pescas responsable en el embalse de la presa la muñeca, ubicada en el estado de san luis potosí. especificaciones para el aprovechamiento de los recursos pesqueros.
NOM-075-FITO-1997	1998-04-23	para regular el uso de sistemas de exclusión de fauna acuática (sefa) en unidades de producción acuícola para el cultivo de camarón en el estado de sinaloa.
NOM-076-FITO-1999	2000-04-03	Por la que se establece los requisitos y especificaciones fitosanitarias para la movilización de frutos hospederos de moscas de la fruta.
NOM-077-FITO-2000	2000-04-11	Sistema preventivo y dispositivo nacional de emergencia contra las moscas exóticas de la fruta.
NOM-079-FITO-2002	2002-05-22	Por la que se establecen los requisitos y especificaciones para la realización de estudios de efectividad biológica de los insumos de nutrición vegetal.
NOM-081-FITO-2001	2002-09-18	Requisitos fitosanitarios para la producción y movilización de material propagativo libre de virus tristeza y otros patógenos asociados a cítricos.
NOM-082-SAG-FITO/SSA1-2017	2017-10-04	Manejo y eliminación de focos de infestación de plagas, mediante el establecimiento o reordenamiento de fechas de siembra, cosecha y destrucción de residuos.
NOM-164-SEMAR/SAGAR-2013	2014-01-03	Límites máximos de residuos. Lineamientos técnicos y procedimiento de autorización y revisión.
		Que establece las características y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y la diversidad biológica y, adicionalmente,

Table 13.18 - Secretaria de Meio Ambiente e Recursos Naturais é o Ministério do Meio Ambiente

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-CONAGUA-2011	2012-02-17	Sistemas de agua potable, toma domiciliar y alcantarillado sanitario-hermeticidad-especificaciones y métodos de prueba.
NOM-001-SEMARNAT-1996	1997-01-06	Que establece los límites máximos permisibles de contaminantes en las descargas de aguas residuales en aguas y bienes nacionales.
NOM-002-SEMARNAT-1996	1998-06-03	Que establece los límites máximos permisibles de contaminantes en las descargas de aguas residuales a los sistemas de alcantarillado.
NOM-003-CONAGUA-1996	1997-02-03	Requisitos durante la construcción de pozos de extracción de agua para prevenir la contaminación de acuíferos.
NOM-003-SEMARNAT-1997	1998-09-21	Que establece los límites máximos permisibles de contaminantes para las aguas residuales tratadas que se reusen en servicios al público.
NOM-004-CONAGUA-1996	1997-08-08	Requisitos para la protección de acuíferos durante el mantenimiento y rehabilitación de pozos de extracción de agua y para el cierre de pozos en general.
NOM-004-SEMARNAT-2002	2003-08-15	Protección ambiental.- lodos y biosólidos.-especificaciones y límites máximos permisibles de contaminantes para su aprovechamiento y disposición final.
NOM-005-ASEA-2016	2016-11-07	Diseño, construcción, operación y mantenimiento de estaciones de servicio para almacenamiento y expendio de diésel y gasolinas.
NOM-005-CONAGUA-1996	1997-07-25	Flujómetros-especificaciones y métodos de prueba.
NOM-005-SEMARNAT-1997	1997-05-20	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de corteza, tallos y plantas completas de vegetación forestal.
NOM-006-CONAGUA-1997	1999-01-29	Fosas sépticas prefabricadas-especificaciones y métodos de prueba
NOM-006-SEMARNAT-1997	1997-05-28	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de hojas de palma.

<u>NOM-007-SEMARNAT-1997</u>	1997-05-30	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de ramas, hojas o pencas, flores, frutos y semillas.
<u>NOM-008-CONAGUA-1998</u>	2001-06-25	Regaderas empleadas en el aseo corporal-especificaciones y métodos de prueba.
<u>NOM-008-SEMARNAT-1996</u>	1996-06-24	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de cogollos.
<u>NOM-009-CONAGUA-2001</u>	2001-08-02	Inodoros para uso sanitario-especificaciones y métodos de prueba.
<u>NOM-009-SEMARNAT-1996</u>	1996-06-26	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de látex y otros exudados de vegetación forestal.
<u>NOM-010-CONAGUA-2000</u>	2003-09-02	Válvula de admisión y válvula de descarga para tanque de inodoro-especificaciones y métodos de prueba.
<u>NOM-010-SEMARNAT-1996</u>	1996-05-28	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de hongos.
<u>NOM-011-CONAGUA-2015</u>	2015-03-27	Conservación del recurso agua-que establece las especificaciones y el método para determinar la disponibilidad media anual de las aguas nacionales.
<u>NOM-011-SEMARNAT-1996</u>	1996-06-26	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de musgo, heno y doradilla.
<u>NOM-012-SEMARNAT-1996</u>	1996-06-26	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de leña para uso doméstico.
<u>NOM-013-SEMARNAT-2010</u>	2010-11-06	Que regula sanitariamente la importación de árboles de navidad naturales de las especies de los géneros pinus y abies y la especie pseudotsuga menziesii.
<u>NOM-014-CONAGUA-2003</u>	2009-08-18	Requisitos para la recarga artificial de acuíferos con agua residual tratada.
<u>NOM-015-CONAGUA-2007</u>	2009-08-18	Infiltración artificial de agua a los acuíferos.- características y especificaciones de las obras y del agua.
<u>NOM-015-SEMARNAT/SAGARPA-2007</u>	2009-01-16	Que establece las especificaciones técnicas de métodos de uso del fuego en los terrenos forestales y en los terrenos de uso agropecuario.
<u>NOM-016-SEMARNAT-2013</u>	2013-03-04	Que regula fitosanitariamente la importación de madera aserrada nueva.
<u>NOM-018-SEMARNAT-1999</u>	1999-10-27	Que establece los procedimientos, criterios y especificaciones técnicas y administrativas para realizar el aprovechamiento sostenible de la hierba de candelila, transporte y almacenamiento del cerote
<u>NOM-019-SEMARNAT-2006</u>	2008-07-23	Que establece los lineamientos técnicos de los métodos para el combate y control de insectos descortezadores.
<u>NOM-019-SEMARNAT-2017</u>	2018-03-22	Que establece los lineamientos técnicos para la prevención, combate y control de insectos descortezadores.
<u>NOM-021-SEMARNAT-2000</u>	2002-12-31	Que establece las especificaciones de fertilidad, salinidad y clasificación de suelos. Estudios, muestreo y análisis.
<u>NOM-022-SEMARNAT-2003</u>	2003-04-10	Que establece las especificaciones para la preservación, conservación, aprovechamiento sustentable y restauración de los humedales costeros en zonas de manglar.
<u>NOM-023-SEMARNAT-2001</u>	2001-12-10	Que establece las especificaciones técnicas que deberá contener la cartografía y la clasificación para la elaboración de los inventarios de suelos.
<u>NOM-024-SEMARNAT-1993</u>	1994-06-29	Por la que se establecen medidas para la protección de las especies de totoaba y vaquita en aguas de jurisdicción federal del Golfo de California.
<u>NOM-026-SEMARNAT-2005</u>	2006-09-28	Que establece los criterios y especificaciones técnicas para realizar el aprovechamiento comercial de resina de pino.
<u>NOM-027-SEMARNAT-1996</u>	1996-06-05	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de tierra de monte.
<u>NOM-028-SEMARNAT-1996</u>	1996-06-24	Que establece los procedimientos, criterios y especificaciones para realizar el aprovechamiento, transporte y almacenamiento de raíces y rizomas de vegetación
<u>NOM-029-SEMARNAT-2003</u>	2003-07-24	Especificaciones sanitarias del bambú, mimbre, bejuco, ratán, caña, junco y rafia, utilizados principalmente en la cestería y espartería.
<u>NOM-034-SEMARNAT-1993</u>	1993-10-18	Que establece los métodos de medición para determinar la concentración de monóxido de carbono en el aire ambiente y los procedimientos para la calibración de los equipos de medición.
<u>NOM-035-SEMARNAT-1993</u>	1993-10-18	Que establece los métodos de medición para determinar la concentración de partículas suspendidas totales en el aire ambiente y el procedimiento para la calibración de equipos de medición.
<u>NOM-036-SEMARNAT-1993</u>	1993-10-18	Que establece los métodos de medición para determinar la concentración de ozono en el aire ambiente y los procedimientos para la calibración de los equipos de medición.
<u>NOM-037-SEMARNAT-1993</u>	1993-10-18	Que establece los métodos de medición para determinar la concentración de bióxido de nitrógeno en el aire ambiente y los procedimientos para la calibración de los equipos de medición.
<u>NOM-038-SEMARNAT-1993</u>	1993-10-18	Que establece los métodos de medición para determinar la concentración de bióxido de azufre en el aire ambiente y los procedimientos para la calibración de los equipos de medición.
<u>NOM-039-SEMARNAT-1993</u>	1993-10-22	Que establece los niveles máximos permisibles de emisión a la atmósfera de bióxido y trióxido de azufre y neblinas de ácido sulfúrico, en plantas productoras
<u>NOM-040-SEMARNAT-2002</u>	2002-12-18	Protección ambiental-fabricación de cemento hidráulico-niveles máximos permisibles de emisión a la atmósfera.

<u>NOM-041-SEMARNAT-2015</u>	2015-06-10	Que establece los límites máximos permisibles de emisión de gases contaminantes provenientes del escape de los vehículos automotores en circulación que usan gasolina como combustible.
<u>NOM-042-SEMARNAT-2003</u>	2005-09-07	Que establece los límites máximos permisibles de emisión de hidrocarburos totales o no metano, monóxido de carbono, óxidos de nitrógeno y partículas provenientes del escape de los vehículos automotores nuevos cuyo peso bruto vehicular no exceda los 3,857
<u>NOM-043-SEMARNAT-1993</u>	1993-10-22	Que establece los niveles máximos permisibles de emisión a la atmósfera de partículas sólidas provenientes de fuentes fijas.
<u>NOM-044-SAG/PESC-2017</u>	2017-08-23	Pesca responsable en el embalse de la presa la boquilla en el estado de chihuahua. Especificaciones para el aprovechamiento de los recursos pesqueros.
<u>NOM-044-SEMARNAT-2017</u>	2018-02-19	Que establece los límites máximos permisibles de emisión de monóxido de carbono, óxidos de nitrógeno, hidrocarburos no metano, hidrocarburos no metano más óxidos de nitrógeno, partículas y amoníaco, provenientes del escape de motores nuevos que utilizan
<u>NOM-045-SEMARNAT-2006</u>	2007-09-13	Protección ambiental.- vehículos en circulación que usan diesel como combustible.- límites máximos permisibles de opacidad, procedimiento de prueba y características técnicas del equipo de medición.
<u>NOM-045-SEMARNAT-2017</u>	2018-03-08	Protección ambiental.- vehículos en circulación que usan diésel como combustible.- límites máximos permisibles de opacidad, procedimiento de prueba y características técnicas del equipo de medición.
<u>NOM-046-SEMARNAT-1993</u>	1993-10-22	Que establece los niveles máximos permisibles de emisión a la atmósfera de bióxido de azufre, neblinas de trióxido de azufre y ácido sulfúrico, provenientes de procesos de producción de ácido dodecibencensulfónico
<u>NOM-047-SEMARNAT-2014</u>	2014-11-26	Que establece las características del equipo y el procedimiento de medición para la verificación de los límites de emisión de contaminantes, provenientes de los vehículos automotores en circulación que usan gasolina, gas licuado de petróleo, gas natural
<u>NOM-048-SEMARNAT-1993</u>	1993-10-22	Que establece los niveles máximos permisibles de emisión de hidrocarburos, monóxido de carbono y humo, provenientes del escape de las motocicletas en circulación que utilizan gasolina o mesclagasolina-aceit como combustible
<u>NOM-049-SEMARNAT-1993</u>	1993-10-22	Que establece las características del equipo y el procedimiento de medición, para la verificación de los niveles de emisión de gases contaminantes, provenientes de las motocicletas en circulación que usan gasolina o mezcla de gasolina-aceite como combus
<u>NOM-050-SEMARNAT-1993</u>	1993-10-22	Que establece los niveles máximos permisibles de emisión de gases contaminantes provenientes del escape de los vehículos automotores en circulación que usan gas licuado de petróleo, gas natural u otros combustibles alternos como combustible.
<u>NOM-052-SEMARNAT-2005</u>	2006-06-23	Que establece las características, el procedimiento de identificación, clasificación y los listados de los residuos peligrosos.
<u>NOM-053-SEMARNAT-1993</u>	1993-10-22	Que establece el procedimiento para llevar a cabo la prueba de extracción para determinar los constituyentes que hacen a un residuo peligroso por su toxicidad al ambiente.
<u>NOM-054-SEMARNAT-1993</u>	1993-10-22	Que establece el procedimiento para determinar la incompatibilidad entre dos o más residuos considerados como peligrosos por la Norma Oficial Mexicana NOM-052-ECOL-1993.
<u>NOM-055-SEMARNAT-2003</u>	2004-11-03	Que establece los requisitos que deben reunir los sitios que se destinarán para un confinamiento controlado de residuos peligrosos previamente estabilizados.
<u>NOM-056-SEMARNAT-1993</u>	1993-10-22	Que establece los requisitos para el diseño y construcción de las obras complementarias de un confinamiento controlado de residuos peligrosos.
<u>NOM-057-SEMARNAT-1993</u>	1993-10-22	Que establece los requisitos que deben observarse en el diseño, construcción y operación de celdas de un confinamiento controlado para residuos peligrosos.
<u>NOM-058-SAG/PESC/SEMAR-2013</u>	2013-12-23	Para Regular El Cultivo De Las Ostras Perleras: Madreperla (Pinctada Mazatlanica), Concha Nacar (Pteria Sterna), Madreperla Del Atlántico (Pinctada Imbricata) Y La Ostra Perlera Alada Del Atlántico (Pteria Colymbus) En Aguas Marinas De Jurisdicción Feder
<u>NOM-058-SEMARNAT-1993</u>	1993-10-22	Que establece los requisitos para la operación de un confinamiento controlado de residuos peligrosos.
<u>NOM-059-SEMARNAT-2010</u>	2010-12-30	Protección ambiental-especies nativas de México de flora y fauna silvestres-categorías de riesgo y especificaciones para su inclusión, exclusión o cambio-lista de especies en riesgo.
<u>NOM-060-SEMARNAT-1994</u>	1994-05-13	Que establecen las especificaciones para mitigar los efectos adversos ocasionados en los suelos y cuerpos de agua por el aprovechamiento forestal.
<u>NOM-061-SAG-PESC/SEMARNAT-2016</u>	2016-12-13	Especificaciones técnicas de los excluidores de tortugas marinas utilizados por la flota de arrastre camarонера en aguas de jurisdicción federal de los estados unidos mexicanos.
<u>NOM-061-SEMARNAT-1994</u>	1994-05-13	Que establece las especificaciones para mitigar los efectos adversos ocasionados en la flora y fauna silvestres por el aprovechamiento forestal.
<u>NOM-064-SAG/PESC/SEMARN-2013</u>	2015-01-21	Sobre sistemas, métodos y técnicas de captura prohibidos en la pesca en aguas de jurisdicción federal de los estados unidos mexicanos.

<u>NOM-076-SEMARNAT-2012</u>	2012-11-27	Que establece los niveles máximos permisibles de emisión de hidrocarburos no quemados, monóxido de carbono y óxidos de nitrógeno provenientes del escape, así como de hidrocarburos evaporativos provenientes del sistema de combustible, que usan gasolina, g
<u>NOM-077-SEMARNAT-1995</u>	1995-11-13	Que establece el procedimiento de medición para la verificación de los niveles de emisión de la opacidad del humo proveniente del escape de los vehículos automotores en circulación que usan diesel como combustible.
<u>NOM-079-SEMARNAT-1994</u>	1995-01-12	Que establece los límites máximos permisibles de emisión de ruido de los vehículos automotores nuevos en planta y su método de medición.
<u>NOM-080-SEMARNAT-1994</u>	1995-01-13	Que establece los límites máximos permisibles de emisión de ruido proveniente del escape de los vehículos automotores, motocicletas y triciclos motorizados en circulación y su método de medición.
<u>NOM-081-SEMARNAT-1994</u>	1995-01-13	Que establece los límites máximos permisibles de emisión de ruido de las fuentes fijas y su método de medición.
<u>NOM-082-SEMARNAT-1994</u>	1995-01-16	Que establece los límites máximos permisibles de emisión de ruido de las motocicletas y triciclos motorizados nuevos en planta y su método de medición.
<u>NOM-083-SEMARNAT-2003</u>	2004-10-20	Especificaciones de protección ambiental para la selección del sitio, diseño, construcción, operación, monitoreo, clausura y obras complementarias de un sitio de disposición final de residuos sólidos urbanos y de manejo especial
<u>NOM-085-SEMARNAT-2011</u>	2012-02-02	Contaminación atmosférica-niveles máximos permisibles de emisión de los equipos de combustión de calentamiento indirecto y su medición.
<u>NOM-086-SEMAR-SENER-SCFI-2005</u>	2006-01-30	Especificaciones de los combustibles fósiles para la protección ambiental.
<u>NOM-087-SEMARNAT-SSA1-2002</u>	2003-02-17	Protección ambiental - salud ambiental - residuos peligrosos biológico-infecciosos - clasificación y especificaciones de manejo.
<u>NOM-097-SEMARNAT-1995</u>	1996-02-01	Que establece los límites máximos permisibles de emisión a la atmósfera de material particulado y óxidos de nitrógeno en los procesos de fabricación de vidrio.
<u>NOM-098-SEMARNAT-2002</u>	2004-10-01	Protección ambiental-incineración de residuos, especificaciones de operación y límites de emisión de contaminantes.
<u>NOM-105-SEMARNAT-1996</u>	1998-04-02	Que establece los niveles máximos permisibles de emisiones a la atmósfera de partículas sólidas totales y compuestos de azufre reducido total provenientes de los procesos de recuperación de químicos de las plantas de fabricación de celulosa.
<u>NOM-115-SEMARNAT-2003</u>	2004-08-27	Que establece las especificaciones de protección ambiental que deben observarse en las actividades de perforación y mantenimiento de pozos petroleros terrestres para exploración y producción en zonas agrícolas, ganaderas y eriales, fuera de áreas naturale
<u>NOM-116-SEMARNAT-2005</u>	2005-11-07	Que establece las especificaciones de protección ambiental para prospecciones sísmológicas terrestres que se realicen en zonas agrícolas, ganaderas y eriales.
<u>NOM-117-SEMARNAT-2006</u>	2009-10-29	Que establece las especificaciones de protección ambiental durante la instalación, mantenimiento mayor y abandono, de sistemas de conducción de hidrocarburos y petroquímicos en estado líquido y gaseoso por ducto, que se realicen en derechos de vía existe
<u>NOM-120-SEMARNAT-2011</u>	2012-03-13	Que establece las especificaciones de protección ambiental para las actividades de exploración minera directa, en zonas agrícolas, ganaderas o eriales y en zonas con climas secos y templados en donde se desarrolle vegetación de matorral xerófilo, bosque
<u>NOM-121-SEMARNAT-1997</u>	1998-07-14	Que establece los niveles máximos permisibles de emisión a la atmósfera de compuestos orgánicos volátiles (covs) provenientes de las operaciones de recubrimiento de carrocerías nuevas en planta de automóviles, unidades de uso múltiple, de pasajeros y ut
<u>NOM-123-SEMARNAT-1998</u>	1999-06-14	Que establece el contenido máximo permisible de compuestos orgánicos volátiles (covs), en la fabricación de pinturas de secado al aire base disolvente para uso doméstico y los procedimientos para la determinación del contenido de los mismos en pinturas
<u>NOM-126-SEMARNAT-2000</u>	2001-03-20	Por la que se establecen las especificaciones para la realización de actividades de colecta científica de material biológico de especies de flora y fauna silvestres y otros recursos biológicos en el territorio nacional.
<u>NOM-129-SEMARNAT-2006</u>	2007-07-17	Redes de distribución de gas natural.- que establece las especificaciones de protección ambiental para la preparación del sitio, construcción, operación, mantenimiento y abandono de redes de distribución de gas natural que se pretendan ubicar en áreas ur
<u>NOM-130-SEMARNAT-2000</u>	2001-03-23	Protección ambiental-sistemas de telecomunicaciones por red de fibra óptica-especificaciones para la planeación, diseño, preparación del sitio, construcción, operación y mantenimiento.
<u>NOM-131-SEMARNAT-2010</u>	2011-10-17	Que establece lineamientos y especificaciones para el desarrollo de actividades de observación de ballenas, relativas a su protección y la conservación de su hábitat.
<u>NOM-133-SEMARNAT-2015</u>	2016-02-23	Protección ambiental-bifenilos policlorados (bpcs)-especificaciones de manejo.
<u>NOM-135-SEMARNAT-2004</u>	2004-08-27	Para la regulación de la captura para investigación, transporte, exhibición, manejo y manutención de mamíferos marinos en cautiverio.

<u>NOM-137-SEMARNAT-2013</u>	2014-02-20	Contaminación atmosférica.- complejos procesadores de gas.- control de emisiones de compuestos de azufre.
<u>NOM-138-SEMARNAT/SSA1-2012</u>	2013-09-10	Límites máximos permisibles de hidrocarburos en suelos y lineamientos para el muestreo en la caracterización y especificaciones para la remediación.
<u>NOM-141-SEMARNAT-2003</u>	2004-09-13	Que establece el procedimiento para caracterizar los jales, así como las especificaciones y criterios para la caracterización y preparación del sitio, proyecto, construcción, operación y postoperación de presas de jales.
<u>NOM-143-SEMARNAT-2003</u>	2005-03-03	Que establece las especificaciones ambientales para el manejo de agua congénita asociada a hidrocarburos.
<u>NOM-144-SEMARNAT-2012</u>	2012-08-16	Que establece las medidas fitosanitarias reconocidas internacionalmente para el embalaje de madera, que se utiliza en el comercio internacional de bienes y mercancías.
<u>NOM-144-SEMARNAT-2017</u>	2018-02-22	Que establece las medidas fitosanitarias y los requisitos de la marca reconocidas internacionalmente para el embalaje de madera que se utiliza en el comercio internacional de bienes y mercancías.
<u>NOM-145-SEMARNAT-2003</u>	2004-08-27	Confinamiento de residuos en cavidades construidas por disolución en domos salinos geológicamente estables.
<u>NOM-146-SEMARNAT-2005</u>	2005-09-09	Establece la metodología para la elaboración de planos que permitan la ubicación cartográfica de la zona federal marítimo terrestre y terrenos ganados al mar que se soliciten en concesión.
<u>NOM-146-SEMARNAT-2017</u>	2017-12-14	Que establece la metodología para la identificación, delimitación y representación cartográfica que permitan la ubicación geográfica de la zona federal marítimo terrestre y terrenos ganados al mar.
<u>NOM-147-SEMARNAT/SSA1-2004</u>	2007-03-02	Que establece criterios para determinar las concentraciones de remediación de suelos contaminados por arsénico, bario, berilio, cadmio, cromo hexavalente, mercurio, níquel, plata, plomo, selenio, talio y/o vanadio.
<u>NOM-148-SEMARNAT-2006</u>	2007-11-28	Contaminación atmosférica.- recuperación de azufre proveniente de los procesos de refinación del petróleo.
<u>NOM-149-SEMARNAT-2006</u>	2007-01-31	Que establece las especificaciones de protección ambiental que deben observarse en las actividades de perforación, mantenimiento y abandono de pozos petroleros en las zonas marinas mexicanas.
<u>NOM-150-SEMARNAT-2006</u>	2007-03-06	Que establece las especificaciones técnicas de protección ambiental que deben observarse en las actividades de construcción y evaluación preliminar de pozos geotérmicos para exploración, ubicados en z
<u>NOM-150-SEMARNAT-2017</u>	2017-11-22	Que establece las especificaciones técnicas de protección ambiental que deben observarse en las actividades de construcción y evaluación preliminar de pozos geotérmicos para exploración, ubicados en zonas agrícolas, ganaderas y eriales, fuera de áreas na
<u>NOM-152-SEMARNAT-2006</u>	2008-10-17	Que establece los lineamientos, criterios y especificaciones de los contenidos de los programas de manejo forestal para el aprovechamiento de recursos forestales maderables en bosques, selvas y vegetación de zonas áridas.
<u>NOM-155-SEMARNAT-2007</u>	2010-01-15	Que establece los requisitos de protección ambiental para los sistemas de lixiviación de minerales de oro y plata.
<u>NOM-156-SEMARNAT-2012</u>	2012-07-16	Establecimiento y operación de sistemas de monitoreo de la calidad del aire.
<u>NOM-157-SEMARNAT-2009</u>	2011-08-30	Que establece los elementos y procedimientos para instrumentar planes de manejo de residuos mineros.
<u>NOM-159-SEMARNAT-2011</u>	2012-02-13	Que establece los requisitos de protección ambiental de los sistemas de lixiviación de cobre.
<u>NOM-161-SEMARNAT-2011</u>	2013-02-01	Que establece los criterios para clasificar a los residuos de manejo especial y determinar cuáles están sujetos a plan de manejo; el listado de los mismos, el procedimiento para la inclusión o exclusión a dicho listado; así como los elementos y procedimi
<u>NOM-162-SEMARNAT-2012</u>	2013-02-01	Que establece las especificaciones para la protección, recuperación y manejo de las poblaciones de las tortugas marinas en su hábitat de anidación.(contieneacuerdo publicado el 08/03/2012 en el dof)
<u>NOM-163-SEMARNAT-ENER-SCF-2013</u>	2013-06-21	Emisiones de bióxido de carbono (co2) provenientes del escape y su equivalencia en términos de rendimiento de combustible, aplicable a vehículos automotores nuevos de peso bruto vehicular de hasta 3 857 kilogramos.
<u>NOM-164-SEMAR/SAGAR-2013</u>	2014-01-03	Que establece las características y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y la diversidad biológica y, adicionalmente,
<u>NOM-165-SEMARNAT-2013</u>	2014-01-24	Que establece la lista de sustancias sujetas a reporte para el registro de emisiones y transferencia de contaminantes.
<u>NOM-166-SEMARNAT-2014</u>	2015-01-09	Control de emisiones atmosféricas en la fundición secundaria de plomo.
<u>NOM-167-SEMARNAT-2017</u>	2017-09-05	Que establece los límites máximos permisibles de emisión de contaminantes para los vehículos automotores que circulan en las entidades federativas ciudad de México, Hidalgo, Estado de México, Morelos, Puebla y Tlaxcala; los métodos de prueba para la eval
<u>NOM-EM-002-ASEA-2016</u>	2016-11-14	Que establece los métodos de prueba y parámetros para la operación, mantenimiento y eficiencia de los sistemas de recuperación de vapores de gasolinas en estaciones de servicio para expendio al público de gasolinas, para el control de emisiones.
<u>NOM-EM-003-ASEA-2016</u>	2016-11-24	Especificaciones y criterios técnicos de seguridad industrial, seguridad operativa y protección al medio ambiente para el diseño, construcción, pre-

	arranque, operación y mantenimiento de las instalaciones terrestres de almacenamiento de petrolíferos, exc

Table 13.19 - Normas Oficiales Mexicanas (Secretaría de Trabajo y Previsión Social)

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-STPS-2008	2008-11-24	Edificios, locales, instalaciones y áreas en los centros de trabajo-condiciones de seguridad.
NOM-002-STPS-2010	2010-12-09	Condiciones de seguridad-prevención y protección contra incendios en los centros de trabajo.
NOM-003-STPS-1999	1999-12-28	Actividades agrícolas-uso de insumos fitosanitarios o plaguicidas e insumos de nutrición vegetal o fertilizantes-condiciones de seguridad e higiene.
NOM-004-STPS-1999	1999-05-31	Sistemas de protección y dispositivos de seguridad en la maquinaria y equipo que se utilice en los centros de trabajo. (con la entrada en vigor de la presente norma se cancelan las siguientes normas oficiales mexicanas: nom-107-stps-1994,nom-108-stps-1
NOM-005-STPS-1998	1999-02-02	Relativa a las condiciones de seguridad e higiene en los centros de trabajo para el manejo, transporte y almacenamiento de sustancias químicas peligrosas.
NOM-006-STPS-2014	2014-09-11	Manejo y almacenamiento de materiales-condiciones de seguridad y salud en el trabajo.
NOM-007-STPS-2000	2001-03-09	Actividades agrícolas-instalaciones, maquinaria, equipo y herramientas-condiciones de seguridad.
NOM-008-STPS-2013	2013-10-31	Actividades de aprovechamiento forestal maderable y en centros de almacenamiento y transformación en su actividad primaria-condiciones de seguridad y salud en el trabajo.
NOM-009-STPS-2011	2011-05-06	Condiciones de seguridad para realizar trabajos en altura.
NOM-010-STPS-2014	2014-04-28	Agentes químicos contaminantes del ambiente laboral-reconocimiento, evaluación y control.
NOM-011-STPS-2001	2002-04-17	Condiciones de seguridad e higiene en los centros de trabajo donde se genere ruido.
NOM-012-STPS-2012	2012-10-31	Condiciones de seguridad y salud en los centros de trabajo donde se manejen fuentes de radiación ionizante.
NOM-013-STPS-1993	1993-12-06	Relativa a las condiciones de seguridad e higiene en los centros de trabajo donde se generen radiaciones electromagnéticas no ionizantes.
NOM-014-STPS-2000	2000-04-10	Exposición laboral a presiones ambientales anormales-condiciones de seguridad e higiene.
NOM-015-STPS-2001	2002-06-14	Condiciones térmicas elevadas o abatidas-condiciones de seguridad e higiene.
NOM-016-STPS-2001	2001-07-12	Operación y mantenimiento de ferrocarriles-condiciones de seguridad e higiene.
NOM-017-STPS-2008	2008-12-09	Equipo de protección personal-selección, uso y manejo en los centros de trabajo.
NOM-018-STPS-2000	2000-10-27	Sistema para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo. (cancela a la nom-114-stps-1994)
NOM-018-STPS-2015	2015-10-09	Sistema armonizado para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo.
NOM-019-STPS-2011	2011-04-13	Constitución, integración, organización y funcionamiento de las comisiones de seguridad e higiene.
NOM-020-STPS-2011	2011-12-27	Recipientes sujetos a presión, recipientes criogénicos y generadores de vapor o calderas - funcionamiento - condiciones de seguridad.
NOM-022-STPS-2015	2016-04-01	Electricidad estática en los centros de trabajo-condiciones de seguridad.
NOM-023-STPS-2012	2012-10-11	Minas subterráneas y minas a cielo abierto - condiciones de seguridad y salud en el trabajo.
NOM-024-STPS-2001	2002-01-11	Vibraciones-condiciones de seguridad e higiene en los centros de trabajo.
NOM-025-STPS-2008	2008-12-30	Condiciones de iluminación en los centros de trabajo.
NOM-026-STPS-2008	2008-11-25	Colores y señales de seguridad e higiene, e identificación de riesgos por fluidos conducidos en tuberías.
NOM-027-STPS-2008	2008-11-07	Actividades de soldadura y corte-condiciones de seguridad e higiene.
NOM-028-STPS-2012	2012-09-06	Sistema para la administración del trabajo-seguridad en los procesos y equipos críticos que manejen sustancias químicas peligrosas.
NOM-029-STPS-2011	2011-12-29	Mantenimiento de las instalaciones eléctricas en los centros de trabajo-condiciones de seguridad.
NOM-030-STPS-2009	2009-12-22	Servicios preventivos de seguridad y salud en el trabajo-funciones y actividades.
NOM-031-STPS-2011	2011-05-04	Construcción-condiciones de seguridad y salud en el trabajo.
NOM-032-STPS-2008	2008-12-23	Seguridad para minas subterráneas de carbón.
NOM-033-STPS-2015	2015-08-31	Condiciones de seguridad para realizar trabajos en espacios
NOM-034-STPS-2016	2016-07-20	, Condiciones de seguridad para el acceso y desarrollo de actividades de trabajadores con discapacidad en los centros de trabajo.
NOM-100-STPS-1994	1996-01-08	Seguridad-Extintores contra incendio a base de polvo químico seco con presión contenida-Especificaciones.
NOM-101-STPS-1994	1996-01-08	Seguridad-Extintores a base de espuma química.
NOM-102-STPS-1994	1996-01-10	Seguridad-Extintores contra incendio a base de bióxido de carbono. Parte 1. Recipientes.

<u>NOM-103-STPS-1994</u>	1996-01-10	Seguridad-Extintores contra incendio a base de agua con presión contenida.
<u>NOM-104-STPS-2001</u>	2002-04-17	Agentes extinguidores-Polvo químico seco tipo ABC a base de fosfato mono amónico.
<u>NOM-106-STPS-1994</u>	1996-01-11	Seguridad-Agentes extinguidores-Polvo químico seco tipo BC, a base de bicarbonato de sodio.
<u>NOM-113-STPS-2009</u>	2009-12-22	Seguridad-equipos de protección personal-calzado de protección-clasificación, especificaciones y métodos de prueba.(contiene una aclaración a la modificación de la nom)
<u>NOM-115-STPS-2009</u>	2009-12-22	Seguridad-equipos de protección personal-cascos de protección-clasificación, especificaciones y métodos de prueba.(contiene dos modificaciones)
<u>NOM-116-STPS-2009</u>	2009-12-22	Seguridad-equipos de protección personal-respiradores purificadores de aire de presión negativa contra partículas nocivas-especificaciones y métodos de prueba.

Table 13.20 - Normas Oficiales Mexicanas (Secretaría de Energía)

CLAVE	FECHA	DESCRIPCIÓN
<u>NOM-001-ENER-2014</u>	2014-08-06	Eficiencia energética de bombas verticales tipo turbina con motor externo eléctrico vertical. Límites y método de prueba.
<u>NOM-001-NUCL-2013</u>	2013-12-06	Factores para el cálculo del equivalente de dosis.
<u>NOM-001-SECRE-2010</u>	2010-03-19	Especificaciones del gas natural (cancela y sustituye a la nom-001-secre-2003, calidad del gas natural y la nom-em-002-secre-2009, calidad del gas natural durante el periodo de emergencia severa).
<u>NOM-001-SEDE-2012</u>	2012-11-29	Instalaciones eléctricas (utilización)
<u>NOM-001-SESH-2014</u>	2014-10-22	Plantas de distribución de gas l.p. Diseño, construcción y condiciones seguras en su operación.
<u>NOM-002-NUCL-2015</u>	2015-10-26	Pruebas de fuga y hermeticidad para fuentes selladas.
<u>NOM-002-SECRE-2010</u>	2011-02-04	Instalaciones de aprovechamiento de gas natural (cancela y sustituye a la nom-002-secre-2003, instalaciones de aprovechamiento de gas natural).
<u>NOM-002-SEDE/ENER-2014</u>	2014-08-29	Requisitos de seguridad y eficiencia energética para transformadores de distribución.
<u>NOM-002-SESH-2009</u>	2009-05-20	Bodegas de distribución de gas l.p. Diseño, construcción, operación y condiciones de seguridad.
<u>NOM-003-ENER-2011</u>	2011-08-09	Eficiencia térmica de calentadores de agua para uso doméstico y comercial. Límites, método de prueba y etiquetado.
<u>NOM-003-NUCL-1994</u>	1996-02-07	Clasificación de instalaciones o laboratorios que utilizan fuentes abiertas.
<u>NOM-003-SECRE-2011</u>	2013-05-13	Distribución de gas natural y gas licuado de petróleo por ductos
<u>NOM-003-SEDG-2004</u>	2005-04-28	Estaciones de gas l.p. Para carburación. Diseño y construcción.
<u>NOM-004-ENER-2014</u>	2014-09-30	Eficiencia energética para el conjunto motor-bomba, para bombeo de agua limpia de uso doméstico, en potencias de 0,180 kw (¼ hp) hasta 0,750 kw (1 hp).- límites, métodos de prueba y etiquetado.
<u>NOM-004-NUCL-2013</u>	2013-05-07	Clasificación de los desechos radiactivos.
<u>NOM-004-SEDG-2004</u>	2004-12-02	Instalaciones de aprovechamiento de gas l.p. Diseño y construcción.
<u>NOM-005-ENER-2012</u>	2012-11-06	Eficiencia energética de lavadoras de ropa electrodomésticas. Límites, método de prueba y etiquetado.
<u>NOM-005-ENER-2016</u>	2016-11-15	Eficiencia energética de lavadoras de ropa electrodomésticas. Límites, métodos de prueba y etiquetado.
<u>NOM-005-SESH-2010</u>	2010-11-26	Equipos de carburación de gas l.p. En motores de combustión interna. Instalación y mantenimiento.
<u>NOM-006-ENER-2015</u>	2015-05-21	Eficiencia energética electromecánica en sistemas de bombeo para pozo profundo en operación. Límites y método de prueba.
<u>NOM-006-SESH-2010</u>	2010-11-26	Talleres de equipos de carburación de gas l.p.-diseño, construcción, operación y condiciones de seguridad.
<u>NOM-007-ENER-2014</u>	2014-08-07	Eficiencia energética para sistemas de alumbrado en edificios no residenciales.
<u>NOM-007-NUCL-2014</u>	2015-03-05	Requerimientos de seguridad radiológica que deben ser observados en los implantes permanentes de material radiactivo con fines terapéuticos a seres humanos.
<u>NOM-007-SECRE-2010</u>	2011-02-08	Transporte de gas natural (cancela y sustituye a la nom-007-secre-1999, transporte de gas natural).
<u>NOM-007-SESH-2010</u>	2011-07-11	Vehículos para el transporte y distribución de gas l.p.- condiciones de seguridad, operación y mantenimiento.
<u>NOM-008-ENER-2001</u>	2001-04-25	Eficiencia energética en edificaciones, envolvente de edificios no residenciales.
<u>NOM-008-NUCL-2011</u>	2011-10-26	Control de la contaminación radiactiva.
<u>NOM-008-SESH/SCFI-2010</u>	2010-12-21	Recipientes transportables para contener gas l.p. Especificaciones de fabricación, materiales y métodos de prueba.
<u>NOM-009-ENER-2014</u>	2014-08-08	Eficiencia energética en sistemas de aislamientos térmicos industriales
<u>NOM-009-SESH-2011</u>	2011-09-08	Recipientes para contener gas l.p., tipo no transportable. Especificaciones y métodos de prueba.
<u>NOM-010-ENER-2004</u>	2005-04-18	Eficiencia energética del conjunto motor bomba sumergible tipo pozo profundo. Límites y método de prueba.
<u>NOM-010-SESH-2012</u>	2013-05-29	Aparatos domésticos para cocinar alimentos que utilizan gas l.p. O gas natural. Especificaciones y métodos de prueba.
<u>NOM-011-ENER-2006</u>	2007-06-22	Eficiencia energética en acondicionadores de aire tipo central, paquete o dividido. Límites, métodos de prueba y etiquetado.

<u>NOM-011-SECRE-2000</u>	2002-10-23	Gas natural comprimido para uso automotor. Requisitos mínimos de seguridad en instalaciones vehiculares.
<u>NOM-011-SESH-2012</u>	2013-04-12	Calentadores de agua de uso doméstico y comercial que utilizan como combustible gas l.p. O gas natural.- requisitos de seguridad, especificaciones, métodos de prueba, marcado e información comercial (cancela a la nom-020-sedg-2003).
<u>NOM-011/1-SEDG-1999</u>	2000-03-30	Condiciones de seguridad de los recipientes portátiles para contener gas l.p. En uso.
<u>NOM-012-NUCL-2016</u>	2017-01-16	Requisitos y criterios de funcionamiento que deben cumplir los instrumentos de medición de radiación ionizante y los dosímetros de lectura directa.
<u>NOM-012-SESH-2010</u>	2010-11-26	Calefactores de ambiente para uso doméstico que empleen como combustible gas l.p. O natural. Requisitos de seguridad y métodos de prueba.(la nom contiene una aclaración)
<u>NOM-013-ENER-2013</u>	2013-06-14	Eficiencia energética para sistemas de alumbrado en vialidades.
<u>NOM-013-NUCL-2009</u>	2009-10-20	Requerimientos de seguridad radiológica para egresar a pacientes a quienes se les ha administrado material radiactivo
<u>NOM-013-SECRE-2012</u>	2013-09-30	Requisitos de seguridad para el diseño, construcción, operación y mantenimiento de terminales de almacenamiento de gas natural licuado que incluyen sistemas, equipos e instalaciones de recepción, conducción, vaporización y entrega de gas natural (cancela
<u>NOM-013-SEDG-2002</u>	2002-04-26	Evaluación de espesores mediante medición ultrasónica usando el método de pulso-eco, para la verificación de recipientes tipo no portátil para contener gas l.p., en uso.
<u>NOM-014-ENER-2004</u>	2005-04-19	Eficiencia energética de motores eléctricos de corriente alterna, monofásicos, de inducción, tipo jaula de ardilla, enfriados con aire, en potencia nominal de 0,180 kw a 1,500 kw. Límites, método de prueba y marcado.
<u>NOM-014-SESH-2013</u>	2013-10-16	Conexión integral y conexión flexible que se utilizan en instalaciones de aprovechamiento de gas l.p. O gas natural. Especificaciones y métodos de prueba.
<u>NOM-015-ENER-2012</u>	2012-02-16	Eficiencia energética de refrigeradores y congeladores electrodomésticos. Límites, métodos de prueba y etiquetado.
<u>NOM-015-SECRE-2013</u>	2013-12-12	Diseño, construcción, seguridad, operación y mantenimiento de sistemas de almacenamiento de gas licuado de petróleo mediante planta de depósito o planta de suministro que se encuentran directamente vinculados a los sistemas de transporte o distribución p
<u>NOM-015-SESH-2013</u>	2013-10-17	Reguladores de baja presión para gas l.p. Especificaciones y métodos de prueba.
<u>NOM-016-ENER-2016</u>	2016-11-15	Eficiencia energética de motores de corriente alterna, trifásicos, de inducción, tipo jaula de ardilla, en potencia nominal de 0,746 kw a 373 kw. Límites, método de prueba y marcado.
<u>NOM-017-ENER/SCFI-2012</u>	2013-01-09	Eficiencia energética y requisitos de seguridad de lámparas fluorescentes compactas autobalastadas. Límites y métodos de prueba.
<u>NOM-018-ENER-2011</u>	2011-12-14	Aislantes térmicos para edificaciones. Características y métodos de prueba.
<u>NOM-018-NUCL-1995</u>	1996-08-12	Métodos para determinar la concentración de actividad y actividad total en los bultos de desechos radiactivos.
<u>NOM-019-ENER-2009</u>	2009-07-02	Eficiencia térmica y eléctrica de máquinas tortilladoras mecanizadas. Límites, método de prueba y marcado.
<u>NOM-019-NUCL-1995</u>	1996-08-14	Requerimientos para bultos de desechos radiactivos de nivel bajo para su almacenamiento definitivo cerca de la superficie.
<u>NOM-020-ENER-2011</u>	2011-08-09	Eficiencia energética en edificaciones.- envolvente de edificios para uso habitacional.
<u>NOM-020-NUCL-1995</u>	1996-08-15	Requerimientos para instalaciones de incineración de desechos radiactivos.
<u>NOM-021-NUCL-1996</u>	1997-08-04	Requerimientos para las pruebas de lixiviación para especímenes de desechos radiactivos solidificados.
<u>NOM-022-ENER/SCFI-2014</u>	2014-11-27	Eficiencia energética y requisitos de seguridad al usuario para aparatos de refrigeración comercial autocontenidos. Límites, métodos de prueba y etiquetado.
<u>NOM-022/1-NUCL-1996</u>	1997-09-05	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie. Parte 1, sitio.
<u>NOM-022/2-NUCL-1996</u>	1997-09-05	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie. Parte 2, diseño.
<u>NOM-022/3-NUCL-1996</u>	1999-01-14	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie.
<u>NOM-023-ENER-2010</u>	2010-12-20	Eficiencia energética en acondicionadores de aire tipo dividido, descarga libre y sin conductos de aire. Límites, método de prueba y etiquetado.
<u>NOM-024-ENER-2012</u>	2012-10-18	Características térmicas y ópticas del vidrio y sistemas vidriados para edificaciones. Etiquetado y métodos de prueba.
<u>NOM-025-ENER-2013</u>	2013-06-17	Eficiencia térmica de aparatos domésticos para cocción de alimentos que usan gas l.p. O gas natural. Límites, métodos de prueba y etiquetado
<u>NOM-025/2-NUCL-2015</u>	2015-09-21	Requisitos para equipo de radiografía industrial. Parte 2: operación.
<u>NOM-026-ENER-2015</u>	2016-02-09	Eficiencia energética en acondicionadores de aire tipo dividido (inverter) con flujo de refrigerante variable, descarga libre y sin ductos de aire. Límites, métodos de prueba y etiquetado.
<u>NOM-026-NUCL-2011</u>	2011-10-26	Vigilancia médica del personal ocupacionalmente expuesto a radiaciones ionizantes.

NOM-026-SESH-2007	2007-08-29	Lineamientos para los trabajos de prospección sísmológica petrolera y especificaciones de los niveles máximos de energía.
NOM-027-NUCL-1996	1997-09-23	Especificaciones para el diseño de las instalaciones radiactivas tipo II clases A, B y C.
NOM-027-SESH-2010	2010-04-07	Administración de la integridad de ductos de recolección y transporte de hidrocarburos.
NOM-028-ENER-2010	2010-12-06	Eficiencia energética de lámparas para uso general. Límites y métodos de prueba.
NOM-028-ENER-2017	2018-03-09	Eficiencia energética de lámparas para uso general. Límites y métodos de prueba.
NOM-028-NUCL-2009	2009-08-04	Manejo de desechos radiactivos en instalaciones radiactivas que utilizan fuentes abiertas.
NOM-029-ENER-2017	2017-10-27	Eficiencia energética de fuentes de alimentación externa. Límites, métodos de prueba, marcado y etiquetado.
NOM-030-ENER-2016	2017-01-17	Eficacia luminosa de lámparas de diodos emisores de luz (led) integradas para iluminación general. Límites y métodos de prueba.
NOM-031-ENER-2012	2012-11-06	Eficiencia energética para luminarios con diodos emisores de luz (leds) destinados a vialidades y áreas exteriores públicas. Especificaciones y métodos de prueba.
NOM-031-NUCL-2011	2011-10-26	Requisitos para el entrenamiento del personal ocupacionalmente expuesto a radiaciones ionizantes.
NOM-032-ENER-2013	2014-01-23	Límites máximos de potencia eléctrica para equipos y aparatos que demandan energía en espera. Métodos de prueba y etiquetado.
NOM-032-NUCL-2009	2009-10-20	Especificaciones técnicas para la operación de unidades para teleterapia que utilizan material radiactivo.
NOM-033-NUCL-2016	2016-08-04	Especificaciones técnicas para la operación de unidades de teleterapia: aceleradores lineales.
NOM-034-NUCL-2016	2016-12-02	Requerimientos de selección, calificación y entrenamiento del personal de centrales nucleoelectricas.
NOM-035-NUCL-2013	2013-05-07	Criterios para la dispensa de residuos con material radiactivo.
NOM-036-NUCL-2001	2001-09-26	Requerimientos para instalaciones de tratamiento y acondicionamiento de los desechos radiactivos.
NOM-039-NUCL-2011	2011-10-26	Especificaciones para la exención de prácticas y fuentes adscritas a alguna práctica, que utilizan fuentes de radiación ionizante, de alguna o de todas las condiciones reguladoras.
NOM-040-NUCL-2016	2016-08-04	Requisitos de seguridad radiológica para la práctica de medicina nuclear.
NOM-041-NUCL-2013	2013-05-06	Límites anuales de incorporación y concentraciones en liberaciones.
NOM-086-SEMAR-SENER-SCFI-2005	2006-01-30	Especificaciones de los combustibles fósiles para la protección ambiental.
NOM-094-SCFI-1994	1995-12-13	Uso del gas natural licuado como combustible vehicular-requisitos de seguridad para instalaciones vehiculares.
NOM-163-SEMARNAT-ENER-SCF-2013	2013-06-21	Emisiones de bióxido de carbono (co2) provenientes del escape y su equivalencia en términos de rendimiento de combustible, aplicable a vehículos automotores nuevos de peso bruto vehicular de hasta 3 857 kilogramos.

Table 13.21 - Normas Oficiales Mexicanas (Saúde)

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-SSA1-2010	2011-01-26	Que instituye el procedimiento por el cual se revisará, actualizará y editará la farmacopea de los estados unidos mexicanos.
NOM-001-SSA3-2012	2013-01-04	Educación en salud. Para la organización y funcionamiento de residencias médicas.
NOM-002-SSA1-1993	1994-11-14	Salud ambiental. Bienes y servicios. Envases metálicos para alimentos y bebidas. Especificaciones de la costura. Requisitos sanitarios.
NOM-002-SSA3-2007	2009-06-11	Para la organización, funcionamiento e ingeniería sanitaria de los servicios de radioterapia.
NOM-003-SSA1-2006	2008-08-04	Salud ambiental. Requisitos sanitarios que debe satisfacer el etiquetado de pinturas, tintas, barnices, lacas y esmaltes.
NOM-003-SSA3-2010	2010-07-08	Para la práctica de la hemodiálisis.
NOM-004-SSA1-2013	2014-05-02	Salud ambiental. Limitaciones y especificaciones sanitarias para el uso de los compuestos de plomo.
NOM-004-SSA3-2012	2012-10-15	Del expediente clínico.
NOM-005-SSA1-1993	1994-11-17	Salud ambiental. Pigmentos de cromato de plomo y de cromomolibdato de plomo. Extracción y determinación de plomo soluble. Métodos de prueba.
NOM-005-SSA2-1993	1994-05-30	De los servicios de planificación familiar.
NOM-005-SSA3-2010	2010-08-16	Que establece los requisitos mínimos de infraestructura y equipamiento de establecimientos para la atención médica de pacientes ambulatorios.
NOM-006-SSA1-1993	1994-11-17	Salud ambiental. Pinturas y barnices. Preparación de extracciones ácidas de las capas de pintura seca para la determinación de plomo soluble. Métodos de prueba.
NOM-006-SSA2-2013	2013-11-13	Para la prevención y control de la tuberculosis.
NOM-006-SSA3-2011	2012-03-23	Para la práctica de la anestesiología.
NOM-007-SSA2-2016	2016-04-07	Para la atención de la mujer durante el embarazo, parto y puerperio, y de la persona recién nacida.
NOM-007-SSA3-2011	2012-03-27	Para la organización y funcionamiento de los laboratorios clínicos.

<u>NOM-008-SSA1-1993</u>	1994-11-28	Salud ambiental. Pinturas y barnices. Preparación de extracciones ácidas de pinturas líquidas o en polvo para determinación de plomo soluble y otros métodos.
<u>NOM-008-SSA3-2010</u>	2010-08-04	Para el tratamiento integral del sobrepeso y la obesidad.
<u>NOM-009-SSA2-2013</u>	2013-12-09	Promoción de la salud escolar.
<u>NOM-009-SSA3-2013</u>	2014-08-07	Educación en salud. Criterios para la utilización de los establecimientos para la atención médica como campos clínicos para la prestación del servicio social de medicina y estomatología.
<u>NOM-010-SSA2-2010</u>	2010-11-10	Para la prevención y el control de la infección por virus de la inmunodeficiencia humana.
<u>NOM-011-SSA2-2011</u>	2011-12-08	Para la prevención y control de la rabia humana y en los perros y gatos.
<u>NOM-011-SSA3-2014</u>	2014-12-09	Criterios para la atención de enfermos en situación terminal a través de cuidados paliativos.
<u>NOM-012-SSA3-2012</u>	2013-01-04	Que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos.
<u>NOM-013-SSA2-2015</u>	2016-11-23	Para la prevención y control de enfermedades bucales.
<u>NOM-014-SSA2-1994</u>	1995-01-16	Para la prevención, detección, diagnóstico, tratamiento, control y vigilancia epidemiológica del cáncer cérvico uterino.
<u>NOM-014-SSA3-2013</u>	2014-11-11	Para la asistencia social alimentaria a grupos de riesgo.
<u>NOM-015-SSA2-2010</u>	2010-11-23	Para la prevención, tratamiento y control de la diabetes mellitus.
<u>NOM-015-SSA3-2012</u>	2012-09-14	Para la atención integral a personas con discapacidad.
<u>NOM-016-SSA2-2012</u>	2012-10-23	Para la vigilancia, prevención, control, manejo y tratamiento del cólera.
<u>NOM-016-SSA3-2012</u>	2013-01-08	Que establece las características mínimas de infraestructura y equipamiento de hospitales y consultorios de atención médica especializada.
<u>NOM-017-SSA2-2012</u>	2013-02-19	Para la vigilancia epidemiológica.
<u>NOM-017-SSA3-2012</u>	2012-09-18	Regulación de servicios de salud. Para la práctica de la acupuntura humana y métodos relacionados.
<u>NOM-019-SSA3-2013</u>	2013-09-02	Para la práctica de enfermería en el sistema nacional de salud.
<u>NOM-020-SSA1-2014</u>	2014-08-19	Salud ambiental. Valor límite permisible para la concentración de ozono (o3) en el aire ambiente y criterios para su evaluación.
<u>NOM-021-SSA1-1993</u>	1994-12-23	Salud ambiental. Criterio para evaluar la calidad del aire ambiente con respecto al monóxido de carbono (co). Valor permisible para la concentración de monóxido de carbono en aire ambiente, como medida de protección a la salud de la población.
<u>NOM-021-SSA2-1994</u>	1996-08-21	Para la vigilancia, prevención y control del complejo taeniosis/cisticercosis en el primer nivel de atención médica.
<u>NOM-022-SSA1-2010</u>	2010-09-08	Salud ambiental. Criterio para evaluar la calidad del aire ambiente, con respecto al dióxido de azufre (so2). Valor normado para la concentración de dióxido de azufre (so2) en el aire ambiente, como medida de protección a la salud de la población.
<u>NOM-022-SSA2-2012</u>	2012-07-11	Para la prevención y control de la brucelosis en el ser humano.
<u>NOM-022-SSA3-2012</u>	2012-09-18	Que instituye las condiciones para la administración de la terapia de infusión en los estados unidos mexicanos.
<u>NOM-023-SSA1-1993</u>	1994-12-23	Salud ambiental. Criterio para evaluar la calidad del aire ambiente con respecto al bióxido de nitrógeno (no2). Valor normado para la concentración de bióxido de nitrógeno (no2) en el aire ambiente como medida de protección a la salud de la población
<u>NOM-024-SSA3-2012</u>	2012-11-30	Sistemas de información de registro electrónico para la salud. Intercambio de información en salud.
<u>NOM-025-SSA1-2014</u>	2014-08-20	Salud ambiental. Valores límite permisibles para la concentración de partículas suspendidas pm10 y pm2.5 en el aire ambiente y criterios para su evaluación.
<u>NOM-025-SSA2-2014</u>	2015-09-04	Para la prestación de servicios de salud en unidades de atención integral hospitalaria médico-psiquiátrica.
<u>NOM-025-SSA3-2013</u>	2013-09-17	Para la organización y funcionamiento de las unidades de cuidados intensivos.
<u>NOM-026-SSA1-1993</u>	1994-12-23	Salud ambiental. Criterio para evaluar la calidad del aire ambiente con respecto al plomo (pb). Valor normado para la concentración de plomo (pb) en el ambiente como medida de protección a la salud de la población.
<u>NOM-026-SSA3-2012</u>	2012-08-07	Para la práctica de la cirugía mayor ambulatoria.
<u>NOM-027-SSA2-2007</u>	2009-08-31	Para la prevención y control de la lepra.
<u>NOM-027-SSA3-2013</u>	2013-09-04	Regulación de los servicios de salud. Que establece los criterios de funcionamiento y atención en los servicios de urgencias de los establecimientos para la atención médica.
<u>NOM-028-SSA2-2009</u>	2009-08-21	Para la prevención, tratamiento y control de las adicciones.
<u>NOM-028-SSA3-2012</u>	2013-01-07	Regulación de los servicios de salud. Para la práctica de la ultrasonografía diagnóstica.
<u>NOM-029-SSA2-1999</u>	2001-02-02	Para la vigilancia epidemiológica, prevención y control de la leptospirosis en el humano.
<u>NOM-029-SSA3-2012</u>	2012-08-02	Regulación de los servicios de salud. Para la práctica de la cirugía oftalmológica con láser excimer.
<u>NOM-030-SSA2-2009</u>	2010-05-31	Para la prevención, detección, diagnóstico, tratamiento y control de la hipertensión arterial sistémica.
<u>NOM-030-SSA3-2013</u>	2013-09-12	Que establece las características arquitectónicas para facilitar el acceso, tránsito, uso y permanencia de las personas con discapacidad en

		establecimientos para la atención médica ambulatoria y hospitalaria del sistema nacional de salud.
NOM-031-SSA2-1999	2001-02-09	Para la atención a la salud del niño.
NOM-031-SSA3-2012	2012-09-13	Asistencia social. Prestación de servicios de asistencia social a adultos y adultos mayores en situación de riesgo y vulnerabilidad.
NOM-032-SSA2-2014	2015-04-16	Para la vigilancia epidemiológica, promoción, prevención y control de las enfermedades transmitidas por vectores.
NOM-032-SSA3-2010	2011-02-25	Asistencia social. Prestación de servicios de asistencia social para niños, niñas y adolescentes en situación de riesgo y vulnerabilidad.
NOM-033-SSA2-2011	2011-12-08	Para la vigilancia, prevención y control de la intoxicación por picadura de alacrán.
NOM-034-SSA2-2013	2014-06-24	Para la prevención y control de los defectos al nacimiento.
NOM-034-SSA3-2013	2014-09-23	Regulación de los servicios de salud. Atención médica prehospitalaria.
NOM-035-SSA2-2012	2013-01-07	Para la prevención y control de enfermedades en la perimenopausia y postmenopausia de la mujer. Criterios para brindar atención médica.
NOM-035-SSA3-2012	2012-11-30	En materia de información en salud.
NOM-036-SSA2-2012	2012-09-28	Prevención y control de enfermedades. Aplicación de vacunas, toxoides, faboterápicos (sueros) e inmunoglobulinas en el humano.(el documento contiene la aclaración publicada el 12/10/2012)
NOM-037-SSA2-2012	2012-07-13	Para la prevención, tratamiento y control de las dislipidemias.
NOM-037-SSA3-2016	2017-02-21	Para la organización y funcionamiento de los laboratorios de anatomía patológica.
NOM-038-SSA2-2010	2011-04-21	Para la prevención, tratamiento y control de las enfermedades por deficiencia de yodo.
NOM-039-SSA2-2014	2017-06-01	Para la prevención y control de las infecciones de transmisión sexual.
NOM-040-SSA1-1993	1995-03-13	Bienes y servicios. Sal yodada y sal yodada fluorurada. Especificaciones sanitarias.
NOM-041-SSA2-2011	2011-06-09	Para la prevención, diagnóstico, tratamiento, control y vigilancia epidemiológica del cáncer de mama.
NOM-042-SSA2-2006	2008-11-06	Prevención y control de enfermedades. Especificaciones sanitarias para los centros de atención canina.
NOM-043-SSA2-2012	2013-01-22	Servicios básicos de salud. Promoción y educación para la salud en materia alimentaria. Criterios para brindar orientación.
NOM-045-SSA2-2005	2009-11-20	Para la vigilancia epidemiológica, prevención y control de las infecciones nosocomiales.
NOM-046-SSA2-2005	2009-04-16	Violencia familiar, sexual y contra las mujeres. Criterios para la prevención y atención.
NOM-047-SSA1-2011	2012-06-06	Salud ambiental-índices biológicos de exposición para el personal ocupacionalmente expuesto a sustancias químicas.
NOM-047-SSA2-2015	2015-08-12	Para la atención a la salud del grupo etario de 10 a 19 años de edad.
NOM-048-SSA1-1993	1996-01-09	Que establece el método normalizado para la evaluación de riesgos a la salud como consecuencia de agentes ambientales.
NOM-048-SSA2-2017	2017-12-15	Para la prevención, detección, diagnóstico, tratamiento, vigilancia epidemiológica y promoción de la salud sobre el crecimiento prostático benigno (hiperplasia de la próstata) y cáncer de próstata (tumor maligno de la próstata).
NOM-051-SCFI/SSA1-2010	2010-04-05	Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-información comercial y sanitaria.
NOM-059-SSA1-2015	2016-02-05	Buenas prácticas de fabricación de medicamentos.
NOM-064-SSA1-1993	1995-02-24	Que establece las especificaciones sanitarias de los equipos de reactivos utilizados para diagnóstico.
NOM-065-SSA1-1993	1995-02-27	Que establece las especificaciones sanitarias de los medios de cultivo. Generalidades.
NOM-072-SSA1-2012	2012-11-21	Etiquetado de medicamentos y de remedios herbolarios.
NOM-073-SSA1-2015	2016-06-07	Estabilidad de fármacos y medicamentos, así como de remedios herbolarios.
NOM-076-SSA1-2002	2004-02-09	Modificación a la norma oficial mexicana nom-076-ssa1-1993, salud ambiental-que establece los requisitos sanitarios del proceso del etanol (alcohol etílico) para quedar como nom-076-ssa1-2002, salud ambiental.- que establece los requisitos sanitarios d
NOM-077-SSA1-1994	1996-07-01	Que establece las especificaciones sanitarias de los materiales de control (en general) para laboratorios de patología clínica.
NOM-078-SSA1-1994	1996-07-01	Que establece las especificaciones sanitarias de los estándares de calibración utilizados en las mediciones realizadas en los laboratorios de patología clínica.
NOM-082-SAG-FITO/SSA1-2017	2017-10-04	Límites máximos de residuos. Lineamientos técnicos y procedimiento de autorización y revisión.
NOM-086-SSA1-1994	1996-06-26	Bienes y servicios. Alimentos y bebidas no alcohólicas con modificaciones en su composición. Especificaciones nutrimentales.
NOM-087-SEMARNAT-SSA1-2002	2003-02-17	Protección ambiental - salud ambiental - residuos peligrosos biológico-infecciosos - clasificación y especificaciones de manejo.
NOM-089-SSA1-1994	1995-09-25	Bienes y servicios. Métodos para la determinación del contenido microbiano en productos de belleza.
NOM-092-SSA1-1994	1995-12-12	Bienes y servicios. Método para la cuenta de bacterias aerobias en placa.
NOM-110-SSA1-1994	1995-10-16	Bienes y servicios. Preparación y dilución de muestras de alimentos para su análisis microbiológico.

NOM-111-SSA1-1994	1995-09-13	Bienes y servicios. Método para la cuenta de mohos y levaduras en alimentos.
NOM-113-SSA1-1994	1995-08-25	Bienes y servicios método para la cuenta de microorganismos coliformes totales en placa.
NOM-116-SSA1-1994	1995-08-10	Bienes y servicios. Determinación de humedad en alimentos por tratamiento térmico. Método por arena o gasa.
NOM-117-SSA1-1994	1995-08-16	Bienes y servicios. Método de prueba para la determinación de cadmio, arsénico, plomo, estaño, cobre, fierro, zinc y mercurio en alimentos, agua potable y agua purificada por espectrometría de absorción atómica.
NOM-125-SSA1-1994	1996-10-08	Que establece los requisitos sanitarios para el proceso y uso de asbesto.
NOM-125-SSA1-2016	2017-02-28	Que establece los requisitos sanitarios para el proceso y uso de asbesto.
NOM-127-SSA1-1994	1996-01-18	Salud ambiental, agua para uso y consumo humano-límites permisibles de calidad y tratamientos a que debe someterse el agua para su potabilización.
NOM-128-SSA1-1994	1996-06-12	Bienes y servicios. Que establece la aplicación de un sistema de análisis de riesgos y control de puntos críticos en la planta industrial procesadora de productos de la pesca
NOM-130-SSA1-1995	1997-11-21	Bienes y servicios. Alimentos envasados en recipientes de cierre hermético y sometidos a tratamiento térmico. Disposiciones y especificaciones sanitarias.
NOM-131-SSA1-2012	2012-09-10	Productos y servicios. Fórmulas para lactantes, de continuación y para necesidades especiales de nutrición. Alimentos y bebidas no alcohólicas para lactantes y niños de corta edad. Disposiciones y especificaciones sanitarias y nutrimentales. Etiquetado y
NOM-137-SSA1-2008	2008-12-12	Etiquetado de dispositivos médicos.
NOM-138-SEMARNAT/SSA1-2012	2013-09-10	Límites máximos permisibles de hidrocarburos en suelos y lineamientos para el muestreo en la caracterización y especificaciones para la remediación.
NOM-138-SSA1-2016	2017-04-25	Que establece las especificaciones sanitarias del alcohol etílico desnaturalizado, utilizado como material de curación, así como para el alcohol etílico de 96° g.l. Sin desnaturalizar, utilizado como materia prima para la elaboración y/o envasado de alco
NOM-141-SSA1/SCFI-2012	2012-09-19	Etiquetado para productos cosméticos preenvasados. Etiquetado sanitario y comercial.
NOM-142-SSA1/SCFI-2014	2015-03-23	Bebidas alcohólicas. Especificaciones sanitarias. Etiquetado sanitario y comercial.
NOM-147-SEMARNAT/SSA1-2004	2007-03-02	Que establece criterios para determinar las concentraciones de remediación de suelos contaminados por arsénico, bario, berilio, cadmio, cromo hexavalente, mercurio, níquel, plata, plomo, selenio, talio y/o vanadio.
NOM-159-SSA1-2016	2018-01-16	Productos y servicios. Huevo y sus productos. Disposiciones y especificaciones sanitarias. Método de prueba.
NOM-164-SSA1-2015	2016-02-04	Buenas prácticas de fabricación de fármacos.
NOM-167-SSA1-1997	1999-11-17	Para la prestación de servicios de asistencia social para menores y adultos mayores.
NOM-174-SSA1-1998	2000-04-12	Para el manejo integral de la obesidad.
NOM-177-SSA1-2013	2013-09-20	Que establece las pruebas y procedimientos para demostrar que un medicamento es intercambiable. Requisitos a que deben sujetarse los terceros autorizados que realicen las pruebas de intercambiabilidad.
NOM-179-SSA1-1998	2001-09-24	Requisitos para realizar los estudios de biocomparab Vigilancia y evaluación del control de calidad del agua para uso y consumo humano, distribuida por sistemas de abastecimiento público.
NOM-182-SSA1-2010	2011-04-21	Etiquetado de nutrientes vegetales.
NOM-186-SSA1/SCFI-2013	2014-03-28	Cacao, chocolate y productos similares, y derivados del cacao.
NOM-187-SSA1/SCFI-2002	2003-08-18	Especificaciones sanitarias. Denominación comercial. Métodos de prueba. Productos y servicios. Masa, tortillas, tostadas y harinas preparadas para su elaboración y establecimientos donde se procesan. Especificaciones sanitarias. Información comercial. Métodos de prueba.
NOM-189-SSA1/SCFI-2002	2002-12-02	Productos y servicios. Etiquetado y envasado para productos de aseo de uso doméstico.
NOM-194-SSA1-2004	2004-09-18	Productos y servicios. Especificaciones sanitarias en los establecimientos dedicados al sacrificio y faenado de animales para abasto, almacenamiento, transporte y expendio. Especificaciones sanitarias de productos.
NOM-199-SSA1-2000	2002-10-18	Salud ambiental. Niveles de plomo en sangre y acciones como criterios para proteger la salud de la población expuesta no ocupacionalmente.
NOM-201-SSA1-2015	2015-12-22	Productos y servicios. Agua y hielo para consumo humano, envasados y a granel. Especificaciones sanitarias.
NOM-210-SSA1-2014	2015-06-26	Productos y servicios. Métodos de prueba microbiológicos. Determinación de microorganismos indicadores. Determinación de microorganismos patógenos.
NOM-213-SSA1-2002	2005-07-11	Productos y servicios. Productos carnicos procesados. Especificaciones sanitarias. Metodos de prueba.
NOM-218-SSA1-2011	2012-02-10	Productos y servicios. Bebidas saborizadas no alcohólicas, sus congelados, productos concentrados para prepararlas y bebidas adicionadas con cafeína. Especificaciones y disposiciones sanitarias. Métodos de prueba.
NOM-220-SSA1-2016	2017-07-19	Instalación y operación de la farmacovigilancia
NOM-229-SSA1-2002	2006-09-15	Salud ambiental. Requisitos técnicos para las instalaciones, responsabilidades sanitarias, especificaciones técnicas para los equipos y protección radiológica en establecimientos de diagnóstico médico con rayos x.

NOM-230-SSA1-2002	2005-07-12	Salud ambiental. Agua para uso y consumo humano. Requisitos sanitarios que se deben cumplir en los sistemas de abastecimiento públicos y privados durante el manejo del agua. Procedimientos sanitarios para el muestreo.
NOM-231-SSA1-2016	2016-10-25	Artículos de alfarería vidriada, cerámica vidriada, porcelana y artículos de vidrio-límites máximos permisibles de plomo y cadmio solubles-método de ensayo.
NOM-232-SSA1-2009	2010-04-13	Plaguicidas: que establece los requisitos del envase, embalaje y etiquetado de productos grado técnico y para uso agrícola, forestal, pecuario, jardinería, urbano, industrial y doméstico.
NOM-234-SSA1-2003	2005-01-06	Utilización de campos clínicos para ciclos clínicos e internado de pregrado.
NOM-240-SSA1-2012	2012-10-30	Instalación y operación de la tecnovigilancia.
NOM-241-SSA1-2012	2012-10-11	Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de dispositivos médicos.
NOM-242-SSA1-2009	2011-02-10	Productos y servicios. Productos de la pesca frescos, refrigerados, congelados y procesados. Especificaciones sanitarias y métodos de prueba.
NOM-243-SSA1-2010	2010-09-27	Productos y servicios. Leche, fórmula láctea, producto lácteo combinado y derivados lácteos. Disposiciones y especificaciones sanitarias. Métodos de prueba.
NOM-244-SSA1-2008	2009-09-04	Equipos y sustancias germicidas para tratamiento doméstico de agua. Requisitos sanitarios.
NOM-245-SSA1-2010	2012-06-25	Requisitos sanitarios y calidad del agua que deben cumplir las albercas.
NOM-247-SSA1-2008	2009-07-27	Productos y servicios. Cereales y sus productos. Cereales, harinas de cereales, sémolas o semolinas. Alimentos a base de: cereales, semillas comestibles, de harinas, sémolas o semolinas o sus mezclas. Productos de panificación. Disposiciones y especifica
NOM-248-SSA1-2011	2012-03-22	Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de remedios herbolarios. (queda sin efecto el punto 9.8.6 de la norma por entrar en vigor la nom-073-ssa1-2015)
NOM-249-SSA1-2010	2011-03-04	Mezclas estériles: nutricionales y medicamentosas, e instalaciones para su preparación.
NOM-251-SSA1-2009	2010-03-01	Prácticas de higiene para el proceso de alimentos, bebidas o suplementos alimenticios.
NOM-252-SSA1-2011	2012-05-15	Salud ambiental. Juguetes y artículos escolares. Límites de biodisponibilidad de metales pesados. Especificaciones químicas y métodos de prueba.
NOM-253-SSA1-2012	2012-10-26	Para la disposición de sangre humana y sus componentes con fines terapéuticos.
NOM-256-SSA1-2012	2013-01-29	Condiciones sanitarias que deben cumplir los establecimientos y personal dedicados a los servicios urbanos de control de plagas mediante plaguicidas.
NOM-257-SSA1-2014	2014-12-11	En materia de medicamentos biotecnológicos.

Table 13.22 - Normas Oficiais Mexicanas (Comunicações e Transportes)

CLAVE	FECHA	DESCRIPCIÓN
NOM-001-SCT-2-2016	2016-06-24	Placas metálicas, calcomanías de identificación y tarjetas de circulación empleadas en automóviles, tractocamiones, autobuses, camiones, motocicletas, remolques, semirremolques, convertidores y grúas, matriculados en la república mexicana, licencia feder
NOM-001-SCT1-1993	1993-11-10	Especificaciones y requerimientos para la instalación de estaciones de radiodifusión sonora moduladas en amplitud.
NOM-002-SCT/2011	2012-01-27	Listado de las sustancias y materiales peligrosos más usualmente transportados.
NOM-002-SCT1-1993	1993-11-11	Especificaciones y requerimientos para la instalación y operación de estaciones de radio-difusión sonora en la banda de 88 a 108 mhz, con portadora principal (esta nom. Cuenta con dos modificaciones)
NOM-002-SCT3-2012	2013-10-31	Que establece el contenido del manual general de operaciones.
NOM-002-SCT4-2013	2014-03-04	Terminología marítima-portuaria.
NOM-002/1-SCT/2009	2010-03-04	Listado de las sustancias y materiales peligrosos más usualmente transportados, instrucciones y uso de envases y embalajes, recipientes intermedios para graneles (rig s), grandes envases y embalajes, cisternas portátiles, contenedores de gas de elemento
NOM-003-SCT/2008	2008-08-15	Características de las etiquetas de envases y embalajes, destinadas al transporte de sustancias, materiales y residuos peligrosos.
NOM-003-SCT1-1993	1993-11-15	Especificaciones y requerimientos para la instalación y operación de estaciones de radio-difusión de televisión monocroma y a color (bandas vhf y uhf).(aclaración 14/04/1994)
NOM-003-SCT3-2010	2012-02-24	Que establece el uso dentro del espacio aéreo mexicano, del transpondedor para aeronaves, así como los criterios para su instalación, especificaciones y procedimientos de operación.
NOM-004-SCT/2008	2008-08-18	Sistemas de identificación de unidades destinadas al transporte de sustancias, materiales y residuos peligrosos.
NOM-004-SCT1-1993	1993-11-16	Especificaciones y requerimientos para la instalación y operación de sistemas destinados al servicio de música continua.
NOM-005-SCT/2008	2008-08-14	Información de emergencia para el transporte de sustancias, materiales y residuos peligrosos.

<u>NOM-005-SCT1-1993</u>	1993-11-17	Especificaciones y requerimientos para la instalación y operación de sistemas de televisión por cable.(para saber la fecha de vigencia, favor de consultar el texto de la nom)
<u>NOM-005-SCT4-2006</u>	2006-06-15	Especificaciones técnicas que deben cumplir los aros salvavidas.
<u>NOM-006-SCT2/2011</u>	2011-08-22	Aspectos básicos para la revisión ocular diaria de la unidad destinada al autotransporte de materiales y residuos peligrosos.
<u>NOM-006-SCT3-2012</u>	2015-09-14	Que establece el contenido del manual general de mantenimiento.
<u>NOM-006-SCT4-2015</u>	2016-01-28	Especificaciones técnicas que deben cumplir los chalecos salvavidas.
<u>NOM-007-SCT2/2010</u>	2010-09-06	Marcado de envases y embalajes destinados al transporte de sustancias y residuos peligrosos.
<u>NOM-007-SCT4-1994.</u>	1998-09-02	Prueba de inclinación para embarcaciones - método
<u>NOM-008-SCT2-2013</u>	2013-11-01	Amortiguadores de impacto en carreteras y vialidades urbanas.
<u>NOM-008-SCT3-2002</u>	2003-05-14	Que establece los requisitos técnicos a cumplir por los concesionarios y permisionarios del servicio al público de transporte aéreo, para la obtención del certificado de explotador de servicios aéreos, así como los requisitos técnicos a cumplir por lo
<u>NOM-008-SCT4-1994</u>	1997-02-21	Especificaciones técnicas que deben cumplir las hélices para embarcaciones.
<u>NOM-009-SCT2/2009</u>	2010-02-12	Especificaciones especiales y de compatibilidad para el almacenamiento y transporte de las sustancias, materiales y residuos peligrosos de la clase 1 explosivos.
<u>NOM-009-SCT3-2012</u>	2014-02-24	Que regula los requisitos y especificaciones para el establecimiento y funcionamiento de oficinas de despacho en sus diferentes modalidades.
<u>NOM-010-SCT2/2009</u>	2009-09-01	Disposiciones de compatibilidad y segregación para el almacenamiento y transporte de sustancias, materiales y residuos peligrosos.
<u>NOM-011-SCT2/2012</u>	2012-07-05	Condiciones para el transporte de las sustancias y materiales peligrosos envasadas y/o embaladas en cantidades limitadas.
<u>NOM-011-SCT3-2001</u>	2001-12-03	Que establece las especificaciones para las publicaciones técnicas aeronáuticas.
<u>NOM-012-SCT-2-2017</u>	2017-12-26	Sobre el peso y dimensiones máximas con los que pueden circular los vehículos de autotransporte que transitan en las vías generales de comunicación de jurisdicción federal.
<u>NOM-012-SCT3-2012</u>	2012-08-14	Que establece los requerimientos para los instrumentos, equipo, documentos y manuales que han de llevarse a bordo de las aeronaves.
<u>NOM-012-SCT4-2007</u>	2007-09-25	Lineamientos para la elaboración del plan de contingencias para embarcaciones que transportan mercancías peligrosas.
<u>NOM-014-SCT4-1994</u>	1998-12-14	Requisitos para estaciones que prestan servicios a balsas de salvamento autoinflables.
<u>NOM-017-SCT4-2011</u>	2011-11-07	Especificaciones técnicas que deben cumplir los planos para embarcaciones y artefactos navales.
<u>NOM-018-SCT3-2012</u>	2013-05-30	Que establece el contenido del manual de vuelo.
<u>NOM-019-SCT2/2015</u>	2016-01-27	Especificaciones técnicas y disposiciones generales para la limpieza y control de remanentes de sustancias y residuos peligrosos en las unidades que transportan materiales y residuos peligrosos.
<u>NOM-019-SCT4-2009</u>	2009-08-31	Requisitos para estaciones que prestan servicio a equipos contraincendio de embarcaciones, artefactos navales e instalaciones portuarias.
<u>NOM-020-SCT2-1995</u>	1997-11-17	Requerimientos generales para el diseño y construcción de autotanques destinados al transporte de materiales y residuos peligrosos, especificaciones sct 306, sct 307 y sct 312.
<u>NOM-020-SCT4-1995</u>	1999-05-14	Frecuencia de inspecciones en seco para embarcaciones y artefactos navales.
<u>NOM-021-SCT2/2017</u>	2017-06-12	Disposiciones de compatibilidad y segregación en trenes de unidades de arrastre que transportan materiales y residuos peligrosos.
<u>NOM-021-SCT4-1995</u>	1998-06-15	Condiciones que deben cumplir las embarcaciones para el transporte de productos petroquímicos.
<u>NOM-021/3-SCT3-2010</u>	2012-01-18	Que establece los requerimientos que deben cumplir los estudios técnicos para las modificaciones o alteraciones que afecten el diseño original de una aeronave.
<u>NOM-021/5-SCT3-2001</u>	2002-04-08	Que establece el contenido del manual de control de producción.
<u>NOM-022-SCT3-2011</u>	2012-02-09	Que establece el uso de registradores de vuelo instalados en aeronaves que operen en el espacio aéreo mexicano, así como sus características.
<u>NOM-022-SCT4-1995</u>	1999-05-11	Requisitos que deben cumplir los sistemas automáticos contraincendio a base de aspersores de agua para uso en embarcaciones
<u>NOM-023-SCT2/2011</u>	2011-09-14	Información que debe contener la placa técnica que deben portar los autotanques, cisternas portátiles y recipientes metálicos intermedios a granel (rig) que transportan sustancias, materiales y residuos peligrosos.
<u>NOM-023-SCT4-1995</u>	1998-12-15	Condiciones para el manejo y almacenamiento de mercancías peligrosas en puertos, terminales y unidades mar adentro
<u>NOM-024-SCT2/2010</u>	2010-11-23	Especificaciones para la construcción y reconstrucción, así como los métodos de ensayo (prueba) de los envases y embalajes de las sustancias, materiales y residuos peligrosos.
<u>NOM-024-SCT4-1995</u>	1999-12-20	Conexiones internacionales a tierra para sistemas contra incendio. Requisitos y especificaciones.
<u>NOM-025-SCT2-2016</u>	2017-05-26	Disposiciones de seguridad para el equipo de arrastre ferroviario al servicio de carga
<u>NOM-025-SCT4-1995</u>	1998-12-21	Detección, identificación, prevención y sistemas contraincendio para embarcaciones que transportan hidrocarburos, químicos y petroquímicos de alto riesgo.

<u>NOM-027-SCT2/2009</u>	2010-02-17	Especificaciones especiales y adicionales para los envases, embalajes, recipientes intermedios a granel, cisternas portátiles y transporte de las sustancias, materiales y residuos peligrosos de la división 5.2 peróxidos orgánicos.
<u>NOM-028-SCT2/2010</u>	2010-05-10	Disposiciones especiales y generales para el transporte de las sustancias, materiales y residuos peligrosos de la clase 3 líquidos inflamables.
<u>NOM-029-SCT2/2011</u>	2012-01-17	Especificaciones para la construcción y reconstrucción de recipientes intermedios para graneles (rig), destinados al transporte de sustancias, materiales y residuos peligrosos.
<u>NOM-030-SCT2/2009</u>	2010-02-25	Especificaciones y características relativas al diseño, construcción, inspección y pruebas de cisternas portátiles de gases licuados refrigerados.
<u>NOM-030-SCT4-1996</u>	1999-01-04	Condiciones de seguridad para la estiba y trincado de carga en embarcaciones sobre cubierta y en bodegas
<u>NOM-032-SCT2/2009</u>	2010-02-16	Especificaciones y características relativas al diseño, construcción, inspección y pruebas de cisternas portátiles destinadas al transporte de las sustancias, materiales y residuos peligrosos de las clases 1, 3 a 9.
<u>NOM-032-SCT4-1996</u>	1999-12-20	Elaboración y presentación del cuaderno de estabilidad.
<u>NOM-033-SCT4-2013</u>	2013-10-21	Lineamientos para el ingreso de mercancías peligrosas a instalaciones portuarias.
<u>NOM-034-SCT2-2011</u>	2011-11-16	Señalamiento horizontal y vertical de carreteras y vialidades urbanas.
<u>NOM-034-SCT4-2009</u>	2009-02-24	Equipo mínimo de seguridad, comunicación y navegación para embarcaciones nacionales, hasta 15 metros de eslora.
<u>NOM-035-SCT-2-2010</u>	2010-09-30	Remolques y semirremolques-especificaciones de seguridad y métodos de prueba.
<u>NOM-035-SCT4-1999</u>	2002-10-23	Equipo de protección personal y de seguridad para la atención de incendios, accidentes e incidentes que involucren mercancías peligrosas en embarcaciones y artefactos navales.
<u>NOM-036-SCT2-2016</u>	2016-10-03	Rampas de emergencia para frenado en carreteras.
<u>NOM-036-SCT3-2000</u>	2001-02-19	Que establece dentro de la república mexicana los límites máximos permisibles de emisión de ruido producido por las aeronaves de reacción subsónicas, propulsadas por hélice, supersónicas y helicópteros, su método de medición, así como los requerimiento
<u>NOM-036-SCT4-2007</u>	2007-08-17	Administración de la seguridad operacional y prevención de la contaminación por las embarcaciones y artefactos navales.
<u>NOM-037-SCT2-2012</u>	2012-09-14	Barreras de protección en carreteras y vialidades urbanas.
<u>NOM-037-SCT4-1999</u>	2005-02-17	Requisitos que deben cumplir las estaciones que prestan servicios a botes salvavidas totalmente cerrados.
<u>NOM-038-SCT4-2009</u>	2009-04-15	Especificaciones técnicas que deben cumplir las canastillas para embarque y desembarque, utilizadas para trasladar al personal con su equipo o herramientas entre una embarcación, un muelle y un artefacto naval.
<u>NOM-039-SCT3-2010</u>	2011-04-26	Que regula la aplicación de directivas de aeronavegabilidad y boletines de servicio a aeronaves y sus componentes
<u>NOM-040-SCT-2-2012</u>	2013-03-20	Para el transporte de objetos indivisibles de gran peso y/o volumen, peso y dimensiones de las combinaciones vehiculares y de las grúas industriales y su tránsito por caminos y puentes de jurisdicción federal.
<u>NOM-040-SCT3-2001</u>	2002-11-28	Que establece el contenido del manual de despacho para empresas de transporte aéreo de servicio al público, así como para empresas que prestan el servicio de despacho o despacho y control de vuelos.
<u>NOM-043-SCT/2003</u>	2004-01-27	Documento de embarque de sustancias, materiales y residuos
<u>NOM-043/1-SCT3-2001</u>	2002-04-08	Que regula el servicio de mantenimiento y/o reparación de aeronaves y sus componentes en el extranjero.
<u>NOM-044/1-SCT2-1997</u>	1998-06-01	Instrucciones para la ejecución de inspecciones y reparaciones programables de conservación del equipo tractivo ferroviario. Parte 1. Inspección diaria o de viaje.
<u>NOM-044/2-SCT2-1995</u>	1997-05-12	Instrucciones para la ejecución de inspecciones y reparaciones programables de conservación del equipo tractivo ferroviario. Parte 2, inspección trimestral o de 48,000 kilómetros de recorrido.
<u>NOM-046-SCT2/2010</u>	2010-05-26	Especificaciones y características relativas al diseño, construcción, inspección y pruebas de cisternas portátiles de gases licuados no refrigerados.
<u>NOM-051-SCT2/2011</u>	2011-12-08	Especificaciones para la clasificación de las sustancias infecciosas y especificaciones especiales y adicionales para la construcción y ensayo (prueba) de los envases y/o embalajes que transporten sustancias infecciosas de la división 6.2, categoría a.
<u>NOM-051-SCT3-2011</u>	2011-12-08	Que regula los procedimientos de aplicación del sistema mundial de determinación de la posición (gps), como medio de navegación dentro del espacio aéreo mexicano.
<u>NOM-053-SCT-2-2010</u>	2011-04-01	Transporte terrestre-características y especificaciones técnicas y de seguridad de los equipos de las grúas para arrastre, arrastre y salvamento.
<u>NOM-055-SCT2-2000</u>	2001-05-08	Para vía continua, unión de rieles mediante soldadura.
<u>NOM-055-SCT2-2016</u>	2017-05-26	Para vía continua, unión de rieles mediante soldadura.
<u>NOM-056-SCT1-1993</u>	1994-12-06	Definiciones para fuentes de alimentación utilizadas en telefonía.
<u>NOM-056-SCT2-2000</u>	2001-05-02	Para durmientes de madera.
<u>NOM-056-SCT2-2016</u>	2017-05-26	Para durmientes de madera.
<u>NOM-057-SCT2/2003</u>	2004-01-26	Requerimientos generales para el diseño y construcción de autotanques destinados al transporte de gases comprimidos, especificación sct 331.

<u>NOM-060-SCT1-1993</u>	1994-12-06	Terminología y conceptos básicos aplicables a los sistemas de transmisión de datos. Parte 1: modems.
<u>NOM-060-SCT3-2011</u>	2011-12-08	Que establece las especificaciones para conformar un sistema de identificación de defectos y fallas ocurridas a las aeronaves.
<u>NOM-061-SCT1-1993</u>	1994-12-07	Definiciones empleadas en equipos de radiocomunicación para servicios móviles.
<u>NOM-062-SCT1-1994</u>	1995-01-04	Terminología y conceptos básicos aplicables a transmisión de telefonía por microondas.
<u>NOM-063-SCT1-1993</u>	1994-12-07	Vocabulario electrotécnico parte 5. Perturbaciones radioeléctricas.
<u>NOM-064-SCT2-2001</u>	2002-01-21	Reglas de seguridad e inspecciones periódicas a los diversos sistemas que constituyen el equipo tractivo ferroviario diesel-eléctrico.
<u>NOM-064-SCT3-2012</u>	2013-01-07	Que establece las especificaciones del sistema de gestión de seguridad operacional (sms: safety management system).
<u>NOM-065-SCT1-1993</u>	1994-12-06	Vocabulario electrotécnico. Parte 15. Telecontrol.
<u>NOM-067-SCT-2/SECOFI-1999</u>	1999-11-01	Transporte terrestre-servicio de autotransporte económico y mixto-midibús-características y especificaciones técnicas y de seguridad.
<u>NOM-068-SCT-2-2014</u>	2015-01-19	Transporte terrestre-servicio de autotransporte federal de pasaje, turismo, carga, sus servicios auxiliares y transporte privado-condiciones físico-mecánica y de seguridad para la operación en vías generales de comunicación de jurisdicción federal.
<u>NOM-069-SCT3-2010</u>	2011-02-04	Que establece el uso del sistema de anticollisión de a bordo (acas) en aeronaves de ala fija que operen en espacio aéreo mexicano, así como sus características.
<u>NOM-070-SCT3-2010</u>	2011-02-15	Que establece el uso del sistema de advertencia de la proximidad del terreno (gpws) en aeronaves de ala fija que operen en espacio aéreo mexicano, así como sus características.
<u>NOM-081-SCT1-1993</u>	1994-08-19	Sistemas de radio telefonía con tecnología celular que operan en la banda de 800 mhz.
<u>NOM-083-SCT1-2002</u>	2003-04-16	Telecomunicaciones-radiocomunicación-especificaciones técnicas para los equipos transmisores utilizados en el servicio de radiolocalización móvil de personas de una vía.
<u>NOM-084-SCT1-2002</u>	2003-04-17	Telecomunicaciones-radiocomunicación-especificaciones técnicas de los equipos transmisores destinados al servicio móvil de radiocomunicación especializada de flotillas.
<u>NOM-086-SCT2-2015</u>	2016-06-24	Señalamiento y dispositivos para protección en zonas de obras viales.
<u>NOM-088/1-SCT1-2002</u>	2003-04-18	Telecomunicaciones-radiocomunicación-equipos de microondas para sistemas del servicio fijo multicanal punto a punto y punto a multipunto-parte i: radioacceso múltiple.
<u>NOM-088/2-SCT1-2002</u>	2003-04-21	Telecomunicaciones-radiocomunicación-equipos de microondas para sistemas del servicio fijo multicanal punto a punto y punto a multipunto-parte II: transporte.
<u>NOM-091-SCT3-2004</u>	2009-03-23	Que establece las operaciones en el espacio aéreo mexicano con separación vertical mínima reducida (mrvm).
<u>NOM-111-SCT1-1999</u>	1999-11-22	Telecomunicaciones-interfaz-parte de transferencia de mensaje del sistema de señalización por canal común.
<u>NOM-112-SCT1-1999</u>	2000-05-22	Telecomunicaciones-interfaz-parte de usuario de servicios integrados del sistema de señalización por canal común.
<u>NOM-117-SCT3-2016</u>	2017-12-08	Que establece las especificaciones para la gestión de la fatiga en la tripulación de vuelo.
<u>NOM-145/1-SCT3-2001</u>	2003-01-17	Que regula los requisitos y especificaciones para el establecimiento y funcionamiento del taller aeronáutico.
<u>NOM-145/2-SCT3-2001</u>	2003-03-17	Que establece el contenido del manual de procedimientos del taller de aeronáutico.
<u>NOM-192-SCFI/SCT1-2013</u>	2013-10-14	Telecomunicaciones-aparatos de televisión y decodificadores-especificaciones.

B. Colombia

Table 13.23 - Hybrid Technical Regulation

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Refrigeradores	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución N° 2507 del 26 de diciembre de 2018	Por la cual se extiende la vigencia de las Resoluciones 1652 de 2007 y 0171 de 2013.
2	Refrigeradores	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución No 171 del 22 de Febrero de 2013	Por la cual se prohíbe la fabricación e importación de refrigeradores, congeladores y combinaciones de refrigerador - congelador, de uso doméstico, que contengan o requieran para su producción u operación las sustancias Hidroclorofluorocarbonadas (HCFC) listadas en el Anexo C del Protocolo de Montreal, y se adoptan otras determinaciones
3	Leche	Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social	Decreto N° 2500 del 29 de diciembre de 2018	Por el cual se determina la permanencia del reglamento técnico sobre los requisitos que debe cumplir la leche para el consumo humano que se obtenga, procese, envase, transporte, comercialice, expendia, importe o exporte en el país.
4	Leche	Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social	Decreto N° 1880 del 27 de mayo de 2011	Por el cual se señalan los requisitos para la comercialización de la leche cruda para consumo directo en el territorio nacional.
5	Leche	Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social	Decreto N° 616 del 28 de febrero de 2006	Por el cual se expide el Reglamento Técnico sobre los requisitos que debe cumplir la leche para el consumo humano que se obtenga, procese, envase, transporte, comercializa, expendia, importe o exporte en el país
6	Bebidas alcohólicas	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social.	Decreto N° 216 del 14 de febrero de 2019	Por el cual se modifica el Decreto 262 de 2017.
7	Bebidas alcohólicas	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social.	Decreto N° 262 del 14 de febrero de 2017	Por el cual se concede un plazo y se dictan otras disposiciones.
8	Bebidas alcohólicas	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social.	Decreto N° 1506 del 12 de agosto de 2014	Por el cual se modifica el artículo 42 del Decreto 1686 de 2012.

9	Bebidas alcohólicas	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social.	Decreto N° 1686 del 9 de agosto de 2012	Por el cual se establece el reglamento técnico sobre los requisitos sanitarios que deben cumplir para la fabricación, elaboración, hidratación, envase, almacenamiento, distribución, transporte, comercialización, expendio, exportación e importación de bebidas alcohólicas destinadas para consumo humano"
10	Carne, productos cárnicos comestibles	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Ambiente y Desarrollo Sostenible./ Ministerio de Transporte	Decreto N° 2499 del 29 de diciembre de 2018	Por el cual se determina la permanencia del reglamento técnico a través del cual se crea el Sistema Oficial de Inspección, Vigilancia y Control de la Carne, Productos Cárnicos Comestibles y Derivados Cárnicos, destinados para el Consumo Humano y los requisitos sanitarios y de inocuidad que se deben cumplir en su producción primaria, beneficio, desposte, desprese, procesamiento, almacenamiento, transporte comercialización, expendio, importación o exportación.
11	Carne, productos cárnicos comestibles	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Ambiente y Desarrollo Sostenible./ Ministerio de Transporte	Decreto N° 2270 del 2 de noviembre de 2012	Por el cual se modifica el Decreto 1500 de 2007, modificado por los Decretos 2965 de 2008, 2380, 4131, 4974 de 2009, 3961 de 2011, 917 de 2012 y se dictan otras disposiciones.
12	Carne, productos cárnicos comestibles	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Ambiente y Desarrollo Sostenible./ Ministerio de Transporte	Decreto N° 0917 del 3 de mayo de 2012	Por el cual se modifica el Decreto 1500 de 2007, modificado por los Decretos 2965 de 2008, 2380, 4131. 4974 de 2009 y 3961 de 2011 y se dictan otras disposiciones
13	Carne, productos cárnicos comestibles	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Ambiente y Desarrollo Sostenible./ Ministerio de Transporte	Decreto N° 2380 del 25 de junio de 2009	Por el cual se modifican los decretos 1500 de 2007 y 2965 de 2008 y se dictan otras disposiciones

14	Carne, productos cárnicos comestibles	Ministerio de Comercio, Industria y Turismo / Ministerio de Salud y Protección Social / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Ambiente y Desarrollo Sostenible./ Ministerio de Transporte	Decreto N° 1500 del 4 de mayo de 2007	Por el cual se establece el reglamento técnico a través del cual se crea el Sistema Oficial de Inspección, Vigilancia y Control de la Carne, Productos Cárnicos Comestibles y Derivados Cárnicos, destinados para el Consumo Humano y los requisitos sanitarios y de inocuidad que se deben cumplir en su producción primaria, beneficio, desposte, desprese, procesamiento, almacenamiento, transporte comercialización, expendio, importación o exportación.
15	Sustancias Agotadoras de la Capa de Ozono	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución N° 2507 del 26 de diciembre de 2018	Por la cual se extiende la vigencia de las Resoluciones 1652 de 2007 y 0171 de 2013.
16	Sustancias Agotadoras de la Capa de Ozono	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución N° 1652 del 10 de septiembre de 2007	Por la cual se prohíbe la fabricación e importación de equipos y productos que contengan o requieran para su producción u operación las sustancias agotadoras de la capa de ozono listadas en los Anexos A y B del Protocolo de Montreal, y se adoptan otras determinaciones
17	Sistema Globalmente Armonizado de clasificación y etiquetado de productos químicos	Ministerio de Comercio, Industria y Turismo / Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social / Ministerio de Trabajo	Decreto 1496 de 2018	Por el cual se adopta el Sistema Globalmente Armonizado de Clasificación y Etiquetado de Productos Químicos y se dictan otras disposiciones en materia de seguridad química.
18	Etanol anhidro combustible y etanol anhidro combustible desnaturalizado	Ministerio de Minas y Energía / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 0789 del 20 de mayo de 2016	Por la cual se establece el Reglamento Técnico para los requisitos de calidad del etanol anhidro combustible y etanol anhidro combustible desnaturalizado utilizado como componente oxigenante de gasolinas y se dictan otras disposiciones
19	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.

20	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2875 del 27 de agosto de 2015	Por la cual se modifica el artículo 20 de la Resolución 481 del 4 de marzo de 2009 del Ministerio de Comercio, Industria y Turismo
21	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 5543 del 29 de noviembre de 2013	Por la cual se modifican las Resoluciones 935 de 2008, 934 de 2008, 481 de 2009 y 1949 de 2009
22	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2899 del 5 de Agosto de 2011	Por la cual se modifican las Resoluciones 481 de 2009 y 230 de 2010 del Ministerio de Comercio, Industria y Turismo
23	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0230 del 27 de enero de 2010	Modifica Resolución 481 de 2009
24	Llantas neumáticas de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0481 del 4 de marzo de 2009	Deroga la Resolución 3156 de 2006 y sus modificaciones. Reglamento Técnico
25	Cinturones de Seguridad de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.
26	Cinturones de Seguridad de uso en automotores	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 1949 del 17 de Julio de 2009	Deroga Resolución 1274 y se expide Resolución "Por la cual se expide el reglamento técnico aplicable a cinturones de seguridad para uso en vehículos automotores, que se fabriquen, importen o comercialicen en Colombia
27	Detergentes y jabones	Ministerio de Salud y Protección Social / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 1770 de 2018	Por la cual se modifica la Resolución N° 689 del 3 de mayo de 2016
28	Detergentes y jabones	Ministerio de Salud y Protección Social / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 837 del 4 de mayo de 2017	Por el cual se modifican los artículo 10 y 14 de la Resolución 0689 de 2016.
29	Detergentes y jabones	Ministerio de Salud y Protección Social / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 0689 del 3 de mayo de 2016	Por la cual se adopta el reglamento técnico que establece los límites máximos de fósforo y la biodegradabilidad de los tensoactivos presentes en detergentes y jabones

30	Biocombustibles para uso en motores diésel	Ministerio de Minas y Energía / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 40724 del 27 de julio de 2016	Por la cual se modifica el artículo 1o de la Resolución 9 0963 de 2014, que modificó el artículo 4o de la Resolución 898 de 1995, en relación con los criterios de calidad del combustible diésel (ACPM) y los biocombustibles para su uso en motores diésel como componente de la mezcla en procesos de combustión.
31	Biocombustibles para uso en motores diésel	Ministerio de Minas y Energía / Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 90963 del septiembre de 2014	Por la cual se modifica el artículo 4 de la Resolución 898 de 1995, modificado por la Resolución 18 2087 de 2007
32	Cintas retrorreflectivas	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.
33	Cintas retrorreflectivas	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 538 del 25 de febrero de 2013	Por la cual se expide el Reglamento Técnico aplicable a cintas retrorreflectivas para uso en vehículos automotores y sus remolques que se fabriquen, importen o comercialicen en Colombia
34	Combustibles de aviación	Ministerio de Minas y Energía / Ministerio de Transporte	Decreto N° 2496 del 26 de diciembre de 2018	Por la cual se extiende la vigencia de algunos reglamentos aplicables a sectores de hidrocarburos, biocombustibles y minería.
35	Combustibles de aviación	Ministerio de Minas y Energía / Ministerio de Transporte	Resolución No 180790 del 31 de julio de 2002	Por la cual se establecen los requisitos de calidad, de almacenamiento, transporte y suministro de los combustibles de aviación para motores tipo turbina y se dictan otras disposiciones
36	Sistema de Frenos	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.
37	Sistema de Frenos	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 3203 del 25 de julio de 2013.	Suspende la vigencia de la Resolución N° 4983 del 13 de diciembre de 2011 hasta el 22 de noviembre de 2013
38	Sistema de Frenos	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2198 del 29 de mayo de 2013	Modifica los artículos 4, 5, 6, 17, 20, 22 y 29 de la Resolución 4983 y se ha posterga entrada en vigor.

39	Sistema de Frenos	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2236 del 8 de junio de 2012	Por la cual se modifica la fecha de entrada en vigencia de la Resolución 4983 del 13 de diciembre de 2011
40	Sistema de Frenos	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 4983 del 13 de diciembre de 2011, la cual entro en vigor el 23 de junio de 2012.	Por la cual se expide el Reglamento Técnico aplicable a componentes de sistemas de frenos para uso en vehículos automotores o en sus remolques, que se importen o se fabriquen nacionalmente para su uso o comercialización en Colombia
41	Pilas de Zinc y Alcalinas	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución 082 del 16 de enero de 2019	Por el cual se aplaza la entrada en vigencia de la Resolución 0721 del 16 de abril de 2018.
42	Pilas de Zinc y Alcalinas	Ministerio de Comercio, Industria y Turismo / Ministerio de Ambiente y Desarrollo Territorial	Resolución N° 721 del 16 de Abril de 2018	Por el cual se expide el Reglamento Técnico para Pilas, Zinc-Carbón y Alcalinas que se importen o fabriquen nacionalmente para su comercialización en Colombia
43	Acrilamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.
44	Acrilamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 5543 del 29 de noviembre del 2013	Por la cual se modifican las Resoluciones 935 de 2008, 934 de 2008, 481 de 2009 y 1949 de 2009
45	Acrilamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0934 del 21 de Abril del 2008	Por la cual se expide el Reglamento Técnico para acrilamientos de seguridad resistentes a las balas para uso en vehículos automotores y sus remolques, tanto de fabricación nacional como importados, para su comercialización en Colombia Deroga la Resolución N° 0322 de 2002 a partir del 28 de octubre de 2008
46	Acrilamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 1289 del 27 de Mayo del 2008	Por la cual se modifica parcialmente la Resolución 935 del 21 de abril de 2008

47	Acristalamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0935 del 21 de Abril del 2008	Por la cual se modifica parcialmente la Resolución 322 del 19 de abril de 2002 y se adoptan otras disposiciones
48	Acristalamientos de seguridad de uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución No 0322 del 19 de abril de 2002	"Por la cual se expide el Reglamento Técnico No RTC-002MDE para acristalamientos de seguridad que se fabriquen o importen o comercialicen para uso en vehículos automotores y sus remolques, que circulen en Colombia"
49	Plaguicidas LMR en alimentos	Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social	Resolución N° 5897 del 28 de diciembre de 2018	Por la cual se determina la permanencia del reglamento técnico que regula los Límites Máximos de Residuos de Plaguicidas - LMR- en alimentos para consumo humano y en piensos o forrajes.
50	Plaguicidas LMR en alimentos	Ministerio de Agricultura y Desarrollo Rural / Ministerio de Salud y Protección Social	Resolución N° 2906 del 22 de agosto de 2007	Por la cual se establecen los Límites Máximos de Residuos de Plaguicidas LMR en alimentos para consumo humano y en piensos o forrajes
51	Acristalamientos de seguridad resistente a las balas para uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución 2606 del 28 de diciembre de 2018.	Por la cual se prorroga la vigencia de las Resoluciones 934 de 2008, 935 de 2008, 481 de 2009, 1949 de 2009, 4983 de 2011 y 538 de 2013 del Ministerio de Comercio, Industria y Turismo y sus respectivas resoluciones modificatorias.
52	Acristalamientos de seguridad resistente a las balas para uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 5543 del 29 de noviembre de 2013	Por la cual se modifican las Resoluciones 935 de 2008, 934 de 2008, 481 de 2009 y 1949 de 2009
53	Acristalamientos de seguridad resistente a las balas para uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0901 del 14 de abril de 2010	Por la cual se modifica parcialmente la Resolución 0934 del 21 de abril de 2008

54	Acristalamientos de seguridad resistente a las balas para uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 2649 del 2 de octubre de 2008	Por la cual se modifica la Resolución 934 del 21 de abril de 2008
55	Acristalamientos de seguridad resistente a las balas para uso en vehículos automotores y sus remolques	Ministerio de Comercio, Industria y Turismo / Ministerio de Transporte	Resolución N° 0934 del 21 de Abril de 2008	Por la cual se expide el Reglamento Técnico para acristalamientos resistentes a las balas para uso en vehículos automotores y sus remolques, tanto de fabricación nacional como importados, para su comercialización en Colombia

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.24 - Technical Regulation from Ministerio de Comercio, Industria y Turismo

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Remanufacturados	Mincisterio de Comercio, Industria y Turismo	Resolución N° 2574 del 26 de diciembre de 2018.	por la cual se extiende la vigencia de la Resolución número 497 del 20 del 2013 que contiene el reglamento técnico para etiquetado de productos en circunstancias especiales señaladas en el artículo 15 de la Ley 1480 del 12 de octubre de 2011.
2	Remanufacturados	Ministerio de Comercio, Industria y Turismo	Resolución N° 0497 del 20 de Febrero de 2013	Por la cual se expide el reglamento técnico para etiquetado de productos en circunstancias especiales señaladas en el artículo 15 de la Ley 1480 del 12 de octubre de 2011
3	Etiquetado de Confecciones	Ministerio de Comercio, Industria y Turismo	Resolución N° 1373 del 13 de julio de 2018	Por la cual se modifica el Reglamento Técnico sobre Etiquetado de Confecciones
4	Etiquetado de Confecciones	Ministerio de Comercio, Industria y Turismo	Resolución N° 2250 del 31 de Mayo de 2013, la cual entró en vigor el 18 de junio de 2013.	Por la cual se modifican las Resoluciones 0933 del 21 de abril de 2008 y 1950 del 17 de julio de 2009.
5	Etiquetado de Confecciones	Ministerio de Comercio, Industria y Turismo	Resolución N° 1950 del 17 de Julio del 2009	Por la cual se expide el Reglamento Técnico sobre Etiquetado de Confecciones.
6	Pinturas	Ministerio de Comercio, Industria y Turismo	Resolución N° 1154 del 22 de junio de 2016	Por la cual se expide el reglamento técnico aplicable a la etiqueta de pinturas base agua tipo emulsión de uso arquitectónico, para interiores o exteriores, que se fabriquen, importen o comercialicen en Colombia

7	Alambre de acero liso y grafilado y mallas electrosoldadas	Ministerio de Comercio, Industria y Turismo	Resolución N° 0277 del 2 de febrero de 2015	Por la cual se expide el reglamento técnico aplicable a alambre de acero liso, grafilado y mallas electrosoldadas, para refuerzo de concreto que se fabriquen, importen o comercialicen en Colombia.
8	Gasodomésticos que funcionan con combustibles gaseosos	Ministerio de Comercio, Industria y Turismo	Resolución N° 1814 del 21 de septiembre de 2016	Por la cual se modifica parcialmente el Reglamento Técnico para algunos Gasodomésticos, que se fabriquen nacionalmente o importen, para ser comercializados en Colombia.
9	Gasodomésticos que funcionan con combustibles gaseosos	Ministerio de Comercio, Industria y Turismo	Resolución N° 0680 del 6 de marzo de 2015, la cual entrará en vigor el 18 de septiembre de 2015.	Por la cual se expide el Reglamento Técnico para algunos gasodomésticos que se fabriquen o importen para ser comercializados en Colombia
10	Baldosas cerámicas	Ministerio de Comercio, Industria y Turismo	Resolución N° 220 del 11 de febrero de 2019	Por la cual se expide el reglamento técnico aplicable a la etiqueta de baldosas cerámicas, que se produzcan, importen y comercialicen en Colombia. Será de obligatorio en el territorio nacional a partir del 20 de agosto de 2019 y quedará derogada la Resolución 180 de 2013.
11	Baldosas cerámicas	Ministerio de Comercio, Industria y Turismo	Resolución N° 180 del 21 de enero de 2013	Por la cual se expide el reglamento técnico para etiquetado de baldosas cerámicas, que se importen o se fabriquen nacionalmente para su comercialización o uso en Colombia
12	Cilindros para Gases Industriales y Medicinales	Ministerio de Comercio, Industria y Turismo	Resolución N° 2580 del 26 de diciembre de 2018.	Por la cual se extiende la vigencia de la Resolución número 2876 de julio 5 de 2013 que contiene el Reglamento Técnico aplicable a la información del estampe original, etiquetado y aspecto físico de cilindros transportables sin costuras o sin soldaduras, de alta presión para gases industriales y medicinales, que se importen o se fabriquen nacionalmente para su comercialización o uso en Colombia.
13	Cilindros para Gases Industriales y Medicinales	Ministerio de Comercio, Industria y Turismo	Resolución N° 2876 del 5 de julio de 2013	“Por la cual se expide el reglamento técnico aplicable a la información del estampe original, etiquetado y aspecto físico de cilindros transportables sin costuras o sin soldaduras, de alta presión para gases industriales y medicinales, que se importen o se fabriquen

				nacionalmente para su comercialización o uso en Colombia”
14	Barras Corrugadas	Ministerio de Comercio, Industria y Turismo	Resolución N° 1856 del 4 de octubre de 2017	Por la cual se expide el Reglamento Técnico aplicable a barras corrugadas de baja aleación para refuerzo de concreto en construcciones sismo resistentes que se fabriquen, importen o comercialicen en Colombia.
15	Ollas de presión	Ministerio de Comercio, Industria y Turismo	Resolución N° 942 de 2018	Por la cual se expide el reglamento técnico para Ollas de Presión de uso doméstico que se importen o produzcan nacionalmente para su comercialización en Colombia.
16	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 2881 del 1° de julio de 2014	Por la cual se modifica la Resolución 957 del 2012 expedida por el Ministerio de Comercio, Industria y Turismo.
17	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 0344 del 29 de enero de 2014	Por la cual se prorroga el régimen de transición previsto en el artículo 51 de la Resolución 957 de 2012.
18	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 003 del 2 de enero de 2014	Por la cual se expide el Reglamento Técnico aplicable a talleres, equipos y procesos de conversión a gas natural comprimido para uso vehicular.
19	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 4340 del 27 de septiembre de 2013	Por la cual prorroga el régimen de transición previsto en el artículo 51 de la Resolución 957.
20	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 6103 del 21 de diciembre de 2012	Por la cual se modifica la fecha de entrada en vigencia de la Resolución número 0957 del 21 de marzo de 2012.
21	Talleres de Conversión a gas natural	Ministerio de Comercio, Industria y Turismo	Resolución N° 0957 del 21 de marzo de 2012	Por la cual se expide el Reglamento Técnico aplicable a talleres, equipos y procesos de conversión a gas natural comprimido para uso vehicular.
22	Calzado y Marroquinería	Ministerio de Comercio, Industria y Turismo	Resolución N° 3720 de 16 de diciembre de 2015	Por la cual se modifica la resolución 3024 de 2015.
23	Calzado y Marroquinería	Ministerio de Comercio, Industria y Turismo	Resolución N° 3024 de 18 de septiembre de 2015	Por la cual se modifica la Resolución 933 de 21 de abril de 2008.
24	Calzado y Marroquinería	Ministerio de Comercio, Industria y Turismo	Resolución N° 2250 del 31 de Mayo de 2013	Por la cual se modifican las Resoluciones 933 del 21 de abril de 2008 y 1950 del 17 de julio de 2009 .
25	Calzado y Marroquinería	Ministerio de Comercio, Industria y Turismo	Resolución N° 0933 del 21 de Abril de 2008	Por la cual se expide el Reglamento Técnico sobre etiquetado de Calzado y algunos artículos de

				marroquinería, y se derogan las Resoluciones 0510 de 2004 y 1011 de 2005.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.25 - Technical Regulation from Ministerio de Ambiente y Desarrollo Sostenible

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Camiones	Ministerio de Ambiente y Desarrollo Sostenible.	Resolución N° 2502 del 26 de diciembre de 2018.	Por la cual se extiende la vigencia de la Resolución 910 de 2008, modificada por la Resolución 1111 de 2013.
2	Camiones	Ministerio de Ambiente y Desarrollo Sostenible.	Resolución N° 1111 del 2 de septiembre de 2013	Por la cual se modifica la Resolución 910 2008.
3	Camiones	Ministerio de Ambiente y Desarrollo Sostenible	Resolución N° 0910 del 5 de junio de 2008	Por la cual se reglamentan los niveles permisibles de emisión de contaminantes producidos por fuentes móviles terrestres, se definen los equipos y procedimientos de medición de dichas emisiones, se reglamenta el artículo 91 del Decreto 948 de 1995 y se adoptan otras disposiciones.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.26 - Technical Regulation from Ministerio de Salud y Protección Social

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Hortalizas	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
2	Hortalizas	Ministerio de Salud y Protección Social	Resolución N° 2155 del 2 de agosto de 2012	Por el cual se expide el Reglamento Técnico sobre los requisitos sanitarios que deben cumplir las hortalizas que se procesen, empaquen, transporten, importen y comercialicen en el territorio nacional
3	Frutas	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
4	Frutas	Ministerio de Salud y Protección Social	Resolución N° 003929 del 2 de octubre de 2013, la cual entrará en vigor el 5 de abril de 2014.	Por el cual se establece el reglamento técnico sobre los requisitos sanitarios que deben cumplir las frutas

				que se procesen, empaquen, transporten, importen y comercialicen en el territorio nacional
5	Organismos Genéticamente Modificados	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
6	Organismos Genéticamente Modificados	Ministerio de Salud y Protección Social	Resolución N° 4254 del 22 de septiembre de 2011	Por el cual se adopta el reglamento técnico sobre requisitos para el etiquetado de alimentos e identificación de materias primas para el consumo humano que contengan Organismos Genéticamente Modificados y se dictan otras disposiciones.
7	Aceites y grasas de origen vegetal o animal	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
8	Aceites y grasas de origen vegetal o animal	Ministerio de Salud y Protección Social	Resolución N° 2154 del 2 de agosto de 2012	Por la cual se establece el reglamento técnico sobre los requisitos que deben cumplir los aceites y grasas de origen vegetal o animal que se procesen, envasen, almacenen, transporten, exporten, importen y/o comercialicen en el país, destinados para el consumo humano y se dictan otras disposiciones
9	Rotulado de los Aditivos	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
10	Rotulado de los Aditivos	Ministerio de Salud y Protección Social	Resolución N° 1506 del 6 de mayo de 2011	Por la cual se establece el reglamento técnico sobre los requisitos de rotulado o etiquetado que deben cumplir los aditivos que se empleen para la elaboración de alimentos para consumo humano en el territorio nacional
11	Envases de Vidrio para Alimentos	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.

12	Envases de Vidrio para Alimentos	Ministerio de Salud y Protección Social	Resolución N° 835 del 26 de marzo de 2013	Por medio de la cual se establece el reglamento técnico sobre los requisitos que deben cumplir los materiales, objetos, envases y equipamientos de vidrios y cerámicas destinados a estar en contacto con alimentos y bebidas para consumo humano
13	Envases Celulósicos para Alimentos	Ministerio de Salud y Protección Social	Resolución N° 834 del 26 de marzo de 2013	Por el cual se establece el reglamento técnico sobre los requisitos que deben cumplir los materiales, objetos, envases y equipamientos celulósicos y sus aditivos destinados a entrar en contacto con alimentos y bebidas alcohólicas para consumo humano
14	Envases Metálicos	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
15	Envases Metálicos	Ministerio de Salud y Protección Social	Resolución N° 4142 del 7 de diciembre de 2012	Por medio de la cual se establece el reglamento técnico sobre los requisitos que deben cumplir los materiales, objetos, envases y equipamientos metálicos destinados a entrar en contacto con alimentos y bebidas para consumo humano
16	Envases Plásticos	Ministerio de Salud y Protección Social	Resolución N° 4143 del 7 de diciembre de 2012	Por medio de la cual se establece el reglamento técnico sobre los requisitos sanitarios que deben cumplir los materiales, objetos, envases y equipamientos plásticos y elastoméricos y sus aditivos, destinados a entrar en contacto con alimentos y bebidas alcohólicas para consumo humano
17	Envases Plásticos	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
18	Envases Plásticos	Ministerio de Salud y Protección Social	Resolución N° 4143 del 7 de diciembre de 2012	Por medio de la cual se establece el reglamento técnico sobre los requisitos sanitarios que deben cumplir los materiales, objetos, envases y equipamientos plásticos y elastoméricos y sus aditivos, destinados a entrar en contacto con

				alimentos y bebidas alcohólicas para consumo humano
19	Chocolate.	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
20	Chocolate	Ministerio de Salud y Protección Social	Resolución N° 1511 del 6 de mayo de 2011	Por la cual se establece el reglamento técnico sobre los requisitos sanitarios que debe cumplir el chocolate y productos de chocolate para consumo humano, que se procese, envase, transporte, comercialice, expendia, importe o exporte en el territorio nacional
21	Gases medicinales	Ministerio de Salud y Protección Social	Resolución N° 5849 del 21 de diciembre de 2018	Por la cual se determina la permanencia de unos reglamentos técnicos en materia de medicamentos.
22	Gases medicinales	Ministerio de Salud y Protección Social	Resolución N° 04410 del 17 de noviembre de 2009	Por la cual se expide el Reglamento Técnico que contiene el Manual de Buenas Prácticas de Manufactura de los Gases Medicinales.
23	Carne de Cocodrilo	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
24	Carne de Cocodrilo	Ministerio de Salud y Protección Social	Resolución N° 3009 del 4 de agosto de 2010	Por la cual se establece el reglamento técnico sobre los requisitos sanitarios y de inocuidad de la carne proveniente del orden Crocodylia destinada para el consumo humano y las disposiciones para su beneficio, desposte, almacenamiento, comercialización, expendio, transporte, importación o exportación
25	Envases para Alimentos	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
26	Envases para Alimentos	Ministerio de Salud y Protección Social	Resolución N° 0683 del 28 de marzo de 2012	Por medio de la cual se establece el reglamento técnico sobre los requisitos que deben cumplir los materiales, objetos, envases y equipamientos

				destinados a entrar en contacto con alimentos y bebidas alcohólicas para consumo humano
27	Bebidas energizantes	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
28	Bebidas energizantes	Ministerio de Salud y Protección Social	Resolución N° 4150 del 30 de octubre de 2009	Por la cual se establece el reglamento técnico sobre los requisitos que deben cumplir las bebidas energizantes para consumo humano
29	Tabaco	Ministerio de Salud y Protección Social	Resolución N° 5914 de 2018 del 31 de diciembre de 2018	Por la cual se determina la permanencia del reglamento técnico en materia de etiquetado y empaquetado de productos de tabaco y sus derivados.
30	Tabaco	Ministerio de Salud y Protección Social	Resolución N° 3961 del 21 de Octubre de 2009	Por la cual se establecen los requisitos de empaquetado y etiquetado del tabaco y sus derivados.
31	Alimentos acidificados	Ministerio de Salud y Protección Social	Resolución N° 5865 de 2018 del 27 de diciembre de 2018	Por la cual se determina la permanencia de los reglamentos técnicos que regulan la producción, procesamiento de alimentos y bebidas, en el marco del proceso de la cadena productiva.
32	Alimentos acidificados	Ministerio de Salud y Protección Social	Resolución N° 2195 del 10 de junio de 2010	Por la cual se establece el Reglamento Técnico sobre los requisitos que se deben cumplir durante el proceso térmico de alimentos envasados herméticamente de baja acidez y acidificados, que se importen o exporten para el consumo humano
33	Juguetes	Ministerio de Salud y Protección Social	Resolución N° 686 de 2018 del 5 de marzo de 2018.	Por el cual se expide el reglamento técnico que deben cumplir los juguetes y sus accesorios, que se fabriquen, importen, y comercialicen en el territorio nacional
34	Juguetes	Ministerio de Salud y Protección Social	Resolución 3388 del 8 de septiembre de 2008	Por la cual se expide el reglamento técnico de sobre los requisitos de ensayo que, deben cumplir los juguetes, sus componentes y accesorios, que se comercialicen en Colombia

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.27 - Technical Regulation from Ministerio de Minas y Energía

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Biocombustibles para vehículos y artefactos a motor que necesiten combustible.	Ministerio de Minas y Energía	Decreto 2496 de 2018 del 29 de diciembre de 2018	Por el cual se extiende la vigencia de algunos reglamentos técnicos aplicables a los sectores de hidrocarburos, biocombustibles y minería.
2	Biocombustibles para vehículos y artefactos a motor que necesiten combustible.	Ministerio de Minas y Energía	Decreto 4892 del 23 de diciembre de 2011.	Por el cual se dictan disposiciones aplicables al uso de alcoholes carburantes y biocombustibles para vehículos automotores.
3	Biocombustibles para vehículos y artefactos a motor que necesiten combustible.	Ministerio de Minas y Energía	Decreto 1135 del 31 de marzo de 2009.	Por el cual se modifica el Decreto 2629 de 2007, en relación con el uso de alcoholes carburantes en el país y con las medidas aplicables a los vehículos automotores que utilicen gasolinas para su funcionamiento.
4	Biocombustibles para vehículos y artefactos a motor que necesiten combustible.	Ministerio de Minas y Energía	Decreto 2629 del 10 de julio de 2007	Por medio del cual se dictan disposiciones para promover el uso de biocombustibles en el país, así como medidas aplicables a los vehículos y demás artefactos a motor que utilicen combustibles para su funcionamiento.
5	Combustibles líquidos derivados del petróleo.	Ministerio de Minas y Energía	Decreto 2496 de 2018 del 29 de diciembre de 2018	Por el cual se extiende la vigencia de algunos reglamentos técnicos aplicables a los sectores de hidrocarburos, biocombustibles y minería.
6	Combustibles líquidos derivados del petróleo.	Ministerio de Minas y Energía	Decreto 1717 del 21 de mayo de 2008	Por el cual se modifica el Decreto 4299 de 2005 y se establecen otras disposiciones.

7	Combustibles líquidos derivados del petróleo.	Ministerio de Minas y Energía	Decreto 1333 del 19 de abril de 2007	Modifica Decreto N° 4299 de 2005.
8	Combustibles líquidos derivados del petróleo.	Ministerio de Minas y Energía	Decreto 4299 del 25 de noviembre de 2005	Por el cual se reglamenta el Artículo 61 de la Ley 812 de 2003 y se establecen otras disposiciones.
9	Alcoholes carburantes.	Ministerio de Minas y Energía	Resolución 18 0687 del Ministerio de Minas y Energía el 17 de junio de 2003	Por la cual se expide la regulación técnica prevista en la Ley 693 de 2001, en relación con la producción, acopio, distribución y puntos de mezcla de los alcoholes carburantes y su uso en los combustibles nacionales e importados.
10	RETIQ.	Ministerio de Minas y Energía	Resolución 4 0993 de 2018	Por la cual se modifican plazos de exigibilidad de etiquetado y se aclaran algunos requisitos establecidos en el Anexo General del Reglamento Técnico de Etiquetado - RETIQ.
11	RETIQ.	Ministerio de Minas y Energía	Resolución 4 0298 del 8 de marzo de 2018	Por el cual se amplían plazos de entrada en vigencia de algunos requisitos y se aclaran y flexibilizan unas condiciones aplicables al control y evaluación de la conformidad, establecidas en el Anexo General del Reglamento Técnico de Etiquetado - RETIQ".
12	RETIQ.	Ministerio de Minas y Energía	Resolución 4 0951 del 15 de septiembre de 2017	Por el cual se amplía la vigencia para uso y expedición de las declaraciones del productor para demostrar la conformidad con los requisitos del Anexo General del "Reglamento Técnico de Etiquetado -RETIQ" Resolución 41012 del 18 de septiembre de 2015.
13	RETIQ.	Ministerio de Minas y Energía	Resolución 4 0947 del 3 de octubre de 2016	Por la cual se derogan y suspende temporalmente algunos requisitos del Anexo General de la Resolución 4 1012 del 18 de septiembre de 2015 "Reglamento Técnico de Etiquetado - RETIQ".

14	RETIQ.	Ministerio de Minas y Energía	Resolución 4 1012 del 18 de septiembre de 2015	Por la cual se expide el Reglamento Técnico de Etiquetado - RETIQ, con fines de Uso Racional de Energía aplicable a algunos equipos de uso final de energía eléctrica y gas combustible, para su comercialización en Colombia.
15	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 40908 del 5 de septiembre 2018	Por la cual se decide la permanencia del Reglamento Técnico de Instalaciones Eléctricas - RETIE.
16	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 1294 del 6 de Agosto de 2008	Por la cual se modifica el Reglamento Técnico de Instalaciones Eléctricas - RETIE.
17	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 0632 del 29 de Abril de 2008	Por la cual se amplía la vigencia del Reglamento Técnico de Instalaciones Eléctricas - RETIE, así como la transitoriedad para demostrar la conformidad en unas instalaciones de uso final de la electricidad.
18	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 0466 del 2 de Abril de 2007	Por la cual se modifica el Reglamento Técnico de Instalaciones Eléctricas - RETIE.
19	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 181419 del 1 de Noviembre de 2005	Por la cual se aclara algunos aspectos del Reglamento Técnico de Instalaciones Eléctricas RETIE.
20	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 0498 del 29 de Abril de 2005	Por la cual se modifica parcialmente la Resolución 180398 de 2004.
21	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 0372 del 31 de Marzo de 2005	Por la cual se prorroga la entrada en vigencia de la Resolución 18 0398 del 7 de abril de 2004.
22	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 1760 del 23 de Diciembre de 2004	Por la cual se prorroga la entrada en vigencia de la Resolución 18 0398 del 7 de abril de 2004.
23	Instalaciones eléctricas.	Ministerio de Minas y Energía	Resolución 18 0398 del 7 de Abril de 2004	Por el cual se expide el Reglamento Técnico de Instalaciones Eléctricas - RETIE, que fija las condiciones técnicas que garantizan la seguridad en los procesos de Generación, Transmisión, Transformación, Distribución, y Utilización de la energía eléctrica en la República de Colombia y se dicta otras disposiciones.

24	Instalaciones Internas de Gas Combustible	Ministerio de Minas y Energía	Resolución 41385 del 7 de diciembre de 2017	Por la cual se modifica la Resolución 9 0902 de 2013 "Por medio de la cual se expide el Reglamento Técnico de Instalaciones Internas a Gas Combustible.
25	Instalaciones Internas de Gas Combustible	Ministerio de Minas y Energía	Resolución 90902 del 24 de octubre de 2013	Por la cual se expide el Reglamento Técnico de Instalaciones Internas de Gas Combustible
26	RETILAP - Alumbrado público	Ministerio de Minas y Energía	Resolución 40122 del 8 de febrero de 2016.	Por la cual se adiciona y modifica el Reglamento Técnico de Iluminación y Alumbrado Público - RETILAP
27	RETILAP - Alumbrado público	Ministerio de Minas y Energía	Resolución 18 1331 del 6 de agosto de 2009	Por la cual se expide el Reglamento Técnico de Iluminación y Alumbrado Público - RETILAP y se dictan otras disposiciones.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.28 - Technical Regulation from Comunidad Andina/ Ministerio de Salud y Protección Social

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Productos de Higiene Doméstica y Productos Absorbentes de Higiene Personal	Comisión de la Comunidad Andina/ Ministerio de Salud y Protección Social.	Decisión 721 del 27 de noviembre de 2009	Requisitos para el Funcionamiento de Establecimientos dedicados a la Fabricación de Productos de Higiene Doméstica y Productos Absorbentes de Higiene Personal.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.29 - Technical Regulation from Instituto Colombiano Agropecuario - ICA

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Fertilizantes y Acondicionadores de Suelos.	Instituto Colombiano Agropecuario - ICA	Resolución N° 40207 del 31 de diciembre de 2018.	Por medio de la cual se amplía la vigencia de algunos Reglamentos Técnicos del Instituto Colombiano Agropecuario (ICA).
2	Fertilizantes y Acondicionadores de Suelos.	Instituto Colombiano Agropecuario - ICA	Resolución N° 0968 del 10 de marzo de 2010.	Por medio de la cual se modifica la Resolución 150 de 2003.

3	Fertilizantes y Acondicionadores de Suelos.	Instituto Colombiano Agropecuario - ICA	Resolución N° 150 del 21 de enero de 2003.	Por la cual se adopta el Reglamento Técnico de Fertilizantes y Acondicionadores de Suelos para Colombia.
4	Semillas	Instituto Colombiano Agropecuario - ICA	Resolución N° 3888 del 17 de diciembre de 2015.	Por medio de la cual se adiciona un artículo transitorio y se modifica la Resolución ICA 3168 de 2015.
5	Semillas	Instituto Colombiano Agropecuario - ICA	Resolución N° 3168 del 7 de septiembre de 2015	Por medio de la cual se reglamenta la producción, importación, comercialización, y exportación de semillas producto del mejoramiento genético para la siembra en el país, así como el registro de las unidades de evaluación agronómica y las unidades de investigación en fitomejoramiento y se dictan otras disposiciones.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.30 - Technical Regulation from Superintendencia de Industria y Comercio

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Productos preempacados	Superintendencia de Industria y Comercio	Resolución N° 92672 de 2018 del 21 de diciembre de 2018	Por la cual se extiende la vigencia de la resolución 16379 de 2003 que contiene el reglamento técnico de control metrológico de contenido de productos preempacados.
2	Alcoholímetros, etilómetros, o alcohosensores evidenciales.	Superintendencia de Industria y Comercio	Resolución N° 88919 del 28 de diciembre de 2017	Por el cual se adiciona el Capítulo Noveno en el Título VI de la Circular Única y se reglamenta el control metrológico aplicable a alcoholímetros, etilómetros o alcohosensores evidenciales.
3	Taxímetros electrónicos.	Superintendencia de Industria y Comercio	Resolución N° 88918 del 28 de diciembre de 2017	Por el cual se adiciona el Capítulo Octavo en el Título VI de la Circular Única y se reglamenta el control metrológico aplicable a taxímetros electrónicos.
4	Surtidores, dispensadores y/o medidores de combustibles líquidos.	Superintendencia de Industria y Comercio	Resolución N° 77507 del 10 de noviembre de 2016	Por la cual se adiciona el Capítulo Séptimo en el Título VI de la Circular Única y se reglamenta el control metrológico aplicable a surtidores, dispensadores y/o medidores de combustibles líquidos.

5	Instrumentos de pesaje de funcionamiento no automático.	Superintendencia de Industria y Comercio	Resolución N° 77506 del 10 de noviembre de 2016	Por la cual se adiciona el Capítulo Sexto en el Título VI de la Circular Única y se reglamenta el control metrológico aplicable a instrumentos de pesaje de funcionamiento no automático.
6	Productos preempacados.	Superintendencia de Industria y Comercio	Resolución N° 16379 del 18 de Junio de 2003	Por la cual se reglamenta el control metrológico del contenido neto en los productos preempacados.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

Table 13.31 - Technical Regulation from Ministerio de Comercio, Industria y Turismo

No	Producto	Entidad responsable	Acto administrativo	Descripción
1	Remanufacturados	Ministerio de Comercio, Industria y Turismo	Resolución N° 2574 del 26 de diciembre de 2018.	Por la cual se extiende la vigencia de la Resolución número 497 del 20 del 2013 que contiene el reglamento técnico para etiquetado de productos en circunstancias especiales señaladas en el artículo 15 de la Ley 1480 del 12 de octubre de 2011.
2	Remanufacturados	Ministerio de Comercio, Industria y Turismo	Resolución N° 0497 del 20 de Febrero de 2013.	Por la cual se expide el reglamento técnico para etiquetado de productos en circunstancias especiales señaladas en el artículo 15 de la Ley 1480 del 12 de octubre de 2011.
3	Etiquetado de Confecciones.	Ministerio de Comercio, Industria y Turismo	Resolución N° 1373 del 13 de julio de 2018	Por la cual se modifica el Reglamento Técnico sobre Etiquetado de Confecciones.
4	Etiquetado de Confecciones.	Ministerio de Comercio, Industria y Turismo	Resolución N° 2250 del 31 de Mayo de 2013, la cual entro en vigor el 18 de junio de 2013.	Por la cual se modifican las Resoluciones 0933 del 21 de abril de 2008 y 1950 del 17 de julio de 2009.
5	Etiquetado de Confecciones.	Ministerio de Comercio, Industria y Turismo	Resolución N° 1950 del 17 de Julio del 2009	Por la cual se expide el Reglamento Técnico sobre Etiquetado de Confecciones.
6	Pinturas	Ministerio de Comercio, Industria y Turismo	Resolución N° 1154 del 22 de junio de 2016	Por la cual se expide el reglamento técnico aplicable a la etiqueta de pinturas base agua tipo emulsión de uso arquitectónico, para interiores o exteriores, que se fabriquen, importen o comercialicen en Colombia.
7	Alambre de acero liso y grafilado y mallas electrosoldadas.	Ministerio de Comercio, Industria y Turismo	Resolución N° 0277 del 2 de febrero de 2015	Por la cual se expide el reglamento técnico aplicable a alambre de acero liso, grafilado y mallas electrosoldadas, para refuerzo de concreto que se fabriquen, importen o comercialicen en Colombia.
8	Gasodomésticos que funcionan con	Ministerio de Comercio, Industria y Turismo	Resolución N° 1814 del 21 de septiembre de 2016	Por la cual se modifica parcialmente el Reglamento Técnico para algunos Gasodomésticos, que se

	combustibles gaseosos.			fabriquen nacionalmente o importen, para ser comercializados en Colombia.
9	Gasodomésticos que funcionan con combustibles gaseosos.	Ministerio de Comercio, Industria y Turismo	Resolución N° 0680 del 6 de marzo de 2015, la cual entrara en vigor el 18 de septiembre de 2015.	Por la cual se expide el Reglamento Técnico para algunos gasodomésticos que se fabriquen o importen para ser comercializados en Colombia.
10	Baldosas cerámicas.	Ministerio de Comercio, Industria y Turismo	Resolución N° 220 del 11 de febrero de 2019	Por la cual se expide el reglamento técnico aplicable a la etiqueta de baldosas cerámicas, que se produzcan, importen y comercialicen en Colombia. Será de obligatorio en el territorio nacional a partir del 20 de agosto de 2019 y quedará derogada la Resolución 180 de 2013.
11	Baldosas cerámicas.	Ministerio de Comercio, Industria y Turismo	Resolución N° 180 del 21 de enero de 2013	Por la cual se expide el reglamento técnico para etiquetado de baldosas cerámicas, que se importen o se fabriquen nacionalmente para su comercialización o uso en Colombia.
12	Cilindros para Gases Industriales y Medicinales.	Ministerio de Comercio, Industria y Turismo	Resolución N° 2580 del 26 de diciembre de 2018.	Por la cual se extiende la vigencia de la Resolución número 2876 de julio 5 de 2013 que contiene el Reglamento Técnico aplicable a la información del estampe original, etiquetado y aspecto físico de cilindros transportables sin costuras o sin soldaduras, de alta presión para gases industriales y medicinales, que se importen o se fabriquen nacionalmente para su comercialización o uso en Colombia.
13	Cilindros para Gases Industriales y Medicinales.	Ministerio de Comercio, Industria y Turismo	Resolución N° 2876 del 5 de julio de 2013	“Por la cual se expide el reglamento técnico aplicable a la información del estampe original, etiquetado y aspecto físico de cilindros transportables sin costuras o sin soldaduras, de alta presión para gases industriales y medicinales, que se importen o se fabriquen nacionalmente para su comercialización o uso en Colombia”
14	Barras Corrugadas.	Ministerio de Comercio, Industria y Turismo	Resolución N° 1856 del 4 de octubre de 2017	Por la cual se expide el Reglamento Técnico aplicable a barras corrugadas de baja aleación para refuerzo de concreto en construcciones sismos

				resistentes que se fabriquen, importen o comercialicen en Colombia.
15	Ollas de presión.	Ministerio de Comercio, Industria y Turismo	Resolución N° 942 de 2018	Por la cual se expide el reglamento técnico para Ollas de Presión de uso doméstico que se importen o produzcan nacionalmente para su comercialización en Colombia.
16	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 2881 del 1º de julio de 2014	Por la cual se modifica la Resolución 957 del 2012 expedida por el Ministerio de Comercio, Industria y Turismo.
17	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 0344 del 29 de enero de 2014	Por la cual se prorroga el régimen de transición previsto en el artículo 51 de la Resolución 957 de 2012.
18	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 003 del 2 de enero de 2014	Por la cual se establece la equivalencia de la norma R110 de las Naciones Unidas frente a las normas técnicas referenciadas en la Resolución 957 de 2012.
19	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 4340 del 27 de septiembre de 2013	Por la cual prorroga el régimen de transición previsto en el artículo 51 de la Resolución 957.
20	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 6103 del 21 de diciembre de 2012	Por la cual se modifica la fecha de entrada en vigencia de la Resolución número 0957 del 21 de marzo de 2012.
21	Talleres de Conversión a gas natural.	Ministerio de Comercio, Industria y Turismo	Resolución N° 0957 del 21 de marzo de 2012	Por la cual se expide el Reglamento Técnico aplicable a talleres, equipos y procesos de conversión a gas natural comprimido para uso vehicular.
22	Calzado y Marroquinería.	Ministerio de Comercio, Industria y Turismo	Resolución N° 3720 de 16 de diciembre de 2015	Por la cual se modifica la resolución 3024 de 2015.
23	Calzado y Marroquinería.	Ministerio de Comercio, Industria y Turismo	Resolución N° 3024 de 18 de septiembre de 2015	Por la cual se modifica la Resolución 933 de 21 de abril de 2008.
24	Calzado y Marroquinería.	Ministerio de Comercio, Industria y Turismo	Resolución N° 2250 del 31 de Mayo de 2013	Por la cual se modifican las Resoluciones 933 del 21 de abril de 2008 y 1950 del 17 de julio de 2009.
25	Calzado y Marroquinería.	Ministerio de Comercio, Industria y Turismo	Resolución N° 0933 del 21 de Abril de 2008	Por la cual se expide el Reglamento Técnico sobre etiquetado de Calzado y algunos artículos de marroquinería, y se derogan las Resoluciones 0510 de 2004 y 1011 de 2005.

Source: Dirección de Regulación del Ministerio de Comercio, Industria y Turismo. Elaborated by CCGI-EESP/FGV.

C. Chile

Table 13.32 - Chilean Standards (vehicles)

Número	Título	Fecha	Estado
NCh2190:2019	Transporte terrestre de mercancías peligrosas - Distintivos para identificación de peligros	28/01/2019	Vigente
NCh1776:2016	Neumáticos - Terminologías y definiciones	28/03/2016	Vigente
NCh3413/1:2016	Neumáticos para automóviles y camionetas - Parte 1: Requisitos y ensayos	28/03/2016	Vigente
NCh3413/2:2016	Neumáticos para automóviles y camionetas - Parte 2: Criterios de selección y recomendaciones de seguridad	28/03/2016	Vigente
NCh3384:2015	Neumáticos para camiones y buses - Requisitos y ensayos	30/09/2015	Vigente
NCh2910:2014	Transporte de ácido sulfúrico por vía terrestre - Vehículos tanque de carretera - Requisitos de diseño y fabricación	30/10/2014	Vigente
NCh3331:2013	Método de prueba para la determinación del consumo de combustible para vehículos de transporte terrestre	29/08/2013	Vigente
NCh2108:2000 Mod 2007	Gases licuados de petróleo (GLP) - Tanques de acero soldados, para uso de GLP como combustible en vehículos motorizados - Requisitos generales de diseño, fabricación y mantenimiento	24/09/2007	Vigente
NCh3051/2:2007	Dispositivos para la sujeción de la carga en vehículos de carretera - Seguridad - Parte 2: Cintas de amarre fabricadas a partir de fibras químicas	15/03/2007	Vigente
NCh2891:2004	Transporte de ácido sulfúrico por vía terrestre - Tanque para vagón-tanque de ferrocarril - Requisitos de diseño y fabricación	27/07/2004	Vigente
NCh2136:2003	Transporte de ácido sulfúrico por vía terrestre - Disposiciones de seguridad	19/06/2003	Vigente
NCh2094/1:2001	Vidrios de seguridad para vehículos a motor - Parte 1: Especificaciones de calidad y seguridad	28/12/2000	Vigente
NCh2094/2:2001	Vidrios de seguridad para vehículos a motor - Parte 2: Métodos de muestreo y ensayos	28/12/2000	Vigente
NCh2538:2003	Vehículos de carretera - Bomba de inyección de combustibles - Método de ensayo	06/12/2000	Vigente
NCh2032/1:1999	Sistemas de contención vial - Parte 1: Terminología y clasificación	05/01/1999	Vigente
NCh2032/2:1998	Sistemas de contención vial - Parte 2: Barrera metálica de seguridad - Especificaciones	23/12/1998	Vigente
NCh2435:1998	Gases licuados de petróleo para uso automotriz - Cálculo del número octano motor a partir del análisis de la composición	30/04/1998	Vigente
NCh2310:1996	Remolques y semirremolques - Sistemas de alumbrado y señalización - Requisitos de seguridad	30/01/1996	Vigente
NCh2311:1996	Remolques y semirremolques - Ejes - Requisitos de seguridad	30/01/1996	Vigente
NCh1772:1995	Remolques y semirremolques - Equipo de frenado - Requisitos generales y requisitos de seguridad	25/10/1995	Vigente
NCh1784:1995	Remolques y semirremolques - Parachoque - Requisitos de seguridad	25/10/1995	Vigente
NCh2308:1995	Vehículos de carretera - Conexiones mecánicas entre vehículo tractor y remolques - Requisitos de seguridad	31/08/1995	Vigente
NCh2309:1995	Vehículos de carretera - Acoplamiento mecánico entre tractocamión y semirremolque - Requisitos de seguridad	31/08/1995	Vigente

NCh2277:1994	Lubricantes para cajas de transmisión manual y cajas de diferencial de vehículos motorizados - Clasificación por su comportamiento en servicio	27/01/1994	Vigente
NCh2200:1993	Vehículos livianos a gasolina - Medición de contaminantes en los gases de escape	14/01/1993	Vigente
NCh2191/1:1992	Vehículos de carretera - Número de identificación de los vehículos (VIN) - Parte 1: Contenido y estructura	09/01/1992	Vigente
NCh2191/2:1992	Vehículos de carretera - Número de identificación de los vehículos (VIN) - Parte 2: Código identificador de fabricantes (WMI)	09/01/1992	Vigente
NCh2191/3:1992	Vehículos de carretera - Número de identificación de los vehículos (VIN) - Parte 3: Ubicación y fijación	09/01/1992	Vigente
NCh2158:1991	Pinturas de tránsito - Determinación del grado de sangrado	15/01/1991	Vigente
NCh2145:1990	Estaciones revisoras de vehículos de carretera - Requisitos y procedimientos de revisión (OBSERVACION: Norma técnica antigua que ha sido escaneada. Baja calidad)	14/09/1990	Vigente
NCh2140:1989	Pinturas de tránsito - Determinación del tiempo de secado apto tránsito	23/05/1989	Vigente
NCh2156:1989	Pinturas de tránsito - Determinación de la estabilidad	23/05/1989	Vigente
NCh2157:1989	Pinturas de tránsito - Determinación del contenido de microesferas de vidrio	23/05/1989	Vigente
NCh1963:1986	Neumáticos recauchados para automóviles de pasajeros - Requisitos	11/12/1985	Vigente
NCh1927:1984	Colores para señales de tránsito - Designación por el sistema Munsell	20/07/1984	Vigente
NCh1770:1981	Vehículos de carretera - Remolques y semirremolques - Resortes planos - Generalidades y terminología	16/01/1981	Vigente
NCh1811:1981	Vehículos de carretera - Acoplamiento mecánico entre tractocamión y semirremolque - Intercambiabilidad	16/01/1981	Vigente
NCh1733:1980	Contenedores - Dimensiones exteriores y pesos brutos máximos	17/10/1980	Vigente
NCh1734:1980	Contenedores de la serie 1, para uso general - Dimensiones interiores mínimas	17/10/1980	Vigente
NCh1793:1980	Camiones-tractor y remolques - Muelas de acoplamiento para pasador de 50 mm - Dimensiones, capacidad de carga y designación	17/10/1980	Vigente
NCh1795:1980	Vehículos de carretera - Tractocamiones - Quinta rueda - Montaje	17/10/1980	Vigente
NCh1798:1980	Vehículos de carretera - Camiones tractores y remolques - Muelas de acoplamiento para pasador de 50 mm - Montaje	17/10/1980	Vigente
NCh1809:1980	Contenedores de la serie 1 - Rotulación	17/10/1980	Vigente
NCh1810:1980	Contenedores de la serie 1 - Manipulación y trincado	17/10/1980	Vigente
NCh1819:1980	Contenedores - Código para rótulos de identificación	17/10/1980	Vigente
NCh1794:1980	Vehículos de carretera - Tractocamiones - Quinta rueda	13/06/1980	Vigente
NCh1661:1980	Frenado de vehículos automotores y de sus remolques - Terminología	30/01/1980	Vigente
NCh1777:1980	Vehículos de carretera - Conexiones mecánicas entre vehículo tractor y remolques - Intercambiabilidad	30/01/1980	Vigente
NCh1608:1979	Remolques y semirremolques - Requisitos de diseño de bastidores y cajas	24/08/1979	Vigente
NCh1615:1979	Vehículos de carretera - Remolques - Barras de acoplamiento - Requisitos	24/08/1979	Vigente

NCh1616:1979	Vehículos de carretera - Semirremolques - Perno real - Requisitos	24/08/1979	Vigente
NCh1660:1979	Vehículos de carretera - Símbolos para mandos, indicadores y dispositivos de aviso	24/08/1979	Vigente
NCh1440:1979	Vehículos de carretera - Tipos - Terminología y definiciones	19/01/1979	Vigente
NCh1609:1979	Remolques y semirremolques - Clasificación	17/01/1979	Vigente
NCh1425:1977	Vehículos terrestres - Pesos - Terminología (OBSERVACION: Norma técnica antigua que ha sido escaneada. Muy baja calidad)	29/12/1977	Vigente
NCh1422:1978	Vehículos motorizados y sus acoplados - Dimensiones - Designaciones y definiciones	16/12/1977	Vigente
NCh1255:1977	Protección personal - Cinturones de seguridad para automovilistas - Métodos de ensayo	29/12/1976	Vigente
NCh1256:1977	Protección personal - Cinturones de seguridad para automovilistas - Requisitos	29/12/1976	Vigente
NCh1257:1977	Protección personal - Cinturones de seguridad para automovilistas - Puntos de anclaje	29/12/1976	Vigente
NCh1259:1977	Protección personal - Elementos de sujeción de niños en vehículos motorizados - Especificaciones	29/12/1976	Vigente
NCh894:1972	Transportes - Símbolos para orientación al público en estaciones y vehículos	24/04/1973	Vigente
NCh893:1972	Transportes - Ferrocarriles - Vías y material rodante - Terminología	28/11/1972	Vigente
NCh696:1970	Ruedas para camiones - Llantas planas - Forma y dimensiones	15/09/1970	Vigente
NCh693:1970	Ruedas estampadas para camiones y buses - Terminología y clasificación	12/05/1970	Vigente
NCh694:1970	Ruedas estampadas para camiones - Requisitos generales	12/05/1970	Vigente
NCh695:1970	Ruedas estampadas para camiones - Inspección y ensayos	12/05/1970	Vigente
NCh390:1960	Medidas adicionales de seguridad en el transporte ferroviario de explosivos y de materiales inflamables	25/06/1959	Vigente
NCh393:1960	Medidas especiales de seguridad en el transporte ferroviario o en camiones, de petróleo, sus productos y de materiales similares	25/06/1959	Vigente
NCh391:1960	Medidas adicionales de seguridad en el transporte en camiones de explosivos y de materias inflamables	11/06/1959	Vigente
NCh445:1952	Líquidos para frenos de vehículos automotores	27/11/1952	Vigente

Source: INN. Elaborated by CCGI-EESP/FGV.

Table 13.33 - Chilean Standards for Health Products

Número	Título	Fecha	Estado
NCh2190:2019	Transporte terrestre de mercancías peligrosas - Distintivos para identificación de peligros	28/01/2019	Vigente
NCh1776:2016	Neumáticos - Terminologías y definiciones	28/03/2016	Vigente
NCh3413/1:2016	Neumáticos para automóviles y camionetas - Parte 1: Requisitos y ensayos	28/03/2016	Vigente
NCh3413/2:2016	Neumáticos para automóviles y camionetas - Parte 2: Criterios de selección y recomendaciones de seguridad	28/03/2016	Vigente
NCh3384:2015	Neumáticos para camiones y buses - Requisitos y ensayos	30/09/2015	Vigente
NCh2910:2014	Transporte de ácido sulfúrico por vía terrestre - Vehículos tanque de carretera - Requisitos de diseño y fabricación	30/10/2014	Vigente

NCh2196:2014	Gases comprimidos - Redes centralizadas y equipos para distribución de gases no inflamables de uso médico - Requisitos generales para su construcción y funcionamiento	29/09/2014	Vigente
NCh3338:2013	Servicios para la promoción de la autonomía personal - Gestión del servicio de ayuda a domicilio - Requisitos	26/12/2013	Vigente
NCh-ISO15189:2013	Laboratorios clínicos - Requisitos para la calidad y la competencia	26/12/2013	Vigente
NCh3337:2013	Servicios para la promoción de la autonomía personal - Gestión de Centros de Día - Requisitos	28/11/2013	Vigente
NCh3336:2013	Gestión de Establecimientos de Larga Estadía para Adultos Mayores - Requisitos	25/10/2013	Vigente
NCh3331:2013	Método de prueba para la determinación del consumo de combustible para vehículos de transporte terrestre	29/08/2013	Vigente
NCh2108:2000 Mod 2007	Gases licuados de petróleo (GLP) - Tanques de acero soldados, para uso de GLP como combustible en vehículos motorizados - Requisitos generales de diseño, fabricación y mantenimiento	24/09/2007	Vigente
NCh3051/2:2007	Dispositivos para la sujeción de la carga en vehículos de carretera - Seguridad - Parte 2: Cintas de amarre fabricadas a partir de fibras químicas	15/03/2007	Vigente
NCh2893/13:2004 IEC 60601-1-3:1994	Equipos electromédicos - Parte 1: Requisitos generales de seguridad - Norma Colateral 3: Requisitos generales de radioprotección en equipos de rayos X para diagnóstico	30/12/2004	Vigente
NCh2893/14:2004 IEC 60601-1-4:1996	Equipos electromédicos - Parte 1: Requisitos generales para la seguridad - Norma Colateral 4: Sistemas electromédicos programables	30/12/2004	Vigente
NCh2893/226:2004 IEC 60601-2-26:1994	Equipos electromédicos - Parte 2: Requisitos particulares de seguridad - Norma Colateral 26: Electroencefalógrafos	30/12/2004	Vigente
NCh2503:2004	Agujas hipodérmicas estériles para un solo uso	18/11/2004	Vigente
NCh2504/1:2004	Jeringas hipodérmicas estériles para un solo uso - Parte 1: Jeringas de uso manual	18/11/2004	Vigente
NCh2893/1:2004 IEC 60601-1:1988	Equipos electromédicos - Requisitos generales de seguridad	18/11/2004	Vigente
NCh2893/11:2004 IEC 60601-1-1:1996	Equipos electromédicos - Parte 1: Requisitos generales de seguridad - Norma colateral 1: Requisitos de seguridad para sistemas electromédicos	18/11/2004	Vigente
NCh2856/3:2004 ISO 10993-3:2003	Evaluación biológica de dispositivos médicos - Parte 3: Ensayos de genotoxicidad, carcinogenicidad y toxicidad reproductiva	27/07/2004	Vigente
NCh2891:2004	Transporte de ácido sulfúrico por vía terrestre - Tanque para vagón-tanque de ferrocarril - Requisitos de diseño y fabricación	27/07/2004	Vigente
NCh2856/10:2004 ISO 10993-10:2002	Evaluación biológica de dispositivos médicos - Parte 10: Ensayos para irritación e hipersensibilidad tipo retardada	29/06/2004	Vigente
NCh2854:2004	Radiología médica - Terminología	31/05/2004	Vigente
NCh2883:2004	Sistemas de ensayo de diagnóstico in vitro - Requisitos para sistemas de monitoreo de glucosa en sangre para auto control en el manejo de la diabetes mellitus	29/04/2004	Vigente
NCh2885:2004	Evaluación del funcionamiento de los dispositivos médicos para diagnóstico in vitro	26/02/2004	Vigente
NCh2887:2004	Dispositivos médicos - Información suministrada por el fabricante con los reactivos de diagnóstico in vitro para uso profesional	26/02/2004	Vigente
NCh2877:2004	Dispositivos médicos - Sistema de nomenclatura destinado al intercambio de datos regulatorios - Requisitos	21/01/2004	Vigente
NCh2856/7:2004	Evaluación biológica de dispositivos médicos - Parte 7: Residuos de esterilización con óxido de etileno	07/01/2004	Vigente

NCh2882/1:2004	Dispositivos médicos - Requisitos de los dispositivos médicos para ser designados Estéril - Parte 1: Requisitos de los dispositivos médicos esterilizados en su estado terminal	07/01/2004	Vigente
NCh2876:2004	Dispositivos médicos - Requisitos generales para la caracterización de un agente esterilizante y desarrollo, validación y control de rutina de un proceso de esterilización	22/12/2003	Vigente
NCh2856/2:2004	Evaluación biológica - Parte 2: Requisitos de bienestar para los animales de experimentación	18/12/2003	Vigente
NCh2869:2003 ISO 9637:1989	Hemodializadores, hemofiltros y hemoconcentradores - Requisitos	26/11/2003	Vigente
NCh2857:2004 ISO 15223:2000	Dispositivos médicos - Símbolos para utilizar en la etiqueta, etiquetado e información suministrada en los dispositivos médicos	29/10/2003	Vigente
NCh2136:2003	Transporte de ácido sulfúrico por vía terrestre - Disposiciones de seguridad	19/06/2003	Vigente
NCh2094/1:2001	Vidrios de seguridad para vehículos a motor - Parte 1: Especificaciones de calidad y seguridad	28/12/2000	Vigente
NCh2094/2:2001	Vidrios de seguridad para vehículos a motor - Parte 2: Métodos de muestreo y ensayos	28/12/2000	Vigente
NCh2538:2003	Vehículos de carretera - Bomba de inyección de combustibles - Método de ensayo	06/12/2000	Vigente
NCh2524/1:1999 ISO 8669-1	Bolsas colectoras para orina - Parte 1: Vocabulario	29/12/1999	Vigente
NCh2524/2:1999 ISO 8669-2	Bolsas colectoras para orina - Parte 2: Requisitos y métodos de ensayo	29/12/1999	Vigente
NCh2032/1:1999	Sistemas de contención vial - Parte 1: Terminología y clasificación	05/01/1999	Vigente
NCh2032/2:1998	Sistemas de contención vial - Parte 2: Barrera metálica de seguridad - Especificaciones	23/12/1998	Vigente
NCh2426:1998	Ambulancias para el transporte terrestre de pacientes - Clasificación y requisitos de transformación y equipamiento	25/07/1998	Vigente
NCh2435:1998	Gases licuados de petróleo para uso automotriz - Cálculo del número octano motor a partir del análisis de la composición	30/04/1998	Vigente
NCh2310:1996	Remolques y semirremolques - Sistemas de alumbrado y señalización - Requisitos de seguridad	30/01/1996	Vigente
NCh2311:1996	Remolques y semirremolques - Ejes - Requisitos de seguridad	30/01/1996	Vigente
NCh1772:1995	Remolques y semirremolques - Equipo de frenado - Requisitos generales y requisitos de seguridad	25/10/1995	Vigente
NCh1784:1995	Remolques y semirremolques - Parachoque - Requisitos de seguridad	25/10/1995	Vigente
NCh2308:1995	Vehículos de carretera - Conexiones mecánicas entre vehículo tractor y remolques - Requisitos de seguridad	31/08/1995	Vigente
NCh2309:1995	Vehículos de carretera - Acoplamiento mecánico entre tractocamión y semirremolque - Requisitos de seguridad	31/08/1995	Vigente
ISO 13402:1995	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure	27/07/1995	Vigente
NCh2277:1994	Lubricantes para cajas de transmisión manual y cajas de diferencial de vehículos motorizados - Clasificación por su comportamiento en servicio	27/01/1994	Vigente
NCh2224/1:1993	Preservativos - Condones de látex caucho - Parte 1: Requisitos	15/06/1993	Vigente
NCh2224/10:1993	Preservativos - Condones de látex de caucho - Parte 10: Envases y rotulación	15/06/1993	Vigente
NCh2224/2:1993	Preservativos - Condones de látex de caucho - Parte 2: Determinación del largo	15/06/1993	Vigente
NCh2224/3:1993	Preservativos - Condones de látex de caucho - Parte 3: Determinación del ancho	15/06/1993	Vigente
NCh2224/5:1993	Preservativos - Condones de látex de caucho - Parte 5: Ensayo para detectar orificios	15/06/1993	Vigente
NCh2224/6:1993	Preservativos - Condones de látex de caucho - Parte 6: Determinación del volumen y presión de ruptura	15/06/1993	Vigente

NCh2224/7:1993	Preservativos - Condones de látex de caucho - Parte 7: Determinación de la resistencia al deterioro durante el almacenamiento	15/06/1993	Vigente

Source: INN. Elaborated by CCGI-EESP/FGV.

Table 13.34 - Chilean Standards for Oil and Gas

Número	Título	Fecha	Estado
NCh3289:2013	Especificación técnica para equipos paquetizados y encasetados para compresión y almacenamiento de GNC	28/11/2013	Vigente
NCh65:2012	Gasolina de aviación - Requisitos	21/12/2012	Vigente
NCh3189:2010	Artefactos que usan combustibles líquidos - Métodos de ensayo	04/03/2010	Vigente
NCh3217:2010	Artefactos de calefacción que usan combustibles líquidos - Estufas con quemadores de vaporización conectadas a un conducto de evacuación de gases - Requisitos generales	08/01/2010	Vigente
NCh1907/1:2010	Artefactos de calefacción que usan combustibles líquidos - Parte 1: Estufas a kerosene Tipo A, con sistema de mecha - Requisitos generales	23/12/2009	Vigente
NCh1976:2009	Artefactos que utilizan exclusivamente gases licuados del petróleo - Artefactos domésticos de calefacción no conectados a un conducto de evacuación (incluidos los artefactos de calefacción por combustión catalítica difusiva)	18/06/2009	Vigente
NCh957:2008	Cilindros portátiles soldados y rellenables para gases licuados de petróleo - Inspección periódica y reparación	27/10/2008	Vigente
NCh3148:2008	Combustibles líquidos - Mecheros para estufas que usan kerosene	29/04/2008	Vigente
NCh3127:2008	Bidones portátiles de uso doméstico para transportar kerosene o diesel	21/12/2007	Vigente
NCh3090:2007	Artefactos que usan exclusivamente gases licuados de petróleo GLP - Generadores de aire caliente móviles y portátiles, por convección forzada, para calefacción directa de locales de uso no doméstico	24/09/2007	Vigente
NCh3105:2007	Artefactos que usan exclusivamente GLP - Quemadores de usos múltiples con soporte integrado para uso al aire libre	16/08/2007	Vigente
NCh2427:2004 Modificación 2005	Gases licuados de petróleo - Tanques estacionarios de presión para el almacenamiento de GLP - Inspección periódica, reparación y modificación	27/09/2005	Vigente
NCh2476:2000 Modificación 2005	Gases licuados de petróleo - Tanques estacionarios de acero soldados, para almacenamiento de GLP - Tanques de capacidad menor que 500 dm ³ - Requisitos generales de diseño y fabricación	27/09/2005	Vigente
NCh364:2004	Electricidad - Conductores eléctricos - Alambre de cobre desnudo para trolley - Requisitos	07/01/2004	Vigente
NCh366:2004	Electricidad - Conductores de cobre desnudos de formación no concéntrica de temple blando o recocido - Requisitos	07/01/2004	Vigente
NCh367:2004	Electricidad - Cables de cobre desnudos de conductores cableados con componentes de formación concéntrica - Requisitos	07/01/2004	Vigente
NCh368:2004	Electricidad - Cables de cobre desnudos de conductores cableados con componentes de formación no concéntrica - Requisitos	07/01/2004	Vigente
NCh2102:2004	Gases licuados de petróleo - Sistema para el uso de GLP como combustible de vehículos motorizados - Requisitos mínimos de seguridad	26/11/2003	Vigente
NCh362:2004	Electricidad - Conductores eléctricos - Alambre de cobre desnudo de sección circular de temple medio duro - Requisitos	29/10/2003	Vigente
NCh363:2004	Electricidad - Conductores eléctricos - Alambre de cobre desnudo estañado de sección circular de temple blando o recocido - Requisitos	29/10/2003	Vigente
NCh2831:2003	Productos de petróleo - Procedimientos prácticos especificados para transferencia de combustibles marinos a naves	19/06/2003	Vigente
NCh2733/1:2002	Electrónica - Antenas - Métodos de medición para antenas receptoras de transmisiones de radiodifusión satelital en la banda de 11/12 GHz - Parte 1: Mediciones eléctricas	31/07/2002	Vigente

NCh2733/2:2002	Electrónica - Antenas - Métodos de medición para antenas receptoras de transmisiones de radiodifusión satelital en la banda de 11/12 GHz - Parte 2: Mediciones mecánicas y medioambientales	<u>31/07/2002</u>	<u>Vigente</u>
NCh2719:2002	Electrónica - Transmisores - Requisitos de seguridad para equipos radiotransmisores	<u>27/06/2002</u>	<u>Vigente</u>
NCh2707:2002	Electrónica - Transmisor/receptor - Métodos de medición en sistemas de radio repetidor terrestre de microondas digital	<u>31/05/2002</u>	<u>Vigente</u>
NCh2708:2002	Electrónica - Antenas - Medición de la exposición a radiofrecuencias de campos electromagnéticos en el rango de frecuencia 100 kHz a 1GHz	<u>31/05/2002</u>	<u>Vigente</u>
NCh2724:2002	Electrónica - Antenas - Métodos de medición para estaciones terrenas satelitales	<u>31/05/2002</u>	<u>Vigente</u>
NCh2565:2002	Artefactos que usan combustibles líquidos - Estufas de ambiente, de tiro natural y tiro forzado - Especificaciones y marcas	<u>28/12/2001</u>	<u>Vigente</u>
NCh2683:2001	Electrónica - Antenas - Equipos de radio que se usan en servicios móviles - Métodos de medición	<u>28/12/2001</u>	<u>Vigente</u>
NCh2705:2002	Comportamiento de artefactos eléctricos de uso doméstico - Lavavajillas - Métodos de ensayo	<u>13/12/2001</u>	<u>Vigente</u>
NCh2664:2002	Artefactos refrigerantes de uso doméstico - Refrigeradores con o sin compartimento de baja temperatura - Características y métodos de ensayo	<u>21/11/2001</u>	<u>Vigente</u>
NCh2665:2002	Artefactos refrigerantes de uso doméstico con descongelamiento automático - Refrigeradores, refrigeradores-congeladores, gabinetes de almacenamiento de alimentos congelados y congeladores de alimentos enfriados por circulación forzada de aire interno - Ca	<u>21/11/2001</u>	<u>Vigente</u>
NCh2666:2002	Artefactos refrigerantes de uso doméstico - Gabinetes almacenadores de alimentos congelados y congeladores de alimentos - Características y métodos de ensayo	<u>21/11/2001</u>	<u>Vigente</u>
NCh2689:2001	Electrónica - Antenas - Métodos de medición de productos de intermodulación causados por dos o más transmisores que usan la misma antena o antenas adyacentes	<u>21/11/2001</u>	<u>Vigente</u>
NCh2690:2001	Electrónica - Antenas - Métodos de medición para sistemas de radio repetidor terrestre de microondas digital	<u>21/11/2001</u>	<u>Vigente</u>
NCh2693:2002	Comportamiento de artefactos eléctricos de uso doméstico - Aspiradoras de vacío - Métodos de ensayo	<u>21/11/2001</u>	<u>Vigente</u>
NCh2645:2001	Electrónica - Antenas - Vocabulario	<u>30/10/2001</u>	<u>Vigente</u>
NCh2672:2002	Comportamiento de artefactos eléctricos de uso doméstico - Planchas - Método de ensayo	<u>30/10/2001</u>	<u>Vigente</u>
NCh2555:2001	Productos de petróleo - Determinación de punto de escurrimiento - Método automático por inclinación	<u>31/08/2001</u>	<u>Vigente</u>
NCh2646:2001	Comportamiento de artefactos eléctricos de uso doméstico - Afeitadoras - Métodos de ensayo	<u>31/08/2001</u>	<u>Vigente</u>
NCh2554:2001	Productos de petróleo - Ensayos - Punto de inflamación - Micrométodo	<u>26/06/2001</u>	<u>Vigente</u>
NCh2553:2001	Petróleo crudo y combustibles residuales - Determinación de níquel, vanadio, hierro y sodio - Método por espectrometría de absorción atómica en la llama	<u>27/04/2001</u>	<u>Vigente</u>
NCh1945:2002	Productos líquidos del petróleo - Determinación de tipos de hidrocarburos - Método por indicador de fluorescencia de adsorción	<u>28/02/2001</u>	<u>Vigente</u>
NCh822:2002	Petróleo crudo y productos líquidos de petróleo - Determinación de densidad, densidad relativa y gravedad API - Método del densímetro	<u>28/02/2001</u>	<u>Vigente</u>
NCh2103:2001	Gases licuados de petróleo - Estaciones surtidoras de GLP para uso como combustible de vehículos motorizados - Requisitos mínimos de seguridad	<u>28/12/2000</u>	<u>Vigente</u>
NCh2568:2001	Reguladores de baja presión de servicio que utilizan combustibles gaseosos	<u>28/12/2000</u>	<u>Vigente</u>
NCh2552:2006	Combustibles de bajo contenido de olefinas para motores de ignición por chispa - Tipos de hidrocarburos- Determinación de oxigenados, parafinas, olefinas, naftenos y aromáticos - Método por cromatografía en fase gaseosa	<u>06/12/2000</u>	<u>Vigente</u>
NCh1436:2001	Combustibles líquidos - Surtidores - Verificación de la exactitud del volumen de entrega o expendio	<u>26/10/2000</u>	<u>Vigente</u>
NCh1988:2001	Combustibles destilados - Determinación del índice de cetano calculado	<u>26/10/2000</u>	<u>Vigente</u>

NCh1985:2001	Productos de petróleo - Determinación del residuo carbonoso Ramsbottom	<u>27/09/2000</u>	<u>Vigente</u>
NCh1982:2000	Petróleo combustible - Determinación de agua y sedimento - Método de la centrífuga (Procedimiento de laboratorio)	<u>01/06/2000</u>	<u>Vigente</u>
NCh328:2006	Gases licuados de petróleo - Cilindros y tanques de acero soldados - Métodos de ensayo	<u>02/03/2000</u>	<u>Vigente</u>
NCh70:2000	Productos de petróleo - Acción corrosiva sobre el cobre - Ensayo de la lámina de cobre	<u>28/01/2000</u>	<u>Vigente</u>
NCh1983:2000	Productos de petróleo - Determinación del punto de escurrimiento	<u>21/12/1999</u>	<u>Vigente</u>
NCh1984:2000	Productos de petróleo - Determinación de cenizas	<u>21/12/1999</u>	<u>Vigente</u>
NCh2468:2000	Gasolina - Determinación de MTBE, ETBE, TAME, DIPE, metanol, etanol y ter-butanol - Método por espectroscopía de infrarrojo	<u>21/12/1999</u>	<u>Vigente</u>
NCh2490:2000	Gasolina - Determinación de aromáticos - Método por cromatografía gaseosa	<u>21/12/1999</u>	<u>Vigente</u>
NCh2466:2000	Combustibles líquidos - Determinación de la temperatura de relación vapor-líquido - Método de la cámara al vacío	<u>25/11/1999</u>	<u>Vigente</u>
NCh2212/7:2000	Combustibles gaseosos - Artefactos para cocinar, de uso colectivo - Parte 7: Gabinetes térmicos	<u>29/10/1999</u>	<u>Vigente</u>
NCh2467:2000	Productos de petróleo - Determinación de la presión de vapor - Método Mini	<u>29/10/1999</u>	<u>Vigente</u>
NCh2212/5:2000	Combustibles gaseosos - Artefactos para cocinar de uso colectivo - Parte 5: Gratinadoras	<u>21/09/1999</u>	<u>Vigente</u>
NCh1937:2000	Kerosene de aviación - Requisitos (Se debe usar ASTM D 1655)	<u>26/08/1999</u>	<u>Vigente</u>
NCh2423/2:2001	Artefactos a gas - Condiciones de instalación - Parte 2: Especificaciones para la admisión de aire comburente y extracción de aire viciado	<u>29/07/1999</u>	<u>Vigente</u>
NCh1904:2000	Productos de petróleo - Relación entre los resultados de los ensayos y la precisión del método para determinar conformidad con las especificaciones	<u>01/07/1999</u>	<u>Vigente</u>
NCh2423/1:2001	Artefactos a gas - Condiciones de instalación - Parte 1: Especificaciones para la evacuación de gases de la combustión en circuito abierto y tiro natural	<u>01/07/1999</u>	<u>Vigente</u>
NCh2054:2000	Productos de petróleo - Tipos de hidrocarburos en destilados medios - Determinación por espectrometría de masas	<u>27/05/1999</u>	<u>Vigente</u>
NCh2146:2001	Combustibles para motores de ignición por chispa - Determinación del número de octano - Método Research y método motor	<u>27/05/1999</u>	<u>Vigente</u>
NCh2037:1999	Petróleo Diesel y combustibles para turbinas de aviación - Determinación de aromáticos y aromáticos polinucleares - Método por cromatografía de fluido supercrítico	<u>25/03/1999</u>	<u>Vigente</u>
NCh2226:2000	Combustibles gaseosos - Llaves de paso de accionamiento manual, para presión nominal menor o igual a 500 kPa - Requisitos generales	<u>29/01/1999</u>	<u>Vigente</u>
NCh2441:1999	Productos de petróleo - Gases licuados de petróleo (GLP) - Determinación de los residuos de evaporización - Método a alta temperatura	<u>23/12/1998</u>	<u>Vigente</u>
NCh825:1999	Productos de petróleo - Combustibles destilados y solventes - Determinación cualitativa de azufre activo - Ensayo Doctor	<u>23/12/1998</u>	<u>Vigente</u>
NCh2036:1999	Hidrocarburos líquidos de petróleo - Trazas de nitrógeno - Método por combustión oxidante y detección de quemiluminiscencia	<u>26/11/1998</u>	<u>Vigente</u>
NCh61:1999	Petróleo combustible (fuel oil) - Requisitos	<u>26/11/1998</u>	<u>Vigente</u>
NCh1924:2000	Cilindros de acero, portátiles, soldados, para gases licuados de petróleo (tipos 2 y 3) - Requisitos generales de diseño y fabricación	<u>22/10/1998</u>	<u>Vigente</u>
NCh2035:1999	Destilados de petróleo - Determinación de hidrocarburos aromáticos - Método por cromatografía líquida de alto rendimiento con detección de índice de refracción	<u>22/10/1998</u>	<u>Vigente</u>
NCh62:2000	Petróleo Diesel - Requisitos	<u>22/10/1998</u>	<u>Vigente</u>

NCh63:2000	Kerosene - Requisitos	<u>22/10/1998</u>	<u>Vigente</u>
NCh66:2000	Productos de petróleo - Ensayo de destilación - Métodos manual y automático	<u>22/10/1998</u>	<u>Vigente</u>
NCh2273:1999	Gases licuados de petróleo - Componentes del sistema de combustibles de los vehículos motorizados - Requisitos de fabricación y funcionamiento	<u>26/08/1998</u>	<u>Vigente</u>
NCh2395:1999	Productos de petróleo - Determinación de la densidad y densidad relativa mediante densímetro digital	<u>26/08/1998</u>	<u>Vigente</u>
NCh2212/5:2000	Combustibles gaseosos - Artefactos para cocinar de uso colectivo - Parte 5: Gratinadoras	<u>21/09/1999</u>	<u>Vigente</u>
NCh1937:2000	Kerosene de aviación - Requisitos (Se debe usar ASTM D 1655)	<u>26/08/1999</u>	<u>Vigente</u>
NCh2423/2:2001	Artefactos a gas - Condiciones de instalación - Parte 2: Especificaciones para la admisión de aire comburente y extracción de aire viciado	<u>29/07/1999</u>	<u>Vigente</u>
NCh1904:2000	Productos de petróleo - Relación entre los resultados de los ensayos y la precisión del método para determinar conformidad con las especificaciones	<u>01/07/1999</u>	<u>Vigente</u>
NCh2423/1:2001	Artefactos a gas - Condiciones de instalación - Parte 1: Especificaciones para la evacuación de gases de la combustión en circuito abierto y tiro natural	<u>01/07/1999</u>	<u>Vigente</u>
NCh2054:2000	Productos de petróleo - Tipos de hidrocarburos en destilados medios - Determinación por espectrometría de masas	<u>27/05/1999</u>	<u>Vigente</u>
NCh2146:2001	Combustibles para motores de ignición por chispa - Determinación del número de octano - Método Research y método motor	<u>27/05/1999</u>	<u>Vigente</u>
NCh2037:1999	Petróleo Diesel y combustibles para turbinas de aviación - Determinación de aromáticos y aromáticos polinucleares - Método por cromatografía de fluido supercrítico	<u>25/03/1999</u>	<u>Vigente</u>
NCh2226:2000	Combustibles gaseosos - Llaves de paso de accionamiento manual, para presión nominal menor o igual a 500 kPa - Requisitos generales	<u>29/01/1999</u>	<u>Vigente</u>
NCh2441:1999	Productos de petróleo - Gases licuados de petróleo (GLP) - Determinación de los residuos de evaporización - Método a alta temperatura	<u>23/12/1998</u>	<u>Vigente</u>
NCh825:1999	Productos de petróleo - Combustibles destilados y solventes - Determinación cualitativa de azufre activo - Ensayo Doctor	<u>23/12/1998</u>	<u>Vigente</u>
NCh2036:1999	Hidrocarburos líquidos de petróleo - Trazas de nitrógeno - Método por combustión oxidante y detección de quemiluminiscencia	<u>26/11/1998</u>	<u>Vigente</u>
NCh61:1999	Petróleo combustible (fuel oil) - Requisitos	<u>26/11/1998</u>	<u>Vigente</u>
NCh1924:2000	Cilindros de acero, portátiles, soldados, para gases licuados de petróleo (tipos 2 y 3) - Requisitos generales de diseño y fabricación	<u>22/10/1998</u>	<u>Vigente</u>
NCh2035:1999	Destilados de petróleo - Determinación de hidrocarburos aromáticos - Método por cromatografía líquida de alto rendimiento con detección de índice de refracción	<u>22/10/1998</u>	<u>Vigente</u>
NCh62:2000	Petróleo Diesel - Requisitos	<u>22/10/1998</u>	<u>Vigente</u>
NCh63:2000	Kerosene - Requisitos	<u>22/10/1998</u>	<u>Vigente</u>
NCh66:2000	Productos de petróleo - Ensayo de destilación - Métodos manual y automático	<u>22/10/1998</u>	<u>Vigente</u>
NCh2273:1999	Gases licuados de petróleo - Componentes del sistema de combustibles de los vehículos motorizados - Requisitos de fabricación y funcionamiento	<u>26/08/1998</u>	<u>Vigente</u>
NCh2395:1999	Productos de petróleo - Determinación de la densidad y densidad relativa mediante densímetro digital	<u>26/08/1998</u>	<u>Vigente</u>
NCh1962:1996	Gases licuados de petróleo (GLP) - Determinación de azufre - Método del quemador de oxi-hidrógeno	<u>26/06/1996</u>	<u>Vigente</u>
NCh2350:1996	Gasolina - Determinación de plomo - Método del monocloruro de yodo	<u>26/06/1996</u>	<u>Vigente</u>

NCh71:1996	Productos de petróleo - Determinación de azufre - Método de la lámpara en productos líquidos	25/04/1996	Vigente
NCh60:1996	Petróleo y productos de petróleo - Muestreo - Procedimiento manual	30/01/1996	Vigente
NCh2352:1996	Gasolina sin plomo - Determinación de trazas de plomo - Método rápido de terreno, por colorimetría	22/12/1995	Vigente
NCh2329:1995	Gasolina - Determinación de plomo - Método por espectroscopía de rayos X	25/10/1995	Vigente
NCh2225:1995	Artefactos portátiles que utilizan gases licuados de petróleo operando a presión directa de vapor - Especificaciones	28/09/1995	Vigente
NCh2325:1995	Productos de petróleo - Determinación de azufre total en hidrocarburos livianos, combustibles para motores y lubricantes - Método por fluorescencia ultravioleta	31/08/1995	Vigente
NCh2328:1995	Gasolina y mezclas gasolina-oxigenados - Determinación de presión de vapor - Método seco	31/08/1995	Vigente
NCh2323:1995	Productos de petróleo - Determinación de azufre - Método por hidrogenólisis y cinética colorimétrica	28/07/1995	Vigente
NCh2324:1995	Productos de petróleo - Determinación de azufre - Método de la bomba	28/07/1995	Vigente
NCh2271:1995	Artefactos portátiles que utilizan gases licuados de petróleo, operando a presión directa de vapor - Adaptador tipo universal - Especificaciones	12/07/1995	Vigente
NCh1896:1997	Productos de petróleo - Determinación de azufre - Método por espectrometría de rayos X	25/05/1995	Vigente
NCh64:1995	Gasolina para motores de ignición por chispa - Requisitos	25/05/1995	Vigente
NCh2301:1995	Petróleo combustible - Determinación de vanadio	23/12/1994	Vigente
NCh2302:1995	Petróleo crudo y petróleo combustible - Determinación de sodio, níquel y vanadio - Método por espectroscopía de absorción atómica	23/12/1994	Vigente
NCh1947:1995	Productos de petróleo - Determinación de azufre - Método de alta temperatura	25/11/1994	Vigente
NCh2287:1995	Combustibles destilados de petróleo - Determinación del punto de obstrucción del filtro en el filtrado en frío	25/10/1994	Vigente
NCh2294:1995	Productos de petróleo - Determinación de azufre - Método de espectroscopía por fluorescencia de rayos X por energía dispersiva	25/10/1994	Vigente
NCh2295:1995	Productos de petróleo - Determinación del punto de enturbiamiento	25/10/1994	Vigente
NCh1906:1993	Cilindros portátiles soldados para gases licuados de petróleo - Revestimiento de pintura	16/11/1993	Vigente
NCh59:1994	Productos de petróleo - Vocabulario	28/09/1993	Vigente
NCh1800:1993	Válvulas para cilindros portátiles soldados para gases licuados de petróleo - Inspección y mantención	15/06/1993	Vigente
NCh2246:1993	Gasolina - Determinación de benceno y tolueno por cromatografía de gases	15/06/1993	Vigente
NCh2198:1993	Artefactos que usan combustibles - Elementos para el rotulado - Clasificación, requisitos generales y métodos de ensayos	18/05/1993	Vigente
NCh2211/1:1993	Conexión flexible para uso en gases licuados de petróleo - Parte 1: Conectores metálicos	18/05/1993	Vigente
NCh1514/1:1993	Válvulas de accionamiento automático destinadas a cilindros portátiles soldados para gases licuados de petróleo - Requisitos generales de fabricación y métodos de ensayo	09/07/1992	Vigente
NCh2195:1993	Productos de petróleo - Gasolina - Determinación de benceno - Método por espectroscopía de infrarroja	09/07/1992	Vigente
NCh2192:1992	Productos de petróleo - Lubricantes - Terminología particular	11/06/1992	Vigente
NCh1377:1990	Gases comprimidos - Cilindros de gas para uso industrial - Marcas para identificación del contenido y de los riesgos inherentes	20/11/1990	Vigente
NCh1514/2:1990	Válvulas de accionamiento manual destinadas a cilindros portátiles soldados para gases licuados de petróleo - Requisitos generales de fabricación y métodos de ensayo	20/11/1990	Vigente

NCh1025:1990	Gases comprimidos - Cilindros de gas para uso médico y para esterilización - Marcas de identificación del contenido y de los riesgos inherentes	09/01/1990	Vigente
NCh1987:1989	Petróleo Diesel - Determinación de la calidad de ignición - Método del cetano	06/12/1988	Vigente
NCh2118:1989	Gases licuados de petróleo - Válvulas de accionamiento automático - Anillo de ajuste para hermeticidad - Especificaciones	06/12/1988	Vigente
NCh2116/2:1989	Gas manufacturado - Método de ensayo - Parte 2: Determinación de ácido cianhídrico - Método volumétrico de Seil-Tutwiler modificado	11/11/1988	Vigente
NCh2116/1:1989	Gas manufacturado - Método de ensayo - Parte 1: Determinación de humedad - Método gravimétrico	03/10/1988	Vigente
NCh2116/3:1989	Gas manufacturado - Método de ensayo - Parte 3: Determinación de ácido sulfhídrico - Método volumétrico de Tutwiler modificado	03/10/1988	Vigente
NCh2116/5:1989	Gas manufacturado - Método de ensayo - Parte 5: Determinación de amoníaco - Método volumétrico	03/10/1988	Vigente
NCh2116/7:1989	Gas manufacturado - Método de ensayo - Parte 7: Determinación de naftaleno - Método volumétrico	03/10/1988	Vigente
NCh2116/8:1989	Gas manufacturado - Método de ensayo - Parte 8: Determinación de óxido de nitrógeno II - Método volumétrico de Guyer y Weber	03/10/1988	Vigente

Table 13.35 - List of Products Certification Bodies in Chile

N°	N° Certi	Organización/Unidad	Tipo de OEC	Área
1	CP 048	ECOCERT CHILE S.A.	Organismos de certificación de productos	Agricultura orgánica
2	CP 095	BIOAUDITA LTDA.	Organismos de certificación de productos	Agricultura orgánica
3	CP 097	World Survey Services S.A.	Organismos de certificación de productos	Artículos para Seguridad de Vehículos de Carretera
4	CP 098	World Survey Services S.A.	Organismos de certificación de productos	Dispositivos de protección contra incendio
5	CP 103	Ingeniería y Certificación Nacional Ltda., INCEN Ltda.	Organismos de certificación de productos	Dispositivos de protección contra incendio
6	CP 009	CESMEC Ltda. / Division Certificacion	Organismos de certificación de productos	Elementos de protección personal
7	CP 055	INTECIL Ltda.	Organismos de certificación de productos	Estanques para sustancias peligrosas
8	CP 067	Sociedad Tecnica de Inspeccion S.A., STI	Organismos de certificación de productos	Estanques para sustancias peligrosas
9	CP 102	SITEC LTDA.	Organismos de certificación de productos	Estanques para sustancias peligrosas
10	CP 004	IDIEM, Universidad de Chile / Estructura y Construcción, Sección Física de la Construcción	Organismos de certificación de productos	Extintores
11	CP 089	CESMEC Ltda. - Division Certificacion	Organismos de certificación de productos	Extintores
12	CP 099	Ingeniería y Certificación Nacional Ltda., INCEN Ltda.	Organismos de certificación de productos	Extintores
13	CP 091	QMI-SAI CANADA LIMITED	Organismos de certificación de productos	Forestal
14	CP 092	Bureau Veritas Certification Chile S.A.	Organismos de certificación de productos	Forestal
15	CP 093	SGS Chile Ltda., Sector Certification And Business Enhancement (CBE)	Organismos de certificación de productos	Forestal
16	CP 088	CESMEC S.A., Division Certificacion	Organismos de certificación de productos	Insumos médicos
17	CP 004	IDIEM, Universidad de Chile / Estructura y Construcción, Sección Física de la Construcción	Organismos de certificación de productos	Materiales de construcción
18	CP 015	DICTUC S.A. / Servicios Mecánicos	Organismos de certificación de productos	Materiales de construcción

19	CP 056	IDIEM de la Universidad de Chile, Unidad de Certificacion	Organismos de certificación de productos	Materiales de construcción
20	CP 085	CESMEC Ltda. - Divison Certificacion	Organismos de certificación de productos	Materiales de construcción
21	CP 015	DICTUC S.A., AREA SERVICIOS MECANICOS	Organismos de certificación de productos	Materiales para obras e instalaciones sanitarias
22	CP 084	CESMEC Ltda. - Division Certificacion	Organismos de certificación de productos	Materiales para obras e instalaciones sanitarias
23	CP 028	Sociedad Certificadora del Maule Ltda.	Organismos de certificación de productos	Pecuaria
24	CP 035	CERTVET Ltda.	Organismos de certificación de productos	Pecuaria
25	CP 036	W.Q.S. Certificacoes Limitada	Organismos de certificación de productos	Pecuaria
26	CP 037	Certificadora de Productos Agropecuarios Ltda., CERTIEXPORT Ltda.	Organismos de certificación de productos	Pecuaria
27	CP 038	TECNOCARNES Ltda.	Organismos de certificación de productos	Pecuaria
28	CP 058	CERTILAB Chile E.I.R.L.	Organismos de certificación de productos	Pecuaria
29	CP 094	AGROINNOVA Ltda.	Organismos de certificación de productos	Pecuaria
30	CP 096	LIAF CONTROL S.R.L.	Organismos de certificación de productos	Pecuaria
31	CP 060	SICAL Ingenieros S.A.	Organismos de certificación de productos	Productos eléctricos
32	CP 061	INGCER S.A.	Organismos de certificación de productos	Productos eléctricos
33	CP 065	Laboratorios CERTIGAS/CERTELEC Ltda.	Organismos de certificación de productos	Productos eléctricos
34	CP 070	UNDERFIRE S.A.	Organismos de certificación de productos	Productos eléctricos
35	CP 076	CAM Chile SpA	Organismos de certificación de productos	Productos eléctricos
36	CP 077	Energia Ltda.	Organismos de certificación de productos	Productos eléctricos
37	CP 080	TUV Rheinland Chile S.A.	Organismos de certificación de productos	Productos eléctricos
38	CP 083	LENOR Chile SpA	Organismos de certificación de productos	Productos eléctricos
39	CP 087	CESMEC Ltda. - Division Certificacion	Organismos de certificación de productos	Productos eléctricos
40	CP 100	CERTIFICACION PROFESIONAL CERTPRO SPA	Organismos de certificación de productos	Productos eléctricos
41	CP 106	LACEM Ltda.	Organismos de certificación de productos	Productos eléctricos
42	CP 006	Bureau Veritas S. A. / Division Industrias	Organismos de certificación de productos	Productos para combustibles
43	CP 008	Servicio de Inspeccion Tecnica Ltda., SITEC	Organismos de certificación de productos	Productos para combustibles
44	CP 012	CATOX Ltda.	Organismos de certificación de productos	Productos para combustibles
45	CP 013	SICAL Ingenieros S.A.	Organismos de certificación de productos	Productos para combustibles
46	CP 014	DICTUC S.A. / Servicios Mecanicos	Organismos de certificación de productos	Productos para combustibles
47	CP 016	INTECIL Ltda.	Organismos de certificación de productos	Productos para combustibles
48	CP 017	Laboratorios CERTIGAS CERTELEC Ltda. / Combustibles	Organismos de certificación de productos	Productos para combustibles
49	CP 020	Sociedad Tecnica de Inspeccion S.A., STI	Organismos de certificación de productos	Productos para combustibles
50	CP 023	5M S.A., Departamento Industria	Organismos de certificación de productos	Productos para combustibles
51	CP 025	Empresa de Inspecciones Tecnicas y Control de Calidad, ITC Ltda.	Organismos de certificación de productos	Productos para combustibles
52	CP 040	Certificacion Industrial Certank Ltda.	Organismos de certificación de productos	Productos para combustibles
53	CP 051	Servicios de Ingeñeria SINCO Ltda.	Organismos de certificación de productos	Productos para combustibles

54	CP 062	INGCER S.A.	Organismos de certificación de productos	Productos para combustibles
55	CP 066	Inspeccion y Certificacion BBF Ltda.	Organismos de certificación de productos	Productos para combustibles
56	CP 071	ICOMCER Ltda.	Organismos de certificación de productos	Productos para combustibles
57	CP 072	Inspecciones Tecnicas S-INTEC Ltda.	Organismos de certificación de productos	Productos para combustibles
58	CP 086	CESMEC Ltda. - Division Certificacion	Organismos de certificación de productos	Productos para combustibles
59	CP 101	CERTIFICACION PROFESIONAL CERTPRO SPA	Organismos de certificación de productos	Productos para combustibles
60	CP 104	CERYLAB LTDA.	Organismos de certificación de productos	Productos para combustibles
61	CP 055	INTECIL Ltda.	Organismos de certificación de productos	Recipientes
62	CP 042	Certificacion Industrial Certank Ltda.	Organismos de certificación de productos	Recipientes e instalaciones industriales
63	CP 052	Servicios de Ingeñeria SINCO Ltda.	Organismos de certificación de productos	Recipientes e instalaciones industriales
64	CP 105	5M S.A., Departamento Industria	Organismos de certificación de productos	Recipientes e instalaciones industriales

Source: INI. Elaborated by CCGI-EESP/FGV.

13.3. Appendix 3 – Technical Regulations by sectors

A. Technical Regulations in Colombia

Table 13.36 - Technical regulation of vehicles and auto-parts (Colombia)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Resolution 2502/2018</i>		Extends the validity of Resolution 910/2008 on permissible levels of emission of pollutants produced by land mobile sources, on equipment and procedures for measuring these emissions and other provisions	N.A.
<i>Resolution 2875/2015</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies article 20 of Resolution 481/2009 of the Ministry of Commerce, Industry and Tourism	N.A.
<i>Resolution 5543/2013</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies Resolutions 935/2008, 934/2008, 481/2009 and 1949/2009	N.A.

<i>Resolution 2198/2013</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies articles 4, 5, 6, 17, 20, 22 and 29 of Resolution 4983 and has postponed its entry into force	FMVSS 105 ó FMVSS 121 ó FMVSS 135 CMVSS 135 Directivas 71/320/ECC (98/12) ECE R13 ó ECE R13-H ó ECE R13-05 ó ECE R13/06 ó 09norma australianas ADR 31 ó ADR 35A, ó ADR 35/01; la norma china GB 12676; La regulación japonesa del Ministerio de Infraestructura, Transporte y Turismo No. 1490 del 9 de noviembre de 2007 aplicable únicamente para buses y camiones; o las normas cuyos referentes correspondan con las normas mencionadas y, especialmente, las recomendaciones del documento TRANS/WP.29/343 Rev.18 del Foro Mundial para la Armonización de la Reglamentación sobre vehículos (WP.29) de la Comisión Económica para Europa de la ONU
<i>Resolution 1111/2013</i>		Modifies Resolution 910/2008 on permissible levels of emission of pollutants produced by land mobile sources, on equipment and procedures for measuring these emissions and other provisions	EURO IV, EURO V; Standard EPA; CFR 86; CFR 87; CFR 88; CFR 89;
<i>Resolution 538/2013</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Issues the Technical Regulation applicable to retroreflective tapes for use in motor vehicles and their trailers that are manufactured, imported or marketed in Colombia	NTC/ISO/IEC 17050; Norma Técnica Colombiana NTC 5807; Norma NTC-ISO 17025; Guía Técnica Colombiana GTC-ISO-IEC 67; ASTM D4956-11 ^a ; la DOT- C2; la Norma FMVS 08
<i>Resolution 2236/2012</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies the date of entry into force of Resolution 4983/2011	N.A.
<i>Resolution 4983/2011</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Issues the Technical Regulation applicable to components of brake systems for use in motor vehicles or their trailers, which are imported or manufactured domestically for use or commercialization in Colombia	FMVSS 105, 106, 116, 121, 135; NTC 1721; JIS 2233, 2601, 2605; SAE 661, 1153, 160, 1401, 1601, 1703, 1505, 1603; ECE R90
<i>Resolution 2899/2011</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies Resolutions 481/2009 and 230/2010 of the Ministry of Commerce, Industry and Tourism	N.A.

<i>Resolution 901/2010</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Partially modifies Resolution 934/2008	N.A.
<i>Resolution 230/2010</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies Resolution 481/2009	N.A.
<i>Resolution 1949/2009</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Derogates Resolution 1274 and issues Resolution "Whereby the technical regulation applicable to safety belts for use in motor vehicles, which are manufactured, imported or marketed in Colombia"	NTC 1570; NTC- ISO/IEC 17050 (Partes 1 y 2); Japonesa JIS D4604 reglamento Europeo ECE 16-04, en el reglamento de la Naciones Unidas ONU R16, o en la Norma Estadounidense FMVSS 209, la norma Australiana ADR 4/04, la norma China GB 14166 y las normas Brasileñas NBR 7337 98 y NBR 7338 98.
<i>Resolution 481/2009</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Derogates Resolution 3156/2006 and its amendments	N.A.
<i>Resolution 2649/2008</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Modifies Resolution 934/2008	NTC-ISSO-IEC-17050
<i>Resolution 1289/2008</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Partially modifies Resolution 935/2008	NTC-ISSO-IEC-17050; NTC1467
<i>Resolution 935/2008</i>	Ministry of Trade, Industry and Tourism/Ministry of Transport	Partially modifies Resolution 322/2002 and other provisions are adopted	ANSI/SAE Z26.1-1996, American National Standard for Safety Glazing Materials for Glazing Motor Vehicles and Motor Vehicle Equipment operating on Land Highways - Safety Standard o de la norma FMVSS 205 de noviembre 2 de 2006, Glazing Materials; o de los ensayos de las normas JIS R 3211:1998, Glazing Materials for Road Vehicles, y JIS R 3212:1998, Standard Test Method of Safety Glazing Materials for Road Vehicles; o de los ensayos del Regulación UNECE R-43; NTC 467:1996 (Primera actualización), Método estándar para determinar las propiedades del caucho. Grado de dureza (ASTM D 2240). NTC 914:1975, Toldeno. Especificaciones (ASTM D 362). NTC 1653:1981 (Primera actualización), Petróleo y sus derivados. Queroseno. Especificaciones (ASTM D

		3699).NTC 3337:1998 (Primera actualización), Plásticos. Determinación de la opacidad y la transmitancia; luminosa de plásticos transparentes (ASTM D 1003). NTC 4539:1998, Operación de aparatos expuestos a la luz y al agua, (tipo fluorescente UVCondensación) para exposición de materiales no metálicos (ASTM G53). NTC 4622:1999, Preservativos para madera. Tablas normalizadas para la corrección del volumen y de la gravedad específica para la creosota (ASTM D 618). 1985 annual Book of ASTM Standards2; SAE J673 APR 93, Automotive Safety Glazing; SAE J2020 JUN 89 Accelerated Exposure of Automotive Exterior Materials Using a Fluorescent UV and Condensation Apparatus; ISO 3536/1-92 Road vehicles-Safety glazing materials-Vocabulary-Part 14; ISO 3537-93 Road vehicles-Safety glazing materials-Test methods for mechanical properties; ISO 3538-78 Road vehicles-Safety glazing materials-Test methods for optical properties; ISO 3917-92 Road vehicles-Safety glazing materials-Test methods for resistance to radiation, High temperature, humidity, fire, and simulated weathering; ISO 4892-1 Plastics-Methods of exposure to laboratory light sources-Part 1: General guidance; ISO 4892-2 Plastics-Methods of exposure to laboratory light sources-Part 2: Xenon arc sources; ISO 4893-3 Plastics-Methods of exposure to laboratory light sources-Part 3: Fluorescent UV lamps; ISO 4892-4:1994, Methods of exposure to laboratory light sources-Part 4: Open flame carbon arc lamps; FMVSS 210, 49 CFR 571.210 Seat Assembly Anchorages; OSHA Standard 29 CFR 1910.106- Handling Storage and Use of Flammable Combustible Liquids; UL 752-1995, Safety Standard for Bullet Resistant Equipment
Resolution 934/2008	Ministry of Trade, Industry and Tourism/Ministry of Transport	Issues the Technical Regulation for security glazing resistant to bullets for use in automotive vehicles and their trailers, both domestic and imported, for sale in Colombia ANSI/SAE Z26.1-1996, American National Standard for Safety Glazing Materials for Glazing Motor Vehicles and Motor Vehicle Equipment operating on Land Highways - Safety Standard o de la norma FMVSS 205 de noviembre 2 de 2006, Glazing

		Materials; o de los ensayos de las normas JIS R 3211:1998, Glazing Materials for Road Vehicles, y JIS R 3212:1998, Standard Test Method of Safety Glazing Materials for Road Vehicles; o de los ensayos del Regulación UNECE R-43 (Revisión 1/Add.42 Rev.2 de febrero 11 de 2004), Uniform Provisions concerning the Approval of Safety Glazing and Glazing Materials. NTC 467:1996 (Primera actualización), Método estándar para determinar las propiedades del caucho. Grado de dureza (ASTM D 2240). NTC 914:1975, Toldeno. Especificaciones (ASTM D 362). NTC 1653:1981 (Primera actualización), Petróleo y sus derivados. Queroseno. Especificaciones (ASTM D 3699). NTC 3337:1998 (Primera actualización), Plásticos. Determinación de la opacidad y la transmitancia luminosa de plásticos transparentes (ASTM D 1003). NTC 4539:1998, Operación de aparatos expuestos a la luz y al agua, (tipo fluorescente UVCondensación) para exposición de materiales no metálicos (ASTM G53). NTC 4622:1999, Preservativos para madera. Tablas normalizadas para la corrección del volumen y de la gravedad específica para la creosota (ASTM D 618). 1985 annual Book of ASTM Standards² SAE J673 APR 93, Automotive Safety Glazing³ SAE J2020 JUN 89 Accelerated Exposure of Automotive Exterior Materials Using a Fluorescent UV and Condensation Apparatus³ ISO 3536/1-92 Road vehicles-Safety glazing materials-Vocabulary-Part 14 ISO 3537-93 Road vehicles-Safety glazing materials-Test methods for mechanical properties⁴ ISO 3538-78 Road vehicles-Safety glazing materials-Test methods for optical properties⁴ ISO 3917-92 Road vehicles-Safety glazing materials-Test methods for resistance to radiation, High

			temperature, humidity, fire, and simulated weathering ⁴ ISO 4892-1 Plastics-Methods of exposure to laboratory light sources-Part 1: General guidance ⁴ ISO 4892-2 Plastics-Methods of exposure to laboratory light sources-Part 2: Xenon arc sources ⁴ ISO 4893-3 Plastics-Methods of exposure to laboratory light sources-Part 3: Fluorescent UV lamps ⁴ ISO 4892-4:1994, Methods of exposure to laboratory light sources-Part 4: Open flame carbon arc lamps ⁴ FMVSS 210, 49 CFR 571.210 Seat Assembly Anchorages ⁵ OSHA Standard 29 CFR 1910.106- Handling Storage and Use of Flammable Combustible Liquids ⁶ UL 752-1995, Safety Standard for Bullet Resistant Equipment ⁷
Resolution 910/2008		Regulates the permissible levels of emission of pollutants produced by land mobile sources, defines the equipment and procedures for measuring said emissions, regulates article 91 of Decree 948/1995 and other provisions are adopted	N.A.
Resolution 322/2002	Ministry of Trade, Industry and Tourism/Ministry of Transport	Issues the Technical Regulation RTC-002MDE for security glazing that is manufactured or imported or traded for use in motor vehicles and their trailers, which circulate in Colombia	N.A.

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

Table 13.37 - Technical regulation of electric products (Colombia)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Resolution 40908/2018</i>	Ministry of Mines and Energy	Decides the permanence of the Technical Regulation of Electrical Facilities	There is no supporting standard
<i>Resolution 171/2013</i>	Ministry of Trade, Industry and Tourism/Ministry of the	Prohibits the manufacture and import of refrigerators, freezers and refrigerator-freezer combinations, for domestic use, that contain or require for their production or operation the	There is no supporting standard

Resolution 181294/2008	Environment and Territorial Development	hydrochlorofluorocarbon (HCFC) substances listed in Annex C of the Montreal Protocol, and other determinations are adopted	
	Ministry of Mines and Energy	Modifies the Technical Regulation of Electrical Facilities	NTC 4120 IEC 60479-2 NTC 2050 NTC 1340 IEC 60617, ANSI Y32, CSA Z99 e IEEE 315 IEC 60617 NTC 1461 ISO 3461 ANSIZ 535 ISO 3864-2 IEC 60417-1 National Electrical Safety Code, ANSI C2 versión 2002 IEC 60364 IEC 61936 -1 IEC 60479 IEEE 80 IEEE 837 NTC 2206 IEC-61000-5- 2 NTC 2050 IEC 60364-5-54 BS 7430 AS 1768 UL 467 UNESA 6501F NTC 2050 ASTM G 162 o la Norma ASTM G 1 IEC 60364-5-54 ANSI/IEEE 80 IEEE 242 IEC 60364-4-442 NTC 4552 IEEE- 81.2 IEC 61936-1 IEEE 1048 IEC 61230 ASTM F 855 IEC 60754-1-2 IEC 601034-2 IEC 331 IEC 332-3 IEC 332-1 UL 83 NTC 1332 IEC 60228 IEC-60064 IEC- 60432-1 IEC 60968 IEC 60969 UL 935 IEC-60335-2- 76 IEC 60454-3, NTC-1023 NTC 2208 NTC 3302, UL 510 ASTM - D 1000 NTC-1650 IEC- 60884-1 IEC 60309 - parte 1 y parte 2 UL 943 IEC 61008 -1 IEC 61008 - 2-1 IEC 61008 - 2-2, IEC 61009 -1 e IEC 61009 -2 IEC 61643-12 IEC 60664 IEC 60664-1 IEC 60071, IEC 60099, IEC 60364-4- 443 IEC 60364-5-534, IEC 61000-5-6, IEC 61312, IEEE 141 IEEE 142 NTC 4552 IEC 61643-1 IEC 60099-1 IEC 60099-4 UL 1449 IEEE C62.41-1 IEEE C62.41-2 e IEEE C62.45 NTC 1337 IEC.60669-1 IEC 60947-5 IEC 60947-1 IEC 60947- 5-1 IEC 60947-5-4 NTC 2116 NTC-IEC 947-2 IEC 60898 UL 489 NTC 2116 NTC-IEC 947-2 IEC 60898 y UL 489 IEC 17050UL 67 UL 508 NTC 3475 NTC 3278 NTC-IEC 60439-3 NTC 2050 NTC 1156 ASTM 117 IEC 62271-1 IEC 62271-200 UL 347 ANSI IEEE C37 NTC 1490 NTC 1656 NTC 3607 NTC 3997 NTC 4907 NTC 1954NTC 2050 IEC 60364-5-52 IEC601084 IEC60439-1 IEC60439-2 IEC60529 IEC61000-2-4 IEC 60423 IEC 60614-2-7 NEMA FG1 UL 85 UL 5 UL 870 UNE-EN 50086-2-3 NTC 979 NTC 1630NTC 3363 NTC171 NTC169 NTC105 IEC 439-2 IEC60439-2 UL 857NTC 2958 UL 50 UL 746C IEC 60670-1 IEC 60670-24 IEC 60998-2-5 ASTM A 633IEC 60826 IEC 60305 IEC 60060-2 IEC 60383 IEC 60273 NTC 2685 NTC 60660 NTC 1329 NTC 776 NTC 1056 NTC

			2222 ASTM D 4923 NTC 776, NTC 1056, NTC 2222 NTC 1093 NTC 1057 NTC 2083 NTC 1966 NTC 5193 NTC 172 ASTM - A 123, ASTM B 633 ASTM A 653 ISO 9223 NFPA 251 NFPA 252 NFPA 257 NFPA 80 ANSI A156.3 UL 10 B ASTM A 653 M ASTM E152 y EN 1634 -1 IEC 60269-1 IEC 60269-2-1 NTC 2133 IEC60282-1 IEC 60282-2 NTC 2132 IEC 60947-4-2 IEC 60947-1 IEC 60947-5-1 IEC 60947.4.1 JISC 4520 UL 508 CSA C22.2 SPEC 14 IEC 60831-1 IEC 60831-2 BS 1650 VDE 0560 CSA 22-2-190 UL 810 UL 945VA JIS C 4901NTC 3422 NTC 2834 NTC 2807 UL1778 IEEE 516 IEC 62271-200 IEC 60364-7-710 IEC 60364-7-7 10UL1047 NFPA número 99 IEC 61557-8 DIN VDE 0118-1 NEMA WC-58 ISO 17020
<i>Resolution 180632/2008</i>	Ministry of Mines and Energy	Extends the validity of the Technical Regulation of Electrical Facilities - RETIE, as well as the transience to demonstrate the conformity in facilities of final use for electricity	
<i>Resolution 180466/2007</i>	Ministry of Mines and Energy	Modifies the Technical Regulation of Electrical Facilities	There is no supporting standard NTC 2050 IEC serie 50 IEEE 100 NTC 4120 IEC 60479-2 NTC 1340 IEC 60617 ANSI Y32 CSA Z99 IEEE 315 NTC 1461 ISO 3461 National Electrical Safety Code, ANSI C2 versión 2002 IEC 60364-4-44 IEEE 80 IEC-61000-5-2 NTC 2050 IEC 60364-5-54 BS 7430 AS 1768 UL 467 UNESA 6501F NTC 2050 ASTM B117 ASTM G1 ASTM G162-99 ASTM G8-90 IEEE 81 IEEE-81.2 IEEE 1048 IEC 61230 ISO 8995 IEC-60064 IEC- 60432-1 UL 496 NTC 189 NTC 5103 IEC-60335-2-76 NTC-1650 IEC-60884-1 IEC 60309 UL 943 IEC 61008 -1 IEC 61008 - 2-1 IEC 61008 - 2-2 IEC 61009 -1 IEC 61009 -2 IEC 61643-12 IEC 60664 IEC 60664-1 IEC 60071 IEC 60099 IEC 60364-4-443 IEC 60364-5- 534 IEC 61000-5-6 IEC 61312 IEEE 141 IEEE 142 NTC 4552 IEC 61643-12 IEC 60664 IEC 60664-1IEC 60071 IEC 60099 IEC 60364-4-443 IEC 60364-5- 534 IEC 61000-5-6 IEC 61312 IEEE 141 IEEE 142 NTC 4552 NTC 1337 IEC 60669-1 IEC 60947-5 NTC 2116 NTC-IEC 947-2 UL 489 NTC 2805 IEC 61557-8 NTC 3475, NTC 3278, NTC IEC 60439-3 NTC 1490 NTC 1656 NTC 3607 NTC 3997 NTC

			4907 NTC 3609 NTC 618 NTC 1954 NFPA 251 NFPA 252 NFPA 257 NFPA 80 ANSI A156.3 UL 10 B ASTM A 653 M ASTM E152 y EN 1634 -1 NTC 2050 NEMA VE1 NEMA FG1 NEMA VE2 IEC601084 IEC60439-1 IEC60439-2 IEC60529 IEC61000-2-4 NTC171 NTC169 y NTC105 IEC 60071-2
<i>Resolution 4002/2007</i>	Ministry of Health and Social Protection	Adopts the Manual of Storage Capacity Requirements and/or conditioning for Medical Devices	There is no supporting standard
<i>Decree 4957/2007</i>	Ministry of Health and Social Protection	Establishes a deadline for obtaining the sanitary registration or marketing permit of some medical devices for human use and other provisions are issued	There is no supporting standard
<i>Decree 4725/2005</i>	Ministry of Health and Social Protection	Regulates the regime of sanitary registrations, marketing authorization and sanitary surveillance of medical devices for human use	There is no supporting standard
<i>Resolution 181419/2005</i>	Ministry of Mines and Energy	Clarifies some aspects of the Technical Regulation of Electrical Facilities	There is no supporting standard
<i>Resolution 180498/2005</i>	Ministry of Mines and Energy	Modifies partially Resolution 180398/2004	IEC 60617, ANSI Y32, CSA Z99, IEEE 315 National Electrical Safety Code, ANSI C2 versión 2002 IEEE 80 IEC 61000-5-2 NTC 2050 IEC 60364-5-54, BS 7430, AS 1768, UL 467, UNESA 6501F y NTC 2050 ASTM B117 Y ASTM G1 ASTM G162-99 y ASTM G8-90 IEC 60364-4-442, ANSI/IEEE 80, NTC 2050, NTC 4552 IEEE 1048 IEC 61230 IEC-60335-2-76 NTC-1650, IEC-60884-1, IEC 60309 - parte 1 y parte 2 UL 943, IEC 61008 -1, IEC 61008 - 2-1, IEC 61008 - 2-2, IEC 61009 -1 e IEC 61009 -2 IEC 61643-12, IEC 60664, IEC 60071, IEC 60099, IEC 60364-4- 443, IEC 60364-5-534, IEC 61000-5-6, IEC 61312, IEEE 141, IEEE 142 y NTC 4552 IEC 61643-1, IEC 60099-1, IEC 60099-4, UL 1449, IEEE C62.41-1, IEEE C62.41-2, IEEE C62.45 NTC 1490, NTC 1656, NTC 3607, NTC 3997, NTC 4907 NTC-3609 IEC 60826 IEC 62305-3 National Electrical Safety Code, ANSI C2-1997 NTC 317 ANSI/NEMA 250-1991 NTC 3229 ANSI/UL 1203-1988 NTC 2832 NTC 3765 NTC 2183 NTC 2386 NTC 2505 NTC 1340 NTC 1650 NTC 2545 NTC 2131 NTC 4552 (PAREI NA PAG 116)

<i>Resolution 180372/2005</i>	Ministry of Mines and Energy	Extends the entry into force of Resolution 180398/2004	There is no supporting standard
<i>Resolution 181760/2004</i>	Ministry of Mines and Energy	Extends the entry into force of Resolution 180398/2004	There is no supporting standard
<i>Resolution 180398/2004</i>	Ministry of Mines and Energy	Issues the Technical Regulation of Electrical Installations - RETIE, which sets the technical conditions that guarantee safety in the processes of Generation, Transmission, Transformation, Distribution, and Utilization of Electricity in the Republic of Colombia and dictates other provisions	IEC 60417-1 IEC serie 50 6 IEEE 100 IEC 60479-2 NTC 1340 IEC 60617, ANSI Y32, CSA Z99, IEEE 315 IEC 60364-4-44 IEC 60364-5-54 BS 7430 AS 1768 UL 467 UNESA 6501F NTC 2050 ANSI/IEEE 80 IEEE 1100 FIPS Pub 94 ISO 8995 IEC 64 NTC 3607 NTC-3609 NTC 2050 NTC -618 NTC 2050 ANSI C2

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.38 - Technical regulation of food (Colombia)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Decree 216/2019</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection	Modifies decree 262/2017	There is no supporting standard
<i>Resolution 5865/2018</i>	Ministry of Health and Social Protection	Determines the permanence of the technical regulations that regulate the production, processing of food and beverages, within the framework of the production chain process	There is no supporting standard
<i>Decree 2500/2018</i>	Ministry of Agriculture and Rural Development/Ministry of Health and Social Protection	Determines the permanence of the technical regulation on the requirements that milk must meet for human consumption that is obtained, processed, packaged, transported, sold, imported or exported in the country	There is no supporting standard

<i>Decree 2499/2018</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection/Ministry of Agriculture and Rural Development/Ministry of the Environment and Sustainable Development/Ministry of Transport	Determines the permanence of the technical regulation through which the Official Inspection, Surveillance and Control System for Meat, Meat Products and Meat Derivatives is created, destined for Human Consumption and the health and safety requirements that must be met in its primary production, profit, stripping, depress, processing, storage, transport marketing, sale, import or export	There is no supporting standard
<i>Decree 2476/2018</i>	Ministry of Health and Social Protection	Determines the permanence of the technical regulation that regulates the sanitary requirements that must be fulfilled by the establishments dedicated to the processing, packaging, transport, sale, import, export, and commercialization of snails destined for human consumption	There is no supporting standard
<i>Decree 2474/2018</i>	Ministry of Health and Social Protection	Determines the permanence of the technical regulation that regulates the manufacture, marketing, packaging, labeling, sanitary registration regime, quality control, sanitary surveillance and sanitary control of dietary supplements	There is no supporting standard
<i>Decree 262/2017</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection	Grants a deadline and other provisions are issued	There is no supporting standard
<i>Resolution 3888/2015</i>	Colombian Agricultural Institute	Adds a transitory article and modifies Resolution ICA 3168/2015	There is no supporting standard

<i>Resolution 3168/2015</i>	Colombian Agricultural Institute	Regulates the production, import, marketing, and export of seeds resulting from genetic improvement for planting in the country, as well as the registration of agronomic evaluation units and research units in plant breeding and other provisions are dictated	There is no supporting standard
<i>Resolution 719/2015</i>	Ministry of Health and Social Protection	Establishes the classification of foods for human consumption according to public health risk	There is no supporting standard
<i>Decree 1506/2014</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection	Modifies article 42 of decree 1686/2012	There is no supporting standard
<i>Resolution 3929/2014</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements to be met by fruits that are processed, packaged, transported, imported and commercialized in the national territory	Comisión del Codex Alimentarius FAO/OMS (utilización de aditivos alimentarios en las frutas procesadas)
<i>Resolution 2674/2013</i>	Ministry of Health and Social Protection	Regulates article 126 of Decree law 19/2012 and dictates other dispositions	There is no supporting standard
<i>Resolution 835/2013</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements that the materials, objects, containers and equipment of glasses and ceramics destined to be in contact with food and beverages for human consumption must comply	There is no supporting standard
<i>Resolution 834/2013</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements to be met by materials, objects, packaging and cellulose equipment and their additives intended to come into contact with food and alcoholic beverages for human consumption	There is no supporting standard

<i>Resolution 544/2013</i>	Ministry of Health and Social Protection	Modifies article 11 of Resolution 2508/2012	There is no supporting standard
<i>Resolution 242/2013</i>	Ministry of Health and Social Protection	Establishes the sanitary requirements for the operation of the plants of poultry benefit, depress and storage, commercialization, expenditure, transport, import or export of meat and edible meat products	There is no supporting standard
<i>Resolution 241/2013</i>	Ministry of Health and Social Protection	Establishes the sanitary requirements that must be met by special poultry benefit plants	There is no supporting standard
<i>Resolution 240/2013</i>	Ministry of Health and Social Protection	Establishes the sanitary requirements for the operation of the animal benefit plants of the bovine, bufalin and porcine species, plants of stripping and storage, commercialization, expenditure, transport, import or export of meat and edible meat products	There is no supporting standard
<i>Decree 2270/2012</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection/Ministry of Agriculture and Rural Development/Ministry of the Environment and Sustainable Development/Ministry of Transport	Modifies decree 1500/2007 and other provisions are dictated	There is no supporting standard
<i>Decree 1686/2012</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection	Establishes the technical regulation on the health requirements that must be met for the manufacture, processing, hydration, packaging, storage, distribution, transportation, marketing, sale, export and import of alcoholic beverages intended for human consumption	There is no supporting standard

<i>Decree 917/2012</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection/Ministry of Agriculture and Rural Development/Ministry of the Environment and Sustainable Development/Ministry of Transport	Modifies decree 1500/2007 and other provisions are dictated	
			There is no supporting standard
<i>Resolution 4143/2012</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements to be met by materials, objects, plastic and elastomeric containers and equipment and their additives, destined to come into contact with food and alcoholic beverages for human consumption	
			There is no supporting standard
<i>Resolution 4142/2012</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements that must be met by materials, objects, containers and metal equipment destined to come into contact with food and beverages for human consumption	
			Decisão 562/3003 da CAN
<i>Resolution 2508/2012</i>	Ministry of Health and Social Protection	Establishes the Technical Regulation on the requirements to be met by packaged foods containing trans fats and/or saturated fats	
			There is no supporting standard
<i>Resolution 2155/2012</i>	Ministry of Health and Social Protection	Issues the Technical Regulation on the sanitary requirements that must be fulfilled by the vegetables that are processed, packed, transported, imported and commercialized in the national territory	
			Codex Alimentarius Commission

<i>Resolution 2154/2012</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements to be met by oils and fats of vegetable or animal origin that are processed, packaged, stored, transported, exported, imported and/or marketed in the country, destined for human consumption and other provisions are issued	There is no supporting standard
<i>Resolution 683/2012</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements that must be met by materials, objects, containers and equipment destined to come into contact with food and alcoholic beverages for human consumption	There is no supporting standard
<i>Resolution 468/2012</i>	Ministry of Health and Social Protection	Establishes the technical regulation on sanitary requirements to be met by ships or vessels engaged in the capture, freezing or processing of fishery products and the procedure for certification of the HACCP system in motorboats or fishing vessels to the European Union is established	There is no supporting standard
<i>Resolution 122/2012</i>	Ministry of Health and Social Protection	Partially modifies Resolution 776/2008, which establishes the technical regulation on the physicochemical and microbiological requirements to be met by fishery products, in particular fish, molluscs and crustaceans for human consumption	There is no supporting standard
<i>Decree 1880/2011</i>	Ministry of Agriculture and Rural Development/Ministry of Health and Social Protection	Indicate the requirements for the commercialization of raw milk for direct consumption in the national territory	There is no supporting standard
<i>Resolution 4254/2011</i>	Ministry of Health and Social Protection	Adopts the technical regulation on requirements for the labeling of foods and identification of raw materials for human consumption that contain Genetically	There is no supporting standard

		Modified Organisms and other dispositions are dictated	
<i>Resolution 1511/2011</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements to be met by chocolate and chocolate products for human consumption, which is processed, packaged, transported, sold, imported or exported into the national territory	There is no supporting standard
<i>Resolution 1506/2011</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements of labeling that must comply the additives that are used for the preparation of food for human consumption in the national territory	There is no supporting standard
<i>Resolution 1185/2011</i>	Ministry of Health and Social Protection	Modifies item "c" of article 5 of Resolution 2997/2007 modified by article 1 of Resolution 1707/2010	There is no supporting standard
<i>Resolution 333/2011</i>	Ministry of Health and Social Protection	Establishes the technical regulation on labeling or nutritional labeling requirements that food packaged for human consumption must comply with	There is no supporting standard
<i>Resolution 3009/2010</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the health and safety requirements of meat coming from the order Crocodylia destined for human consumption and the dispositions for its benefit, stripping, storage, commercialization, sale, transport, import or export	There is no supporting standard
<i>Resolution 2195/2010</i>	Ministry of Health and Social Protection	Establishes the Technical Regulation on the requirements that must be met during the thermal process of hermetically packaged foods of low acidity and acidified, that are imported or exported for human consumption	There is no supporting standard

<i>Resolution 1031/2010</i>	Ministry of Health and Social Protection	Modifies article 6 of Resolution 2997/2007	There is no supporting standard
<i>Resolution 4150/2009</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements to be met by energy drinks for human consumption	There is no supporting standard
<i>Resolution 2606/2009</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements to be met by food additives that are manufactured, processed, packaged, stored, transported, sold, imported, exported, marketed and used in the manufacture of food for human consumption in the national territory	Codex Alimentarius Commission
<i>Resolution 715/2009</i>	Ministry of Health and Social Protection	Modifies article 6 of Resolution 2997/2007	There is no supporting standard
<i>Decree 2380/2009</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection/Ministry of Agriculture and Rural Development/Ministry of the Environment and Sustainable Development/Ministry of Transport	Modifies decrees 1500/2007 and 2965/2008 and other provisions are enacted	There is no supporting standard
<i>Decree 3863/2008</i>	Ministry of Health and Social Protection	Modifies Decree 3249/2006 and other provisions are enacted	CODEX, FDA, EC
<i>Decree 2490/2008</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements that must be fulfilled by the establishments dedicated to the processing, packaging, transportation, sale, import, export and commercialization of snails destined for human consumption	There is no supporting standard

<i>Resolution 776/2008</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the physicochemical and microbiological requirements to be met by fishery products, in particular fish, molluscs and crustaceans for human consumption	There is no supporting standard
<i>Resolution 775/2008</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements to be met by vinegar for human consumption	There is no supporting standard
<i>Resolution 3096/2007</i>	Ministry of Health and Social Protection	Regulates Decree 3249/2006 and other provisions are issued	There is no supporting standard
<i>Resolution 2997/2007</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the sanitary requirements to be met by powder whey as raw material for food for human consumption and other provisions are issued	There is no supporting standard
<i>Resolution 148/2007</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements to be met by canned tuna and the preparations of tuna that are manufactured, imported or exported for human consumption	There is no supporting standard
<i>Decree 4857/2007</i>	Ministry of Health and Social Protection	Modifies article 52 of Decree 3249/2006	There is no supporting standard
<i>Decree 1500/2007</i>	Ministry of Trade, Industry and Tourism/Ministry of Health and Social Protection/Ministry of Agriculture and Rural Development/Ministry of the Environment and Sustainable Development/Ministry of Transport	Establishes the technical regulation through which the Official Inspection, Surveillance and Control System for Meat, Meat Products and Meat Derivatives is created, destined for human consumption and the sanitary and safety requirements that must be met in its primary production, profit, stripping, depress, processing, storage, transport marketing, sale, import or export	There is no supporting standard

<i>Decree 3249/2006</i>	Ministry of Health and Social Protection	Regulates the manufacture, marketing, packaging, labeling, sanitary registration regime, quality control, health surveillance and sanitary control of dietary supplements, other provisions are enacted and Decree 3636/2005 is revoked	There is no supporting standard
<i>Decree 616/2006</i>	Ministry of Agriculture and Rural Development/Ministry of Health and Social Protection	Issues the technical regulation on the requirements that milk must meet for human consumption that is obtained, processed, packaged, transported, sold, imported or exported into the country	There is no supporting standard
<i>Resolution 337/2006</i>	Ministry of Health and Social Protection	Issues the Technical Regulation on the requirements that canned sardines must meet that are manufactured, imported or exported for human consumption	There is no supporting standard
<i>Resolution 5109/2005</i>	Ministry of Health and Social Protection	Establishes the technical regulation on the requirements of labeling or labeling that must be met by packaged foods and raw materials of food for human consumption	There is no supporting standard

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.39 - Technical regulation of oil and gas (Colombia)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Resolution 2580/2018</i>	Ministry of Trade, Industry and Tourism	Extends the validity of Resolution 2876/2013 that contains the Technical Regulation applicable to the information of the original stamp, labeling and physical appearance of transportable cylinders without seams or without welding, of high pressure for industrial and medicinal gases, which are imported or manufactured domestically for marketing or use in Colombia	There is no supporting standard

<i>Resolution 2502/2018</i>	Ministry of the Environment and Sustainable Development	Extends the validity of Resolution 910/2008 on permissible levels of emission of pollutants produced by land mobile sources, on equipment and procedures for measuring these emissions and other provisions	There is no supporting standard
<i>Decree 2496/2018</i>	Ministry of Mines and Energy/Ministry of Transport	Extends the validity of some regulations applicable to the hydrocarbons, biofuels and mining sectors	There is no supporting standard
<i>Resolution 41385/2017</i>	Ministry of Mines and Energy	Modifies Resolution 90902/2013 by means of which the Technical Regulation of Internal Facilities for Combustible Gas is issued	NTC 3631;
<i>Resolution 77507/2016</i>	Superintendence of Industry and Commerce	Adds the Seventh Chapter in Title VI of the Single Circular and regulates the metrological control applicable to liquid fuel dispensers and/or meters	There is no supporting standard
<i>Resolution 40724/2016</i>	Ministry of Mines and Energy/Ministry of the Environment and Sustainable Development	Modifies article 1 of Resolution 90963/2014, which amended article 4 of Resolution 898/1995, in relation to diesel fuel quality criteria (ACPM) and biofuels for use in diesel engines as a component of the mixing in combustion processes	There is no supporting standard
<i>Resolution 1814/2016</i>	Ministry of Trade, Industry and Tourism	Partially modifies the Technical Regulation for some gas appliances, which are manufactured domestically or imported, to be marketed in Colombia	EN 15376:2011; NTC/IEC/ISO 17025:2005 - Requisitos generales para la competencia de los laboratorios de ensayo y calibración;
<i>Resolution 789/2016</i>	Ministry of Mines and Energy/Ministry of the Environment	Establishes the technical regulations for the quality requirements of anhydrous ethanol fuel and anhydrous denatured fuel ethanol used as an	NTC/IEC/ISO 17025:2005 - Requisitos generales para la competencia de los laboratorios de ensayo y calibración; Norma ISO/IEC 17067

	and Sustainable Development	oxygenating component of gasolines and other provisions are dictated	
<i>Resolution 680/2015</i>	Ministry of Trade, Industry and Tourism	Issues the Technical Regulation for some gas appliances that are manufactured or imported to be marketed in Colombia	NTC-2832-1; NTC 3631; NTC 3531; NTC-3631; NTC 5042; NTC 888; NTC 3833; NTC-5042; Norma Técnica NTC-ISO-IEC 17067
<i>Resolution 90963/2014</i>	Ministry of Mines and Energy	Modifies article 4 of Resolution 898/1995, modified by Resolution 182087/2007	ASTM (42); ISO (38); JIS (5); EM (8); IFQC; RFS
<i>Resolution 2881/2014</i>	Ministry of Trade, Industry and Tourism	Modifies Resolution 957/2012 issued by the Ministry of Commerce, Industry and Tourism about workshops, equipment and processes of conversion by compressed natural gas for vehicular use	NTC-ISO/IEC 17024
<i>Resolution 344/2014</i>	Ministry of Trade, Industry and Tourism	Extends the transition regime foreseen in article 51 of Resolution 957/2012 about workshops, equipment and processes of conversion by compressed natural gas for vehicular use	There is no supporting standard
<i>Resolution 3/2014</i>	Ministry of Trade, Industry and Tourism	Issues the Technical Regulation applicable to workshops, equipment and processes of conversion to compressed natural gas for vehicular use	Norma R110 ONU
<i>Resolution 90902/2013</i>	Ministry of Mines and Energy	Issues the Technical Regulation of Internal Fuel Gas Facilities	NTC- ISO/ IEC 17050 (Partes 1 y 2); NTC 5347; NTC 2505; NTC 3833; NTC 3631; NTC 3631; NTC 2050; NTC 3949; ISO 17020
<i>Resolution 2876/2013</i>	Ministry of Trade, Industry and Tourism	Issues the technical regulation applicable to the information of the original stamp, labeling and physical appearance of transportable cylinders without seams or welding, of high pressure for industrial and medicinal gases, that are imported or manufactured domestically for commercialization or use in Colombia	NTC 5719; NTC 4584; NTC 2699; 49 CFR180.205; NTC-ISO-IEC 17000 y NTC-ISO-IEC 17020; NTC-ISO-IEC 17000; NTC-ISO-IEC 17020; CFR 49; ISO 13769; ISO 11114-1; NTC 2699:2009

<i>Resolution 1111/2013</i>	Ministry of the Environment and Sustainable Development	Modifies Resolution 910/2008 on permissible levels of emission of pollutants produced by land mobile sources, on equipment and procedures for measuring these emissions and other provisions	EURO V, EURO IV, EPA 10, ECE R-40, ECE R-49, CFR
<i>Resolution 6103/2012</i>	Ministry of Trade, Industry and Tourism	Modifies the date of entry into force of Resolution 957/2012	There is no supporting standard
<i>Resolution 957/2012</i>	Ministry of Trade, Industry and Tourism	Issues the Technical Regulation applicable to workshops, equipment and processes of conversion by compressed natural gas for vehicular use	NTCISO/IEC 17000 ; GTC-ISO/IEC 99; NTC 4822, NTC 1461; NTC 4821; ISO 15500-4; NTC 4830-5; ISO 15500-6; GTC-ISO-IEC 67; ISO 11439; GTC-ISO-IEC 67
<i>Decree 4892/2011</i>	Ministry of Mines and Energy	Dictates dispositions applicable to the use of fuel alcohols and biofuels for motor vehicles	There is no supporting standard
<i>Decree 1135/2009</i>	Ministry of Mines and Energy	Modifies Decree 2629/2007, in relation to the use of alcohol fuels in the country and with the measures applicable to automotive vehicles that use gasoline for its operation	There is no supporting standard
<i>Decree 1717/2008</i>	Ministry of Mines and Energy	Modifies Decree 4299/2005 and other provisions are established	There is no supporting standard
<i>Resolution 910/2008</i>	Ministry of the Environment and Sustainable Development	Regulates the permissible levels of emission of pollutants produced by land mobile sources, defines the equipment and procedures for measuring said emissions, regulates article 91 of Decree 948/1995 and other provisions are adopted	FTP-75; ECE-15+EUDC; ECE R-40; NTC 4542; Código Federal de Regulaciones de los Estados Unidos (CFR) partes 86 a 99 o en la Directiva 93/59 de la Unión Europea
<i>Decree 2629/2007</i>	Ministry of Mines and Energy	Dictates provisions to promote the use of biofuels in the country, as well as measures applicable to vehicles and other motorized devices that use fuels for their operation	There is no supporting standard

<i>Decree 1333/2007</i>	Ministry of Mines and Energy	Modifies Decree 4299/2005	There is no supporting standard
<i>Decree 4299/2005</i>	Ministry of Mines and Energy	Regulates article 61 of Law 812/2003 and other provisions are established	There is no supporting standard
<i>Resolution 180687/2003</i>	Ministry of Mines and Energy	Issues the technical regulation provided for in Law 693/2001, in relation to the production, storage, distribution and mixing points of fuel alcohols and their use in domestic and imported fuels	ASTM D 323 o D 5191; NTC - 2801
<i>Resolution 180790/2002</i>	Ministry of Mines and Energy/Ministry of Transport	Establishes the quality, storage, transport and supply requirements for aviation fuels for turbine engines and other provisions are issued	There is no supporting standard

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.40 - Pharmaceuticals (Colombia)

**TECHNICAL
REGULATION**
**RESPONSIBLE
ENTITY**

DESCRIPTION

SUPPORTING STANDARDS

<i>SUDecree 2473/2018</i>	Ministry of Health and Social Protection	Determines the permanence of some technical regulations regarding medicines and medical devices	There is no supporting standard
<i>Resolution 5849/2018</i>	Ministry of Health and Social Protection	Determines the permanence of some technical regulations on medicines	There is no supporting standard

<i>Resolution 5848/2018</i>	Ministry of Health and Social Protection	Determines the permanence of some technical regulations regarding medicines, medical devices, phytotherapeutic, homeopathic products and in vitro diagnostic reagents	There is no supporting standard
<i>Decree 821/2017</i>	Ministry of Health and Social Protection	Establishes the emergency technical regulation for obtaining the sanitary registry of antivenoms and adopts the Guide of Good Manufacturing Practices for its manufacture	WHO guidelines for the production control and regulation of Snake Antivenom Immunoglobulin; ISO 14644
<i>Resolution 553/2017</i>	Ministry of Health and Social Protection	Modifies Resolution 4490 of 2016 issued by the Guide for the Evaluation of Immunogenicity for Biological Medicines	WHO 67.21
<i>Resolution 4620/2016</i>	Ministry of Health and Social Protection	Grants a term to obtain the certification of Good Practices of Laboratory of Quality Control of Pharmaceutical Products and other dispositions are dictated	There is no supporting standard
<i>Resolution 4490/2016</i>	Ministry of Health and Social Protection	Issues the "Guide for the Evaluation of Immunogenicity for Biological Medicines" and other provisions are issued	1) "Guidance for Industry: Immunogenicity Assesment for Therapeutic Protein Products", emitida en agosto de 2014 por las siguientes entidades: Center for Drug Evaluation and Research (CDER) y Center for Biologics Evaluation and Research (CBER) de la Agencia Sanitaria de Estados Unidos, Food And Drug Administration -FDA-, adscrita al U.S. Department of Health and Human Services y 2) "Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins" emitida en diciembre de 2007 por el Committee for Medicinal Products for Human Use (CHMP) de la Agencia Sanitaria Europea, European Medicines Agency -EMA- (Documento Ref. EMEA/CHMP/BMWP/14327/2006). FDA
<i>Resolution 3690/2016</i>	Ministry of Health and Social Protection	Issues the Guide for the Stability of Biological Medicines	WHO Technical Report Series 962. Annex 3: Guidelines on stability evaluation of vaccines" de la Organización Mundial de la Salud —OMS-, "Quality of Biotechnological Products: Stability Testing of

			Biotechnological/Biological Products" de la Conferencia Internacional de Armonización —ICH
<i>Resolution 5402/2015</i>	Ministry of Health and Social Protection	Issues the Manual of Good Manufacturing Practices for the manufacture of biological medicines and establishes the instrument for its verification and dictates other provisions	Manual de Buenas Prácticas de Manufactura BPM, de la Organización Mundial de la Salud (OMS),
<i>Decree 1782/2014</i>	Ministry of Health and Social Protection	Regulates, for sanitary registration purposes, the evaluation procedure of quality, safety and efficacy of biological medicines and other provisions are dictated	
<i>Resolution 4058/2014</i>	Ministry of Health and Social Protection	Modifies Resolution 3619/2013 modified by Resolution 719/2014	There is no supporting standard
<i>Resolution 1606/2014</i>	Ministry of Health and Social Protection	Establishes provisions related to vaccines that are marketed in the country	There is no supporting standard
<i>Resolution 719/2014</i>	Ministry of Health and Social Protection	Modifies Resolution 3619/2013	Estados Unidos de Norteamérica (USP), Británica (BP), Codex Francés, Alemana (DAB), Europea e Internacional (OMS) o la que en su momento rija para la Unión Europea
<i>Resolution 3619/2013</i>	Ministry of Health and Social Protection	Adopts the Good Laboratory Practices for Quality Control Laboratories of Pharmaceutical Products and other dispositions are dictated	There is no supporting standard
<i>Resolution 4410/2009</i>	Ministry of Health and Social Protection	Issues the Technical Regulation that contains the Manual of Good Manufacturing Practices for Medicinal Gases	FDA, EMA, OMS
			NFPA99 (National Fire Production Association), la ISO10083 (National Standar Oxygen Concentrators for Use whith Medical Gas Pipeline System) de 1992, el Informe número 32 de la Organización Mundial de la Salud, OMS

<i>Decree 1030/2007</i>	Ministry of Health and Social Protection	Issues the Technical Regulation on the requirements to be met by medical devices on measure for visual and ocular health and the establishments in which these inputs are prepared and marketed and other provisions are issued	There is no supporting standard
<i>Resolution 1087/2001</i>	Ministry of Health and Social Protection	Adopts the Inspection Guide for Laboratories or Pharmaceutical Production Establishments, to obtain the Certificate of Compliance with Good Manufacturing Practices	There is no supporting standard
<i>Decree 549/2001</i>	Ministry of Health and Social Protection	Establishes the procedure for obtaining the Certificate of Compliance with Good Manufacturing Practices by drug manufacturing laboratories that are imported or produced in the country	There is no supporting standard

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

B. Technical Regulations in Chile

Table 13.41 - Technical Regulation on Vehicles and Auto-Parts

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Exempt resolution 335/2019</i>	Ministry of Transport and Telecommunications	Authorizes workshop to adapt vehicles to the use of compressed natural gas as fuel	NCh 2102, NCh 2109
<i>Law 21088/2018</i>	Ministry of Transport and Telecommunications	Modifies the traffic law to incorporate provisions on coexistence of the different means of transport	There are no supporting standards.

<i>Supreme decree 7/2015</i>	Ministry of the Environment	Establishes noise emission standard for light, medium and motorcycle vehicles	There are no supporting standards.
<i>Exempt resolution 2398/2014</i>	Ministry of Transport and Telecommunications	Modifies exempt resolution 613/2007 that establishes general guidelines for the accreditation of safety conditions and construction criteria of bodies of buses that perform interurban services of public transport of passengers	There are no supporting standards.
<i>Supreme decree 158/2013</i>	Ministry of Transport and Telecommunications	Provides systems and safety devices that must be complied by buses intended to provide interurban services of transport of public and private passengers indicated and amends Decree 175/2006	There are no supporting standards.
<i>Decree law 1/2009</i>	Ministry of Transport and Telecommunications	Establishes coordinated and systematized text of the Traffic Law	There are no supporting standards.
<i>Exempt resolution 613/2007</i>	Ministry of Transport and Telecommunications	Establishes the general guidelines for the accreditation of security conditions and construction criteria of bodies of buses intended to perform interurban services of public transportation of passengers	There are no supporting standards.
<i>Decree 175/2006</i>	Ministry of Transport and Telecommunications	Establishes safety conditions and construction criteria of bodies of buses intended to perform interurban services of public transportation of passengers	Article 95 of KMVSS, article 97 of KMVSS, article 103 of KMVSS
<i>Exempt resolution 2113/2004</i>	Ministry of Transport and Telecommunications	Sets general guidelines for accreditation of compliance with decree 55/94	There are no supporting standards.
<i>Supreme decree 129/2003</i>	Ministry of Transport and Telecommunications	Establishes rule of noise emission for buses of urban and rural collective locomotion	There are no supporting standards.

<i>Supreme decree 38/1999</i>	Ministry of Transport and Telecommunications	Establishes a conformity assessment procedure	There are no supporting standards.
<i>Supreme decree 160/1997</i>	Ministry of Transport and Telecommunications	Establishes conditions of granting and characteristics of individual certificates of homologation	There are no supporting standards.
<i>Supreme decree 54/1997</i>	Ministry of Transport and Telecommunications	Establishes rules of homologation of vehicles and issuance of certificates of individual homologation	There are no supporting standards.
<i>Supreme decree 165/1996</i>	Ministry of Transport and Telecommunications	Complements decree 211/91 of the same ministry that introduces the process of conformity assessment	NCh 1208
<i>Supreme decree 55/1994</i>	Ministry of Transport and Telecommunications	Establishes emission standards applicable to heavy motor vehicles indicated	There are no supporting standards.
<i>Law 17613/1972</i>	Ministry of Finance	Authorizes the free importation to the vehicle that indicates	There are no supporting standards.
<i>Law 17532/1971</i>	Ministry of Finance	Authorizes importation and frees of taxes indicated to the pointed out vehicle	There are no supporting standards.
<i>Law 17380/1970</i>	Ministry of Finance	Authorizes import and free of payment of rights indicated by the international of the vehicle that points out and modifies law 12120	There are no supporting standards.
<i>Law 16960/1968</i>	Ministry of Finance	Authorizes the importation of the motorized vehicle that indicates and frees it from indicated taxes and rights	There are no supporting standards.
<i>Law 16584/1966</i>	Ministry of Finance	Authorizes the international of the automobile indicated in the conditions pointed out	There are no supporting standards.

<i>Law 14868/1962</i>	Ministry of Finance	Establishes that extraordinary works made by the personnel of the Currency House of Chile, until the maximum that it points out, will not be subject to article 79 of the decree with force of law 338/1960; frees pointed out vehicles of the same service of the indicated obligation	There are no supporting standards.
<i>Law 12912/1958</i>	Ministry of Finance	Frees of all rights, taxes or contributions the internation of the indicating vehicle, intended for the municipality of the Andes	There are no supporting standards.
<i>Law 11117/1952</i>	Ministry of Finance	Frees of all right the internation of a van whose characteristics are pointed, intended for the public assistance of Cartagena	There are no supporting standards.

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.42 - Technical Regulation on Eletric Products

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARD
<i>Law 20701/2013</i>	Ministry of Energy	Procedure for granting electric concessions	There are no supporting standards
<i>Exempt resolution 649/2010</i>	Superintendence of electricity and fuels	Establishes the exceptional procedure for the execution and energization of new emergency internal electric facilities of new housing and existing houses damaged by the earthquake	NCh 10/84, NCh Elec. 4/2003
<i>Exempt resolution 1782/2008</i>	Superintendence of electricity and fuels	Establishes the procedure to be authorized as Verification Body of Electric Meters	There are no supporting standards
<i>Exempt resolution 262/2008</i>	Superintendence of electricity and fuels	Establishes the term for obtaining authorization as certification body and/or test laboratory according to D.S. N° 298, of 2005,	There are no supporting standards

		of the Ministry of Economy, Promotion and Reconstruction	
<i>Exempt resolution 236/2008</i>	Superintendence of electricity and fuels	Establishes a term to obtain the approved certificates indicated	There are no supporting standards
<i>Exempt resolution 740/2007</i>	Superintendence of electricity and fuels	Modifies the protocol for the product	There are no supporting standards
<i>Exempt resolution 90/2007</i>	Superintendence of electricity and fuels	Modifies resolution 1334 about labeling of electric products	There are no supporting standards
<i>Decree law 4/2007</i>	Ministry of Economy, Promotion and Reconstruction	Establishes the coordinated and systematized text of the decree with force of law 1/1982, general law of electrical services, in electrical energy	There are no supporting standards
<i>Supreme decree 62/2006</i>	Ministry of Economy, Promotion and Reconstruction	Approves power transfers regulation between generating companies established in the general electric services law	There are no supporting standards
<i>Exempt resolution 1607 2005</i>	Superintendence of electricity and fuels	Establishes periodicity of 10 years for the maintenance of electric meters that are not electronic	There are no supporting standards
<i>Exempt resolution 1139/2005</i>	Superintendence of electricity and fuels	Establishes procedure for the communication of commissioning of electric fences	AS/NZS 3016, IEC 60335-2-76, NCh Elec. 10/84
<i>Decree 298/2005</i>	Ministry of Economy, Promotion and Reconstruction	Approves regulation for the certification of electrical and fuel products, and repeals the indicative decree	ISO/CASCO system 8, ISO/CASCO system 7, ISO/CASCO System 5, ISO/CASCO System 3, ISO/CASCO System 1
<i>Decree 158/2003</i>	Ministry of Economy, Promotion and Reconstruction	Modifies Supreme Decree 327	There are no supporting standards

<i>Decree 119/1989</i>	Ministry of Economy, Promotion and Reconstruction	Approves sanctions regulation on electricity and fuels	There are no supporting standards
<i>Law 18410/1985</i>	Ministry of Finance	Creates the Superintendence of Electricity and Fuels	There are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.43 - Technical Regulation on Food

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARD
<i>Decree 123/2019</i>	Ministry of Agriculture	Modifies Decree 2/2016, of the Ministry of Agriculture, which approves technical standards of Law 20089, which creates the National System of Certification of Agricultural Organic Products	There are no supporting standards
<i>Decree 306/2017</i>	Ministry of Agriculture	Modifies Decree 122/2014, of the Ministry of Agriculture, that approves the special regulation for the vineyard grape, in the framework of Law 20656, that regulates the commercial transactions of agricultural products	There are no supporting standards
<i>Decree 122/2016</i>	Ministry of Agriculture	Approves Special Regulation for the vineyard grape, in the framework of the law that regulates the commercial transactions of agricultural products	ISO 17025
<i>Exempt decree 369/2016</i>	Ministry of Agriculture	Modifies Exempt Decree 156/1998, that enables ports for the importation of vegetables, animals, products and sub-products, and agricultural and livestock supplies, to the national territory	There are no supporting standards
<i>Decree 3/2016</i>	Ministry of Agriculture	Approves Regulation of Law 20089 that creates the national certification system for organic agricultural products	NCh-ISO 17065:2013, ISO/IEC 17065
<i>Decree 2/2016</i>	Ministry of Agriculture	Approves standards of Law 20089, which creates the national system of certification of agricultural organic products	NIMF 5, Chilean standard of organic production,

<i>Decree 18/2015</i>	Ministry of Agriculture	Modifies Supreme Decree 51/2011, of the Ministry of Agriculture, that establishes the Regulation of Law 20412, that establishes a system of incentives for the agro-environmental sustainability of the agricultural soils	There are no supporting standards
<i>Decree 12/2015</i>	Ministry of Agriculture	Modifies Decree 20/2013, of the Ministry of Agriculture, which approves the Special Regulation for corn, in the framework of Law 20656, which regulates the commercial transactions of agricultural products	There are no supporting standards
<i>Decree 7/2015</i>	Ministry of Agriculture	Modifies Decree 464/1994, of the Ministry of Agriculture, that establishes viticulture zoning and establishes norms for its use	There are no supporting standards
<i>Exempt decree 318/2015</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, on agriculture, which provides ports for the importation of vegetables, animals, products and by-products and agricultural and livestock inputs to the national territory for the temporary entry of products, by Angamos port in the region of Antofagasta	There are no supporting standards
<i>Decree 124/2015</i>	Ministry of Agriculture	Modifies Decree 19/2013, which approves the Regulation of Law 20656, which regulates the commercial transactions of agricultural products	ISO 17025
<i>Law 20797/2014</i>	Ministry of Agriculture	Creates a voluntary record of agricultural contracts	There are no supporting standards
<i>Exempt decree 317/2014</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, which enables ports for the import of vegetables, animals, products and sub-products and agricultural and livestock inputs to the national territory for the temporary entry of products, by puerto Punta Caullahuapi in the Region of Los Lagos	There are no supporting standards
<i>Decree 68/2014</i>	Ministry of Agriculture	Modifies Decree 464/1994, that establishes viticulture zoning and establishes norms for its use	There are no supporting standards
<i>Decree 64/2014</i>	Ministry of Agriculture	Modifies Corn Regulation, in the framework of the law that regulates the commercial transactions of agricultural products	NCh 531

<i>Decree 63/2014</i>	Ministry of Agriculture	Approves special regulation for wheat, in the framework of the law that regulates the commercial transactions of agricultural products	ISO 17025, U.S. standard 100
<i>Decree 62/2014</i>	Ministry of Agriculture	Modifies the Regulation of the law that regulates the commercial transactions of agricultural products	There are no supporting standards
<i>Law 20656/2013</i>	Ministry of Agriculture	Regulates commercial transactions of agricultural products	There are no supporting standards
<i>Decree 54/2013</i>	Ministry of Agriculture	Creates the National Beekeeping Commission	There are no supporting standards
<i>Decree 41/2013</i>	Ministry of Agriculture	Modifies Decree 95/2006, which created the Advisory Commission of the Minister of Agriculture for the Chilean food industry	There are no supporting standards
<i>Decree 39/2013</i>	Ministry of Agriculture	Approves modification to Regulation on structure and operation of slaughterhouses, refrigeration establishments, refrigeration chambers and peel plants	There are no supporting standards
<i>Decree 30/2013</i>	Ministry of Agriculture	Approves Regulation on livestock protection during transportation	There are no supporting standards
<i>Decree 29/2013</i>	Ministry of Agriculture	Modifies Decree 78/1986, which regulates Law 18455, that establishes rules on production, preparation and trade of ethyl alcohols, alcoholic beverages and vinegar	There are no supporting standards
<i>Decree 20/2013</i>	Ministry of Agriculture	Approves Special Regulation for corn, in the framework of the law that regulates the commercial transactions of agricultural products	ISO 17025, NCh 531
<i>Decree 19/2013</i>	Ministry of Agriculture	Approves Regulation of the law that regulates the commercial transactions of agricultural products	ISO 17025
<i>Exempt decree 780/2013</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, that enables ports for the importation of vegetables, animals, products, sub-products and agricultural and livestock supplies to the national territory	There are no supporting standards
<i>Exempt decree 388/2013</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, of the Ministry of Agriculture, which provides ports for the importation of vegetables, animals, products, by-products and agricultural and livestock inputs into the national territory for the temporary entry of products,	There are no supporting standards

		through Mataverí airport in Easter Island, Valparaíso Region and Port of Angamos of the Antofagasta Region	
<i>Decree 59/2012</i>	Ministry of Agriculture	Modifies Decree 78/1986, of the Ministry of Agriculture, which regulates Law 18455, which sets standards for the production, creation and sale of ethyl alcohol, alcoholic beverages and vinegars	There are no supporting standards
<i>Decree 51/2012</i>	Ministry of Agriculture	Establishes Regulation of Law 20412 establishing an incentive system for the agro-environmental sustainability of agricultural soils	There are no supporting standards
<i>Exempt decree 714/2012</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, of the Ministry of Agriculture, which temporarily enables ports for the importation of vegetables, animals, products, by-products and agricultural and livestock inputs to the national territory	There are no supporting standards
<i>Exempt decree 413/2012</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, that enables ports for the importation of vegetables, animals, products, by-products and agricultural supplies and livestock to the national territory for the admission of vegetables temporarily by the springs indicated by the port of colonel of the same commune, in the region of Biobío	There are no supporting standards
<i>Exempt decree 475/2011</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, of the Ministry of Agriculture, which authorizes ports for the importation of vegetables, animals, products and by-products and agricultural and livestock inputs into the national territory	There are no supporting standards
<i>Exempt decree 9/2011</i>	Ministry of Agriculture	Complements Exempt Decree 156/1998, of the Ministry of Agriculture, which provides ports for the importation of vegetables, animals, products and by-products and agricultural and livestock inputs into the national territory	There are no supporting standards
<i>Decree 100/2011</i>	Ministry of Agriculture	Modifica Decreto N° 78 de 1986, del Ministerio de Agricultura que reglamenta Ley N° 18455, que fija normas sobre producción, elaboración y	There are no supporting standards

		comercialización de alcoholes etílicos, bebidas alcohólicas y vinagres	
<i>Decree 86/2011</i>	Ministry of Agriculture	Modifies Supreme Decree 17, which formalizes technical standards of Law 20089, which creates a national system for certification of agricultural organic products and Supreme Decree 36, which approved the regulations of Law 20089	COPANT/ISO/IEC 65:1998, ISO/IEC 65:1996, NIMF 5
<i>Law 20412/2010</i>	Ministry of Agriculture	Establishes a system of incentives for the agro-environmental sustainability of agricultural land	There are no supporting standards
<i>Decree 59/2010</i>	Ministry of Agriculture	Establishes Regulation of Law 20412 that establishes a system of incentives for the Agro-environmental Sustainability of Agricultural Soils	NCh 2880:2004
<i>Decree 12/2010</i>	Ministry of Agriculture	Modifies Decree 464/1994, of the Ministry of Agriculture, which establishes viticulture zoning and sets standards for its use	There are no supporting standards
<i>Decree 11/2010</i>	Ministry of Agriculture	Modifies Decree 78/1986, of the Ministry of Agriculture, which establishes standards on production, creation and marketing of ethyl alcohol, alcoholic beverages and vinegars	There are no supporting standards
<i>Law 20358/2009</i>	Ministry of Agriculture	Modifies Law 19162, establishing traceability system for livestock and meat	There are no supporting standards
<i>Law 20332/2009</i>	Ministry of Agriculture	Modifies Law 18455, on production, processing and marketing of ethyl alcohols, alcoholic beverages and vinegars, to adapt their provisions to international commitments acquired by Chile and to improve their inspection mechanisms	There are no supporting standards
<i>Decree 98/2009</i>	Ministry of Agriculture	Modifies Decree 17/2007, which officializes technical standards of Law 20089 which created the National System of Certification of Agricultural Organic Products	There are no supporting standards
<i>Decree 94/2009</i>	Ministry of Agriculture	Approves Regulation on the structure and functioning of slaughterhouses, refrigeration establishments, refrigeration chambers and deposit plants and establishes minimum equipment of such establishments	There are no supporting standards

<i>Decree 25/2009</i>	Ministry of Agriculture	Creates International Coordinating Committee of the Ministry of Agriculture	There are no supporting standards
<i>Exempt decree 360/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 359/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 358/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 357/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 354/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 353/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 352/2009</i>	Ministry of Agriculture	Declares official standard of the Republic of Chile that indicates	There are no supporting standards
<i>Exempt decree 203/2009</i>	Ministry of Agriculture	Declares Official Rules of the Republic of Chile which indicate	There are no supporting standards
<i>Exempt decree 173/2009</i>	Ministry of Agriculture	Declares Official Rules of the Republic of Chile which indicate	There are no supporting standards
<i>Decree 95/2007</i>	Ministry of Agriculture	Creates Advisory Commission of the Minister of Agriculture for the Chilean food industry	There are no supporting standards
<i>Decree 80/2006</i>	Ministry of Agriculture	Creates a Council of the Silvoagropecuary Exports Fund, regulates its functioning and establishes rules to approve the projects posted to be financed with a charge to such fund	There are no supporting standards
<i>Decree 464/1995</i>	Ministry of Agriculture	Establishes viticulture zoning and establishes rules for its use	There are no supporting standards
<i>Law 19162/1992</i>	Ministry of Agriculture	Establishes compulsory system of classification of livestock, typification and nomenclature of its meat and regulates the operation of slaughterhouses, refrigerators and establishments of the meat industry	There are no supporting standards
<i>Decree 78/1986</i>	Ministry of Agriculture	Regulates Law 18455 that establishes rules on production, processing and marketing of ethylic alcohols, alcoholic beverages and vinegars	There are no supporting standards

<i>Law 18455/1985</i>	Ministry of Agriculture	Establishes rules on production, processing and marketing of ethyl alcohols, alcoholic beverages and vinegars, and derogates Book I of Law 17105	There are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.44 - Technical Regulation on Oil and Gas

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Exempt resolution 336/2019</i>	Ministry of Transport and Telecommunications	Authorizes workshop for the effects of the provisions of number 5 of Resolution 65/2000, of the Ministry of Transport and Telecommunications	There are no supporting standards
<i>Decree 108/2014</i>	Ministry of Finance	Security Regulation for facilities of storage, transportation and distribution of liquefied petroleum gas and associated operations	There are no supporting standards
<i>Decree 102/2013</i>	Ministry of Energy	Approves safety Regulation for the transportation of licuated natural gas	NCh 2404.Of1997
<i>Decree 101/2013</i>	Ministry of Energy	Modifies the safety regulation for facilities and operations of production and refinement, transport, storage, distribution and catering of liquid fuels	EN 14620-3 and NFPA 59A - 2006
<i>Decree 67/2012</i>	Ministry of Energy	Approves Regulation of safety of plants of licuated natural gas	NFPA 59A-2006, UNE-6210 Edition 2001
<i>Exempt resolution 3034/2011</i>	Ministry of Energy	Authorizes provisionally the project of Satellite Plant for Regasification of Liquefied Natural Gas in Agrícola Chorombo	There are no supporting standards
<i>Law 20339/2009</i>	Superintendence of electricity and fuels	Incorporates to law n° 20.063, the liquefied natural gas fuel and modifies the enforcement of decree law 1/1978, of the Ministry of Mining	There are no supporting standards

<i>Exempt resolution</i> 2076/2009	Superintendence of electricity and fuels	Approves protocols to the certification, periodic inspection and the verification of conversion of interior gas installations	There are no supporting standards
<i>Exempt resolution</i> 1250/2009	Superintendence of electricity and fuels	Establishes a procedure for the authorization and control of certification entities of internal gas installations and procedures for certification, inspection and verification of the conversion of indoor facilities	UNE EN 30-1-1
<i>Exempt resolution</i> 292/2009	Superintendence of electricity and fuels	Establishes requirements for the authorization of testing laboratories, inspection bodies and certification bodies, and the Liquefied Natural Gas Plant certification system	There are no supporting standards
<i>Exempt resolution</i> 259/2009	Superintendence of electricity and fuels	Authorizes the project of Satellite Plant for Regasification of Liquefied Natural Gas (LNG) of Pemuco	ASTM B 88:2002, ASTM B 837:2001, NCh 953, UNE 60765:1997, UNE-EN 625:1996, UNE EN 397:1994
<i>Decree</i> 280/2009	Ministry of Economy, Promotion and Reconstruction	Approves safety regulation for the transport and distribution of gas of the network	There are no supporting standards
<i>Decree</i> 160/2009	Ministry of Economy, Promotion and Reconstruction	Establishes the new "Regulation of Safety for Facilities and Operations of Production, Refining, Transportation, Storage, Distribution and Supply of Liquid Fuels"	There are no supporting standards
<i>Circular office</i> 496/2008	Superintendence of electricity and fuels	Establishes information to be delivered regarding the installation of devices and systems for the evacuation of gases produced by combustion	There are no supporting standards
<i>Decree</i> 20/2008	Ministry of Economy, Promotion and Reconstruction	Modifies the Regulation of Indoor Facilities and Gas Meters	NCh 2404.Of1997

<i>Exempt resolution 1146/2008</i>	Superintendence of electricity and fuels	Establishes electronic procedure for issuing and registering certificates of fuel products, which are indicated	EN 14620-3 and NFPA 59A - 2006
<i>Exempt resolution 262/2008</i>	Superintendence of electricity and fuels	Establishes the term for obtaining authorization as certification body and/or test laboratory according to D.S. 298/2005, of the Ministry of Economy, Development and Reconstruction	NFPA 59A-2006, UNE-6210 Edition 2001
<i>Exempt resolution 60/2008</i>	Superintendence of electricity and fuels	Modifies test protocols for the products indicated	There are no supporting standards
<i>Exempt resolution 1191/2007</i>	Superintendence of electricity and fuels	Establishes conditions of accreditation for the application of transitory article of the Supreme Decree 66/2007 of the Ministry of Economy, Promotion and Reconstruction	There are no supporting standards
<i>Exempt resolution 1080/2007</i>	Superintendence of electricity and fuels	Approves and replaces test protocols for the indicated fuel products	There are no supporting standards
<i>Decree 277/2007</i>	Ministry of Economy, Promotion and Reconstruction	Approves Safety Regulation for Liquefied Natural Gas Plants	UNE EN 30-1-1
<i>Decree 66/2007</i>	Ministry of Economy, Promotion and Reconstruction	Approves Regulation of Indoor Installations and Gas Meters	There are no supporting standards
<i>Exempt resolution 1234/2006</i>	Superintendence of electricity and fuels	Establishes procedure for the realization, by electronic means, of procedures indicated before the Superintendence of electricity and fuels	ASTM B 88:2002, ASTM B 837:2001, NCh 953, UNE 60765:1997, UNE-EN 625:1996, UNE EN 397:1994
<i>Decree 319/2005</i>	Ministry of Economy, Promotion and Reconstruction	Establishes quality specifications of the indicated fuels	There are no supporting standards

<i>Decree 298/2005</i>	Ministry of Economy, Promotion and Reconstruction	Approves regulation for the certification of electrical and fuel products, and repeals the indicative decree	There are no supporting standards
<i>Resolution 1384/2005</i>	Ministry of Economy, Promotion and Reconstruction	Revokes Resolution 2016/2005	There are no supporting standards
<i>Decree 67/2004</i>	Ministry of Economy, Promotion and Reconstruction	Approves network gas service regulation	NCh 2404.Of1997
<i>Exempt resolution 1852/2002</i>	Ministry of Economy, Promotion and Reconstruction	Modifies the Exempt Resolution 489/1999, which updates the procedure for the periodic inspection of gas facilities	EN 14620-3 and NFPA 59A - 2006
<i>Exempt resolution 1073/2002</i>	Ministry of Economy, Promotion and Reconstruction	Modifies Exempt Resolution 489/1999, which updates procedure for the periodic inspection of gas facilities	NFPA 59A-2006, UNE-6210 Edition 2001
<i>Exempt resolution 579/2001</i>	Ministry of Economy, Promotion and Reconstruction	Complements procedure for periodic inspection of gas facilities	There are no supporting standards
<i>Exempt resolution 1277/1999</i>	Ministry of Economy, Promotion and Reconstruction	Updates procedure for periodic inspection of gas facilities	There are no supporting standards
<i>Exempt resolution 489/1999</i>	Ministry of Economy, Promotion and Reconstruction	Updates procedure for the periodic inspection of gas facilities	There are no supporting standards
<i>Decree 90/1996</i>	Ministry of Economy, Promotion and Reconstruction	Approves safety regulations for storage, refining, transportation and posting to the public of liquid fuels derived from petroleum	UNE EN 30-1-1

<i>Decree 263/1995</i>	Ministry of Economy, Promotion and Reconstruction	Approves Regulation on provisional and definitive concessions for the distribution and transportation of gas	There are no supporting standards
<i>Decree 254/1995</i>	Ministry of Economy, Promotion and Reconstruction	Approves safety Regulation for transportation and distribution of natural gas	ASTM B 88:2002, ASTM B 837:2001, NCh 953, UNE 60765:1997, UNE-EN 625:1996, UNE EN 397:1994
<i>Decree 119/1989</i>	Ministry of Economy, Promotion and Reconstruction	Approves the regulation of sanctions on electricity and fuels	There are no supporting standards
<i>Decree 379/1986</i>	Ministry of Economy, Promotion and Reconstruction	Approves regulation on minimum requirements for safety for storage and handling of liquid fuels derived from petroleum, intended to own consumption	There are no supporting standards
<i>Law 18410/1985</i>	Ministry of Finance	Creates the Superintendence of Electricity and Fuels	There are no supporting standards
<i>Decree 226/1982</i>	Ministry of Economy	Security requirements for facilities and premises of storage of fuels	NCh 2404.Of1997
<i>Decree 132/1979</i>	Ministry of Economy, Promotion and Reconstruction	Establishes technical, quality and development standards control procedure applicable to crude petroleum, to fuels derived from this and to any other class of fuel	EN 14620-3 and NFPA 59A - 2006
<i>Decree law 1/1979</i>	Ministry of Mining	Derogates Decree 20/1964 and replaces it for other rules	NFPA 59A-2006, UNE-6210 Edition 2001
<i>Decree law 323/1931</i>	Ministry of Interior	Gas Services Law	There are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

Table 13.45 - Pharmaceutical products (Chile)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>Law 20850/2015</i>	Ministry of Health	Creates a financial protection system for diagnostics and high cost treatments and render posthumous tribute to Don Luis Ricarte Soto Gallegos	There are no supporting standards
<i>Supreme decree 84/2015</i>	Ministry of Health and Ministry of Finance	Modifies supreme decrees 404 and 405, both of 1983, regulation of narcotics and psychotropic regulation, respectively, both of the Ministry of Health	There are no supporting standards
<i>Decree 62/2015</i>	Ministry of Health	Approves the regulation about the use of resources to buy bioequivalent medicines on the primary level of health	Technical norm 136/2012, technical norm 131/2012
<i>Decree 1/2015</i>	Ministry of Health	Modifies the Supreme Regulations 466/1984 of Pharmacies, Drugstores, Pharmaceutical Stores, First Aid and Deposits, 405/1983, Regulation of Psychotropic and Narcotic Products and 3/2010 Regulation of the National System of Control of Pharmaceutical Products for Human Use	There are no supporting standards
<i>Law 20724/2014</i>	Ministry of Health	Modifies the Sanitary Code regarding regulation of pharmacies and medicines	There are no supporting standards
<i>Decree 14/2014</i>	Ministry of Health	Approves conventions for commitment of functions of the Institute of Public Health of Chile to be assumed by the Regional Ministerial Health Secretariats in the field of authorization, control and sanitary audit of establishments and pharmaceutical products	There are no supporting standards

<i>Law 20584/2012</i>	Ministry of Health	Regulates the rights and duties that people have in relation to actions linked to their health care	There are no supporting standards
<i>Decree 38/2012</i>	Ministry of Health	Approves Regulation on the rights and duties of persons in relation to activities linked to their health care	There are no supporting standards
<i>Decree 79/2010</i>	Ministry of Health	Regulation applicable to the preparation of pharmaceutical preparations in pharmacy recipes	There are no supporting standards
<i>Supreme decree 3/2010</i>	Ministry of Health	Approves Regulation of the national system for the control of pharmaceutical products for human use	There are no supporting standards
<i>Decree law 1/2005</i>	Ministry of Health	Establishes coordinated and systematized text of Decree law 2763/1979 and of Laws 18933 and 18469	There are no supporting standards
<i>Exempt resolution 515/2004</i>	Ministry of Health	Approves the National Drug Policy in Health Reform	There are no supporting standards
<i>Exempt resolution 1248/1996</i>	Ministry of Health	Approves the National Drug Policy	There are no supporting standards
<i>Decree law 1/1989</i>	Ministry of Health	Determines matters requiring express health authorization	There are no supporting standards
<i>Decree 466/1984</i>	Ministry of Health	Approves Regulation for pharmacies, drugs, pharmaceutical warehouses, kittens and authorized deposits	There are no supporting standards
<i>Decree 161/1982</i>	Ministry of Health	Approves Hospital and Clinical Regulation	There are no supporting standards
<i>Decree law 725/1967</i>	Ministry of Health	Health Code	There are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

C. Technical Regulations in Mexico

Table 13.46 - Technical regulation of vehicles and auto-parts (Mexico)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>NOM-116-SCFI-1997</i>	Economy Secretariat	automotive industry - lubricating oils for gasoline or diesel engines - commercial information.	there are no supporting standards
<i>NOM-116-SCFI-1997</i>	Economy Secretariat	automotive industry - lubricating oils for gasoline or diesel engines - commercial information.	NMX-L-69-1995-SCFI
<i>NOM-119-SCFI-2000</i>	Economy Secretariat	Automotive Industry-Automotive Vehicles-Safety Belts-Safety specifications and test methods.	NOM-008-SCFI-1993, NMX-A-065-1995-INNTEX , NMX-A-066-1994-INNTEX, NMX-A-070-1964, NMX-A-073-1995-INNTEX, NMX-A-165/1,2,3,4-1995-INNTEX, NMX-CH-027-1994-SCFI, NMX-D-050-1974 , NMX-D-058-1974, NMX-D-060-1974, NMX-D-122-1973, NMX-Z-012-1987.ISO 3776-1989, ISO 1417-1974, FMVSS 209 1993, FMVSS 210 1993, FMVSS 302 1993, SAE-J-4 c 1991, SAE-J-140a 1990, SAE-J-141 1990, SAE-J-117 1992, SAE-J-787 1993, SAE-J-339 1994, SAE-J-114 1993, SAE-J-726-1993.
<i>NOM-160-SCFI-2014</i>	Economy Secretariat	commercial practices-regulatory elements for the commercialization of new vehicles.	there are no supporting standards
<i>NOM-194-SCFI-2015</i>	Economy Secretariat	essential safety devices in new vehicles-safety specifications.	Chilean Standard: "Dictates rules on safety elements of passenger and commercial light vehicles", published as last amended on January 20, 2010 (This Official Mexican Standard partially agrees with this norm)
<i>NOM-001-SCT-2-2016</i>	Secretary of Communication and Transportation	metal plates, identification decals and circulation cards used in automobiles, tractocamiones, buses, trucks, motorcycles, trailers, semi-trailers, converters and cranes, registered in the mexican republic, feder license	NMX-B-001-CANACERO-2009, NMX-B-055-1988, NMX-D-122-1973, NMX-Z-012/1-1987, NMX-Z-012/2-1987, NMX-Z-012/3-1987, NMX-C-426-ONNCCE-2003, NOM-008-SCFI-2002
<i>NOM-163-SEMARNAT-ENER-SCF-2013</i>	Energy	carbon bioxide emissions (co2) from the exhaust and its equivalence in terms of fuel performance, applicable to new automotive	NMX-AA-011-1993-SCFIFederal Code of Regulations of the United States Environmental Protection Agency of America volume 40, parts 85, 86 and 600 revised on July 1, 1994, by the Protection Agency Environmental of the

		vehicles of gross vehicular weight of up to 3 857 kilograms.	United States. Final Regulation of Emissions of Greenhouse Gases for Light Vehicles and the Average Corporation for the Fuel Economy (Light-Duty Vehicle Greenhouse Gas Emissions Standards and Corporate Average Fuel Economy Standards. Final Rule, May 2010).
<i>NOM-011-SECRE-2000</i>	Energy	compressed natural gas for automotive use. minimum safety requirements in vehicle installations.	there are no supporting standards
<i>NOM-080-SEMARNAT-1994</i>	Secretariat of Environment and Natural Resources	That establishes the maximum permissible limits of noise emission from the exhaust of motor vehicles, motorcycles and motorized tricycles in circulation and their measurement method.	there are no supporting standards
<i>NOM-082-SEMARNAT-1994</i>	Secretariat of Environment and Natural Resources	That establishes the maximum permissible limits of noise emission from the exhaust of motor vehicles, motorcycles and motorized tricycles in circulation and their measurement method.	there are no supporting standards
<i>NOM-079-SEMARNAT-1994</i>	Secretariat of Environment and Natural Resources	That establishes the maximum permissible limits of noise emission of new automotive vehicles in plant and their measurement method.	there are no supporting standards
<i>NOM-077-SEMARNAT-1995</i>	Secretariat of Environment and Natural Resources	That establishes the measurement procedure for the verification of emission levels of the opacity of the smoke coming from the exhaust of the automotive vehicles in circulation that use diesel as fuel.	there are no supporting standards
<i>NOM-050-SEMARNAT-1993</i>		Establishing the maximum permissible levels of the emission of pollutant gases from the exhaust of automotive vehicles in circulation using liquefied petroleum gas, natural gas or other alternate fuels as a combustible.	there are no supporting standards
<i>NOM-049-SEMARNAT-1993</i>	Secretariat of Environment and Natural Resources	That establishes the characteristics of the equipment and the measurement procedure, for the verification of the emission levels of polluting gases, coming from the motorcycles in	there are no supporting standards

		circulation that use gasoline or gasoline-oil mixture as combus.	
<i>NOM-048-SEMARNAT-1993</i>	Secretariat of Environment and Natural Resources	That establishes the maximum permissible levels of emission of hydrocarbons, carbon monoxide and smoke, from the exhaust of motorcycles in circulation that use gasoline or mesclagoline-aceit as fuel.	there are no supporting standards
<i>NOM-047-SEMARNAT-2014</i>	Secretariat of Environment and Natural Resources	establishing the characteristics of the equipment and the measurement procedure for the verification of the limits of emission of pollutants, arising from automotive vehicles in circulation using gasoline, liquefied petroleum gas, natural gas	NMX-AA-023-1986 Code of Federal Regulations. Protection of Environment. 40, Parts 86 to 99, revised July 1, 1997, U.S.A
<i>NOM-045-SEMARNAT-2017</i>	Secretariat of Environment and Natural Resources	Environmental protection.- vehicles in circulation using diesel as a combustible.- maximum permissible limits of opacity, test procedure and technical characteristics of the measurement equipment.	NMX-AA-023-1986, NMX-EC-17020-IMNC-2014, NMX-EC-17025-IMNC-2006 ISO 11614-1999, Code of Federal Regulations 40, part 81 to 99, revised july 2000, U.S.A.), Directive of the European Council, of August 2, 1972, SAE-J225-v001 Diesel Engine Smoke Measurement, 1996, ISO 11614-1999, UNE 82503:1999.
<i>NOM-045-SEMARNAT-2006</i>	Secretariat of Environment and Natural Resources	Environmental protection.- vehicles in circulation that use diesel as fuel.- maximum permissible limits of opacity, test procedure and technical characteristics of the measurement equipment.	NMX-AA-023-1986, NMX-S025-IMNC-2000, NMX-EC-17020-IMNC-2000, NMX-EC-17025-IMNC-2000 American National Standard. SAE J-1667, Code of Federal Regulations 40, part. 81 to 99, revised July 2000, U.S.A, DIRECTIVA DEL CONSEJO EUROPEO, del 2 de agosto de 1972, DIRECTIVA DEL CONSEJO EUROPEO, del 2 de agosto de 1972, ISO 11614:1999(E), Internacional Normal ISO 11614, ISO 11614,
<i>NOM-044-SEMARNAT-2017</i>	Secretariat of Environment and Natural Resources	Establishes the maximum permissible limits for the emission of carbon monoxide, nitrogen oxides, non-methane hydrocarbons, non-methane hydrocarbons, non-oxide nitrogen, particles and ammonia, from the exhaust of new engines using	there are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.47 - Technical regulation of electric (Mexico)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>NOM-001-SCFI-1993</i>	Economy Secretariat	Electronic home appliances powered by different sources of electrical energy-Safety requirements and test methods for type approval.	NMX-I-7/12, NMX-I-19, NOM-008-SCFI IEC-65-1985, IEC-65-1987, IEC-529-1976
<i>NOM-003-SCFI-2014</i>	Economy Secretariat	Electrical products-safety specifications.	NMX-J-038/1-ANCE-2005, NMX-J-175/1-ANCE-2005, NMX-J-307-ANCE-2011, NMX-J-515-ANCE-2008, NMX-J-521/1-ANCE-2012, NMX-J-524/1-ANCE-2013, NMX-J-588-ANCE-2012. ISO/IEC 17067:2013, Guide 15 ISO/IEC Code of principles on “Reference to standards”; IEC 60335-1 (2004-07)-Household and similar electrical appliances-Safety-Part 1: General requirements; IEC 60745-1 (2003-08)-Hand-held motor operated tools-Safety-Part 1: General requirements.; IEC 60974-1 (2000-03)-Arc welding equipment-Part 1: Welding power sources; Guide ISO/IEC 51(1999-12), Safety aspects-Guidelines for their inclusion in standards; Guide 104 (2010-08), The preparation of safety publications and the use of basic safety publications and group safety publications; Guide ISO/IEC 37 (2012-12), Instructions for use of products of consumer interest; Guide ISO/IEC 14 (2003-05), Purchase information on goods and services intended for consumers; ISO/IEC 76 (2008-01), Development of service standards-Recommendations for addressing consumer issues; ISO/IEC 31010 (2009-11), Risk management-Risk assessment techniques.
<i>NOM-016-SCFI-1993</i>	Economy Secretariat	Electronic devices for office use and powered by different sources of electrical energy - Safety requirements and test methods. (It is ratified for five years according to the resolution published in D. O. F. on 06/29/2005)	there are no supporting standards
<i>NOM-017-ENER/SCFI-2012</i>	Economy Secretariat	Energy efficiency and safety requirements of compact, self-balanced fluorescent lamps. limits and testing methods.	there are no supporting standards

<i>NOM-021-ENER/SCFI-2017</i>	Economy Secretariat	Energy efficiency and safety requirements for the user in room type air conditioners. Boundaries, testing and labeling methods.	NMX-J-521/1-ANCE-2012, NMX-J-521/2-40-ANCE-2014, ANSI/ASHRAE-16-1983 Method of Testing for Rating Room Air Conditioners and Packaged Terminal Air Conditioners; ANSI/AHAM-RAC-1-2008 Room Air Conditioners; CFR Part 430 Final Rule Energy Conservation Program for Consumer Products; Office of Codes and Standards- Office of Energy Efficiency and Renewable Energy, U.S. Department Of Energy. July 2013; CFR Part 430 Test Procedure Appendix F Subparte B of Part 430 Uniform test method for measuring the energy consumption of room air conditioners. Documento publicado por el U.S. Department Of Energy.
<i>NOM-022-ENER/SCFI-2014</i>	Economy Secretariat	energy efficiency and user safety requirements for self-contained commercial refrigeration apparatus. boundaries, testing and labeling methods.	CSAC22.2.100, IEC34PT-1, IEEE STD, CSA- C747-94, IEC34PT-2, UIS-4203, NEMAMG11, NEMAMG1
<i>NOM-024-SCFI-2013</i>	Economy Secretariat	commercial information for packaging, instructions and guarantees of electronic, electrical and electrical products.	there are no supporting standards
<i>NOM-053-SCFI-2000</i>	Economy Secretariat	Electric traction elevators for passengers and cargo-Safety specifications and test methods for new equipment.	NMX-B-073-1984, NMX-H-084-1983, NMX-J-098-1999, NMX-Z-12-1987 ANSI A 17.1-1998, Specifications of the European Comitee of Normalization CEN Rules of Safety to Construction and Installation of Elevators and electric forklifts
<i>NOM-058-SCFI-2017</i>	Economy Secretariat	controllers for artificial luminous sources, with lighting purposes in general-safety specifications and test methods (cancel to nom-058-scfi-1999)	there are no supporting standards
<i>NOM-063-SCFI-2001</i>	Economy Secretariat	"Electrical products-Drivers-Safety requirements. Publication Date: 2002-02-22 "	there are no supporting standards
<i>NOM-064-SCFI-2000</i>	Economy Secretariat	electrical products-luminaires for use in interiors and exteriors-safety specifications and methods of test.	NMX-J-198-1977, NMX-Z-012/1, 2, 3-SCFI-1987, NMX-J-508-1994, NMX-J-024-1995, NMX-J-230-ANCE-1999 IEC-60 598-1-1999 Luminaires-Part 1: General requirements and tests. UL-1572-1992 High intensity discharge lighting fixtures.

<i>NOM-127-SCFI-1999</i>	Economy Secretariat	Measuring instruments-Multifunction meters for electrical systems-Specifications and test methods .. (To know the effective date, please consult the NOM text)	NMX-Z-012/2-1987-SCFFI ANSI/IEEE C37.90.1-1989. IEEE Standards for Relays Systems Associated with Electric Power Apparatus. ANSI/IEEE C37.90.1-1989. IEEE Standard Surge Withstand Capability (SWC) Test for Protective Relays and Relay Systems. ANSI/IEEE C12.20. American National Standard for Electricity Meter 0,2 and 0,5 Accuracy Class. ANSI/IEEE C12.13. Electronic Time-of use Registers for Electricity Meters. IEC-60687-1991 STATIC WATTHOUR meter Metrological specification for class 0,2 S and 0,5 . IEC-60687-1991.Static Watthour meters Metrological specifications for Class 0,2 S and 0,5 .
<i>NOM-162-SCFI-2004</i>	Economy Secretariat	Electronics-Audio and video-Compact discs recorded with audio, video, data and / or video games-Commercial information and identification of the manufacturer.	Red book Phillips, Yellow Book Phillips, Orange book Phillips.
<i>NOM-185-SCFI-2012</i>	Economy Secretariat	programas informáticos y sistemas electrónicos que controlan el funcionamiento de los sistemas para medición y despacho de gasolina y otros combustibles líquidos-especificaciones, métodos de prueba y de verificación.	International document OIML D 31 Edition 2008. General requirements for software controlled measuring instruments.WELMEC 7.2 (Edición 4), Guía del Software. Directiva 2004/22/EC relativa a instrumentos de medida mayo 2009, edición 4. Directiva 2004/22/EC relativa a Instrumentos de medida.
<i>NOM-186-SSA1/SCFI-2013</i>	Economy Secretariat	cocoa, chocolate and similar products, and cocoa derivatives. sanitary specifications. comercial designation. methods of trial.	there are no supporting standards
<i>NOM-065-SCTI-1993</i>	Secretary of Communication and Transportation	Vocabulario electrotécnico. Parte 15. Telecontrol.	IEC 50 (371) - (1984) "International Electrotechnical Vocabulary. Chapter 371: Telecontrol".
<i>NOM-081-SCTI-1993</i>	Secretary of Communication and Transportation	telephone radio systems with cellular technology operating in the 800 mhz band	IS-54 provisional document of the EIA / TIA where the compatibility standards of base and mobile stations with dual operation (analog and digital) are defined. RECOMMENDATION G162 OF THE CCITT PLENARY ASSEMBLY, MELBOURNE, 1988
<i>NOM-005-ENER-2012</i>	Energy	energy efficiency of apparatus apparatus washing machines. limits, testing method and labeling.	NMX-J-585-ANCE-2007; C360-03, Energy performance, water consumption, and capacity household clothes washers

<i>NOM-005-ENER-2016</i>	Energy	energy efficiency of apparatus apparatus washing machines. boundaries, testing and labeling methods	there are no supporting standards
<i>NOM-023-ENER-2010</i>	Energy	energy efficiency in divided air conditioners, free discharge and without air ducts. limits, testing method and labeling.	ISO 5151 Non Ducted Air Conditioners and Heat Pumps- Testing and Rating for Performance. 61D / 001 / DT Appliances and similar appliances-non-ducted air conditioners and heat pumps-tests and classification for performance.
<i>NOM-015-ENER-2012</i>	Energy	energy efficiency of refrigerators and freezers appliances. boundaries, testing and labeling methods.	CAN/CSA C300-08, Energy Performance and Capacity of Household Refrigerators, Refrigerator-Freezers, and Freezers; CFR 430-1998, Subpart B, Appendix A1 Uniform test method for measuring the energy consumption of electric refrigerators and electric refrigerator-freezers. CFR 430-1998, Subpart B, Appendix B1 Uniform test method for measuring the energy consumption of freezers; CFR 430-2010, Energy Conservation Program: Energy Conservation Standards for Residential Refrigerators, Refrigerator-Freezers, and Freezers; Proposed Rule.

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESFPGV.

Table 13.48 - Technical regulation of food (Mexico)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>NOM-006-SCFI-2012</i>	Economy Secretariat	alcoholic beverages-tequila-specifications. (contains modification published on 12/13/2012)	NMX-V-004-NORMEX-2005, NMX-V-005-NORMEX-2005, NMX-V-006-NORMEX-2005, NMX-V-013-NORMEX-2005, NMX-V-017-NORMEX-2005, NMX-V-049-NORMEX-2004, NMX-V-050-NORMEX-2010,
<i>NOM-051-SCFI/SSA1-2010</i>	Economy Secretariat	general specifications of labeling for pre-spilled food and non-alcoholic beverages-commercial and health information.	NMX-V-004-NORMEX-2013, NMX-V-005-NORMEX-2013, NMX-V-013-NORMEX-2013, NMX-V-017-NORMEX-2014, NMX-V-050-NORMEX-2010 ISO/IEC Guide 37 1995 (E) Instructions for use of products of consumer interest.
<i>NOM-070-SCFI-2016</i>	Economy Secretariat	alcoholic beverages-mezcal-specifications.	NMX-V-005-NORMEX-2013, NMX-V-013-NORMEX-2013, NMX-V-017-NORMEX-2014, NMX-V-050-NORMEX-2010

<i>NOM-080-SCFI-2016</i>	Economy Secretariat	rice of the state of morelos.	there are no supporting standards
<i>NOM-084-SCFI-1994</i>	Economy Secretariat	commercial information-specifications of commercial and sanitary information for tuna and bonita preenvased products.	there are no supporting standards
<i>NOM-086-SEMAR-SENER-SCFI-2005</i>	Economy Secretariat	Specifications of fossil fuels for environmental protection.	there are no supporting standards
<i>NOM-142-SSAI/SCFI-2014</i>	Economy Secretariat	Alcoholic drinks. sanitary specifications. sanitary and commercial labeling.	NMX-V-004-NORMEX-2013, NMX-V-005-NORMEX-2013, Norma Mexicana NMX-V-013-NORMEX-2013, NMX-V-025-NORMEX-2010, NMX-V-027-NORMEX-2009. Argentine Food Code. 2010. Chapter XIV. Spirits, alcohols, drinks, distilled spirits and liquors, Food Law Research Center Institute of European Studies of Brussels. 1984. Food Additives Tables, Class XII-Beverages and Drinks. Elsevier pp. 6-19
<i>NOM-144-SCFI-2000</i>	Economy Secretariat	Alcoholic beverages-Charanda-Specifications	there are no supporting standards
<i>NOM-155-SCFI-2012</i>	Economy Secretariat	Milk-denominations, physicochemical specifications, commercial information and test methods.	NMX-F-744-COFOCALEC-2011, NMX-F-490-1999, NMX-F-737-COFOCALEC-2010 CODEX STAN 207-1999 CODEX standard for powdered milk and cream (cream) powder; CODEX STAN 281-1971 CODEX standard for evaporated milk; CODEX STAN 282-1971 CODEX standard for condensed milk.
<i>NOM-158-SCFI-2003</i>	Economy Secretariat	Ham-denomination and commercial classification, physicochemical, microbiological, organoleptic specifications, commercial information and test methods.	NMX-F-083-1986, NMX-F-089-S-1978, NMX-F-321/S-1978, NMX-F-428-1982, NMX-F-608-NORMEX-2002 CODEX STAN 95-1981
<i>NOM-159-SCFI-2004</i>	Economy Secretariat	Alcoholic beverages-sotol-specifications and test methods.	NMX-V-013-1996, NMX-V-046-NORMEX
<i>NOM-168-SCFI-2004</i>	Economy Secretariat	Alcoholic beverages-bacanora-preparation, packaging and labeling specifications.	NMX-V-004-006, NMX-V-005-2005, NMX-V-013-2005, NMX-V-014-1986, NMX-V-0160-S-1980, NMX-V-017-2005, NMX-V-021-1986
<i>NOM-169-SCFI-2007</i>	Economy Secretariat	Café chiapas-specifications and test methods.	NMX-B-231-1990, NMX-F-013-SCFI-2000, NMX-F-083-SCFI-1996, NMX-F-551-1996-SCFI

<i>NOM-173-SCFI-2009</i>	Economy Secretariat	Pre-spilled fruit juices-denominations, physicochemical specifications, commercial information and test methods.	NMX-F-103-1982, NMX-F-309-NORMEX-2001 Code of Practice publicado por la AINJ (European Fruit Juice Association). Handbook of indices of Food Quality and Authenticity. Woodhead Publishing, 1997
<i>NOM-181-SCFI-2010</i>	Economy Secretariat	Yogurt-denominación, especificaciones fisicoquímicas y microbiológicas, información comercial y métodos de prueba.(contiene tres modificaciones la última del 14/11/2012 en la opción archivo texto de modificaciones)	NMX-F-490-1999-, NMX-F-703-COFOCALEC-2004 Codex Alimentarius, Codex Stan 243-2003 Codex Standard for Fermented Milks, adopted in 2003. Code of Federal Regulations, FDA-USA Title 21: Food and Drugs- TITLE 21-Food and Drugs Chapter, 21 CFR 131.200- Yogurt. Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria. Report of a Joint FAO / WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria.
<i>NOM-182-SCFI-2011</i>	Economy Secretariat	Papantla vanilla, extracts and derivatives- specifications, commercial information and test methods (test).	NMX-F-473-SCFI-2006, NMX-F-473-1987, NMX-F-616-NORMEX-2005, NMX-FF-067-1988, NMX-FF-074-SCFI-2009 ISO 13301:2002, ISO 3493:1999, ISO 5565-1:1999, ISO 5565-2:1999, UNE - ISO 13301:2007
<i>NOM-183-SCFI-2012</i>	Economy Secretariat	Dairy product and combined dairy product- denominations, physicochemical specifications, commercial information and test methods.	NMX-F-490-1999, NMX-F-737-COFOCALEC-2010,NMX-F-744-COFOCALEC-2011 CODEX STAN 206-1999.
<i>NOM-187-SSAI/SCFI-2002</i>	Economy Secretariat	Products and services. mass, tortillas, toasts and flours prepared for the development and establishments where they are processed. sanitary specifications. commercial information. methods of trial.	there are no supporting standards
<i>NOM-188-SCFI-2012</i>	Economy Secretariat	Mango ataulfo of soconusco, chiapas (mangifera caesia jack ex wall) - specifications and methods of test.	NMX-FF-006-1982, NMX-FF-008-1982, NMX-FF-058-2006
<i>NOM-182-SCFI-2011</i>	Economy Secretariat	Papantla vanilla, extracts and derivatives- specifications, commercial information and test methods (test).	there are no supporting standards
<i>NOM-183-SCFI-2012</i>	Economy Secretariat	Dairy product and combined dairy product- denominations, physicochemical specifications, commercial information and test methods	NMX-F-490-1999-NORMEX , NMX-F-737-COFOCALEC-2010, NMX-F-424-S-1982). NMX-F-744-COFOCALEC-2011

<i>NOM-185-SCFI-2012</i>	Economy Secretariat	Computer programs and electronic systems that control the operation of the systems for measurement and dispatch of gasoline and other liquid fuels-specifications, methods of testing and verification.	there are no supporting standards
<i>NOM-186-SSA1/SCFI-2013</i>	Economy Secretariat	Cocoa, chocolate and similar products, and cocoa derivatives. sanitary specifications. comercial designation. methods of trial.	NMX-Z-12/2-1987 AOAC International Official Methods of Analysis, Comisión del Codex Alimentarius. 2001. I, Directive 200/36 / EC of the European Parliament and of the Council of June 23, 2000, Food and Agriculture Organization of the United Nations. International Program on Chemical Safety World Health Organization. Committee on Food Additives (JECFA), Food and Drug Administration FDA-USA, Department of Health and Human Services. Title 21, chapter I, subchapter B food for human consumption, part 163 Cacao products, ICMSF. Microbial ecology of foods. Zaragoza, Spain. ISO 11053: 2009; UNE-EN ISO 23275-1 Oils and fats of animal and vegetable origin. Equivalents of butter of cocoa in cocoa butter and chocolate bars. Part 1: Determination of the presence of equivalents of cocoa butter. Revision 2009; UNE-EN ISO 23275-2
<i>NOM-187-SSA1/SCFI-2002</i>	Economy Secretariat	products and services. mass, tortillas, toasts and flours prepared for the development and establishments where they are processed. sanitary specifications. commercial information. methods of trial.	American Society for Testing and Minerals. Annual Book. (1996), International Commission on Microbiological Specifications for Food (ICMSF). 1985, Microbial Ecology of Foods Vol. 1. Editorial Acribia, S.A. of C.V. Zaragoza, Spain, FAO, WHO, UNEP. 1987. Second Joint FAO / WHO / UNEP International Conference on Mycotoxins. Bangkok, Thailand, September 28-October 3, Food and Agriculture Organization of the United Nations. 1990. Codex Alimentarius Abridged Version, Summarized and Edited by Barry L. Smith. Division 3- Food Additives. ASTM standards. 1992. Chapter 28 p. 22, 23, 30., United Nations Organization for Agriculture and Food. 1996. Commission of the

<i>NOM-188-SCFI-2012</i>	Economy Secretariat	mango ataulfo of soconusco, chiapas (mangifera caesia jack ex wall) - specifications and methods of test.	Codex Alimentarius. Joint FAO / WHO Food Standards Program. Codex Committee on
<i>NOM-189-SCFI-2012</i>	Economy Secretariat	chile habanero de la península de yucatán (capsicum chinense jacq.) - specifications and methods of trial.	Food Additives and Contaminants of Food. Manila, Philippines.
<i>NOM-189-SCFI-2017</i>	Economy Secretariat	chile habanero de la península de yucatán (capsicum chinense jacq.) specifications and methods of trial.	Summary of Evaluations Performed by Joint FAO / WHO Expert Committee on Food Additives and Contaminants (JECFA). 1994
<i>NOM-190-SCFI-2012</i>	Economy Secretariat	milk mixture with vegetable grease-denominations, physicochemical specifications, commercial information and test methods.	there are no supporting standards
<i>NOM-192-SCFI/SCTI-2013</i>	Economy Secretariat	telecommunications-television devices and decoders-specifications.	there are no supporting standards
<i>NOM-196-SCFI-2016</i>	Economy Secretariat	products. terminal equipment that are connected or interconnected through a wireless access to a public telecommunication network	there are no supporting standards
<i>NOM-199-SCFI-2017</i>	Economy Secretariat	alcoholic beverages-denomination, physicochemical specifications, commercial information and test methods.	NMX-V-001-NORMEX-2012, NMX-V-002-NORMEX-2010, NMX-V-011-NORMEX-2013, NMX-V-012-NORMEX-2005, NOM-199-SCFI-2017, NMX-V-018-NORMEX-2009, NMX-V-019-NORMEX-2016, NMX-V-020-NORMEX-2008, NMX-V-030-NORMEX-2016, NMX-V-034-NORMEX-2016, NMX-V-047-NORMEX-2009, NMX-V-049-NORMEX-2004, NMX-V-004-NORMEX-2013, NOM-199-SCFI-2017, NMX-V-005-NORMEX-2013, NMX-V-006-NORMEX-2013, NMX-V-013-NORMEX-2013, NMX-V-015-NORMEX-2014, NMX-V-017-NORMEX-2014, NMX-V-025-NORMEX-2010, NOM-199-SCFI-2017, NMX-V-027-NORMEX-2014, NMX-V-032-NORMEX-2010, NMX-V-048-NORMEX-2009, NMX-V-050-NORMEX-2010. Argentine Food Code. Chapter XIV. Spirits, alcohols, distilled spirits and liqueurs, Regulation (EC) No. 110/2008 of the European Parliament and of the Council, Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 Concerning the

			definition, designation, presentation, labeling and protection of the geographical indication of spirituous beverages and repealing Council Regulation (EEC) No. 1576/89, United States Department of Agriculture, Global Agriculture Information Network, 2016.
<i>NOM-208-SCFI-2016</i>	Economy Secretariat	products. radiocommunication systems that use the disperse spectrum technique-radio communication equipment by frequency jump and digital modulation to operate in the bands 902 mhz-928 mhz, 2400 mhz-2483.5 mhz and 5725 mhz-5850 mhz-specification	there are no supporting standards
<i>NOM-218-SCFI-2017</i>	Economy Secretariat	digital interface to public networks (digital interface a 2 048 kbit s and a 34 368 kbit s).	there are no supporting standards
<i>NOM-196-SCFI-2016</i>	Economy Secretariat	products. terminal equipment that are connected or interconnected through a wireless access to a public telecommunications network.	there are no supporting standards
<i>NOM-001-SSAI-2010</i>	Economy Secretariat	that instituts the procedure by which the pharmacopean of the united mexican states will be reviewed, updated and edited.	there are no supporting standards
<i>NOM-251-SSAI-2009</i>	Economy Secretariat	hygiene practices for the process of food, beverages or food supplements.	Center of Disease Control. Procedure for washing hands. "International Code. Recommended Practice General Principles of Food Hygiene ", CAC / RCP 1-1969, Rev. 4 (2003)., Food and Drug Administration. "Bad Bug Book" http://vm.cfsan.fda.gov , International Commission Microbiological Specifications of Foods. Microbial Ecology of Food. Ed. Acribia. Spain p. 697, Pan American Health Organization. INNPAZ http://www.panalimentos.org , Pan American Health Organization. Division of Disease Prevention and Control. Microbial contamination of street foods sold in Latin America and socioeconomic characteristics of their vendors and consumers. U.S. Government printing office. Washington Office of the Federal Register. 1990. Code of Federal Regulations. 21.110 Current Good Manufacturing Practices.

NOM-247-SSAI-2008	Economy Secretariat	products and services. cereals and their products. cereals, cereal flour, meal or semolina. food based on: cereals, edible seeds, flours, seeds or semolines or their mixtures. bread products. provisions and specific	Pan American Health Organization. Centers for Disease Control and Prevention. The prevention of neural tube defects with folic acid, Food and Drug Administration. 1989. Code of Federal Regulations. 21. PARTS 100 to 169 Revised as of April 1. p. 252-265; Codex Committee on Food Additives. 19th Session The Hague, 5-11 November 1985. Information on Legal and Other Administrative Limits for Contaminants in Food. Annex 1 to CX / Fa 85/18. p. 24, 70, 81, 87, 89; Codex Alimentarius Commission. October 26 to 30, 1992. Report of the 8th. Meeting on Cereals, Pulses and Legumes, Washington, D.C. p. 3. Codex Committee on Food Additives and Contaminants. 22a. The Hague Meeting, 19-24 March 1990, Guidance Levels for Cadmium and Lead in Food CX / FAC 90/18 Add. 3. 22a. Meeting. Hague. p. 1-5. FAO, WHO, PAHO. 1992. International Conference on Nutrition. Report of Mexico. National Food Commission. Mexico, 7a. Meeting, Washington, D.C. October 22-26, 1990 CX / CPL 90/8-Add. May 1, 1990. p. 18, 19, 22, 23. 11.28 Minister of Supply and Services Canada. 1989. Department of National Health and Welfare. Departmental Consolidation of the Food and Drugs Act and of the Food and Drug Regulations. Canada. p. 63 and 63 A.5; Technical-Sanitary Regulations of the Sector.
NOM-243-SSAI-2010	Economy Secretariat	products and services. milk, milk formula, combined dairy and dairy derivatives. sanitary provisions and specifications. methods of trial.	NMX-F-703-COFOCALEC-2004, NMX-F-709-COFOCALEC-2004 Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance. (2003 Revision). Department of Health and Human Services. U.S.A., Food and Agriculture Organization of the United Nations. 1994; "Summary of evaluations performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)". ILSI Press, Washington., U.S. Food & Drug Administration. 2001; Center for Food Safety & Applied Nutrition. Foodborne pathogenic microorganisms and natural toxins handbook. "Bad bug book".

<i>NOM-242-SSAI-2009</i>	Economy Secretariat	products and services. fresh fishery products, chilled, frozen and processed. health specifications and test methods.	there are no supporting standards
<i>NOM-218-SSAI-2011</i>	Economy Secretariat	products and services. flavored non-alcoholic beverages, its frozen products concentrated to prepare them and added beverages with caffeine. specifications and sanitary provisions. methods of trial.	Joint FAO / WHO Expert Committee on Food Additives 1995. Evaluation of certain additives food and contaminants. 44a. Report Rome Italy., Directive 92/2 / CEE of the Commission, of January 13, 1992, by which establishes the sampling procedure and the Community method of analysis for the official control of deep-frozen foods intended for human consumption, Directive 2010/69 / EU of the Commission, of October 22, 2010 by which the annexes are modified of Directive 95/2 / EC of the European Parliament and of the Council on food additives other than those dyes and sweeteners., Food and Agriculture Organization (FAO) 1994. Summary of Evaluations Performed by the Joint FAO / WHO Expert Committee on Food Additives (JECFA), Food Standards Australia New Zealand (ANZFA). 2001. Caffeine in water based non-alcoholic beverages.,-American Public Health Association (APHA). Standard Methods for the Examination of Water and Wastewater. 20th Edition. 1998, Codex Alimentarius Commission. 2001.
<i>NOM-086-SSAI-1994</i>	Economy Secretariat	goods and services. food and non-alcoholic beverages with modifications in its composition. nutrimental specifications.	Association Official Analytical Chemists. 1990. Official Methods of Analysis. 15 th Edition. pp. 1103- 1106, 1167, 1173-1174; Code of Federal Regulations. 1987. Food and Drugs. Vol. 21. Washington. Parts 170 to 199. pp. 44, 462 y 463.
<i>NOM-051-SCFI/SSAI-2010</i>	Economy Secretariat	general specifications of labeling for pre-spilled food and non-alcoholic beverages-commercial and health information.	ISO/IEC Guide 37 1995 (E) Instructions for use of products of consumer interest.
<i>NOM-111-SSAI-1994</i>	Economy Secretariat	goods and services. method for the account of molds and yeasts in food.	Norma ISO 7954. 1987, Bacteriological Analytical Manual. 1984. Food and Drugs Administration FDA. Bureau of Foods. Division of Microbiology. 6a Ed. Washington, D.C.

<i>NOM-186-SSAI/SCFI-2013</i>	Health Secretariat	cocoa, chocolate and similar products, and cocoa derivatives. sanitary specifications. comercial designation. methods of trial.	there are no supporting standards
<i>NOM-213-SSAI-2002</i>	Secretary of Health	products and services. processed meat products. sanitary specifications. test methods.	there are no supporting standards
<i>NOM-130-SSAI-1995</i>	Secretary of Health	goods and services. foods packaged in hermetic closure containers and subjected to thermal treatment. sanitary provisions and specifications.	there are no supporting standards
<i>NOM-086-SSAI-1994</i>	Secretary of Health	goods and services. food and non-alcoholic beverages with modifications in its composition. nutrimental specifications.	there are no supporting standards
<i>NOM-110-SSAI-1994</i>	Secretary of Health	goods and services. preparation and dilution of food samples for your microbiological analysis.	Norma ISO 6887-1983
<i>NOM-116-SSAI-1994</i>	Secretary of Health	goods and services. determination of moisture in food by heat treatment. method by sand or gasa.	Offical Methods of Analysis. 1990. Association of Official Analytical Chemists. 15th ed. Vol. II. Method 925.45D. USA. p. 1010 - 1011.
<i>NOM-182-SSAI-2010</i>	Secretary of Health	labeling of vegetable nutrients	United Nations Food and Agriculture Organization (FAO), 1995. Guidelines for the correct labeling of pesticides. Rome Italy.
<i>NOM-201-SSAI-2015</i>	Secretary of Health	products and services. water and ice for human consumption, packaged and bulk. sanitary specifications	ISO 7704: 1985, Standard Methods for the Examination of Water and Wastewater. American Public Health Association. 21th Ed. Washington D.C. 2005. EUA., WHO Guidelines for Drinking-Water Quality. 3th Edition, Vol. 1. World Health Organization. Geneva, 2004.
<i>NOM-230-SSAI-2002</i>	Secretary of Health	enviromental health. water for use and human consumption. sanitary requirements that must be fulfilled in the public and private supply systems during water management. sanitary procedures for sampling.	OMS.1995. Guides to the quality of potable water, APHA. AWWA.WPCF. Standards for the Examination of Water of Wasterwater
<i>NOM-001-FITO-2001</i>	SAGARPA	By which the campaign against the partial coal of wheat is established.	there are no supporting standards
<i>NOM-001-SAG/BIO-2014</i>	SAGARPA	general specifications of labeling of genetically modified organisms that are seeds or vegetative material intended for sowing, cultivation and agricultural production.	there are no supporting standards

<i>NOM-001-SAG/FITO-2013</i>	SAGARPA	establishing the criteria, procedures and specifications for the preparation of guides for the varietal description and rules to determine the quality of seeds for sowing	Genetic and crops standards of the AOSCA. Association of Official Seed Certifying Agencies. (2011); OECD Seed Schemes 2012. OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade; International Rules for Seed Testing 2012. International Seed Testing Association; International Convention for the Protection of Varieties Vegetables (December 1995);
<i>NOM-001-SAG/GAN-2015</i>	SAGARPA	national system of animal identification for bovine and beehives (compulsory as of 01/02/2017 according to publication agreement on 01/12/2016 in the dof)	Normas ISO 11784, ISO 11785, ISO 3166-1 e ISO 24631-4, características de radiofrecuencia de los dispositivos de identificación animal.
<i>NOM-001-SAG/PESC-2013</i>	SAGARPA	fishing responsible for tuna. specifications for fishing operations with fencing network.	Code of Conduct for Responsible Fisheries. United Nations Organization for Agriculture and Food. 1995; Inter-American Tropical Tuna Commission, 1999;
<i>NOM-001-SAGARPA/SCFI-2016</i>	SAGARPA	commercial practices-specifications on the storage, saving, conservation, handling and control of goods or goods under custody of the general deposit stores. including agricultural and fishery products.	NMX-F-252-SCFI-2011, NMX-F-223-2011, NMX-Z-012/1-1987, NMX-Z-012/2-1987, NMX-Z-012/3-1987, NMX-Z-013-SCFI-2015, NMX-FF-034-1995-SCFI; NMX-FF-034/1-SCFI-2002, Norma Mexicana NMX-FF-036-1996, NMX-FF-037-1994, NMX-FF-035-SCFI-2005, NMX-FF-059-SCFI-2000, NMX-FF-038-SCFI-2013, NMX-FF-089-SCFI-2008, NMX-FF-090-SCFI-2008, NMX-F-107-SCFI-2008; NMX-F-129-SCFI-2008. International Code CAC / RCP 52-2003 Code of Practice for Fish and Fishery Products. Codex Alimentarius. 10.46 International Code CAC / RCP 58/2005, Code of Hygienic Practice for Meat. Codex Alimentarius. 10.47 Recommended International Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk Cac / Rcp 36-1987 (Rev. 1-1999). Codex Alimentarius.
<i>NOM-001-ZOO-1994</i>	SAGARPA	national campaign against the varroasis of the bees.	there are no supporting standards

<i>NOM-002-FITO-2000</i>	SAGARPA	By which the campaign against the coffee berry borer is established.	there are no supporting standards
<i>NOM-002-SAG/FITO-2015</i>	SAGARPA	establishing the characteristics and specifications that the labels of certification of the quality of the seeds for sowing must meet.	AOSCA 2011. Genetic and crops standards of the AOSCA. Association of Official Seed Certifying Agencies. OECD 2012. OECD Seed Schemes “2012” Organization for Economic Co-operation and Development.
<i>NOM-002-SAG/PESC-2013</i>	SAGARPA	para ordenar el aprovechamiento de las especies de camarón en aguas de jurisdicción federal de los estados unidos mexicanos.	there are no supporting standards
<i>NOM-002-SAGARPA-2016</i>	SAGARPA	relative to the characteristics of health, agri-food quality, authenticity, labeling and evaluation of agave fructan conformity.	NMX-F-607-NORMEX-2013, Norma Mexicana NMX-F-317-NORMEX-2013, NMX-F-591-SCFI-2010, NMX-FF-110-SCFI-2008, NMX-F-103-NORMEX-2009, Norma Mexicana NMX-F-083-SCFI-1986. SO TC 34 N 1200 CD 26642 Food Products-Determination of the glycemic index (GI) and relevant classification. International Organization for Standardization, Geneva, Switzerland, 2007. 15.9. International Code of Recommended Practice - General Principles on Food Hygiene. Codex Alimentarius Commission (CAC / RCP 1-1969). 15.10. International Standard CODEX STAN 212-1999. Codex Alimentarius standard for sugars.
<i>NOM-003-PESC-1993</i>	SAGARPA	to regulate the use of the species of sardina monterrey, piña, crinuda, bocona, japanese and the species anchoveta and macarela, with boat climbing, in waters of federal jurisdiction of the pacific ocean	there are no supporting standards
<i>NOM-003-SAG/FITO-2015</i>	SAGARPA	why establish the specifications to be fulfilled by the moral persons in order to be approved as seed certification organisms.	NMX-CC-9-1992, NMX-CC-10-1992, NMX-CC-11-1992: International Rules for the Analysis of Seeds, International Seed Testing Association (ISTA, 2012).6.7 NMX
<i>NOM-003-SAG/GAN-2017</i>	SAGARPA	propolises, production and specifications for their processing.	Official Gazette of the Federative Republic of Brazil. (2001). Ministry of Agriculture and Catering. Normative Instrução No. 3, of 19 de janeiro da 2001. Seção1, p. 18-23. Norma Argentina, Argentine

			Institute of Normalization (2008). IRAM-INTA Standards 15935-1, Part 1: Raw propolis. 10.4 Norma Argentina, Argentine Institute of Normalization (2008). IRAM-INTA Standards 15935-2, Part 2. Extracts of propolis. 10.5 Cuban Branch Standard (1994). Propolis Raw Material. Specifications. Beekeeping NRAG-1135-94. Department of agriculture. Havana Cuba. 10.6 Standard Cuban Branch (1994). NRAG 1129 Ministry of Agriculture. Havana Cuba. Russian Branch Standard RST-RSFSR-317-77. Compulsory Salvadoran Standard NSO 65.19.02.03
<i>NOM-003-SAGARPA-2016</i>	SAGARPA	relative to the characteristics of health, agri-food quality, authenticity, labeling and evaluation of agave syrup conformity.	NMX-F-607-NORMEX-2013, Norma Mexicana NMX-F-317-NORMEX-2013, NMX-F-591-SCFI-2010, NMX-FF-110-SCFI-2008, NMX-F-103-NORMEX-200, NOM-F-83-1986 ISO TC 34 N 1200 CD 26642 Food Products-Determination of the glycemic index (GI) and relevant classification. International Organization for Standardization, Geneva, Switzerland, 2007. International Code of Recommended Practice - General Principles on Food Hygiene. Codex Alimentarius Commission (CAC / RCP 1-1969). International Standard CODEX STAN 212-1999. Codex Alimentarius standard for sugars.
<i>NOM-004-SAG/PESC-2015</i>	SAGARPA	specifications for the use of the catarina shell (<i>argopecten circularis</i>) in waters of federal jurisdiction of the united mexican states.	there are no supporting standards
<i>NOM-005-FITO-1995</i>	SAGARPA	which is established the foreign quarantine to prevent the introduction of the rice beetle (contains four modifications)	there are no supporting standards
<i>NOM-005-PESC-1993</i>	SAGARPA	To regulate the exploitation of the populations of the different species of abulón in waters of federal jurisdiction of the Peninsula of Baja California.	there are no supporting standards

<i>NOM-006-SAG/PESC-2016</i>	SAGARPA	to regulate the use of all lobster species in the federal jurisdiction waters of the gulf of mexico and the caribbean sea, as well as the pacific ocean, including the gulf of california.	there are no supporting standards
<i>NOM-006-ZOO-1993</i>	SAGARPA	biological effectiveness requirements for ixodicides of use in cattle and test method.	International Code of Conduct for the Distribution and Use of Pesticides. Fao, Rome, 1985. Guidelines On Efficacy Data For The Registration Of Pesticides For Plant Protection. Fao, Rome, 1985
<i>NOM-008-PESC-1993</i>	SAGARPA	to order the use of octopus species in the federal jurisdiction waters of the gulf of mexico and the caribbean sea.	there are no supporting standards
<i>NOM-008-ZOO-1994</i>	SAGARPA	animal health specifications for the construction and equipment of establishments for the sacrifice of animals and dedicated to the industrialization of meat products (modified)	there are no supporting standards
<i>NOM-009-ZOO-1994</i>	SAGARPA	sanitary process of the meat.	there are no supporting standards
<i>NOM-023-ZOO-1995</i>	SAGARPA	Identification of animal species in muscle of cattle, sheep, horses, pigs and birds, by gel immunodiffusion test	there are no supporting standards
<i>NOM-032-SAG/PESC-2015</i>	SAGARPA	responsible fishing in the lake of chapala, located in the states of jalisco and michoacán. especifications for use of fishing resources.	there are no supporting standards
<i>NOM-047-SAG/PESC-2014</i>	SAGARPA	For the identification of the origin of cultivated shrimp, marine waters and esteros, marismas and bahías.	there are no supporting standards
<i>NOM-050-PESC--2004</i>	SAGARPA	Responsible fishing in the Lake of Tecocomulco reservoir in the State of Hidalgo. Especifications for use of fishing resources.	there are no supporting standards
<i>NOM-051-ZOO-1995</i>	SAGARPA	Humanitarian treatment in the mobilization of animals.	there are no supporting standards
<i>NOM-063-PESC-2005</i>	SAGARPA	responsible fishing of curvina golfina (cynoscion othonopterus) in water of federal jurisdiction of the high gulf of california and delta del río colorado. specifications for your use.	there are no supporting standards

<i>NOM-044-SAG/PESC-2017</i>	Secretariat of Environment and Natural Resources	responsible fishing in the boat of the dam la boquilla in the state of chihuahua. especifications for use of fishing resources.	there are no supporting standards

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESP/FGV.

Table 13.49 - Technical regulation of oil and gas (Mexico)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>NOM-005-SCFI-2011</i>	Economy Secretariat	Measuring instruments-system for measurement and disposal of gasoline and other liquid fuels-specifications, methods of testing and verification	NMX-Z-12/2-1987International Recommendation Dynamic measuring systems for liquids other than water. Metrological and technical requirements, OIML-R-117-1 (2007); NIST HANDBOOK 44-2003 Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices; UL 330 Standard for gasoline hose, Fourth edition. June 29, 1973. Underwriters' Laboratories Inc., SAE J285 Gasoline dispenser nozzle spouts. Jul. 81, 1985 SAE HANDBOOK.; BIPM 2008 International Vocabulary of Terms in Legal Metrology - Basic and general concepts and associated terms (VIM).
<i>NOM-008-SESH/SCFI-2010</i>	Economy Secretariat	ransportable containers to contain gas l.p. manufacturing specifications, materials and test methods.	NMX-B-086-1991 , NMX-B-172-1988 , NMX-B-266-1989, NMX-D-122-1973 , NMX-H-007-1978, NMX-U-032-1980, NMX-X-015-1981, NMX-X-042-SCFI-2009, NMX-Z-012-1-1987, NMX-Z-012-2-1987, iSO 11228-1:2003 ; ISO 22991; ISO 18172-1; ISO 11119-3; ISO 9328-7:2004; ISO 11114-1:1997; ISO 11114-2:2000; European Norm EN 1442.European Norm EN 12245; NFPA 58.
<i>NOM-014-SCFI-1997</i>	Economy Secretariat	positive displacement meters type diaphragm for natural gas or l.p. with maximum capacity of 16 m3 / h with drop of maximum pressure of 200 pa (20,40 mm of column of water) (this norma cancels to the nom-014-scfi-1993)	NMX-CH-60-1996-IMNC, NMX-Z-012/2-1987-SCFI ANSI B. 109.1-1992 Diaphragm type gas displacement meters under 500 cubic feet per hour capacity.
<i>NOM-001-SECRE-2010</i>	ENERGY	especificaciones del gas natural (cancela y sustituye a la nom-001-secre-2003, calidad del gas natural y la nom-em-002-secre-2009,	American Gas Association. Gas Measurement Manual. General. AGA Report 8, AGA Report No. 4A Natural Gas Contract Measurement and Quality Clauses, Transmission Measurement Committee, American Petroleum Institute.

		calidad del gas natural durante el periodo de emergencia severa).	API Manual of Petroleum Measurement Standards; American Society for Testing and Materials; ASTM D-1142-95 (2006). ASTM D-1945-03; ASTM D-3588-98 (2003); ASTM D-4084-07; STM D-4468-85 (2006); ASTM D5287-97 (2002); ASTM D5454-04, ASTM D5503-94 (2003), ASTM D5504-01 (2006), ASTM D7 164-05, ASTM D7 165-06, ASTM D7 166-05, Engineering Equipment & Materials Users Association. EEMUA 138, GPA 1167-83, GPA 2145-03, GPA 2166-86, GPA 2166-05, GPA 2172-96, GPA 2199-99, GPA 2261-00, GPA 2286-95, ISO 6326:1989, ISO 6327:1981, ISO 6974-1:2000, ISO 6974-2:2001, ISO 6974-3:2000, ISO 6974-4:2000, ISO 6974-5:2000, ISO 6974-6:2005, ISO-6975-1997, ISO-6976-1995, ISO 10715, ISO 10723:1995; ISO-13686-1998; ISO 13734:1998, ISO 14111:1997; ISO 18453:2004; ISO 23874.NMX-B-010-1986, NMX-B-177-1990, NMX-B-179-1983, NMX-E-043-SCFI-2002, NMX-H-022-1989, NMX-W-018-SCFI-2006, NMX-W-101/1-SCFI-2004, NMX-W-101/2-SCFI-2004, NMX-X-021-SCFI-2007, NMX-X-031-SCFI-2005, NMX-X-032-SCFI-2006, NMX-X-044-SCFI-2008
<i>NOM-025-ENER-2013</i>	ENERGY	eficiencia térmica de aparatos domésticos para cocción de alimentos que usan gas l.p. o gas natural. límites, métodos de prueba y etiquetado	
<i>NOM-001-SESH-2014</i>	ENERGY	gas distribution plants l.p. design, construction and safe conditions in your operation.	NMX-B-177-1990 NFPA 15, NFPA 58
<i>NOM-002-SECRE-2010</i>	ENERGY	facilities for the use of natural gas (cancel and replace nom-002-secre-2003, natural gas use facilities).	NMX-B-010-1986,NMX-B-177-1990, NMX-B-179-1983, NMX-E-043-SCFI-2002, NMX-X-021-SCFI-2007, API RP 5L1-1996, API 1104, API RP 521, API RP 526, API Standard 1104, API RP 2201, ASTM B 32; ASTM A 53-1996, ASTM: A 120, ASTM: A 372 / A 372M, ASTM B 813; ASTM B 828; ASTM B 837-1995, ASTM D 1988-1991, ASTM D 2513-1999, ASTM D 2657; ASTM D 3261-1997, ASTM D 2683-1995, ASTM F 905-1996, ASTM F

			1055-1995, ASME B 31.8-2007, ASME BPV-2001, ASME B 16.1-1998, ASME B 16.5-1996, ASME B 16.9-2001, ASME B 16.18-1984 / Reaffirmed 1994, ASME B 16.22-1995, ASME B 16.25-1997, ASME B 16.33-1990, ASME B 16.34-1996, ASME B 16.40-1985 / Reaffirmed 1994, MSS SP-44, MSS SP-75, MSS NFPA 69, ANSI / NFPA 70, NFPA 328, NFPA 5113, Code of Federal Regulations for the Transportation of Natural Gas and Other Gas by Pipeline, U.S. Department of Transportation, October, 1992. Gas Engineers Handbook, The Industrial Press, January, 2008. AGA Technical report No. 10, NACE RP 0169-1996.
NOM-002-SESH-2009	ENERGY	gas distribution bodegas l.p. design, construction, operation and safety conditions.	NFPA 58. Standard for the Storage and Handling of Liquefied Petroleum Gases.
NOM-003-SECRE-2011	ENERGY	distribution of natural gas and liquefied petroleum gas by ducts	NMX-B-010-1986, NMX-B-177-1990, NMX-B-179-1983, NMX-E-043-SCFI-2002, NMX-H-022-1989, NMX-W-018-SCFI-2006, NMX-W-101/1-SCFI-2004, NMX-W-101/2-SCFI-2004, NMX-X-021-SCFI-2007, NMX-X-031-SCFI-2005, NMX-X-032-SCFI-2006, NMX-X-044-SCFI-2008
NOM-002-SEDE/ENER-2014	ENERGY	safety and energy efficiency requirements for distribution transformers.	NMX-J-116-ANCE-2005, NMX-J-169-ANCE-2004, NMX-J-285-ANCE-2013, NMX-J-287-ANCE-1998
NOM-003-SECRE-2011	ENERGY	distribution of natural gas and liquefied petroleum gas by ducts	American Gas Association (AGA), AGA Technical report No. 10, Steady Flow in gas pipelines fluid flow model, American Petroleum Institute (API), ASME B 31.8-1999, Gas transmission and distribution piping systems y ASME B 31.4 P: Pipeline Transportation Systems for liquid Hydrocarbons and other liquids., ASME BPV-2001, Boiler and Pressure Vessel code, section I, section VIII division I, section VIII division 2, section IX., ASME B 16.1-1998, Cast iron pipe flanges and flanged fittings. 16.4.4 ASME B 16.5-1996, Pipe flanges and flanged fittings. 16.4.5 ASME B 16.9-2001, Factory made wrought steel butt

		welding fittings. 16.4.6 ASME B 16.18-1984/Reaffirmed 1994, Cast copper alloy solder joint pressure fittings. 16.4.7 ASME B 16.22-1995, Wrought copper and copper alloy solder joint pressure fittings. 16.4.8 ASME B 16.25-1997, Buttwelding ends. 16.4.9 ASME B 16.33-1990, Manually operated metallic gas valves for use in gas piping systems up to 125 psig, size ½" - 2". 16.4.10 ASME B 16.34-1996, Valves flanged, threaded and welding end. 16.4.11 ASME B 16.38-1985/Reaffirmed 1994, Large metallic valves for gas distribution (manually operated NPS 2 ½" to 12", 125 psig max.). 16.4.12 ASME B 16.40-1985/Reaffirmed 1994, Manually operated thermoplastic gas shut-offs and valves in gas distribution systems. 16.5 American Society for Testing and Materials (ASTM). 16.5.1 ASTM B 32; Standard specification for solder metal 16.5.2 ASTM A 53-1996, Standard specification for pipe, steel, black and hot dipped, zinc coated welded and seamless. 16.5.3 ASTM A 106-1995, Standard specification for seamless carbon steel pipe for high temperature service. 16.5.4 ASTM A 333/A 333M-1994, Standard specification for seamless and welded steel pipe for low temperature service. ASTM A 381-1993, Standard specification for metal arc welded steel pipe for use with high pressure transmission systems., ASTM A 671-1994, Standard specification for electric fusion welded steel pipe for atmospheric and lower temperatures., ASTM A 672-1994, Standard specification for electric fusion welded steel pipe for high pressure service at moderate temperatures., ASTM A 691-1993, Standard specification for carbon and alloy steel pipe, electric fusion welded for high-pressure service at high temperatures.

		ASTM B 813; Standard specification for liquid and paste fluxes for soldering of copper and copper alloy tube., ASTM B 828; Standard practice for making capillary joints by soldering of copper and copper alloys tube and fittings., ASTM B 837-1995, Standard specification for seamless copper tube for natural gas and Liquefied Petroleum (LP) gas distribution systems., ASTM D 1988-1991 (Reapproved 1995), Standard test method for Mercaptans in natural gas using length - of - stain detector tubes., ASTM D 2513-1999, Standard specification for thermoplastic gas pressure pipe, tubing and fittings., ASTM D 2657; Standard practice for heat fusion joining of polyolefin pipe and fittings., ASTM D 3261-1997, Standard specification for butt heat fusion polyethylene (PE) plastic fittings for polyethylene (PE) plastic pipe and tubing., ASTM D 2683-1995, Standard specification for socket type polyethylene fittings for outside diameter controlled polyethylene pipe and tubing., ASTM F 905-1996, Standard practice for qualification of polyethylene saddle fusion joints., ASTM F 1055-1995, Standard specification for electrofusion type polyethylene fittings for outside diameter controlled polyethylene pipe and tubing., Government of the United States of America, Code of Federal Regulations (CFR), Title 49 Department of Transportation (DOT), Chapter 1. - Research and special programs administration , CFR 49 DOT 192-2000, Transportation of natural gas by pipeline: Minimum safety standards., Manufacturers standardization society of the valve and fittings industry (MSS)., MSS SP-44-1996 (R 2001), Steel pipe flanges., MSS SP-75-1998, Specification for high test wrought welding fittings, National Association of Corrosion Engineers (NACE), NACE RP 0169-1996, Standard Recommended Practice. Control of external corrosion on underground or submerged metallic piping systems, NACE TM 0497-1997, NMX-B-010-1986, NMX-B-177-1990, NMX-B-179-1983, NMX-E-043-SCFI-2002, NMX-H-022-1989, NMX-W-018-SCFI-2006, NMX-W-

			101/1-SCFI-2004, NMX-W-101/2-SCFI-2004, NMX-X-021-SCFI-2007, NMX-X-031-SCFI-2005, NMX-X-032-SCFI-2006, NMX-X-044-SCFI-2008
<i>NOM-003-SEDG-2004</i>	ENERGY	gas stations l.p. for carburing. design and construction.	ANSI-B-16.5. Pipe Flanges and Flanged Fittings. III. ANSI-B-2.1. Taper Pipe Threads. IV. ANSI/ASME B-31.3. Chemical Plant and Petroleum Refinery Piping. V. ANSI/ISA-RP12.6. Installation of Intrinsically Safe Instrument Systems in Class I Hazardous Locations. VI. NFPA 58. Standard for the Storage and Handling of Liquefied Petroleum Gases.
<i>NOM-004-SEDG-2004</i>	ENERGY	instalaciones de aprovechamiento de gas l.p. diseño y construcción.	NMX-H-22-1989NFPA 58, Standard for the Storage and Handling of Liquefied Petroleum Gases. 2007 Edition. Handbook LPG NFPA, 2a. Edition, 1989. REGO Technical Guide 105, 1999.
<i>NOM-005-SESH-2010</i>	ENERGY	gas carburing equipment l.p. in internal combustion engines. instalation and maintenance.	NMX-Z-12-2-1987NFPA 58, Standard for the Storage and Handling of Liquefied Petroleum Gases. 2007 Edition. Handbook LPG NFPA, 2a. Edition, 1989. REGO Technical Guide 105, 1999.
<i>NOM-007-SECRE-2010</i>	ENERGY	transportation of natural gas (cancel and substitute to nom-007-secre-1999, transportation of natural gas).	CID-NOR-N-SI-0001, de Petróleos Mexicanos, requisitos mínimos de seguridad para el diseño, construcción, operación, mantenimiento e inspección de ductos de transporte, edición 1998. NO.03.0.02, de Petróleos Mexicanos, Derechos de vía de las tuberías de transporte de fluidos (1990). NRF-030-PEMEX-2006, Diseño, construcción, inspección y mantenimiento de ductos terrestres para transporte y recolección de hidrocarburos. API 5L-2000, Specification for line pipe. API RP 5L1-1996, Recommended practice for railroad transportation of line pipe. Especificación API 6D "Especificación para Válvulas de Tubería (Válvulas de compuerta, de Flotador, de Paso y de Retención)" (1994). Estándar API 1104 "Soldadura de Tuberías e Instalaciones Relacionadas" (1999).

		Estándar API RP 570 “Dimensionamiento, selección e instalación de equipos de alivio de presión en refinerías” Estándar API RP 521 “Guía para los sistemas de alivio de presión y despresurización” Estándar API RP 526 “Válvulas de alivio de presión al acero dulce bridadas API RP 5LW-1996, Recommended practice for transportation of line pipe on barges and marine vessels. API 1104-1999, Welding of pipelines and related facilities. API RP 2201, Prácticas seguras de perforación de tuberías en servicio en las industrias del Petróleo y Petroquímica ASTM B 32; Standard specification for solder metal ASTM A 53-1996, Standard specification for pipe, steel, black and hot dipped, zinc coated welded and seamless. ASTM A 106-1995, Standard specification for seamless carbon steel pipe for high temperature service. ASTM: A 120 "Tubos de acero negro y galvanizado con o sin costura para uso ordinario" (1984). ASTM A 333/A 333M-1994, Standard specification for seamless and welded steel pipe for low temperature service. ASTM: A 372/A 372M "Especificación estándar para piezas forjadas de carbono y aleación de acero para recipientes a presión de pared delgada" (1955). ASTM A 381-1993, Standard specification for metal arc welded steel pipe for use with high pressure transmission systems. ASTM A 671-1994, Standard specification for electric fusion welded steel pipe for atmospheric and lower temperatures. (Segunda Sección) DIARIO OFICIAL Martes 8 de febrero de 2011 ASTM A 672-1994, Standard specification for electric fusion welded steel pipe for high pressure service at moderate temperatures. ASTM D 1988-1991 (Reapproved 1995), Standard test method for Mercaptans in natural gas using lengthof- stain detector tubes. ASTM D 2513-1999, Standard specification for thermoplastic gas pressure pipe, tubing and fittings. ASTM D 2657; Standard practice for heat fusion joining of polyolefin pipe and fittings ASTM D 3261-1997, Standard

		specification for butt heat fusion polyethylene (PE) plastic fittings for polyethylene (PE) plastic pipe and tubing. ASTM D 2683-1995, Standard specification for socket type polyethylene fittings for outside diameter controlled polyethylene pipe and tubing. ASTM F 905-1996, Standard practice for qualification of polyethylene saddle fusion joints. ASTM F 1055-1995, Standard specification for electrofusion type polyethylene fittings for outside diameter controlled polyethylene pipe and tubing. ASME B 31.8-2007, Gas transmission and distribution piping systems ASME BPV-2001, Boiler and Pressure Vessel code, section I, section VIII division I, section VIII division 2, section IX. ASME B 16.1-1998, Cast iron pipe flanges and flanged fittings ASME B 16.5-1996, Pipe flanges and flanged fittings. ASME B 16.9-2001, Factory made wrought steel butt welding fittings. ASME B 16.18-1984/Reaffirmed 1994, Cast copper alloy solder joint pressure fittings. ASME B 16.22-1995, Wrought copper and copper alloy solder joint pressure fittings. ASME B 16.25-1997, Buttwelding ends. B31G - 2009 Manual for Determining the Remaining Strength of Corroded Pipelines: Supplement to ASME B31 Code for Pressure Piping ASME B 16.33-1990, Manually operated metallic gas valves for use in gas piping systems up to 125 psig, size ½"-2". ASME B 16.34-1996, Valves flanged, threaded and welding end. ASME B 16.38-1985/Reaffirmed 1994, Large metallic valves for gas distribution (manually operated NPS 2 ½" to 12", 125 psig max.). ASME B 16.40- 985/Reaffirmed 1994, Manually operated thermoplastic gas shut-offs and valves in gas distribution systems. ANSI/ASME B36.10M-2000 Welded and Seamless Wrought Steel Pipe MSS SP-44 "Bridas para

		Tuberías de Línea de Acero" (1991). MSS-SP-75 "Estándares de conexiones para tuberías" (1988). MSS-SP-58 "Soportes para tubería, diseño y materiales" (1983). NFPA 69, Explosion Prevention Systems, 1992. ANSI/NFPA 70 "Código eléctrico nacional" (1993). NFPA 328, Manholes, Sewers and Similar Underground Structures, 1992. NFPA 5113, Cutting and Welding Processes, 1989. AGA Technical report No. 10, Steady Flow in gas pipelines fluid flow model. NACE RP 0169-1996, Standard Recommended Practice. Control of external corrosion on underground or submerged metallic piping systems. NMX-B-010-1986, NMX-B-177-1990, NMX-B-179-1983, NMX-E-043-SCFI-2002, NMX-X-021-SCFI-2007, NMX-X-031-SCFI-2005, NMX-Z12-1/2-1987,
NOM-011-SECRE-2000	ENERGY	compressed natural gas for automotive use. minimum safety requirements in vehicle installations. AGA (AMERICAN GAS ASSOCIATION), ANSI/AGA NGV 1, 1992; ANSI/ AGA NGV 2, 1992, API (AMERICAN PETROLEUM INSTITUTE): API RP 2003, ASME, ASTM: ASTM A-47-1984, ASTM A-395-1986, ASTM A-536-1984, ASTM A-536-1984, ASTM E-136-1982, ASTM A-269-1982, ASTM A-105-1982, ASTM-106-1982, ASTM-A-106-1982, CGA (CANADIAN GAS ASSOCIATION): CGA S-1.1, ANSI/CSA/CGA, CSA (CANDADIAN STANDARDS ASSOCIATION): CSA B51 1991, CRN (CANADIAN REGISTRATION NUMBER), DOT (DEPARTMENT OF TRANSPORTATION), CFR CH.1, DOT-3AA, ISO 11439:2000, NFPA (NATIONAL FIRE PROTECTION ASSOCIATION): NFPA-37, NFPA-52, NFPA-70, CGA (COMPRESSED GAS ASSOCIATION), INTERNATIONAL ORGANIZATION OF STANDARDIZATION: ISO-9809, ISO/BIS-14446, ISO 15501-1:2000, ISO 15501-2:2001.
NOM-014-ENER-2004	ENERGY	eficiencia energética de motores eléctricos de corriente alterna, monofásicos, de inducción, tipo jaula de ardilla, enfriados there are no supporting standards

		con aire, en potencia nominal de 0,180 kw a 1,500 kw. límites, método de prueba y marcado.	
<i>NOM-094-SCFI-1994</i>	ENERGY	use of liquefied natural gas as vehicular fuel-safety requirements for vehicular installations.	NMX-Z-12, NMX-S-14-SCFI aNSI B31.3, "Especificación para tubo flexible de acero austenítico sin costura y soldado para servicio general". ANSI H23.5 "Especificación para tubería de cobre sin costura para servicio de refrigeración y acondicionamiento de aire". ANSI H36.1 "Especificación para tubería de bronce sin costura". API RP 2003 Protection against ignitions arising out static, lightning and stray currents, fourth edition 1982. ANSI/ASME B31.3 (1980) American National Standard Code for Chemical Plant and Petroleum Refinery Piping. ASTM A-136-1982, Standard Method of Test for Behaviour of Materials in a Vertical Tube Furnace at 750°C. ASTM-A-269-1982, Standard for Stainless Steel Seamless Tubo flexible. 49 CFR CH.1 Research and Special Programs Administration (10-1-86). NFPA-57 1992 Edition.
<i>NOM-086-SEMAR-SENER-SCFI-2005</i>	ENERGY	specifications of fossil fuels for environmental protection.	ASTM 056-05, ASTM 086-05, ASTM 093-02a, ASTM 097-05A, ASTM 0130-04, ASTM 0156-02E, ASTM 0240-02, ASTM D 287-92 (2000), ASTM D 323-99A, ASTM D 0381-04, ASTM 0445-04e2, ASTM 0482-03, ASTM 0524-04, ASTM 0525-05, ASTM 0613-05, ASTM D 975-00, ASTM D 975-00, ASTM 0976-04be1, ASTM D 1094-00, ASTM D 1266-98 (2000) e1, ASTMD1267-02, ASTM D 1298-99e2, ASTM 1319-03, ASTM D 1322 (2002), ASTM D 1405-01, ASTM D 1500-04a, ASTM D 1655-05, ASTM D 1657-02, ASTM 1796-04, ASTM D 1826-94 (2003), ASTM D 1837-02a, ASTM D 1838-05, ASTM D 1840-03, ASTMD1945-03, ASTMD 2158-04, ASTM D 2161-05, ASTM D 2276-00, ASTM D 2386-05, ASTM D 2500-05,

			ASTM D 2533-99, ASTM D 2598-02, ASTM D 2699-04a, ASTM D 2709-06 (2001)e1, ASTM D 2713-91, ASTM D 3227-04a, ASTM D 3228-03, ASTM D 3241-98, ASTM 3243-98, ASTM D 3279-97, ASTM D 3588-98 (2003), ASTM D 3606-04a, ASTM D 3828-05, ASTM D 3948-04, ASTM D 4052-96 (2002)E1, ASTM D 4294-03, ASTM D 4468-85 (2000), ASTM D 4952-02, ASTM D 4953-99a, ASTM D 5188-04, ASTM D 5190-99, ASTM D 5453-05, ASTM D 5500-98 (2005) E1, ASTM D 5598-01, ASTM D 5863-00A (2005).
<i>NOM-026-SESH-2007</i>	ENERGY	guidelines for the work of oil seismological prospection and specifications of maximum energy levels.	DIN 4150-1, Structural vibration, Part.1: Predicting vibration parameters, 2001. 3. DIN 4150-2, Structural vibration, Part. 2: Human exposure to vibration in buildings, 1999. 4. DIN 4150-3, Structural vibration,
<i>NOM-163-SEMARNAT-ENER-SCF-2013</i>	Secretariat of Environment and Natural Resources	carbon bioxide emissions (co2) from the exhaust and its equivalence in terms of fuel performance, applicable to new automotive vehicles of gross vehicular weight of up to 3 857 kilograms	NMX-AA-011-1993-SCFI, Federal Code of Regulations of the United States Environmental Protection Agency of America volume 40, parts 85, 86 and 600 revised on July 1, 1994, by the Protection Agency Environmental of the United States. Final Regulation of Emissions of Greenhouse Gases for Light Vehicles and the Average Corporation for the Fuel Economy (Light-Duty Vehicle Greenhouse Gas Emissions Standards and Corporate Average Fuel Economy Standards. Final Rule, May 2010).
<i>NOM-149-SEMARNAT-2006</i>	Secretariat of Environment and Natural Resources	which establishes the specifications of environmental protection that should be observed in the activities of perforation, maintenance and abandonment of oil wells in the mexican marine areas.	NMX-Z-013/1-1977 International Convention for the Prevention of Pollution from Ships (MARPOL 73/78), published in the Official Gazette of the Federation on October 26, 1993. 9.3 International Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matters, published in the Official Gazette of the Federation on July 16, 1975. 9.4 International Convention on Intervention in the High Seas in Case of Accidents that Cause Pollution by

			Hydrocarbons, published in the Official Gazette of the Federation on May 25, 1976.
<i>NOM-148-SEMARNAT-2006</i>	Secretariat of Environment and Natural Resources	atmospheric contamination.- recovery of sulfur arising from the processes of refining oil.	ASTM D 4294-03, ASTM D 7039-04, ASTM D7041-04, UOP method 9-85
<i>NOM-086-SEMAR-SENER-SCFI-2005</i>	Secretariat of Environment and Natural Resources	specifications of fossil fuels for environmental protection.	there are no supporting standards
<i>NOM-076-SEMARNAT-2012</i>	Secretariat of Environment and Natural Resources	establishing the maximum permissible levels of emission of unburned hydrocarbons, carbon monoxide and nitrogen oxides from the exhaust, as well as evaporative hydrocarbons from the fuel system, using gasoline, g	NMX-AA-23-1986, NMX-Z-013/1-1977, Federal Code of Regulations Title 40, Part 86 of the Environmental Protection Agency of the United States of America. Revised July 1, 1994 (Code of Federal Regulations Title 40, Part 86. Environmental Protection Agency. Reviewed on July 1, 1994); Directives and Regulations 2005/55 / EC, 2008/74 / EC of the European Parliament and of the Council of the Union European Union

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPFGV.

Table 13.50 - Technical Regulation of Pharmaceuticals (Mexico)

TECHNICAL REGULATION	RESPONSIBLE ENTITY	DESCRIPTION	SUPPORTING STANDARDS
<i>NOM-220-SSA1-2016</i>	Secretary of Health	installation and operation of pharmacovigilance	The Uppsala Monitoring Centre/WHO Collaborating Centre for International Monitoring. "Glossary of terms used in pharmacovigilance"; The Uppsala Monitoring Centre/WHO Collaborating Centre for International Monitoring Centre. "How do we identify the risks of medications?", Punto de Vista Bulletin, part 1, page 11, 2003. Pan American Health Organization. "Good Pharmacovigilance Practices for the Americas". Washington, 2010. (Red PARF Technical Document No. 5); The importance of pharmacovigilance. WHO, 2002; Standards and work procedures of the Cuban pharmacovigilance system, 2012; Association of the Spanish Society of Hypertension, Spanish League for the fight against Hypertension May 2004; Guidance for Industry Development and Use of Risk Minimization Action Plans U.S. Department of Health and

			Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) March 2005, FDA; World Health Organization. Global manual on surveillance of adverse events following immunization. Geneva, WHO, 2014; World Health Organization. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO, classification. Geneva, WHO, 2013; Pharmacopoeia of the United Mexican States, World Health Organization. Global Manual on Surveillance of Adverse Events Following Immunization. Draft v2.0, 3 February 2014; Pan American Health Organization. Module IV: Technical and clinical aspects of events supposedly attributable to vaccination or immunization (ESAVI). Washington, D.C, PAHO, 2007; Guideline on good pharmacovigilance practices (GVP) World Health Organization / Uppsala Monitoring Center. Surveillance of the security of the drugs. Guide for the installation and start-up of a Pharmacovigilance Center. 2001.
NOM-001-SSA1-2010	Secretary of Health	that instituts the procedure by which the pharmacopean of the united mexican states will be reviewed, updated and edited.	there are no supporting standards
NOM-059-SSA1-2015	Secretary of Health	good manufacturing practices of medicines.	ISO 9000:2005, ISO 9001:2008, ISO 9004:2009, ISO 14644-1:1999, ISO 14644-2:2000, ISO 14644-3:2005, ISO 14644-4:2001, ISO 14644-5:2004, ISO 31000:2009, I ISO/IEC 31010:2009, World Health Organization. Biosecurity manual in the laboratory, third edition. WHO, Geneva, 2005, World Health Organization. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Vol. 2, 2a. Edition, 2007. Parenteral Drug Association. Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control. Technical Report No. 1 (revised 2007), Supplement Vol. 61, No. S-1. 2007, U.S. Department of

			Health and Human Services, CDC. Biosafety in Microbiological and Biomedical Laboratories, 5th. Edition. 2009, ISPE. GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems. 2008. Validation Guide of the Analytical Method. CNQFBM, 2002. Health Canada. Laboratory Biosafety Guidelines; 3th. Edition. Canada, 2004. James Agalloco, Frederick J. Carleton. Validation of Pharmaceutical Process; 3th edition. Informa Healthcare, 2008. Pharmaceutical Production. An engineering guide, Edited by Bill Bennett and Graham Cole; Institution of Chemical Engineers (IChemE), 2003. ; "Practices of Correct Manufacturing" Guide, Ministry of Health of Spain "Risk Management" 2008; FDA (2004) Pharmaceutical CGMPs for the 21st century - A risk-based approach. Final report; ICH (2005) "Quality risk management ICH Harmonized Tripartite Guideline Guideline, (2008) Pharmaceutical quality system. ICH Harmonized Tripartite Guideline Q10; Pharmaceutical development. ICH Harmonized Tripartite Guideline Q8 (R2); (2011). Analysis techniques for system reliability. Procedure for failure mode and effects analysis (FMEA). International standard 608121985; WHO (2003) Hazard and risk analysis in pharmaceutical products. Technical Report Series, No. 908. Annex 7.
<i>NOM-073-SSA1-2015</i>	Secretary of Health	stability of drugs and medicines, as well as herbal remedies	there are no supporting standards
<i>NOM-072-SSA1-2012</i>	Secretary of Health	labeling of medications and herbolarly remedies.	NMX-Z-055-1997-IMNC Pharmacopoeia of the United Mexican States and its current supplements. Code of Federal Regulation. Title 21, part 201.-- Washington: Office of the Federal Register National Archives and Records Administration, 2001.
<i>NOM-078-SSA1-1994</i>	Secretary of Health	That establishes the sanitary specifications of the calibration standards used in the measurements made in the clinical pathology laboratories.	ASC - 2 "Calibration Reference Materials in Clinical Chemistry" National Committee for Clinical Laboratory Standards (NCCLS) Professional Associations Government - Industry 1975 771 E. Lancaster Avenue Villanova P.A. 19085 U.S.A; NBS "Standard

			Reference Materials for Clinical Laboratory Measurements" U.S. Department of Commerce. National Bureau of Standards 1975. Washington D.C. 20234, U.S.A; F.D.A. GMF. "Current Good Manufacturing Practice for Medical Devices". 1992 Title 21 Sections 800 - 134
NOM-220-SSA1-2016	Secretary of Health	installation and operation of pharmacovigilance	there are no supporting standards
NOM-248-SSA1-2011	Secretary of Health	good manufacturing practices for establishments dedicated to the manufacture of herbolarly remedies. (point 9.8.6 of the standard is necessary to enter into force nom-073-ssa1-2015)	NMX-CC-9000-IMNC-2000, NMX-CC-9001-IMNC-2000AMERICAN NATIONAL STANDARDS INSTITUTE. Generic guidelines for auditing of quality systems ANSI/ASQC Q1-1986. Milwaukee: ASQC Quality Press, 1986. 17.11 U.S. Foods and Drug Administration. "Title 21, parts 11, 58, 210, 211 and 820" Code of Federal Regulations, Washington: Government Printing Office, 2001.

Source: Superintendencia de Industria y Comercio. Elaborated by CCGI-EESPPGV.

13.4. Appendix 4 – Differences between TBT Chapters

Table 13.51 - Differences among TBT chapters in three agreements

United States-Mexico-Canada Agreement (2018) (Final Text)	North American Free Trade Agreement (1994)	Trans-Pacific Partnership (2015)
CHAPTER 11	Chapter Nine: Standards-Related Measures	Chapter 8: Technical Barriers to Trade
TECHNICAL BARRIERS TO TRADE	Part Three: Technical Barriers to Trade	
Article 11.1: Definitions	Article 915: Definitions	Article 8.1: Definitions
1. Annex 1 of the TBT Agreement, including the chapeau and explanatory notes, is incorporated into and made part of this Chapter, mutatis mutandis.		1. The definitions of the terms used in this Chapter contained in Annex 1 of the TBT Agreement, including the chapeau and explanatory notes of Annex 1, are incorporated into this Chapter and shall form part of this Chapter, mutatis mutandis.
2. For the purposes of this Chapter:	1. For purposes of this Chapter:	2. In addition, for the purposes of this Chapter:
	approval procedure means any registration, notification or other mandatory administrative procedure for granting permission for a good or service to be produced, marketed or used for a stated purpose or under stated conditions;	
	assessment of risk means evaluation of the potential for adverse effects;	
	conformity assessment procedure means any procedure used, directly or indirectly, to determine that a technical regulation or standard is fulfilled, including sampling, testing, inspection, evaluation, verification, monitoring, auditing, assurance of conformity, accreditation, registration or approval used for such a purpose, but does not mean an approval procedure;	
		consular transactions means requirements that products of a Party intended for export to the territory of another Party must first be submitted to the supervision of the consul of the importing Party in the territory of the exporting Party for the purpose of obtaining consular invoices or consular visas for conformity assessment documentation;
international conformity assessment systems means systems that facilitate voluntary recognition or acceptance of the results of conformity assessment or accreditation bodies by the authorities of another Party based on compliance with international standards for conformity assessment;		
international standard means a standard that is consistent with the TBT Committee Decision on International Standards;	international standard means a standards-related measure, or other guide or recommendation, adopted by an international standardizing body and made available to the public;	
	international standardizing body means a standardizing body whose membership is open to the relevant bodies of at least all the	

	parties to the <i>GATT Agreement on Technical Barriers to Trade</i> , including the <i>International Organization for Standardization (ISO)</i> , the <i>International Electrotechnical Commission (IEC)</i> , <i>Codex Alimentarius Commission</i> , the <i>World Health Organization (WHO)</i> , the <i>Food and Agriculture Organization (FAO)</i> , the <i>International Telecommunication Union (ITU)</i> ; or any other body that the Parties designate;	
	land transportation service means a transportation service provided by means of motor carrier or rail;	
	legitimate objective includes an objective such as: (a) safety, (b) protection of human, animal or plant life or health, the environment or consumers, including matters relating to quality and identifiability of goods or services, and (c) sustainable development, considering, among other things, where appropriate, fundamental climatic or other geographical factors, technological or infrastructural factors, or scientific justification but does not include the protection of domestic production;	
	make compatible means bring different standards-related measures of the same scope approved by different standardizing bodies to a level such that they are either identical, equivalent or have the effect of permitting goods or services to be used in place of one another or fulfill the same purpose;	
		marketing authorisation means the process or processes by which a Party approves or registers a product in order to authorise its marketing, distribution or sale in the Party's territory. The process or processes may be described in a Party's laws or regulations in various ways, including "marketing authorisation", "authorisation", "approval", "registration", "sanitary authorisation", "sanitary registration" and "sanitary approval" for a product. Marketing authorisation does not include notification procedures;
mutual recognition agreement means an intergovernmental agreement that specifies the conditions by which a Party will recognize the results of conformity assessment procedures produced by another Party's conformity assessment bodies that demonstrate fulfillment of appropriate standards or technical regulations; ¹		mutual recognition agreement means a binding government-to-government agreement for recognition of the results of conformity assessment conducted against the appropriate technical regulations or standards in one or more sectors, including government-to-government agreements to implement the APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment of May 8, 1998 and the Electrical and Electronic Equipment Mutual Recognition Arrangement of July 7, 1999 and other agreements that provide for the recognition of conformity assessment conducted against appropriate technical regulations or standards in one or more sectors;
Footnote 1 For greater certainty, mutual recognition agreements include agreements to implement the APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications		

Equipment of May 8, 1998 and the Electrical and Electronic Equipment Mutual Recognition Arrangement of July 7, 1999.		
mutual recognition arrangement or multilateral recognition arrangement means an international or regional arrangement among accreditation bodies in the territories of the Parties, in which the accreditation bodies, on the basis of peer evaluation, accept the results of each other's accredited conformity assessment bodies or among conformity assessment bodies in the territories of the Parties recognizing the results of conformity assessment;		mutual recognition arrangement means an international or regional arrangement (including a multilateral recognition arrangement) between accreditation bodies recognising the equivalence of accreditation systems (based on peer review) or between conformity assessment bodies recognising the results of conformity assessment;
		post-market surveillance means procedures taken by a Party after a product has been placed on its market to enable the Party to monitor or address compliance with the Party's domestic requirements for products;
proposed technical regulation or conformity assessment procedure means the entirety of the text setting forth: (a) a proposed technical regulation or conformity assessment procedure; or (b) a significant amendment to an existing technical regulation or conformity assessment procedure;		
	services means land transportation services and telecommunications services;	
	standard means a document, approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for goods or related processes and production methods, or for services or related operating methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a good, process, or production or operating method;	
	standardizing body means a body having recognized activities in standardization;	
	standards-related measure means a standard, technical regulation or conformity assessment procedure;	
TBT Agreement means the Agreement on Technical Barriers to Trade, set out in Annex 1A to the WTO Agreement; and		TBT Agreement means the <i>WTO Agreement on Technical Barriers to Trade</i> , as may be amended; and
TBT Committee Decision on International Standards means Annex 2 to Part 1 (Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement) in the Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.13), as may be revised, issued by the WTO Committee on Technical Barriers to Trade.		
	technical regulation means a document which lays down goods characteristics or their related processes and production methods, or services characteristics or their related operating methods, including	

	the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a good, process, or production or operating method; and	
	telecommunications service means a service provided by means of the transmission and reception of signals by any electromagnetic means, but does not mean the cable, broadcast or other electromagnetic distribution of radio or television programming to the public generally.	
		verify means to take action to confirm the veracity of individual conformity assessment results, such as requesting information from the conformity assessment body or the body that accredited, approved, licensed or otherwise recognised the conformity assessment body, but does not include requirements that subject a product to conformity assessment in the territory of the importing Party that duplicate the conformity assessment procedures already conducted with respect to the product in the territory of the exporting Party or a third party, except on a random or infrequent basis for the purpose of surveillance, or in response to information indicating non-compliance.
	2. Except as they are otherwise defined in this Agreement, other terms in this Chapter shall be interpreted in accordance with their ordinary meaning in context and in the light of the objectives of this Agreement, and where appropriate by reference to the terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, <i>General Terms and Their Definitions Concerning Standardization and Related Activities</i> .	
		Article 8.2: Objective
		The objective of this Chapter is to facilitate trade, including by eliminating unnecessary technical barriers to trade, enhancing transparency, and promoting greater regulatory cooperation and good regulatory practice.
Article 11.2: Scope	Article 901: Scope and Coverage	Article 8.3: Scope
1. This Chapter applies to the preparation, adoption and application of standards, technical regulations, and conformity assessment procedures, including any amendments, of central level of government bodies, which may affect trade in goods between the Parties.	1. This Chapter applies to standards-related measures of a Party, other than those covered by Section B of Chapter Seven (Sanitary and Phytosanitary Measures), that may, directly or indirectly, affect trade in goods or services between the Parties, and to measures of the Parties relating to such measures.	1. This Chapter shall apply to the preparation, adoption and application of all technical regulations, standards and conformity assessment procedures of central level of government bodies (and, where explicitly provided for, technical regulations, standards and conformity assessment procedures of government bodies at the level directly below that of the central level of government) that may affect trade in goods between the Parties, except as provided in paragraphs 4 and 5.
		2. Each Party shall take reasonable measures that are within its authority to encourage observance by regional or local government bodies, as the case may be, on the level directly below that of the

		central level of government within its territory which are responsible for the preparation, adoption and application of technical regulations, standards and conformity assessment procedures, of Article 8.5 (International Standards, Guides and Recommendations), Article 8.6 (Conformity Assessment), Article 8.8 (Compliance Period for Technical Regulations and Conformity Assessment Procedures) and each of the Annexes to this Chapter.
		3. All references in this Chapter to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments to them and any addition to the rules or the product coverage of those technical regulations, standards and procedures, except amendments and additions of an insignificant nature.
2. Notwithstanding paragraph 1, this Chapter does not apply to:		
(a) technical specifications prepared by a governmental body for production or consumption requirements of a governmental body; or	2. Technical specifications prepared by governmental bodies for production or consumption requirements of such bodies shall be governed exclusively by Chapter Ten (Government Procurement).	4. This Chapter shall not apply to technical specifications prepared by a governmental entity for its production or consumption requirements. These specifications are covered by Chapter 15 (Government Procurement).
(b) sanitary or phytosanitary measures.		5. This Chapter shall not apply to sanitary and phytosanitary measures. These are covered by Chapter 7 (Sanitary and Phytosanitary Measures).
		6. For greater certainty, nothing in this Chapter shall prevent a Party from adopting or maintaining technical regulations, standards or conformity assessment procedures in accordance with its rights and obligations under this Agreement, the TBT Agreement and any other relevant international agreement.
	Article 902: Extent of Obligations	
	1. Article 105 (Extent of Obligations) does not apply to this Chapter.	
	2. Each Party shall seek, through appropriate measures, to ensure observance of Articles 904 through 908 by state or provincial governments and by non-governmental standardizing bodies in its territory.	
Article 11.3: Incorporation of the TBT Agreement	Article 903: Affirmation of Agreement on Technical Barriers to Trade and Other Agreements	Article 8.4: Incorporation of Certain Provisions of the TBT Agreement
1. The following provisions of the TBT Agreement are incorporated into and made part of this Agreement, mutatis mutandis: (a) Articles 2.1, 2.2, 2.3, 2.4, 2.5, 2.9, 2.10, 2.11, and 2.12; (b) Articles 3.1, 4.1, and 7.1; (c) Articles 5.1, 5.2, 5.3, 5.4, 5.6, 5.7, 5.8, and 5.9; and (d) Paragraphs D, E, F, and J of Annex 3.	Further to Article 103 (Relation to Other Agreements), the Parties affirm with respect to each other their existing rights and obligations relating to standards-related measures under the <i>GATT Agreement on Technical Barriers to Trade</i> and all other international agreements, including environmental and conservation agreements, to which those Parties are party.	1. The following provisions of the TBT Agreement are incorporated into and made part of this Agreement, mutatis mutandis: (a) Articles 2.1, 2.2, 2.4, 2.5, 2.9, 2.10, 2.11, 2.12; (b) Articles 5.1, 5.2, 5.3, 5.4, 5.6, 5.7, 5.8, 5.9; and (c) paragraphs D, E and F of Annex 3.
2. No Party shall have recourse to dispute settlement under Chapter 31 (Dispute Settlement) for a matter arising under this Chapter if the dispute concerns: (a) exclusively claims made under the provisions of the TBT Agreement incorporated under paragraph 1; or (b) a measure that a Party alleges to be inconsistent with this Chapter that:		2. No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for a dispute that exclusively alleges a violation of the provisions of the TBT Agreement incorporated under paragraph 1.

(i) was referred or is subsequently referred to a WTO dispute settlement panel (ii) was taken to comply in response to the recommendations or rulings from the WTO Dispute Settlement Body, or (iii) bears a close nexus, such as in terms of nature, effects, and timing, with respect to a measure described in subparagraph (ii).		
	Article 904: Basic Rights and Obligations	
	<i>Right to Take Standards-Related Measures</i>	
	1. Each Party may, in accordance with this Agreement, adopt, maintain or apply any standards-related measure, including any such measure relating to safety, the protection of human, animal or plant life or health, the environment or consumers, and any measure to ensure its enforcement or implementation. Such measures include those to prohibit the importation of a good of another Party or the provision of a service by a service provider of another Party that fails to comply with the applicable requirements of those measures or to complete the Party's approval procedures.	
	<i>Right to Establish Level of Protection</i>	
	2. Notwithstanding any other provision of this Chapter, each Party may, in pursuing its legitimate objectives of safety or the protection of human, animal or plant life or health, the environment or consumers, establish the levels of protection that it considers appropriate in accordance with Article 907(2).	
	<i>Non-Discriminatory Treatment</i>	
	3. Each Party shall, in respect of its standards-related measures, accord to goods and service providers of another Party:	
	(a) national treatment in accordance with Article 301 (Market Access) or Article 1202 (Cross-Border Trade in Services); and	
	(b) treatment no less favorable than that it accords to like goods, or in like circumstances to service providers, of any other country.	
	<i>Unnecessary Obstacles</i>	
	4. No Party may prepare, adopt, maintain or apply any standards-related measure with a view to or with the effect of creating an unnecessary obstacle to trade between the Parties. An unnecessary obstacle to trade shall not be deemed to be created where:	
	(a) the demonstrable purpose of the measure is to achieve a legitimate objective; and	
	(b) the measure does not operate to exclude goods of another Party that meet that legitimate objective.	
Article 11.4: International Standards, Guides and Recommendations	Article 905: Use of International Standards	Article 8.5: International Standards, Guides and Recommendations
1. The Parties recognize the important role that international standards, guides, and recommendations can play in supporting greater regulatory alignment and good regulatory practices, and in reducing unnecessary barriers to trade.		1. The Parties recognise the important role that international standards, guides and recommendations can play in supporting greater regulatory alignment, good regulatory practice and reducing unnecessary barriers to trade.

	1. Each Party shall use, as a basis for its standards-related measures, relevant international standards or international standards whose completion is imminent, except where such standards would be an ineffective or inappropriate means to fulfill its legitimate objectives, for example because of fundamental climatic, geographical, technological or infrastructural factors, scientific justification or the level of protection that the Party considers appropriate.	
2. To determine whether there is an international standard, guide, or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement, each Party shall apply the TBT Committee Decision on International Standards.		2. In this respect, and further to Articles 2.4 and 5.4 and Annex 3 of the TBT Agreement, to determine whether there is an international standard, guide or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement, each Party shall apply the Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.12), as may be revised, issued by the WTO Committee on Technical Barriers to Trade.
3. Each Party shall apply no additional principles or criteria other than those in the TBT Committee Decision on International Standards in order to recognize a standard as an international standard. For greater certainty, criteria that are not relevant to determining whether a standard is an international standard include: (a) the domicile of the standards body; (b) whether the standards body is non-governmental or inter-governmental; and (c) whether the standards body limits participation to delegations.		
	2. A Party's standards-related measure that conforms to an international standard shall be presumed to be consistent with Article 904(3) and (4).	
	3. Nothing in paragraph 1 shall be construed to prevent a Party, in pursuing its legitimate objectives, from adopting, maintaining or applying any standards-related measure that results in a higher level of protection than would be achieved if the measure were based on the relevant international standard.	
4. The Parties shall cooperate with each other in appropriate circumstances to ensure that international standards, guides, and recommendations that are likely to become a basis for technical regulations and conformity assessment procedures do not create unnecessary obstacles to international trade.		3. The Parties shall cooperate with each other, when feasible and appropriate, to ensure that international standards, guides and recommendations that are likely to become a basis for technical regulations and conformity assessment procedures do not create unnecessary obstacles to international trade.
5. No Party shall accord any preference to the consideration or use of standards that are developed through processes that: (a) are inconsistent with the TBT Committee Decision on International Standards; or (b) treat persons of any of the Parties less favorably than persons whose domicile is the same as the standardization body.		
6. With respect to any agreement or understanding establishing a customs union or free-trade area or providing trade-related technical assistance, each Party shall encourage the adoption, and use as the basis for standards, technical regulations, and conformity assessment		

procedures, of any relevant standards, guides, or recommendations developed in accordance with the TBT Committee Decision on International Standards.		
7. Recognizing the importance of maintaining North American commercial integration and maintaining market access for producers in North America, each Party shall ensure that any obligation or understanding it has with a non-Party does not facilitate or require the withdrawal or limitation on the use or acceptance of any relevant standard, guide, or recommendation developed in accordance with the TBT Committee Decision on International Standards or the relevant provisions of this Chapter.		
Article 11.5: Technical Regulations		
<i>Preparation and Review of Technical Regulations</i>		
1. Each Party shall conduct an appropriate assessment concerning any major technical regulations it proposes to adopt. An assessment can include:		
(a) a regulatory impact analysis of the technical regulation's potential impacts; or		
(b) an analysis that requires evaluation of alternative measures, if any, including voluntary actions that are brought to the Party's attention in a timely manner.		
Each Party shall maintain discretion in deciding if a proposed technical regulation is major under this paragraph.		
2. Each Party shall:		
(a) periodically review technical regulations and conformity assessment procedures in order to:		
(i) examine increasing alignment with relevant international standards, including by reviewing any new developments in the relevant international standards and whether the circumstances that have given rise to divergences from any relevant international standard continue to exist, and		
(ii) consider the existence of any less trade-restrictive approaches; or		
(b) maintain a process whereby a person of another Party may directly petition the Party's regulatory authorities to review a technical regulation or conformity assessment procedure on the grounds that:		
(i) circumstances that were relevant to the content of the technical regulation have changed, or		
(ii) a less trade-restrictive method to fulfil the technical regulation's objective exists, such as a technical regulation based on the international standard.		
<i>Use of Standards in Technical Regulations</i>		
3. If there are multiple international standards that would be effective and appropriate to fulfil the Party's legitimate objectives of a		

technical regulation or conformity assessment procedure, the Party shall:		
(a) consider using as a basis for the technical regulation or conformity assessment procedure each of the international standards that fulfill the legitimate objectives of the technical regulation or conformity assessment procedure; and		
(b) if the Party has rejected an international standard that was brought to its attention, issue a written explanation wherever practicable.		
The written explanation provided for in subparagraph (b) must include the reasons for the Party's decision to reject an international standard and shall be provided directly to the person that proposed a particular international standard or in a document that is published at the same time that the Party publishes the final technical regulation or conformity assessment procedure.		
4. If no international standard is available that fulfils the legitimate objectives of the technical regulation or conformity assessment procedure, each Party shall consider whether a standard developed by a standardizing body domiciled in any of the Parties can fulfill its legitimate objectives. To that end, each Party shall:		
(a) consider and decide whether to accept the standard developed by a standardizing body domiciled in any of the Parties fulfils its legitimate objectives; and		
(b) if the Party has rejected a standard that was brought to its attention, issue a written explanation wherever practicable.		
The written explanation provided for in subparagraph (b) must include the reasons for the Party's decision to reject an international standard and shall be provided directly to the person that proposed a particular standard or in a document that is published at the same time the Party publishes the final technical regulation or conformity assessment procedure.		
5. In order for a Party to consider accepting or using a standard as provided for in paragraphs 4 and 5, the Parties recognize that a standard must be brought to the attention of a Party, in a language the Party utilizes for the publication of technical regulations and conformity assessment procedures. This must be done during the Party's planning stage or when the proposed technical regulation or conformity assessment procedure is published for comment as provided for in Article 11.7 (Transparency).		
<i>Information Exchange</i>		
6. If a Party has not used an international standard as a basis for a technical regulation, a Party shall, on request from another Party, explain why it has not used a relevant international standard or has substantially deviated from an international standard. The explanation shall address why the standard has been judged		

inappropriate or ineffective for the objective pursued, and identify the scientific or technical evidence on which this assessment is based. To facilitate an appropriate explanation, the requesting Party shall in its request:		
(a) identify a relevant international standard that the technical regulation has purportedly not used as its basis; and		
(b) describe how the technical regulation is constraining or has the potential to constraint its exports.		
The requesting Party shall also endeavour to indicate whether the international standard was brought to the responding Party's attention when it was developing the technical regulation.		
7. In addition to Article 2.7 of the TBT Agreement, a Party shall, on request of another Party, ² provide the reasons why it has not or cannot accept a technical regulation of that Party as equivalent to its own. The Party to which the request is made should provide its response within a reasonable period of time.		
Footnote 2 The Party's request should identify with precision the respective technical regulations it considers to be equivalent and any data or evidence that supports its position.		
<i>Labeling</i>		
8. In order to avoid disrupting North American trade, and consistent with the obligations contained in Article 11.3 (Incorporation of the TBT Agreement), each Party shall ensure that its technical regulations concerning labels:		
(a) accord treatment no less favorable than that accorded to like goods of national origin; and		
(b) do not create unnecessary obstacles to trade between the Parties.		
	Article 906: Compatibility and Equivalence	Article 8.9: Cooperation and Trade Facilitation
	1. Recognizing the crucial role of standards-related measures in achieving legitimate objectives, the Parties shall, in accordance with this Chapter, work jointly to enhance the level of safety and of protection of human, animal and plant life and health, the environment and consumers.	
	2. Without reducing the level of safety or of protection of human, animal or plant life or health, the environment or consumers, without prejudice to the rights of any Party under this Chapter, and taking into account international standardization activities, the Parties shall, to the greatest extent practicable, make compatible their respective standards-related measures, so as to facilitate trade in a good or service between the Parties.	2. The Parties recognise that a broad range of mechanisms exist to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region, including:
		(a) regulatory dialogue and cooperation to, among other things:
		(i) exchange information on regulatory approaches and practices;
		(ii) promote the use of good regulatory practices to improve the efficiency and effectiveness of technical regulations, standards and conformity assessment procedures;

		(iii) provide technical advice and assistance, on mutually agreed terms and conditions, to improve practices related to the development, implementation and review of technical regulations, standards, conformity assessment procedures and metrology; or
		(iv) provide technical assistance and cooperation, on mutually agreed terms and conditions, to build capacity and support the implementation of this Chapter;
		(b) greater alignment of national standards with relevant international standards, except where inappropriate or ineffective;
		(c) facilitation of the greater use of relevant international standards, guides and recommendations as the basis for technical regulations and conformity assessment procedures; and
		(d) promotion of the acceptance of technical regulations of another Party as equivalent.
	3. Further to Articles 902 and 905, a Party shall, on request of another Party, seek, through appropriate measures, to promote the compatibility of a specific standard or conformity assessment procedure that is maintained in its territory with the standards or conformity assessment procedures maintained in the territory of the other Party.	5. A Party shall, on request of another Party, give due consideration to any sector-specific proposal for cooperation under this Chapter.
	4. Each importing Party shall treat a technical regulation adopted or maintained by an exporting Party as equivalent to its own where the exporting Party, in cooperation with the importing Party, demonstrates to the satisfaction of the importing Party that its technical regulation adequately fulfills the importing Party's legitimate objectives.	
	5. The importing Party shall provide to the exporting Party, on request, its reasons in writing for not treating a technical regulation as equivalent under paragraph 4.	6. Further to Article 2.7 of the TBT Agreement, a Party shall, on request of another Party, explain the reasons why it has not accepted a technical regulation of that Party as equivalent.
	6. Each Party shall, wherever possible, accept the results of a conformity assessment procedure conducted in the territory of another Party, provided that it is satisfied that the procedure offers an assurance, equivalent to that provided by a procedure it conducts or a procedure conducted in its territory the results of which it accepts, that the relevant good or service complies with the applicable technical regulation or standard adopted or maintained in the Party's territory.	1. Further to Articles 5, 6 and 9 of the TBT Agreement, the Parties acknowledge that a broad range of mechanisms exist to facilitate the acceptance of conformity assessment results. In this regard, a Party may:
		(a) implement mutual recognition of the results of conformity assessment procedures performed by bodies located in its territory and another Party's territory with respect to specific technical regulations;
		(b) recognise existing regional and international mutual recognition arrangements between or among accreditation bodies or conformity assessment bodies;

		(c) use accreditation to qualify conformity assessment bodies, particularly international systems of accreditation;
		(d) designate conformity assessment bodies or recognise another Party's designation of conformity assessment bodies;
		(e) unilaterally recognise the results of conformity assessment procedures performed in another Party's territory; and
		(f) accept a supplier's declaration of conformity.
	7. Prior to accepting the results of a conformity assessment procedure pursuant to paragraph 6, and to enhance confidence in the continued reliability of each other's conformity assessment results, the Parties may consult on such matters as the technical competence of the conformity assessment bodies involved, including verified compliance with relevant international standards through such means as accreditation.	
		3. With respect to the mechanisms listed in paragraphs 1 and 2, the Parties recognise that the choice of the appropriate mechanism in a given regulatory context depends on a variety of factors, such as the product and sector involved, the volume and direction of trade, the relationship between Parties' respective regulators, the legitimate objectives pursued and the risks of non-fulfilment of those objectives.
		4. The Parties shall strengthen their exchange and collaboration on mechanisms to facilitate the acceptance of conformity assessment results, to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region.
		7. The Parties shall encourage cooperation between their respective organisations responsible for standardisation, conformity assessment, accreditation and metrology, whether they are public or private, with a view to addressing issues covered by this Chapter.
	Article 907: Assessment of Risk	
	1. A Party may, in pursuing its legitimate objectives, conduct an assessment of risk. In conducting an assessment, a Party may take into account, among other factors relating to a good or service:	
	(a) available scientific evidence or technical information;	
	(b) intended end uses;	
	(c) processes or production, operating, inspection, sampling or testing methods; or	
	(d) environmental conditions.	
	2. Where pursuant to Article 904(2) a Party establishes a level of protection that it considers appropriate and conducts an assessment of risk, it should avoid arbitrary or unjustifiable distinctions between similar goods or services in the level of protection it considers appropriate, where the distinctions:	
	(a) result in arbitrary or unjustifiable discrimination against goods or service providers of another Party;	

	(b) constitute a disguised restriction on trade between the Parties; or	
	(c) discriminate between similar goods or services for the same use under the same conditions that pose the same level of risk and provide similar benefits.	
	3. Where a Party conducting an assessment of risk determines that available scientific evidence or other information is insufficient to complete the assessment, it may adopt a provisional technical regulation on the basis of available relevant information. The Party shall, within a reasonable period after information sufficient to complete the assessment of risk is presented to it, complete its assessment, review and, where appropriate, revise the provisional technical regulation in the light of that assessment.	
Article 11.6: Conformity Assessment	Article 908: Conformity Assessment	Article 8.6: Conformity Assessment
<i>National Treatment</i>		
	1. The Parties shall, further to Article 906 and recognizing the existence of substantial differences in the structure, organization and operation of conformity assessment procedures in their respective territories, make compatible those procedures to the greatest extent practicable.	
1. In addition to Article 6.4 of the TBT Agreement, each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favorable than that it accords to conformity assessment bodies located in its own territory or in the territory of the other Party. Treatment under this paragraph includes procedures, criteria, fees, and other conditions relating to accrediting, approving, licensing, or otherwise recognizing conformity assessment bodies.	2. Recognizing that it should be to the mutual advantage of the Parties concerned and except as set out in Annex 908.2, each Party shall accredit, approve, license or otherwise recognize conformity assessment bodies in the territory of another Party on terms no less favorable than those accorded to conformity assessment bodies in its territory.	1. Further to Article 6.4 of the TBT Agreement, each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party. In order to ensure that it accords such treatment, each Party shall apply the same or equivalent procedures, criteria and other conditions to accredit, approve, license or otherwise recognise conformity assessment bodies located in the territory of another Party that it may apply to conformity assessment bodies in its own territory.
2. In addition to Article 6.4 of the TBT Agreement, if a Party maintains procedures, criteria or other conditions as set out in paragraph 1 and requires conformity assessment results, including test results, certifications, technical reports or inspections as positive assurance that a product conforms to a technical regulation or standard, it shall:		2. Further to Article 6.4 of the TBT Agreement, if a Party maintains procedures, criteria or other conditions as set out in paragraph 1 and requires test results, certifications or inspections as positive assurance that a product conforms to a technical regulation or standard, the Party: (a) shall not require the conformity assessment body that tests or certifies the product, or the conformity assessment body conducting an inspection, to be located within its territory; (b) shall not impose requirements on conformity assessment bodies located outside its territory that would effectively require those conformity assessment bodies to operate an office in that Party's territory; and (c) shall permit conformity assessment bodies in other Parties' territories to apply to the Party for a determination that they comply with any procedures, criteria and other conditions the Party requires to deem them competent or to otherwise approve them to test or certify the product or conduct an inspection.

(a) not require the conformity assessment body to be located within its territory;		
(b) not effectively require the conformity assessment body to operate an office within its territory; and		
(c) permit conformity assessment bodies in other Parties' territories to apply to the Party, or any body that it has recognized or approved for this purpose, for a determination that they comply with any procedures, criteria and other conditions the Party requires to deem them competent or to otherwise approve them to test or certify the product or conduct an inspection.		
		3. Paragraphs 1 and 2 shall not preclude a Party from undertaking conformity assessment in relation to a specific product solely within specified government bodies located in its own territory or in another Party's territory, in a manner consistent with its obligations under the TBT Agreement.
<i>Explanations and Information</i>		
3. If a Party undertakes conformity assessment procedures in relation to specific products by specified government bodies located in its own territory or in another Party's territory, the Party shall, on the request of another Party or if practicable, an applicant of another Party, explain:		4. If a Party undertakes conformity assessment under paragraph 3, and further to Articles 5.2 and 5.4 of the TBT Agreement concerning limitation on information requirements, the protection of legitimate commercial interests and the adequacy of review procedures, the Party shall, on the request of another Party, explain: (a) how the information required is necessary to assess conformity and determine fees; (b) how the Party ensures that the confidentiality of the information required is respected in a manner that ensures legitimate commercial interests are protected; and (c) the procedure to review complaints concerning the operation of the conformity assessment procedure and to take corrective action when a complaint is justified.
(a) how the information it requires is necessary to assess conformity;		
(b) the sequence in which a conformity assessment procedure is undertaken and completed;		
(c) how the Party ensures that confidential business information is protected; and		
(d) the procedure to review complaints concerning the operation of the conformity assessment procedure and to take corrective action when a complaint is justified.		
4. Each Party shall explain, on the request of another Party, the reasons for its decision, whenever it declines to:		
(a) accredit, approve, license, or otherwise recognize a conformity assessment body;		
(b) recognize the results from a conformity assessment body that is a signatory to a mutual recognition arrangement;		
(c) accept the results of a conformity assessment procedure conducted in the territory of another Party; or		
(d) continue negotiations for a mutual recognition agreement.		

		5. Paragraphs 1 and 2(c) shall not preclude a Party from using mutual recognition agreements to accredit, approve, license or otherwise recognise conformity assessment bodies located outside its territory.
		6. Nothing in paragraphs 1, 2 and 5 precludes a Party from verifying the results of conformity assessment procedures undertaken by conformity assessment bodies located outside its territory.
		7. Further to paragraph 6, in order to enhance confidence in the continued reliability of conformity assessment results from the Parties' respective territories, a Party may request information on matters pertaining to conformity assessment bodies located outside its territory.
<i>Subcontracting</i>		
5. If a Party requires conformity assessment as a positive assurance that a product conforms with a technical regulation or standard, it shall not prohibit a conformity assessment body from using subcontractors, or refuse to accept the results of conformity assessment on account of the conformity assessment body using subcontractors, to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of another Party, ³ provided that the subcontractors are accredited and approved in the Party's territory, when required.		
Footnote 3 For greater certainty, this paragraph does not prohibit a Party from taking steps to ensure the performance of the subcontractor meets its requirements.		
<i>Accreditation</i>		
6. In addition to Article 9.2 of the TBT Agreement, no Party shall refuse to accept, or take actions that have the effect of, directly or indirectly, requiring or encouraging the refusal of acceptance of conformity assessment results performed by a conformity assessment body located in the territory of another Party because the accreditation body that accredited the conformity assessment body:		9. Further to Article 9.2 of the TBT Agreement no Party shall refuse to accept conformity assessment results from a conformity assessment body or take actions that have the effect of, directly or indirectly, requiring or encouraging another Party or person to refuse to accept conformity assessment results from a conformity assessment body because the accreditation body that accredited the conformity assessment body: (a) operates in the territory of a Party where there is more than one accreditation body; (b) is a non-governmental body; (c) is domiciled in the territory of a Party that does not maintain a procedure for recognising accreditation bodies, provided that the accreditation body is recognised internationally, consistent with the provisions in paragraph 8; (d) does not operate an office in the Party's territory; or (e) is a for-profit entity.
(a) operates in the territory of a Party where there is more than one accreditation body;		
(b) is a non-governmental body;		
(c) is domiciled in the territory of a Party that does not maintain a procedure for recognizing accreditation bodies, provided that the accreditation body is recognized internationally, consistent with paragraph 7;		

(d) does not operate an office in the Party's territory; or (e) is a for-profit entity.		
		10. Nothing in paragraph 9 prohibits a Party from refusing to accept conformity assessment results from a conformity assessment body on grounds other than those set out in paragraph 9 if that Party can substantiate those grounds for the refusal, and that refusal is not inconsistent with the TBT Agreement and this Chapter.
7. In addition to Article 9.1 of the TBT Agreement, each Party shall:		8. Further to Article 9.1 of the TBT Agreement, a Party shall consider adopting measures to approve conformity assessment bodies that have accreditation for the technical regulations or standards of the importing Party, by an accreditation body that is a signatory to an international or regional mutual recognition arrangement. ¹ The Parties recognise that these arrangements can address the key considerations in approving conformity assessment bodies, including technical competence, independence, and the avoidance of conflicts of interest.
(a) adopt or maintain measures to facilitate and encourage its authorities to rely on mutual or multilateral recognition arrangements to accredit, approve, license or otherwise recognize conformity assessment bodies where effective and appropriate to fulfill the Party's legitimate objectives; and		
(b) consider approving or recognizing accredited conformity assessment bodies for its technical regulations or standards, by an accreditation body that is a signatory to a mutual or multilateral recognition arrangement, for example, the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF).		
The Parties recognize that the arrangements referenced in subparagraph (b) can address considerations in approving conformity assessment bodies, including technical competence, independence, and the avoidance of conflicts of interest.		
		Footnote 1 The Committee shall be responsible for developing and maintaining a list of such arrangements.
<i>Choice of Conformity Assessment</i>		
8. The Parties recognize that the choice of conformity assessment procedures in relation to a specific product covered by a technical regulation or standard should include an evaluation of the risks involved, the need to adopt procedures to address those risks, relevant scientific and technical information, incidence of non-compliant products, and possible alternative approaches for establishing that the technical regulation or standard has been met.		
<i>Fees</i>		
9. Nothing in this Article precludes a Party from requesting that conformity assessment procedures in relation to specific products are		

performed by specified government authorities of the Party. In those cases, the Party conducting the conformity assessment procedures shall:		
(a) limit any fees it imposes for conformity assessment procedures on products from the other Parties to the costs of services rendered;		
(b) not impose fees on an applicant of another Party to deliver conformity assessment services, except to recover costs incurred from services rendered;		
(c) make the amounts of any fees for conformity assessment procedures publicly available;		
(d) not apply a new or modified fee for conformity assessment procedures until the fee and the method for assessing the fee are published and, if practicable, the Party has provided an opportunity for interested persons to comment on the proposed introduction or modification of a conformity assessment fee.		
10. On request of a Party, or an applicant's request if practicable, a Party shall explain how:		
(a) any fees it imposes for such conformity assessment are no higher than the cost of services rendered;		
(b) fees for its conformity assessment procedures are calculated; and		
(c) any information it requires is necessary to calculate fees.		
<i>Exceptions</i>		
11. For greater certainty, nothing in paragraphs 1 or 2 precludes a Party from taking actions to verify the results from a conformity assessment procedure, including requesting information from the conformity assessment or accreditation body. These actions shall not subject a product to duplicative conformity assessment procedures, except when necessary to address non-compliance. The verifying Party may share information it has requested with another Party, provided it protects confidential information.		
12. Paragraphs 2(b) and 5 do not apply to any requirement a Party may have concerning the use of products, conformity assessment procedures or related services in the commercial maritime or civil aviation sectors.		
		11. A Party shall publish, preferably by electronic means, any procedures, criteria and other conditions that it may use as the basis for determining whether conformity assessment bodies are competent to receive accreditation, approval, licensing or other recognition, including accreditation, approval, licensing or other recognition granted pursuant to a mutual recognition agreement.
		12. If a Party: (a) accredits, approves, licenses or otherwise recognises a body assessing conformity with a particular technical regulation or standard in its territory, and refuses to accredit, approve, license or otherwise recognise a body assessing conformity with that technical regulation or standard in the territory of another

		Party; or (b) declines to use a mutual recognition arrangement, it shall, on request of the other Party, explain the reasons for its decision.
		13. If a Party does not accept the results of a conformity assessment procedure conducted in the territory of another Party, it shall, on the request of the other Party, explain the reasons for its decision.
		14. Further to Article 6.3 of the TBT Agreement, if a Party declines the request of another Party to enter into negotiations to conclude an agreement for mutual recognition of the results of each other's conformity assessment procedures, it shall, on request of that other Party, explain the reasons for its decision.
		15. Further to Article 5.2.5 of the TBT Agreement any conformity assessment fees imposed by a Party shall be limited to the approximate cost of services rendered.
		16. No Party shall require consular transactions, including related fees and charges, in connection with conformity assessment. ²
		Footnote 2
		For greater certainty, this paragraph shall not apply to a Party verifying conformity assessment documents during a marketing authorisation or reauthorisation process.
	3. Each Party shall, with respect to its conformity assessment procedures:	
	(a) not adopt or maintain any such procedure that is stricter, nor apply the procedure more strictly, than necessary to give it confidence that a good or a service conforms with an applicable technical regulation or standard, taking into account the risks that non-conformity would create; (b) initiate and complete the procedure as expeditiously as possible; (c) in accordance with Article 904(3), undertake processing of applications in non-discriminatory order; (d) publish the normal processing period for each such procedure or communicate the anticipated processing period to an applicant on request;	
	(e) ensure that the competent body (i) on receipt of an application, promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of any deficiency, (ii) transmits to the applicant as soon as possible the results of the conformity assessment procedure in a form that is precise and complete so that the applicant may take any necessary corrective action, (iii) where the application is deficient, proceeds as far as practicable with the procedure where the applicant so requests, and (iv) informs the applicant, on request, of the status of the application and the reasons for any delay;	
	(f) limit the information the applicant is required to supply to that necessary to conduct the procedure and to determine appropriate fees;	

	(g) accord confidential or proprietary information arising from, or supplied in connection with, the conduct of the procedure for a good of another Party or for a service provided by a person of another Party (i) the same treatment as that for a good of the Party or a service provided by a person of the Party, and (ii) in any event, treatment that protects an applicant's legitimate commercial interests to the extent provided under the Party's law;	
	(h) ensure that any fee it imposes for conducting the procedure is no higher for a good of another Party or a service provider of another Party than is equitable in relation to any such fee imposed for its like goods or service providers or for like goods or service providers of any other country, taking into account communication, transportation and other related costs; (i) ensure that the location of facilities at which a conformity assessment procedure is conducted does not cause unnecessary inconvenience to an applicant or its agent; (j) limit the procedure, for a good or service modified subsequent to a determination that the good or service conforms to the applicable technical regulation or standard, to that necessary to determine that the good or service continues to conform to the technical regulation or standard; and (k) limit any requirement regarding samples of a good to that which is reasonable, and ensure that the selection of samples does not cause unnecessary inconvenience to an applicant or its agent.	
	4. Each Party shall apply, with such modifications as may be necessary, the relevant provisions of paragraph 3 to its approval procedures.	
	5. Each Party shall, on request of another Party, take such reasonable measures as may be available to it to facilitate access in its territory for conformity assessment activities.	
	6. Each Party shall give sympathetic consideration to a request by another Party to negotiate agreements for the mutual recognition of the results of that other Party's conformity assessment procedures.	
Article 11.7: Transparency	Article 909: Notification, Publication, and Provision of Information	Article 8.7: Transparency
1. Each Party shall allow persons of another Party to participate in the development of technical regulations, standards and conformity assessment procedures ⁴ by its central government bodies on terms no less favorable than those that it accords to its own persons.		1. Each Party shall allow persons of another Party to participate in the development of technical regulations, standards and conformity assessment procedures by its central government bodies ³ on terms no less favourable than those that it accords to its own persons.
Footnote 4 A Party satisfies this obligation by, for example, providing interested persons a reasonable opportunity to provide comments on the measure it proposes to develop and by taking those comments into account in the development of the measure.		Footnote 3 A Party satisfies this obligation by, for example, providing interested persons a reasonable opportunity to provide comments on the measure it proposes to develop and taking those comments into account in the development of the measure.

2. Further to Articles 2.9 and 5.6 of the TBT Agreement, if a Party prepares or proposes to adopt a technical regulation or conformity assessment procedure that is not in response to an urgent situation as referred to in Article 2.10 and Article 5.7 of the TBT Agreement, the Party shall:	1. Further to Articles 1802 (Publication) and 1803 (Notification and Provision of Information), each Party proposing to adopt or modify a technical regulation shall:	
(a) publish the proposed technical regulation or conformity assessment procedure;	(a) at least 60 days prior to the adoption or modification of the measure, other than a law, publish a notice and notify in writing the other Parties of the proposed measure in such a manner as to enable interested persons to become acquainted with the proposed measure, except that in the case of any such measure relating to perishable goods, each Party shall, to the greatest extent practicable, publish the notice and provide the notification at least 30 days prior to the adoption or modification of the measure, but no later than when notification is provided to domestic producers;	4. Each Party shall publish all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies.
(b) allow persons of another Party to submit written comments during a public consultation period on no less favorable terms than it provides to its own persons;		
	(b) identify in the notice and notification the good or service to which the measure would apply, and shall provide a brief description of the objective of, and reasons for the measure;	13. A Party that publishes a notice and that files a notification in accordance with Article 2.9, 3.2, 5.6 or 7.2 of the TBT Agreement or this Chapter shall:
		(a) include in the notification an explanation of the objectives of the proposal and how it would address those objectives; and
		(b) transmit the notification and the proposal electronically to the other Parties through their enquiry points established in accordance with Article 10 of the TBT Agreement, at the same time as it notifies WTO Members.
	(c) provide a copy of the proposed measure to any Party or interested person that so requests, and shall, wherever possible, identify any provision that deviates in substance from relevant international standards; and	
(c) publish and allow for written comment in accordance with subparagraphs (a) and (b) at a time when the authority proposing the measure has sufficient time to review those comments and, as appropriate, to revise the measure to take them into account;	(d) without discrimination, allow other Parties and interested persons to make comments in writing and shall, on request, discuss the comments and take the comments and the results of the discussions into account.	14. Each Party shall normally allow 60 days from the date it transmits a proposal under paragraph 13 for another Party or an interested person of another Party to provide comments in writing on the proposal. A Party shall consider any reasonable request from another Party or an interested person of another Party to extend the comment period. A Party that is able to extend a time limit beyond 60 days, for example 90 days, is encouraged to do so.
(d) consider the written comments from a person of another Party on no less favorable terms than it considers those submitted by its own persons; and		
(e) if practicable, ⁵ accept a written request from another Party to discuss written comments that the other Party has submitted.		
Footnote 5 Circumstances when discussions are not practicable include where the Party requesting discussions has failed to submit		

its comments in a timely manner or if discussions would need to take place after the deadline to submit written comments has passed.		
The Party requested under subparagraph (e) to discuss its proposed technical regulation or conformity assessment procedure shall ensure that it has appropriate personnel to participate in the discussions, such as from the competent authority that has proposed the technical regulation or conformity assessment procedure, in order to confirm that the written comments are fully taken into account.		
3. Each Party shall endeavor to promptly make publicly available any written comments it receives under paragraph 2(c), except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content. If it is impracticable to post these comments on a single website, the regulatory authority of a Party shall endeavor to make these comments available via its own website.		
4. Each Party shall publish the final technical regulation or conformity assessment procedure and an explanation of how it has addressed substantive issues raised in comments submitted in a timely manner.		
5. If appropriate, each Party shall encourage non-governmental bodies including standardization bodies in its territory to act consistently with the obligations in paragraphs 1 and 7, in developing standards and voluntary conformity assessment procedures.		3. If appropriate, each Party shall encourage non-governmental bodies in its territory to observe the obligations in paragraphs 1 and 2.
6. Each Party shall ensure that its central government standardizing body's work program, containing the standards it is currently preparing and the standards it has adopted, is published:		
(a) on the central government standardizing body's website;		
(b) in its official gazette; or		
(c) on the website referred to in paragraph 10.		
<i>Stakeholder Participation in Developing Technical Regulations and Mandatory Conformity Assessment Procedures</i>		
7. Each Party shall encourage consideration of methods to provide additional transparency in the development of technical regulations, standards and conformity assessment procedures, including the use of electronic tools and public outreach or consultations.		2. Each Party is encouraged to consider methods to provide additional transparency in the development of technical regulations, standards and conformity assessment procedures, including through the use of electronic tools and public outreach or consultations.
8. If a Party requests a body within its territory to develop a standard for use as a technical regulation or conformity assessment procedure, the Party shall require the body to allow persons of another Party to participate on no less favorable terms than its own persons in groups or committees of the body that is developing the standard, and apply Annex 3 of the TBT Agreement.		
9. Each Party shall take such reasonable measures as may be available to it to ensure proposed and final technical regulations and conformity assessment procedures of regional governments are published. ⁶		

Footnote 6 For greater certainty, a Party may comply with this obligation by ensuring that the proposed and final measures in this paragraph are published on, or otherwise accessible through, the official website of the WTO.		
10. Each Party shall publish online and make freely accessible, preferably on a single website, all proposed and final technical regulations and mandatory conformity assessment procedures, except with respect to any standards that are:		
(a) developed by non-governmental organizations; and		
(b) have been incorporated by reference into a technical regulation or conformity assessment procedure.		
	2. Each Party proposing to adopt or modify a standard or any conformity assessment procedure not otherwise considered to be a technical regulation shall, where an international standard relevant to the proposed measure does not exist or such measure is not substantially the same as an international standard, and where the measure may have a significant effect on the trade of the other Parties:	
	(a) at an early appropriate stage, publish a notice and provide a notification of the type required in paragraph 1(a) and (b); and	
	(b) observe paragraph (c) and (d).	
<i>Notification of Technical Regulations and Conformity Assessment</i>		
11. In accordance with the procedures established under Article 2.9 or Article 5.6 of the TBT Agreement, each Party shall notify proposed technical regulations and conformity assessment procedures that are in accordance with the technical content of relevant international standards, guides, or recommendations if they may have a significant effect on trade. The Party's notification shall identify the precise international standards, guides or recommendations with which the proposal is in accordance.		9. Each Party shall notify proposals for new technical regulations and conformity assessment procedures that are in accordance with the technical content of relevant international standards, guides or recommendations, if any, and that may have a significant effect on trade, according to the procedures established under Article 2.9 or 5.6 of the TBT Agreement.
12. In accordance with the procedures under Article 2.10 or Article 5.7 of the TBT Agreement, and notwithstanding paragraph 11, if urgent problems of safety, health, environmental protection, or national security arise or threaten to arise for a Party, that Party shall notify a technical regulation or conformity assessment procedure that is in accordance with the technical content of relevant international standards, guides or recommendations. In its notification, the Party shall identify the precise international standards, guides, or recommendations with which the proposal is in accordance.	4. Where a Party considers it necessary to address an urgent problem relating to safety or to protection of human, animal or plant life or health, the environment or consumers, it may omit any step set out in paragraph 1 or 3, provided that on adoption of a standards-related measure it shall:	10. Notwithstanding paragraph 9, if urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Party, that Party may notify a new technical regulation or conformity assessment procedure that is in accordance with the technical content of relevant international standards, guides or recommendations, if any, upon the adoption of that regulation or procedure, according to the procedures established under Article 2.10 or 5.7 of the TBT Agreement.
	(a) immediately provide to the other Parties a notification of the type required under paragraph 1(b), including a brief description of the urgent problem;	
	(b) provide a copy of the measure to any Party or interested person that so requests; and	

	(c) without discrimination, allow other Parties and interested persons to make comments in writing, and shall, on request, discuss the comments and take the comments and the results of the discussions into account.	
	5. Each Party shall, except where necessary to address an urgent problem referred to in paragraph 4, allow a reasonable period between the publication of a standards-related measure and the date that it becomes effective to allow time for interested persons to adapt to the measure.	
13. In accordance with the procedures established under Article 2.9 or Article 5.6 of the TBT Agreement, each Party shall endeavor to notify, proposed technical regulations and conformity assessment procedures of regional level of governments that may have a significant effect on trade and that are in accordance with the technical content of relevant international standards, guides, and recommendations.	3. Each Party shall seek, through appropriate measures, to ensure, with respect to a technical regulation of a state or provincial government other than a local government: (a) that, at an early appropriate stage, a notice and notification of the type required under paragraph 1(a) and (b) are made prior to their adoption; and (b) observance of paragraph (c) and (d).	7. Each Party shall take such reasonable measures as may be available to it to ensure that all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of regional or local governments, as the case may be, on the level directly below that of the central level of government, are published.
14. With respect to notifications made under Articles 2.9 and 5.6 of the TBT Agreement and paragraph 11 of this Chapter, each Party shall notify proposed technical regulations and conformity assessment procedures at an early appropriate stage by:		
(a) ensuring the notification is made at a time when the authority developing the measure can introduce amendments, including in response to any comments submitted as set out in subparagraph (d);		
(b) including with its notification:		
(i) any objective for the proposed technical regulation or conformity assessment procedure and its legal basis,		
(ii) an explanation of how the proposed technical regulation or conformity assessment procedure would fulfill the identified objectives, and		
(iii) a copy of the proposed technical regulation or conformity assessment procedure or an online address at which the proposed measure can be accessed;		
(c) transmitting the notification electronically to the other Parties through their enquiry points established in accordance with Article 10 of the TBT Agreement, contemporaneously with the submission of the notification to the WTO Secretariat; and		
(d) providing sufficient time between the end of the comment period and the adoption of the notified technical regulation or conformity assessment procedure to ensure that the responsible authority can fully consider the submitted comments and the Party can issue its responses to the comments.		15. Each Party is encouraged to provide sufficient time between the end of the comment period and the adoption of the notified technical regulation or conformity assessment procedure, for its consideration of, and preparation of responses to, the comments received.
Each Party shall normally allow 60 days from the date it transmits a proposal under subparagraph (b) for another Party or an interested		

person of a Party to provide comments in writing on the proposal. A Party shall consider any reasonable request from another Party or an interested person of a Party to extend the comment period. A Party that is able to extend a time limit beyond 60 days, for example 90 days, shall consider doing so.		
15. Each Party, when making a notification under Article 2.10 or Article 5.7 of the TBT Agreement, shall at the same time transmit electronically the notification and text of the technical regulation or conformity assessment procedure, or an online address where the text of the measure can be viewed, to the Parties' contact points referred to in Article 11.12 (Contact Points).		
16. If a Party is notifying a proposed technical regulation or conformity assessment procedure to the WTO TBT Committee and the other Parties for the first time, ⁷ the Party shall notify it to the WTO TBT Committee and the other Parties as a regular notification. ⁸ Each Party shall endeavor to identify the scope of its proposed technical regulation or conformity assessment procedure in its notification by reference to the specific Harmonized System heading, subheading, or tariff item for the products that would be affected by the proposal.		
Footnote 7 The Parties shall follow the recommendation set forth in G/TBT/35, Coherent Use of Notification Formats.		
Footnote 8 A notification is a document that is circulated by the WTO Secretariat, or submitted to the WTO Secretariat for the purposes of circulation, under the prefix "G/TBT/N."		
17. If a Party is notifying a proposed technical regulation or conformity assessment procedure that is related to a measure that was previously notified, including because it is an revision, amendment, or replacement to the previously notified measure, the Party shall provide the WTO notification symbol for the previously notified measure. ⁹ Each Party shall endeavor to submit a revision to a notification if the notified measure has been substantially redrafted prior to its entry into force. If the Party files a revision or the circumstances in paragraph 18(e) arise, the Party shall endeavor to allow either a new or extended period of time for interested persons to submit comments to the Party.		
Footnote 9 The Parties agree the appropriate place to make the identification is in field 8 of a document produced consistent with the Format and Guidelines for Notification Procedures for Draft Technical Regulations and Conformity Assessment Procedures.		
18. Each Party shall submit an addendum to a notification it has previously made to the WTO TBT Committee and the Parties in any of the following circumstances:		16. Each Party shall endeavour to notify the final text of a technical regulation or conformity assessment procedure at the time the text is adopted or published, as an addendum to the original notification of the proposed measure filed under Article 2.9, 3.2, 5.6 or 7.2 of the TBT Agreement or this Chapter.

(a) the period of time to submit comments on the proposed measure has changed;		
(b) the notified measure has been adopted or otherwise entered into force;		
(c) the compliance dates for the final measure have changed;		
(d) the notified measure has been withdrawn, revoked, or replaced; ¹⁰		
Footnote 10 The Party shall provide the WTO document number identifying the notification of a measure that replaces or has been proposed as a replacement for a withdrawn or revoked measure.		
(e) the content or scope of the notified measure is partially changed or amended;		
(f) any interpretive guidance for a notified measure that has been issued; or		
(g) the final text of the notified measure is published or adopted or otherwise enters into force.		
19. Each Party shall endeavor to submit a corrigendum to a notification if it subsequently determines there are minor administrative or clerical errors in:		
(a) a notification or subsequent related addendum or revision; or		
(b) the text of the notified measure.		
20. If a Party obtains a translation of a measure notified to the WTO TBT Committee, whether official or unofficial, in an official WTO language other than the language of the notification, it shall endeavor to send the translation to the Parties' contact points referred to in Article 11.12 (Contact Points).		
21. For the purposes of determining whether a proposed technical regulation or conformity assessment procedure may have a significant effect on trade and is subject to notification in accordance with Articles 2.9, 2.10, 3.2, 5.6, 5.7, or 7.2 of the TBT Agreement and this Chapter, a Party shall consider, among other things, the relevant guidance in the Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.13), as may be revised.		12. For the purposes of determining whether a proposed technical regulation or conformity assessment procedure may have a significant effect on trade and should be notified in accordance with Article 2.9, 2.10, 3.2, 5.6, 5.7 or 7.2 of the TBT Agreement or this Chapter, a Party shall consider, among other things, the relevant Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev. 12), as may be revised.
22. When a Party has adopted a technical regulation or conformity assessment procedure that may have a significant effect on trade, the Party shall promptly publish online:		18. No later than the date of publication of a final technical regulation or conformity assessment procedure that may have a significant effect on trade, each Party shall, preferably electronically:
(a) an explanation of how the technical regulation or conformity assessment procedure achieves the Party's objectives;		(a) make publicly available an explanation of the objectives and how the final technical regulation or conformity assessment procedure achieves them;
(b) a description of alternative approaches, if any, that the Party considered in developing the adopted technical regulation or conformity assessment procedure and the explanation of why it chose one approach over the others it considered;		(b) provide as soon as possible, but no later than 60 days after receiving a request from another Party, a description of alternative approaches, if any, that the Party considered in developing the final technical regulation or conformity assessment procedure and the merits of the approach that the Party selected; ⁵
		Footnote 5

		For greater certainty, no Party shall be required to provide a description of alternative approaches or significant revisions under subparagraph (b) or (d) prior to the date of publication of the final technical regulation or conformity assessment procedure.
(c) its views on any substantive issues raised in timely submitted comments on the proposed technical regulation or conformity assessment procedure;		(c) make publicly available the Party's responses to significant or substantive issues presented in comments received on the proposal for the technical regulation or conformity assessment procedure; and
(d) any impact assessment it has undertaken;		
(e) if not addressed by an impact assessment, an explanation of the relationship between the regulation and the key evidence, data, and other information the regulatory authority considered in finalizing its work on the regulation; and		
(f) the date by which compliance is required.		
		(d) provide as soon as possible, but no later than 60 days after receiving a request from another Party, a description of significant revisions, if any, that the Party made to the proposal for the technical regulation or conformity assessment procedure, including those made in response to comments.
	6. Where a Party allows non-governmental persons in its territory to be present during the process of development of standards-related measures, it shall also allow non-governmental persons from the territories of the other Parties to be present.	
	7. Each Party shall notify the other Parties of the development of, amendment to, or change in the application of its standards-related measures no later than the time at which it notifies non-governmental persons in general or the relevant sector in its territory.	
	8. Each Party shall seek, through appropriate measures, to ensure the observance of paragraphs 6 and 7 by a state or provincial government, and by non-governmental standardizing bodies in its territory.	
	9. Each Party shall designate by January 1, 1994 a government authority responsible for the implementation at the federal level of the notification provisions of this Article, and shall notify the other Parties thereof. Where a Party designates two or more government authorities for that purpose, it shall provide to the other Parties complete and unambiguous information on the scope of responsibility of each such authority.	
		5. A Party may determine the form of proposals for technical regulations and conformity assessment procedures, which may take the form of: policy proposals; discussion documents; summaries of proposed technical regulations and conformity assessment procedures; or the draft text of proposed technical regulations and conformity assessment procedures. Each Party shall ensure that its proposals contain sufficient detail about the likely content of the

		proposed technical regulations and conformity assessment procedures to adequately inform interested persons and other Parties about whether and how their trade interests might be affected.
		6. Each Party shall publish preferably by electronic means, in a single official journal or website all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies, that a Party is required to notify or publish under the TBT Agreement or this Chapter, and that may have a significant effect on trade. ⁴
		Footnote 4
		For greater certainty, a Party may comply with this obligation by ensuring that the proposed and final measures in this paragraph are published on, or otherwise accessible through, the WTO's official website.
		8. Each Party shall ensure that all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, and to the extent practicable, all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, of regional or local governments on the level directly below that of the central level of government are accessible through official websites or journals, preferably consolidated into a single website.
		11. Each Party shall endeavour to notify proposals for new technical regulations and conformity assessment procedures of regional or local governments, as the case may be, on the level directly below that of the central level of government that are in accordance with the technical content of relevant international standards, guides and recommendations, if any, and that may have a significant effect on trade according to the procedures established under Article 2.9 or 5.6 of the TBT Agreement.
		17. A Party that files a notification in accordance with Article 2.10 or 5.7 of the TBT Agreement and this Chapter shall, at the same time, transmit the notification and text of the technical regulation or conformity assessment procedure electronically to the other Parties through the enquiry points referred to in paragraph 13(b).
		19. Further to paragraph J of Annex 3 of the TBT Agreement, each Party shall ensure that its central government standardising body's work programme, containing the standards it is currently preparing and the standards it has adopted, is available through the central

		government standardising body's website or the website referred to in paragraph 6.
Article 11.8: Compliance Period for Technical Regulations and Conformity Assessment Procedures		Article 8.8: Compliance Period for Technical Regulations and Conformity Assessment Procedures
1. For the purposes of Articles 2.12 and 5.9 of the TBT Agreement, the term "reasonable interval" means normally a period of not less than six months, except when this would be ineffective in fulfilling the legitimate objectives pursued by the technical regulation or the conformity assessment procedure. ¹¹		1. For the purposes of applying Articles 2.12 and 5.9 of the TBT Agreement the term "reasonable interval" means normally a period of not less than six months, except when this would be ineffective in fulfilling the legitimate objectives pursued by the technical regulation or by the requirements concerning the conformity assessment procedure.
Footnote 11 For greater certainty, a Party may decide to set an interval of less than six months between the publication of a measure and its entry into force in certain circumstances, including those where the measure is trade facilitative or is addressing an urgent problem of safety, health, environmental protection, or national security.		
2. If feasible and appropriate, each Party shall endeavor to provide an interval of more than six months between the publication of a final technical regulation or conformity assessment procedure and its entry into force.		2. If feasible and appropriate, each Party shall endeavour to provide an interval of more than six months between the publication of final technical regulations and conformity assessment procedures and their entry into force.
3. In addition to paragraphs 1 and 2, in setting a "reasonable interval" for a specific technical regulation or conformity assessment procedure, each Party provide suppliers with a reasonable period of time, under the circumstances, to be able to demonstrate the conformity of their products with the relevant requirements of the technical regulation by the date of entry into force of the specific technical regulation or conformity assessment procedure. In doing so, each Party shall endeavor to take into account the resources available to suppliers.		3. In addition to paragraphs 1 and 2, in setting a "reasonable interval" for a specific technical regulation or conformity assessment procedure, each Party shall ensure that it provides suppliers with a reasonable period of time, under the circumstances, to be able to demonstrate the conformity of their goods with the relevant requirements of the technical regulation or standard by the date of entry into force of the specific technical regulation or conformity assessment procedure. In doing so, each Party shall endeavour to take into account the resources available to suppliers.
Article 11.9: Cooperation and Trade Facilitation		
1. In addition to Articles 5, 6, and 9 of the TBT Agreement, the Parties acknowledge that a broad range of mechanisms ¹² exists to facilitate the acceptance of conformity assessment results. In this regard, a Party shall give consideration to a request made by another Party with respect to any sector-specific proposal for cooperation including by, as appropriate:		
Footnote 12 With respect to the mechanisms listed in paragraphs 1 and 2, the Parties recognize that the choice of the appropriate mechanism in a given regulatory context depends on a variety of factors, such as the product and sector involved, the volume and direction of trade, the relationship between Parties' respective regulators, the legitimate objectives pursued and the risks of non-fulfilment of those objectives.		

(a) implementing mutual recognition of the results by conformity assessment bodies located in its territory and another Party's territory with respect to specific technical regulations;		
(b) recognizing existing mutual and multilateral recognition arrangements between or among accreditation bodies or conformity assessment bodies;		
(c) using accreditation to qualify conformity assessment bodies, particularly international systems of accreditation;		
(d) designating conformity assessment bodies or recognise the other Party's designation of conformity assessment bodies;		
(e) unilaterally recognizing the results of conformity assessment procedures performed in the other Party's territory; and		
(f) accepting a supplier's declaration of conformity.		
2. The Parties recognize that a broad range of mechanisms exist to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region, including:		
(a) regulatory dialogue and cooperation to, among other things:		
(i) exchange of information on regulatory approaches and practices,		
(ii) promote the use of good regulatory practices to improve the efficiency and effectiveness of technical regulations, standards and conformity assessment procedures,		
(iii) provide technical advice and assistance, on mutually agreed terms and conditions, to improve practices related to the development, implementation and review of technical regulations, standards, conformity assessment procedures and metrology, or		
(iv) provide technical assistance and cooperation, on mutually agreed terms and conditions, to build capacity and support the implementation of this Chapter;		
(b) facilitation of the greater use and alignment of standards, technical regulations, and conformity assessment procedures with relevant international standards, guides, and recommendations; and		
(c) promotion of the acceptance of technical regulations of the other Party as equivalent.		
3. In addition to subparagraph (c), the Parties shall work to develop common standards and conformity assessment procedures in sectors of mutual interest. The Parties shall determine the scope of this work through the Committee on Technical Barriers to Trade established under Article 11.11 (Committee on Technical Barriers to Trade).		
4. The Parties shall strengthen their exchange and collaboration on mechanisms to facilitate the acceptance of conformity assessment results, to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region. To this end, the Parties shall seek to identify, develop, and promote trade-facilitating initiatives regarding standards, technical regulations, and conformity		

assessment procedures that address particular cross-cutting or sector-specific issues.		
5. The Parties shall encourage cooperation between their respective organizations responsible for standardization, conformity assessment, accreditation and metrology, whether they are public or private, with a view to facilitate trade.		
Article 11.10: Information Exchange and Technical Discussions	Article 914: Technical Consultations	Article 8.10: Information Exchange and Technical Discussions
1. The Parties recognize that technical discussions and information exchange can serve an important function in reaching mutually satisfactory solutions to trade concerns by promoting cooperation and consultation informed by relevant technical and scientific information. Accordingly, with respect to a matter that arises under this Chapter, a Party may request that another Party:		
(a) engage in technical discussions concerning the matter; or		
(b) provide information regarding any proposed or final technical regulation or conformity assessment procedure that relates to the matter.		
2. The Party making the request shall do so in writing and identify:		
(a) the matter, including those provisions of the Chapter to which the matter relates;		
(b) the reasons for the request, including any concerns with a proposed or final measure;		
(c) whether the matter is urgent; and		
(d) if applicable, the precise information that is being requested.		
	1. Where a Party requests consultations regarding the application of this Chapter to a standards-related measure, and so notifies the Committee, the Committee may facilitate the consultations, if it does not consider the matter itself, by referring the matter for non-binding technical advice or recommendations to a subcommittee or working group, including an ad hoc subcommittee or working group, or to another forum.	
	2. The Committee should consider any matter referred to it under paragraph 1 as expeditiously as possible and promptly forward to the Parties any technical advice or recommendations that it develops or receives concerning the matter. The Parties involved shall provide a written response to the Committee concerning the technical advice or recommendations within such time as the Committee may request.	5. The Parties shall endeavour to resolve the matter as expeditiously as possible, recognising that the time required to resolve a matter will depend on a variety of factors, and that it may not be possible to resolve every matter through technical discussions.
	3. Where the involved Parties have had recourse to consultations facilitated by the Committee under paragraph 1, the consultations shall, on the agreement of the Parties involved, constitute consultations under Article 2006 (Consultations).	

	4. The Parties confirm that a Party asserting that a standards-related measure of another Party is inconsistent with this Chapter shall have the burden of establishing the inconsistency.	
		1. A Party may request another Party to provide information on any matter arising under this Chapter. A Party receiving a request under this paragraph shall provide that information within a reasonable period of time, and if possible, by electronic means.
		2. A Party may request technical discussions with another Party with the aim of resolving any matter that arises under this Chapter.
		3. For greater certainty, with respect to technical regulations or conformity assessment procedures of regional or local governments, as the case may be, on the level directly below that of the central government that may have a significant effect on trade, a Party may request technical discussions with another Party regarding those matters.
The Party making the request shall transmit it to the Parties through their respective contact points designated pursuant to Article 30.5 (Agreement Coordinator and Contact Points).		7. Requests for information or technical discussions and communications shall be conveyed through the respective contact points designated pursuant to Article 27.5 (Contact Points).
3. With respect to a request made under paragraph 1(a), the requesting Party and the requested Party shall discuss the matter identified within 60 days after the date the request was transmitted to the contact point, unless the request identified the matter as urgent, in which case the Parties shall endeavor to hold the technical discussions sooner. The requested Party, at its discretion, may decide to allow another Party to participate in the technical discussions. With respect to a request made under paragraph 1(b), the Party receiving the request shall provide appropriate information within a reasonable period of time. The Parties shall attempt to obtain satisfactory resolution of the matter.		4. The relevant Parties shall discuss the matter raised within 60 days of the date of the request. If a requesting Party considers that the matter is urgent, it may request that any discussions take place within a shorter time frame. The responding Party shall give positive consideration to that request.
4. Unless the Parties decide otherwise, any discussions or information exchanged under this Article, other than the request referenced in paragraphs 1 and 2, shall be kept confidential and is without prejudice to the Parties' rights and obligations under the Agreement, the WTO Agreement or any other agreement to which the requesting and requested Parties are party.		6. Unless the Parties that participate in the technical discussions agree otherwise, the discussions and any information exchanged in the course of the discussions shall be confidential and without prejudice to the rights and obligations of the participating Parties under this Agreement, the WTO Agreement or any other agreement to which both Parties are party.
Article 11.11: Committee on Technical Barriers to Trade	Article 913: Committee on Standards-Related Measures	Article 8.11: Committee on Technical Barriers to Trade
1. The Parties hereby establish a Committee on Technical Barriers to Trade (TBT Committee), composed of government representatives of each Party.	1. The Parties hereby establish a Committee on Standards-Related Measures, comprising representatives of each Party.	1. The Parties hereby establish a Committee on Technical Barriers to Trade (Committee), composed of government representatives of each Party.
2. Through the TBT Committee, the Parties shall strengthen their joint work in the fields of technical regulations, standards, and conformity assessment procedures with a view to facilitating trade between the Parties.		2. Through the Committee, the Parties shall strengthen their joint work in the fields of technical regulations, standards and conformity assessment procedures with a view to facilitating trade between the Parties.

3. The TBT Committee's functions include:	2. The Committee's functions shall include:	3. The Committee's functions may include:
(a) monitoring and identifying ways to strengthen the implementation and operation of this Chapter, and identifying any potential amendments to or interpretations of this Chapter for referral to the Commission;	(a) monitoring the implementation and administration of this Chapter, including the progress of the subcommittees and working groups established under paragraph 4, and the operation of the inquiry points established under Article 910;	(a) monitoring the implementation and operation of this Chapter, including any other commitments agreed under this Chapter, and identifying any potential amendments to or interpretations of those commitments pursuant to Chapter 27 (Administrative and Institutional Provisions);
	(b) facilitating the process by which the Parties make compatible their standards-related measures;	
(b) as appropriate, discussing proposed and final versions of standards, technical regulations, or conformity assessment procedures of any Party;		
(c) monitoring any technical discussions on matters that arise under this Chapter requested pursuant to paragraph 2 of Article 11.10 (Information Exchange and Technical Discussions);		(b) monitoring any technical discussions on matters that arise under this Chapter requested pursuant to paragraph 2 of Article 8.10 (Information Exchange and Technical Discussions);
	(c) providing a forum for the Parties to consult on issues relating to standards-related measures, including the provision of technical advice and recommendations under Article 914;	
(d) reaching an agreement on priority areas of mutual interest for future work under this Chapter and considering proposals for new sector-specific initiatives or other initiatives;		(c) deciding on priority areas of mutual interest for future work under this Chapter and considering proposals for new sector-specific initiatives or other initiatives;
(e) encouraging cooperation between the Parties in matters that pertain to this Chapter, including the development, review, or modification of technical regulations, standard, and conformity assessment procedures;	(d) enhancing cooperation on the development, application and enforcement of standards-related measures; and	(d) encouraging cooperation between the Parties in matters that pertain to this Chapter, including the development, review or modification of technical regulations, standards and conformity assessment procedures;
	(e) considering non-governmental, regional and multilateral developments regarding standards-related measures, including under the GATT.	
(f) encouraging cooperation between non-governmental bodies in the Parties' territories, as well as cooperation between governmental and non-governmental bodies in the Parties' territories in matters that pertain to this Chapter;		(e) encouraging cooperation between non-governmental bodies in the Parties' territories, as well as cooperation between governmental and non-governmental bodies in the Parties' territories in matters that pertain to this Chapter;
(g) facilitating the identification of technical capacity needs;		(f) facilitating the identification of technical capacity needs;
(h) encouraging the exchange of information between the Parties and their relevant non-governmental bodies, if appropriate, to develop common approaches regarding matters under discussion in non-governmental, regional, plurilateral, and multilateral bodies or international conformity assessment systems or standards development relevant to this Chapter; including the WTO TBT Committee and bodies that develop standards in accordance with the TBT Committee Decision on International Standards, as appropriate;		(g) encouraging the exchange of information between the Parties and their relevant non-governmental bodies, if appropriate, to develop common approaches regarding matters under discussion in non-governmental, regional, plurilateral and multilateral bodies or systems that develop standards, guides, recommendations, policies or other procedures relevant to this Chapter;
(i) encouraging, on request of a Party, the exchange of information between the Parties regarding specific technical regulations, standards, and conformity assessment procedures of non-Parties as well as systemic issues, with a view to fostering a common approach;		(h) encouraging, on request of a Party, the exchange of information between the Parties regarding specific technical regulations, standards and conformity assessment procedures of non-Parties as well as systemic issues, with a view to fostering a common approach;

(j) undertaking initiatives to support greater regulatory alignment in the region, including through the development of common standards or conformity assessment procedures, in sectors of mutual interest;		
(k) reporting to the Commission on the implementation and operation of this Chapter;		(k) reporting to the Commission on the implementation and operation of this Chapter.
		(i) taking any other steps the Parties consider will assist them in implementing this Chapter and the TBT Agreement;
(l) reviewing this Chapter in light of any developments under the TBT Agreement, and developing recommendations for amendments to this Chapter in light of those developments;		(j) reviewing this Chapter in light of any developments under the TBT Agreement, and developing recommendations for amendments to this Chapter in light of those developments; and
(m) engaging, as appropriate, with the public to participate in the work of the TBT Committee, for example by requesting and considering comments on matters related to the implementation of this Chapter; and		
(n) taking any other steps that the Parties consider will assist them in implementing this Chapter.		
4. Unless the Parties decide otherwise, the TBT Committee shall meet at least once a year.	3. The Committee shall: (a) meet on request of any Party and, unless the Parties otherwise agree, at least once each year; and (b) report annually to the Commission on the implementation of this Chapter.	6. The Committee shall meet within one year of the date of entry into force of this Agreement and thereafter as decided by the Parties.
5. The TBT Committee may establish and determine the scope and mandate of working groups to carry out its functions, and may invite, as appropriate, representatives of non-governmental entities to participate in a working group.	4. The Committee may, as it considers appropriate, establish and determine the scope and mandate of subcommittees or working groups, comprising representatives of each Party. Each subcommittee or working group may:	4. The Committee may establish working groups to carry out its functions.
	(a) as it considers necessary or desirable, include or consult with (i) representatives of non-governmental bodies, including standardizing bodies, (ii) scientists, and (iii) technical experts; and (b) determine its work program, taking into account relevant international activities.	
	5. Further to paragraph 4, the Committee shall establish:	
	(a) the following subcommittees (i) Land Transportation Standards Subcommittee, in accordance with Annex 913.5.a-1, (ii) Telecommunications Standards Subcommittee, in accordance with Annex 913.5.a-2, (iii) Automotive Standards Council, in accordance with Annex 913.5.a-3, and (iv) Subcommittee on Labelling of Textile and Apparel Goods, in accordance with Annex 913.5.a-4; and	
	(b) such other subcommittees or working groups as it considers appropriate to address any topic, including: (i) identification and nomenclature for goods subject to standards-related measures, (ii) quality and identity standards and technical regulations, (iii) packaging, labelling and presentation of consumer information, including languages, measurement systems, ingredients, sizes, terminology, symbols and related matters, (iv) product approval and post-market surveillance programs, (v) principles for the accreditation and recognition of conformity assessment bodies,	

	procedures and systems, (vi) development and implementation of a uniform chemical hazard classification and communication system, (vii) enforcement programs, including training and inspections by regulatory, analytical and enforcement personnel, (viii) promotion and implementation of good laboratory practices, (ix) promotion and implementation of good manufacturing practices, (x) criteria for assessment of potential environmental hazards of goods, (xi) methodologies for assessment of risk, (xii) guidelines for testing of chemicals, including industrial and agricultural chemicals, pharmaceuticals and biologicals, (xiii) methods by which consumer protection, including matters relating to consumer redress, can be facilitated, and (xiv) extension of the application of this Chapter to other services.	
	6. Each Party shall, on request of another Party, take such reasonable measures as may be available to it to provide for the participation in the activities of the Committee, where and as appropriate, of representatives of state or provincial governments.	
	7. A Party requesting technical advice, information or assistance pursuant to Article 911 shall notify the Committee which shall facilitate any such request.	
6. To determine what activities the TBT Committee will undertake, the TBT Committee shall consider work that is being undertaken in other fora, with a view to ensuring that any activities undertaken by the TBT Committee do not unnecessarily duplicate that work.		5. To determine what activities the Committee will undertake, the Committee shall consider work that is being undertaken in other fora, with a view to ensuring that any activities undertaken by the Committee do not unnecessarily duplicate that work.
Article 11.12: Contact Points	Article 910: Inquiry Points	Article 8.12: Contact Points
1. Each Party shall designate a contact point and notify it to the other Parties for matters arising under this Chapter in accordance with Article 30.5 (Agreement Coordinator and Contact Points). A Party shall promptly notify the other Parties of any change of its contact point or the details of the relevant officials.	1. Each Party shall ensure that there is an inquiry point that is able to answer all reasonable inquiries from other Parties and interested persons, and to provide relevant documents regarding: (a) any standards-related measure proposed, adopted or maintained in its territory at the federal, state or provincial government level; (b) the membership and participation of the Party, or its relevant federal, state or provincial government authorities, in international and regional standardizing bodies and conformity assessment systems, and in bilateral and multilateral arrangements regarding standards-related measures, and the provisions of those systems and arrangements; (c) the location of notices published pursuant to Article 909, or where the information can be obtained; (d) the location of the inquiry points referred to in paragraph 3; and (e) the Party's procedures for assessment of risk, and factors it considers in conducting the assessment and in establishing, pursuant to Article 904(2), the levels of protection that it considers appropriate.	1. Each Party shall designate and notify a contact point for matters arising under this Chapter, in accordance with Article 27.5 (Contact Points).
	2. Where a Party designates more than one inquiry point, it shall: (a) provide to the other Parties complete and unambiguous information on the scope of responsibility of each inquiry point; and (b) ensure	

	that any inquiry addressed to an incorrect inquiry point is promptly conveyed to the correct inquiry point.	
		2. A Party shall promptly notify the other Parties of any change of its contact point or the details of the relevant officials.
2. The functions of each contact point shall include: (a) communicating with the other Parties' contact points, including facilitating discussions, requests and the timely exchange of information on matters arising under this Chapter; (b) communicating with and coordinating the involvement of relevant government agencies, including regulatory authorities, in the territory of the Party it represents on relevant matters pertaining to this Chapter; (c) consulting and, if appropriate, coordinating with interested persons in the territory of the Party it represents on relevant matters pertaining to this Chapter; and (d) carrying out any additional responsibilities specified by the TBT Committee.	3. Each Party shall take such reasonable measures as may be available to it to ensure that there is at least one inquiry point that is able to answer all reasonable inquiries from other Parties and interested persons and to provide relevant documents or information as to where they can be obtained regarding: (a) any standard or conformity assessment procedure proposed, adopted or maintained by non-governmental standardizing bodies in its territory; and (b) the membership and participation of relevant non-governmental bodies in its territory in international and regional standardizing bodies and conformity assessment systems.	3. The responsibilities of each contact point shall include: (a) communicating with the other Parties' contact points, including facilitating discussions, requests and the timely exchange of information on matters arising under this Chapter; (b) communicating with and coordinating the involvement of relevant government agencies, including regulatory authorities, in its territory on relevant matters pertaining to this Chapter; (c) consulting and if appropriate, coordinating with interested persons in its territory on relevant matters pertaining to this Chapter; and (d) carrying out any additional responsibilities specified by the Committee.
	4. Each Party shall ensure that where copies of documents are requested by another Party or by interested persons in accordance with this Chapter, they are supplied at the same price, apart from the actual cost of delivery, as the price for domestic purchase.	
	Article 911: Technical Cooperation	
	1. Each Party shall, on request of another Party:	
	(a) provide to that Party technical advice, information and assistance on mutually agreed terms and conditions to enhance that Party's standards-related measures, and related activities, processes and systems;	
	(b) provide to that Party information on its technical cooperation programs regarding standards-related measures relating to specific areas of interest; and	
	(c) consult with that Party during the development of, or prior to the adoption or change in the application of, any standards-related measure.	
	2. Each Party shall encourage standardizing bodies in its territory to cooperate with the standardizing bodies in the territories of the other Parties in their participation, as appropriate, in standardizing activities, such as through membership in international standardizing bodies.	
	Article 912: Limitations on the Provision of Information	
	Nothing in this Chapter shall be construed to require a Party to:	
	(a) communicate, publish texts, or provide particulars or copies of documents other than in an official language of the Party; or	
	(b) furnish any information the disclosure of which would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of particular enterprises.	

Fonte: USMCA, NAFTA, TPP. Elaboração: CCGI-EESP/FGV.

PART III
COMPARATIVE STUDY BETWEEN
MERCOSUR AND THE PACIFIC ALLIANCE

1. Introduction

Regulatory barriers are now a new important issue on international trade. Due to the relative success in the elimination or reduction of tariffs on trade, though several rounds of multilateral negotiations in the World Trade Organization (WTO), efforts on trade liberalization are focused on other aspects that interfere with trade flows. Now the focus is on the existence of non-tariff barriers, especially technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) or environmental measures that affect the flow of goods. The proliferation of these non-tariff barriers to trade, which in certain situations may constitute a new wave of protectionism, results from the intense regulatory activity of the states, which are demanded by society to regulate, through normative instruments, the most varied dimensions of the economy, including trade.

The importance of non-tariff barriers is already identified in the multilateral framework of trade, in several rules and activities of the WTO and in the various preferential agreements, including regional integration projects such as Mercosur, ALADI and the European Union. At the same time, the negative impacts of countries' regulatory policies on their trade can be evaluated by comparative analysis between domestic regulatory regimes of trading partners. Such an analysis makes possible the understanding of the dynamics of bilateral trade flows, as well as their trade relations with third countries. This report aims a comparative analysis between Mercosur (Brazil and Argentina) regulatory systems on one side and countries of the Pacific Alliance on the other side. The aim is to examine how convergence of these activities can support international trade and a higher degree of economic integration.

To understand the regulatory frameworks of these countries, the first step is to identify their main regulatory actors: authorities, agencies and government bodies and some private bodies with regulatory responsibilities.

The research identified the main regulatory structure for each country and grouped them on the following categories: public authorities, non-governmental bodies and private actors. Examples of public authorities issuing mainly mandatory rules are ministries, committees inside ministries, secretariats, departments inside secretariats, regulatory agencies and autarchies. Examples of non-governmental bodies issuing mainly non-mandatory rules are the ones that regulate technical standards. The private actors consist of sectoral associations and committees working alone or coordinated with ministries. Despite the private juridical nature of those entities, they can interfere on the regulatory system of the countries and also affect the regulatory activities.

The second step is the identification and mapping of technical, sanitary and phytosanitary regulations through the analysis of notifications to international bodies and identification of domestic regulation through the activities of the main domestic regulatory agencies. This part reviews the notifications made to the WTO Committee on Technical Barriers to Trade (CTBT) and the Committee on Sanitary and Phytosanitary Measures (CSPS). As provided in art. 2.9. of the TBT Agreement and paragraph 5 of Annex B of the SPS Agreement, such notifications, which express compliance with the WTO principle of transparency, would indicate if the regulation or technical standard are different from international standards and potentially relevant to international convergence. Since identification through analysis of notifications allow the contact only to a portion of regulations and standards of a given sector, the research also sought to identify sectoral regulations and standards through an independent search on official websites of the governments, including decentralized bodies.

In practical terms, in the analysis of notifications, the research used three distinct means of searching, since none of them alone would provide satisfactory information. Firstly, the research directly accessed the WTO's information management system (IMS) websites (CTBT: <http://tbtims.wto.org/> and COPS: <http://spsims.wto.org/>). From this search it was extracted information on regulations and standards notified. Frequently, such prescriptive documents were in draft stage or public consultation stage, in accordance with the mentioned provisions of the TBT and SPS Agreements. However, not all notifications provided complete information on the notified regulation. In the case of SPS, only the latest notifications contained complete references to the notified regulation, project or consultation.

TBT and SPS notifications were also collected at the sites of focal points, in compliance with provision WTO TBT and SPS Agreements, regarding the obligations of national enquiry points. Based on the information of these sites, which reproduces and reorganizes the information notified to TBT and SPS Committees the research identified the domestic regulation notified. In the case of TBT, in the website of enquiry points, the research found not only the form sent to the TBT Committee, but also the file of the normative acts that was object of the notification. It should be noted that a similar website was not found for regulations concerning sanitary and phytosanitary measures.

The third source for the search and analysis of notifications was the website of the Latin American Integration Association (ALADI), which contains a copy of the notifications sent to the TBT Committee in a friendlier virtual environment. The search on the ALADI website was mainly aimed at verifying the fulfillment of the commitments made under the Framework Agreement for Trade Promotion by Overcoming Technical Barriers to Trade (*Acuerdo Marco para la Promoción del Comercio Mediante la Superación de Obstáculos Técnicos al Comercio*, 1997), which acquired the status of Regional Agreement no. 8 (AR 8).

Parallel to the research based on the notifications to the TBT and SPS Committees, a separated search was made for the domestic regulations and standards for each sector. Public bodies and agencies issue technical regulations for different economic sectors. Therefore, to identify the main regulation (including those not notified to WTO Committees), the research had to go through different search tools in different governmental websites to put together relevant technical regulations for the economic sectors analyzed. It means that, with current searching tools available to present day, it is not possible to guarantee that tables with those regulations introduced in the reports are exhaustive lists.

The regulatory authority varies according to the sector. Some authorities have the competence to regulate more than one sector. The regulation of other industrial sectors sometimes overlaps with standards developed by national standardization bodies. In fact, the regulatory agencies can build the technical regulation with reference to standards or the agency can design itself the technical prescription with no reference to standards.

Finally, it should be noted that the analysis of the degree of utilization of international and global sectorial supporting standards on regulations and the standardization systems provides only an indication of the degree of convergence and internationalization of the industrial regulatory framework, since there was no comparison of technical content between international and countries standards and regulations

International standards and global sectoral standards: EU x US

Equally important to this research is the premise that, in contemporary reality, there are two major regulatory models that, in a different ways and with the appropriate adaptations, are emulated by the emerging countries.

The US model, market oriented, is based on a logic of decision-making decentralization and multiplicity of actors. There are around 300 Standardization Bodies in the US, under the coordination of ANSI. Because the US is an important trade partner, its standards are considered as relevant international standards. However, there is a controversy in the WTO whether the US standardization bodies are in conformity with the concept of international standardization and regulatory bodies, as established by the WTO, as established by the Code of Good Practices of the Annex 3 of the TBT Agreement. In some areas, such as electronics, however, the United States participate most effectively in international initiatives and is considered more transparent.

Since its inception, the European model has been formulated as an internationalized model. Because of its direct link with the European integration process, this model is characterized by greater centralization, through the EU bodies, especially the EU Commission. Also relevant is the predominance of government actors or officials with official public recognition, as well as strong engagement in internal processes of international organization, such as ISO and IEC. Important roles are played by regional regulatory and standardization bodies, among them CEN-CENELEC.

Two important concepts are used in this project to identify the degree of internalization of the countries examined. One is identified as international standards and the second as global sectoral standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), Codex Alimentarius Commission, World Organisation for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*. International standards are generally produced in accordance with the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectoral standards are private standards developed by relevant standardizing bodies and relevant to international trade. Some examples are those produced in the United States of America (US), as the American Society for Testing and Materials (ASTM), American Petroleum Institute (API), American Society of Mechanical Engineers (ASME) and Underwriters Laboratories (UL). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct of the TBT Agreements for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

Alongside these global technical standards, there are important technical standards produced and used regionally. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), European Telecommunications Standards Institute (ETSI). European standards are essential for the functioning of the EU integrated market and are widely used as the model influencing many standardization and regulatory work in several countries of the world. For Brazil and Argentina, European standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies. Several provisions of the Brazilian technical regulation concerning machinery and mechanical devices safety, and the Argentine regulation for motor vehicles, make direct reference to the European technical standards produced by CEN. However, American standards are more frequent in Mexico, Colombia and Chile.

In view of the existence of these two models, managed by important economic actors, the purpose of this research is also to identify possible connections of the Latin American systems with the American and the European models. Based on the analysis of the descriptions of the regulations, technical standards and mandatory compliance procedures of Brazil, Argentina, Chile, Colombia and Mexico, the research is intended to identify the predominance of some of the models in the national systems and to compare the systems of Mercosur and the Pacific Alliance.

Considering the characteristics of the current trade and the existence of a legal framework for trade liberalization in Latin America (formalized in ALADI and its various ACEs), trade between Brazil and the other Latin American countries could be substantially stimulated through regulatory convergence efforts, as tariffs between these trading partners are relatively low¹⁷⁴. The approximation of the regulatory, standardization and conformity assessment systems¹⁷⁵ of the countries could also strengthen regional industrial production chains as well as create new chains for dynamic and important industrial sectors in these countries.

In this context, a comparative analysis between the regulatory frameworks related to barriers to trade - TBT and SPS can offer solutions to problems and impasses observed in Brazil and within Mercosur. As with bilateral trade with Argentina, the Brazilian trade pattern with the three countries is heavily concentrated in industrialized products with high added value. Considering the export difficulties of Brazilian industry, the study of these markets that demand Brazilian manufactured goods under their own regulations becomes even more relevant.

Selected sectors

After analyzing the main export and import products of Brazil and these Latin American countries, five sectors were selected for the comparative study.

The sectors selected to this research are the following:

¹⁷⁴ See tariffs of ALADI countries:

http://consultawebv2.aladi.org/sicoexV2/jsfAranceles/arancel_vigente_item_entrada.seam?cid=1373530

¹⁷⁵ There is important evidence that the countries analyzed have medium or high regulatory complexity. For international trade, this complexity may represent costs and barriers to the exchange of goods and services. See, for example, the indicators of regulatory complexity calculated by the OECD for Chile, Mexico and Brazil: <http://www.oecd.org/eco/reform/indicatorsofproductmarketregulationhomepage.htm>

Table 1.1 - Selected products

27	Mineral fuels, mineral oils and products of their distillation; bituminous substances; mineral waxes
30	Pharmaceutical products
39	Plastics and articles thereof
84	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof
85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories
87	Vehicles other than railway or tramway rolling-stock, and parts and accessories thereof

Source: ComexStat. Elaborated by CCGI-EESP/FGV.

Regulatory convergence

This study attributes relevance to the existence of several international initiatives to promote convergence and regulatory coherence. For example, the Organization for Economic Cooperation and Development (OECD) has made an important contribution, especially with regard to delimitations of concepts and the proposition of regulatory models of specific sectors. The OECD recommendations and non-prescriptive documents are often used in the processes of administrative modernization and reform of States.

The OECD contains a number of reports and guides that analyze and prescribe procedures for good regulatory practice¹⁷⁶. Transparency in the elaboration of regulations and technical standards, periodic review of rules stock, prior impact analysis and openness to stakeholder participation are some of the practices highlighted by the OECD, so that the regulatory system is internally coherent. Compliance with standards produced by relevant international organizations, the adoption of schemes for the mutual recognition of conformity assessment procedures and ongoing dialogue between technical authorities are important practices for the convergence of different regulatory systems.

Objectives

One of the main practical results of the research will be to suggest the strengthening of communication between business communities, industry associations and regulatory bodies,

¹⁷⁶ ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. OECD Guiding principles for regulatory quality and performance. 2005. Disponível em: <<https://www.oecd.org/fr/reformereg/34976533.pdf>>. Acesso em: 17 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. Recommendation of the Council on Regulatory Policy and Governance. 2012. Disponível em: <<http://www.oecd.org/governance/regulatory-policy/2012-recommendation.htm>>. Acesso em: 18 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. International Regulatory Co-operation: Addressing Global Challenges 2013. OCDE. 2013. Disponível em: <<http://www.oecd.org/env/international-regulatory-co-operation-9789264200463-en.htm>>. Acesso em: 18 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. OECD Regulatory Policy Outlook 2015. OCDE. 2015. Disponível em: <http://www.keepeek.com/Digital-Asset-Management/oecd/governance/oecd-regulatory-policy-outlook2015_9789264238770-en#.WlYy5VMrIdU>. Acesso em: 23 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. Recommendation of the Council on Regulatory Policy and Governance. 2015. OCDE Disponível em: <<http://www.oecd.org/gov/regulatory-policy/49990817.pdf>>. Acesso em: 23 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. International Regulatory Co-operation: the Role of International Organisations in Fostering Better Rules of Globalisation. 2016. Disponível em: <<http://www.oecd.org/gov/regulatory-policy/internationalregulatory-co-operation-9789264244047-en.htm>>. Acesso em: 16 jan. 2019. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. Better Regulation in Europe: United Kingdom. OECD Publishing, 2010, p. 61-62. Disponível em: <www.oecd.org/governance/9789264084483>. Acesso em: 16 jan. 2019.

with the aim of promoting bilateral trade and investment, as well as cooperation in innovation, research and development. There is great potential to strengthen the economic relationship between Mercosur and the Pacific Alliance, through regulatory convergence based on mandated requirements and recommendations from international organizations.

This project, therefore, could provide subsidies for an ambitious regulatory cooperation initiative between Mercosur and the Pacific Alliance, raising some of the most relevant structural obstacles of bilateral and regional trade. The initiatives adopted on the basis of this study could therefore result in greater economic integration and increased business competitiveness and growth in all countries involved.

2. A comparison exercise between Brazil, Argentina, Mexico, Colombia and Chile

The objective of this part of the research is to establish a comparison between the regulatory frameworks, regulations, standardization and conformity assessment systems of five countries: Brazil, Argentina, Mexico, Colombia and Chile. This comparison will make it possible to differentiate some of the main aspects of the Pacific Alliance countries systems in relation to the two Mercosur countries.

The three main dimensions of the quality systems of the five countries will be analyzed: technical regulation, technical standardization and conformity assessment, together with aspects related to metrology. In the comparison, differences and institutional similarities will be highlighted in the functioning of the five systems.

Brazil and Argentina, on one side, and Mexico, Colombia and Chile on the other, have important similarities in their economic structures and, consequently, their participation in international trade, which result from characteristics common to many developing industrialized countries. The five countries share the Iberian colonial past, the primary exporting vocation, high rates of urbanization and late industrialization, induced by the state and based on the process of import substitution.

2.1. Technical regulation

The activity of technical regulation can be summarized as the act of producing compulsory prescriptive documents. In all five countries, this activity is predominantly carried out by government agencies, which regulate specific aspects related to their priority areas of action. There is a plurality of regulatory bodies in the countries, which often have the competence determined by law.

In Brazil, the most relevant aspect is the regulatory competence performed by INMETRO. In addition to carrying out metrology activities and being the main accreditor in Brazilian territory, INMETRO has important regulatory competence, which covers around two hundred types of products¹⁷⁷. The products regulated by INMETRO, in general, are those destined for consumption. The technical regulations designed by INMETRO may contain voluntary and compulsory conformity assessment schemes, which can be foreseen in its different modalities,

¹⁷⁷ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

with emphasis on third party evaluation procedures. INMETRO is under an important reform process aiming to modernize its role as the main governmental body responsible for technical regulations in Brazil.

In Brazil, technical regulations for food products and pharmaceuticals are established by ANVISA that plays a key role in these areas. Examples of issues inserted are the distribution and/or storage good practices certification, administrative procedures to the concession of production good practices certification of medicines, health products, cosmetics, perfumes, personal hygiene products, sanitizers and pharmaceutical inputs and the distribution and/or storage good practices certification of medicines, health products and pharmaceutical inputs¹⁷⁸.

In Brazil, the main institutions that regulate conformity assessment activities are INMETRO, ABNT and ANVISA. INMETRO coordinates activities as the notification center of technical barriers, denominated Focal Point of Technical Barriers to Exportations and, under this mandate, created a conformity assessment program, which has the normative framework for development of conformity assessment activities in Brazil. ABNT acted mainly through the creation of special programs as Certification of Suppliers – ABVTEX and Quality Label ABEOC. Finally, ANVISA provides different certifications that can be granted as the production good practices certification of medicines and the distribution and/or storage good practices certification of health products.

Argentina does not have an organ with the same broad characteristics of INMETRO. The various attributions that, in Brazil, are concentrated in INMETRO are distributed by various agencies in Argentina. The metrology activity is performed by the National Institute of Industrial Technology (INTI), an autarchy linked to the Ministry of Production. Accreditation, in turn, falls within the competence of the Argentine Agency of Accreditation, a private non-profit organization.

Regulatory activity is divided among the various administrative bodies (including decentralized bodies), without a body having residual regulatory competence. Technical regulation is performed by a plurality of governmental bodies and, in exceptional cases, by private bodies endowed by sectoral regulatory competence (for example, the Association of Engineers and Technicians of Automotive, AITA).

In Argentina, a diffuse system encompasses different bodies that perform conformity assessment and examples of them will be provided below. The National Service for Agrifood Health and Quality (*Servicio Nacional de Sanidad y Calidad Agroalimentaria* – SENASA) performs sanitary certification. The National Administration of Medicine, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* – ANMAT) certifies medical products. The Association of Automotive Engineers and Technicians (*Asociación de Ingenieros y Técnicos del Automotor* – AITA) certifies auto parts.

In Argentina, the National Institute of Industrial Technology (*Instituto Nacional de Tecnología Industrial* – INTI) is an institution that is object of the issuing of technical regulations applicable to conformity assessment. INTI's certification body was created through resolution 32/01 of

¹⁷⁸ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

the Directive of INTI Council to certify products on the regulated and voluntary scope and was later recognized as certification body by the National Trade Directorate on provision 775/99¹⁷⁹.

In Mexico there is no body similar to INMETRO, since, as in Argentina, metrology and accreditation activities are not exercised by regulatory agencies. In Mexico, accreditation is mainly performed by the Mexican Accreditation Entity, a private body that competes with other entities in the accreditation activity of conformity assessment bodies.

The National Metrology Center is the main Mexican body dealing with metrology and other technical matters. The Mexican technical regulations originate in several governmental organs and are called Mexican Official Standards (NOX), which are administered by the National Commission of Normalization (CNN) and the Directorate General of Normalization (DGN)¹⁸⁰.

In Colombia technical regulations are given legal status through domestic laws and decrees and Andean Community Decisions. On the national level, technical regulations comprise, for instance, the national standardization, certification and metrological system and the National Quality Subsystem. On the regional level, the objects of technical regulations are, for example, the preparation, adoption and application of technical regulations, the Andean system of standardization, accreditation, testing, certification, technical regulations and metrology, recognition and automatic acceptance of certificates of product conformity with technical regulations issued by accredited or recognized certification bodies and the Notification and Technical Regulation Information System of the Andean Community (SIRT)¹⁸¹.

In Colombia, the MINCIT Regulation Directorate constitutes the body responsible for policies and practices relating to standardization, quality, certification, accreditation, designation and metrology. MINCIT coordinates the National Quality Subsystem (SICAL), which is part of the National Administrative System for Competitiveness and Innovation and has as its basic objectives to promote quality, animal, plant and human safety, environmental conservation and the competitiveness of the production sector, and to protect the interests of consumers.

In Colombia various public and private sector institutions participate in the SICAL, namely: (a) the Colombian Technical Standards Institute (ICONTEC)¹⁸²; (b) the National Institute of Metrology; (c) the MinCIT; (d) the Supervisory Authority for Industry and Trade (SIC); (e) the entities authorized to issue technical regulations (RT); (f) the National Accreditation Organization of Colombia (ONAC)¹⁸³; (g) the Sectoral Standardization Units; (h) accredited certification and inspection bodies; (i) accredited Testing and Calibration Laboratories; and (j)

¹⁷⁹ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁸⁰ WORLD TRADE ORGANIZATION. Trade Policy Review: Mexico. Disponível em: https://www.wto.org/english/tratop_e/tpr_e/tp452_e.htm. Acesso em: 23 jul. 2019. See also MEXICO. Ley Federal Sobre Metrologia y Normalizacion. Disponível em: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acesso em: 22 jul. 2019.

¹⁸¹ WORLD TRADE ORGANIZATION. Trade Policy Review Colombia 2018. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s372_e.pdf.

¹⁸² INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

¹⁸³ ORGANISMO NACIONAL DE ACREDITACION COLOMBIANO. Quiénes somos?. Disponível em: <https://onac.org.co/>. Acesso em: 1 ago. 2019.

other entities with accreditation and control functions such as the National Food and Drug Surveillance Institute (INVIMA) and the Colombian Agricultural Institute (ICA)¹⁸⁴.

In Chile governmental authorities are responsible for regulating their respective areas of competence. Examples are the ministries and their dependent services as the Ministries of the Economy, Health, Agriculture, Transport and Telecommunications, Housing and Urban Planning, and the Superintendence of Electricity and Combustibles (SEC)¹⁸⁵. The origin of the regulation lies in the initiative of the regulatory authority itself or in the agents that are interested in the existence of a regulation and propose it to the authority, who decides on the matter. The National Standardization Institute (INN)¹⁸⁶ is the main authority competent to draft technical regulations that are applied on a voluntary basis. On the multilateral level, the National Commission on Technical Barriers to Trade, under the DIRECON¹⁸⁷, must comply with the TBT agreement commitments and coordinate Chile's position in trade negotiations among participating bodies.

In Chile each regulatory agency has internal mechanisms for coordination with the private sector when drafting technical regulations and conformity assessment procedures. One example of these is the one between the Ministry of Health's Committee on Food Health Regulations and the Ministry of Agriculture's Round Table on Meat. It is customary practice for the competent agencies to review technical regulations on a regular basis in order to amend or repeal them, as appropriate.

The table below summarizes the special characteristics of each of the systems, the main regulatory bodies and the main regulatory competencies of these systems.

Table 2.1 - Technical Regulation: Brazil, Argentina, Mexico, Colombia and Chile

TECHNICAL REGULATION			
	SPECIAL FEATURES OF THE SYSTEM	NAME OF THE REGULATORY ENTITY	ACTIVITIES DESCRIPTION
BRAZIL	The National Institute of Metrology, Quality and Technology (INMETRO) does not have a centralized production and management of technical regulations. But it has a special function, since it acts in a transversal way (several themes) and	National Institute of Metrology, Quality and Technology (INMETRO)	It has a complementary regulatory function, establishing technical regulations for more than two hundred kinds of products. It is the main Brazilian body in the area of technical regulation.
		Ministry of Agriculture Livestock and Food Supply (MAPA)	Has important regulatory role in the food sector and livestock breeding and trade.
		National Health Surveillance Agency (ANVISA)	Regulates a range of products that have the potential to affect human health.

¹⁸⁴ INSTITUTO COLOMBIANO AGROPECUARIO. Disponível em <https://www.ica.gov.co/home?lang=en-us>. Acesso em 16/07/2019.

¹⁸⁵ WORLD TRADE ORGANIZATION. Trade Policy Review Chile 2017, WTO. Disponível em https://www.wto.org/english/tratop_e/tpr_e/s315_e.pdf. Acesso em 16/07/2019.

¹⁸⁶ INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponível em: <https://www.inn.cl/quienes-somos>. Acesso em: 23 jul. 2019.

¹⁸⁷ DIRECON. Quiénes somos. Disponível em: <https://www.subrei.gob.cl/quienes-somos/>. Acesso em: 23 jul. 2019.

	residual (it can regulate whenever there is no specific regulator for the theme)	National Traffic Council (CONTRAN)/National Traffic Department (Denatran)	Regulates aspects related to the passive and active safety of vehicles (currently both are subordinated to the Ministry of Infrastructure)
		National Council for the Environment (CONAMA) Brazilian Institute of Environment and Natural Resources (IBAMA)	Regulates environmental aspects concerning the protection of the environment. Emphasis is given to the rules issued by the two bodies regarding the level of pollutant emission by motor vehicles.
		National Telecommunications Agency (ANATEL)	Disciplines the various dimensions of telecommunications, including aspects pertaining to telecommunications apparatus. Although most of its technical regulation is aimed at the operation of the market and the provision of telecommunication services, ANATEL also regulates aspects related to TBT.
ARGENTINA	There is no centralization of production and management of technical regulations. Governmental and private organizations (due to legal authorization) can act as regulatory agencies. In practice, private bodies transform the activity of standardization into a regulatory activity, by means of legal authorization.	<i>Instituto Nacional de Tecnologia Industrial (INTI) e Ministerio da Produccion</i>	The main function of INTI is related to metrology, but it provides technical subsidies to the regulatory activity of the Ministry of Production.
		<i>Servicio Nacional de Sanidad Agraria (SENASA)</i>	It has regulatory competence in the area of food, livestock and agriculture.
		<i>Instituto Nacional de Alimentos (INAL)/Comissão Nacional de Alimentos (CONAL)</i>	Regulatory competence in the area of food, including processed foods.
		<i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)</i>	Competence to regulate products and services that may affect human health.
		<i>Asociación Electrotécnica Argentina (AEA)</i>	Regulatory and standardization function for electrical and electronic products. It is a private sectoral entity with technical competence.
		<i>Asociación de Ingenieros y Técnicos del Automotor (AITA)</i>	Regulatory and standardization function for automotive products. It is a private sector entity with technical competence.
		<i>Instituto Nacional de Vitivinicultura (INV)</i>	Regulates some aspects of winemaking.
MÉXICO	The production of technical regulations (Mexican official standards) is also decentralized. These rules can originate from various government agencies, especially the Secretariat of Economy and the Secretariat of Environment and	<i>Secretaría de Economía</i>	Regulates various industrial products.
		<i>Secretaría de Turismo</i>	Has competence to regulate the provision of tourist services and related activities
		<i>Secretaría de Agricultura y Desarrollo Rural (ex SAGARPA)</i>	It has regulatory competence in the area of food, livestock and agriculture.
		<i>Secretaría de Medio Ambiente y Recursos Naturales (SEMRNAT)</i>	Regulates environmental aspects concerning the protection of the environment.

	Natural Resources. The National Standardization Commission (CNN) and the Directorate-General for Standardization (DGN), however, have the function of managing the production, modification and repeal of standards, which allows more centralized management of the regulatory stock.	<i>Secretaría de Trabajo y Provisión Social</i>	Aspects related to worker safety
		<i>Secretaría de Energía</i>	It mainly regulates energy production and supply services.
		<i>Secretaría de Desarrollo Social</i>	n.a.
		<i>Secretaría de Salud</i>	Regulates a range of products that have the potential to affect human health.
		<i>Secretaría de Comunicaciones y Transportes</i>	Regulates aspects related to the passive and active safety of vehicles
		<i>Comisión Reguladora de Energía</i>	It mainly regulates energy production and supply services.
		<i>Agencia de Seguridad Energética y Ambiente</i>	It regulates mainly services of production and supply of energy, especially aspects pertaining to environmental protection.
CHILE	There is centralization around the National Institute of Standardization (INN), which is responsible for the elaboration of technical regulations, applied voluntarily. The Regulatory Department of the Directorate General for International Economic Relations (DIRECON) of the Ministry of Foreign Affairs is responsible for	<i>Instituto Nacional de Normalización (INN)</i>	Competence to draft voluntarily applied technical standards
		<i>Superintendencia de Electricidad y Combustibles (SEC)</i>	Competence to improve technical regulations to mobilize energy markets to higher standards.
		<i>Comité Asesor de Alimentos y Nutrición</i>	Competence to support the Ministry of Health in the elaboration and execution of public policies in the area.
		<i>Dirección General de Relaciones Económicas Internacionales (DIRECON)</i>	Regulatory function of acting as the focal point of the TBT agreement on issues related to technical regulations.
		Executive Branch (Ministries)	Competence to issue laws, decrees or resolutions. They are prepared by government authorities responsible for regulating their respective areas of competence, for example, the Ministries of Economy, Health, Agriculture, Transport and Telecommunications, Housing and Urban Planning, and the SEC.
		Private Sector	Each of the regulatory agencies has internal private sector coordination mechanisms in the preparation of technical regulations and conformity assessment procedures.
		Ministry of Health Committee on Sanitary Food Regulations	Cooperates with the private sector in drafting technical regulations
		Ministry of Agriculture Round Table on Meat.	Cooperates with the private sector in drafting technical regulations
		Export Competition Council (submitted to the Ministry of Economy)	One of the objectives of this Council is to eliminate trade barriers faced by the exporting sector.

		Congress	Technical regulations in the form of laws must be approved by Congress.
COLÔMBIA	The preparation of technical regulations in Colombia is not centralized and is the responsibility of various institutions, primarily ministries, regulatory commissions and decentralized bodies. Most technical regulations reflect or are based on ICONTEC (Colombian Institute of Technical Standards and Certification) standards, although there are also technical regulations based on international standards. Most of the technical regulations are issued by the MINCIT and the Ministry of Health and Social Welfare. The criteria most used for the drafting of technical regulations include the protection of human life and health, consumer protection and protection of the environment.	MINCIT (Ministry of Trade, Industry and Tourism)	Responsible for regulating products
		SIC (Supervisory Authority for Industry and Trade)	Responsible for monitoring compliance with technical regulations in the following fields: personal consumer goods, labelling of footwear and clothing, toys; industrial products such as plain and deformed steel wire and electrowelded mesh; electric and gas-powered equipment subject to energy efficiency labelling; corrugated bars and rods; electric fittings; reflective tape for motor vehicles; household consumer products such as ceramic tiles and dishware, batteries, refrigerators, freezers and pressure cookers; in transport, products such as public service vehicles, safety belts, safety windows, braking systems and tyres; and vehicular natural gas (VNG) and household gas.

			The SIC also ensures that conformity assessment bodies register all conformity certificates and inspection reports that they issue in the Conformity Certificates Information System (SICERCO).
		Ministry of Health	Responsible for regulating products
		Ministry of Social Welfare	Responsible for regulating products

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

2.2. Technical standardization

In Brazil, Argentina, Mexico, Colombia and Chile technical standardization is developed by private entities, with a large participation of sectoral associations. However, there are important differences in the degree of centralization of the production of these standards.

In Brazil, the standardization system is centered in the Brazilian Association of Technical Standards - *Associação Brasileira de Normas Técnicas* (ABNT) that is the predominant standardization entity. ABNT, although private in nature, is part of the National System of Metrology, Standardization and Industrial Quality (SINMETRO) and performs a function of public utility. Its mission is the production of normative documents, which allow the production, marketing and use of goods and services in a sustainable and competitive manner. The production of original standards is done according to the following steps: (i) the company demonstrates interest, (ii) the study commission must draw up a standard project following the analysis of the industry technical committee and include it in the Sectorial Normalization Plan (PNS) by consensual decision, (iii) the project is submitted to national consultation and (iv) the standard is approved, receives a ABNT NBR and becomes available to the public¹⁸⁸.

The technical standards are developed by the various ABNT Committees, which are often directed by specific sectoral associations. In many cases, the work of normalization acquires great autonomy, remaining only formally in the ABNT framework. For example, the rules on electrical and electronic products are developed by the Brazilian Committee n. 3 (ABNT / CB-003 - Brazilian Electricity Committee), which coincides, in its institutional function and performance, with the Brazilian Committee on Electricity, Electronics, Lighting and Telecommunications (COBEI)¹⁸⁹.

The Argentine Institute for Standardization and Certification (IRAM) is the most important standardization body in Argentina. Like ABNT, IRAM is a private body that performs a public utility function. IRAM develops technical standards for the various segments of the Argentine economy (of goods and services), on demand of the private sector. Unlike ABNT, however,

¹⁸⁸ All the information in THORSTENSEN, V. et al. *Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional*. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁸⁹ THORSTENSEN, V. et al. *Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional*. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

IRAM in some areas breaks down standardization activity with other organisms. In general, IRAM establishes agreements with these bodies and there is a joint publication of technical standards, but in some cases there is a competitive relationship between standardizers, a common situation in countries with a number of standardization bodies, such as the United States. Examples of sectorial standardization bodies in Argentina are: Association of Engineers and Technicians of Automotive (AITA), Argentinean Institute of Iron and Steel (IAS), Argentinean Electrotechnical Association (AEA)¹⁹⁰.

In Argentina, IRAM is also the responsible body for the centralization of the study and approval of technical standards. IRAM performs this competence in a participatory, transparent and consensual manner, according to international standards. The elaboration of a standard starts with the production of a draft standard by the Executive or by representatives of a specific sector. On the next step, the draft is submitted for public scrutiny during a period that varies between 30 and 180 days. The draft, with the revisions deemed necessary, then receives an official form and is sent to the IRAM Directorate-General to be approved as a standard.

In Mexico the system of standardization is quite distinct from the Brazilian and the Argentinean. In both MERCOSUR countries, a predominant standardization body is evident, even if, in certain situations, other entities are involved in the normalization activity. The Mexican system, however, is characterized by great decentralization in the production of technical norms. At present, there are ten Mexican standardization bodies, which develop sectorial technical standards, according to the entity's specialties. In its plurality of actors of normalization and in the predominance of the competitive relationship between these actors, the Mexican system resembles the American system, in which technical norms and regulations are constructed according to market logic. However, as is evident from the provisions of the Federal Law on Metrology and Standardization, the Mexican Government plays an important role, through the General Directorate of Standards and national standardization programs, in managing the stock of technical standards over time¹⁹¹.

In Colombia, standardization is the exclusive responsibility of the Colombian Technical Standards Institute (ICONTEC)¹⁹², which is the national standardizing body designated by the Government and is the only entity authorized to issue NTCs. ICONTEC is the Colombian member in international and regional standardization organizations, such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the Pan American Standards Commission (COPANT). The five stages in the standardization process are the following: (i) feasibility and planning; (ii) Committee-stage work, in which the study is performed and the standard-setting files are approved in technical standardization committees; (iii) public consultation; (iv) approval, at the stage in which the document is submitted for consideration by an entity that is independent of the committee, in order to ratify the committee's technical decisions and ensure regulatory coherence; and (v) publication and dissemination.

¹⁹⁰ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁹¹ MEXICO. Ley Federal Sobre Metrología y Normalización. Disponível em: <https://www.gob.mx/cms/uploads/attachment/file/107522/LEYFEDERALSOBREMETROLOGIAYNORMALIZACION.pdf>. Acesso em: 22 jul. 2019.

¹⁹² INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

In Chile standardization is performed by private entities, with a huge participation of sectoral associations. There are, however, significant differences on the degree of centralization of production of standards.

The National Standardization Institute (INN)¹⁹³ is competent to draft Chilean technical standards (NCh), whose use is voluntary, and to their dissemination. INN consists on a non-profit-making foundation of private nature created by the Chilean Economic Development Agency (CORFO) whose operation in standardization activities encompasses fostering the development of Chilean production, stimulating the drafting and application of Chilean standards and assisting in ascertaining the need for new standards. The institute can perform its standardization function on its own initiative or after being provoked by the public or private sectors that may ask the INN to draw up one or more standards. It is also up to INN the coordination of the National Metrology Network and the accreditation of conformity assessment bodies. The National Commission of Technical Barriers to Trade coordinates the efforts of different public institutions involved in standardization activities. The commission promotes standardization as an instrument of support to the process of technological modernization of the country.

Table 2.2 - Technical Standardization: Brazil, Argentina, Mexico, Colombia and Chile

TECHNICAL STANDARDIZATION			
	SPECIAL CARACTERISTICS OF THE SYSTEM	NAME OF THE STANDARDIZATION ENTITY	DESCRIPTION OF THE ACTIVITIES.
BRAZIL	Approach the centralized structure. The Brazilian Association of Technical Standards (ABNT) is the leading standardization organization in Brazil.	Brazilian Association of Technical Standards (ABNT)	Brazilian standardization body. Integra SISMETRO and performs a public utility function recognized by law
		Brazilian Committee on Electricity, Electronics, Lighting and Telecommunications (COBEL)	It integrates the ABNT, but it is endowed with a certain degree of autonomy. Participates, as Brazilian representative, of the IEC
ARGENTINA	It has a relatively decentralized structure. The Argentinean Institute of Normalization and Certification (IRAM) is the main standardization body.	<i>Instituto Argentino de Normalización y Certificación</i> (IRAM)	Argentina's leading standardization body. It exercises public utility function recognized by law
		<i>Asociación Electrotécnica Argentina</i> (AEA)	Sector organization that produces technical standards and regulations in the area of electrical and electronic products
		<i>Asociación de Ingenieros y Técnicos del Automotor</i> (AITA)	Sector organization that produces technical standards and regulations in the area of vehicles and auto parts
MÉXICO	It presents a structure of decentralized normalization, similar to	Sociedad Mexicana de Normalización (NORMEX)	Standardization body with general scope

¹⁹³ INSTITUTO NACIONAL DE NORMALIZACIÓN (INN). Quiénes somos. Disponível em: <https://www.inn.cl/quienes-somos>. Acesso em: 23 jul. 2019.

	the North American one. There is no main standardization body, with a market logic prevailing in which standardization bodies compete in the production of standards that will be adopted by companies.	Instituto Mexicano de Normalización y Certificación (IMNC)	Standardization body with a general scope. Accumulates standards development and conformity assessment activities (third party).
		Asociación de Normalización y Certificación (ANCE)	Standardization body with a general scope. Accumulates standards development and conformity assessment activities (third party).
		Instituto Nacional de Normalización Textil (INNTEX)	Body dedicated to sectorial standardization.
		Organismo Nacional de Normalización y Certificación de la Construcción y Edificación (ONNCCE)	Body dedicated to sectorial standardization. Accumulates standards development and conformity assessment activities (third party).
		Normalización y Certificación Electrónica (NYCE)	Body dedicated to sectorial standardization. Accumulates standards development and conformity assessment activities (third party).
		Consejo para el Fomento de la Calidad de la Leche y sus derivados (COFOCALEC)	Body dedicated to sectorial standardization
		Centro de Normalización y Certificación de Productos (CNCP)	Accumulates standards development and conformity assessment activities (third party).
		Cámara Nacional de la Industria del Hierro y del Acero (CANACERO)	Body dedicated to sectorial standardization. Accumulates standards development and conformity assessment activities (third party).
		Organismo Nacional de Normalización de Productos Lácteos, A.C. (ONNPROLAC)	Body dedicated to sectorial standardization
CHILE	Highly centralized around the National Institute of Normalization (INN), the main Chilean body responsible for standardization	National Institute of Normalization (INN)	The INN is a non-profit private law foundation with the objective of boosting the development of Chilean production, promoting the development and use of Chilean standards, coordinating the National Metrology. It is also the role of INN to assist in determining the need for new technical standards.
		Public and Private Sector	Both INN and the public and private sectors can decide when a technical standard needs to be developed.

		Executive Branch	Upon approval, the Chilean Standard is sent to the relevant ministry (ministries) for a decision to include it in the technical regulations or to replace references to previous versions.
COLOMBIA	The process of standardization is centered in ICONTEC. The five stages in the standardization process are the following: feasibility and planning; committee-stage work, in which the study is carried out and the standard-setting documents are approved in technical standardization committees; public consultation; approval, at which stage the document is submitted for consideration by an entity that is independent of the committee, in order to endorse the committee's technical decisions and ensure regulatory coherence; and publication and dissemination.	ICONTEC	created in 1963, is a national government advisor, performs technical normalization on the country, constitutes the national standardization body and is recognized as the national standards body by the Colombian government through decree 1545/2015 and as a leader on the issue in international fora as ISO, IEC, the regional forum of COPANT and on the normalization forum in APEC. The main activity of the body is the study, adoption and promotion of Colombian technical standards (NTCs) on a range of economic and social activities inside the private and governmental sectors in the country. ICONTEC's mission is to promote, develop and guide the application of NTCs and other standard-setting documents. The national standardization body was designed for the development, access and dissemination of national and international technical standards.
		Sectoral Standardization Units (<i>Unidades Sectoriales de Normalización</i> – USNs)	It drafts sectoral technical standards (STCs). Their creation must be approved by the MINCIT Regulation Directorate in accordance with decree 210/2003.
		National System of Quality	In Colombia, a national system of quality (Sistema Nacional de la Calidad – SNC) gathers different aspects. A SNC can be defined as all the frameworks of (public), legal, regulatory and administrative policy and (public or private) institutional arrangements

			that are required to establish and implement in practice standardization

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

2.3.Conformity assessment

In all five countries, conformity assessment is carried out by a network of accredited bodies. The extent and concentration of this network is broadly based on aspects intrinsic to the economies of the three countries. For example, the smallest number of conformity assessment bodies in Argentina and their large concentration in the province of Buenos Aires are the result of the industrialization in the country. Probably the most relevant differences are related to the accreditation process in these three countries.

In Brazil, the conformity assessment is developed by a network of bodies accredited by INMETRO. These bodies are classified according to the type of evaluation service they carry out. In terms of evaluation of material goods, stand out the product certification bodies (OCPs). In Brazil, certifications may be voluntary and compulsory, and conformity assessment bodies may certify the product on the basis of a standard or technical regulation. Although INMETRO does not perform the conformity assessment procedures, INMETRO has a central role in accrediting the evaluating bodies and in creating compulsory and voluntary certification schemes¹⁹⁴.

In Brazil, the main forms of conformity assessment are certification, conformity declaration of the supplier, inspection and test. Seven modalities of certification are recognized that vary according to the type of product to be evaluated and to the guarantee of conformity of the product. In short, they are the following: unique evaluation through submission of one or more samples of a good; unique evaluation based on batch test; tests in samples taken from the producer, followed by evaluation for periodic maintenance of the certification by taking samples of the product on the market; tests carried out on samples taken from the producer, with subsequent evaluation for periodic maintenance of the certification through sample collection of the product in the factory; tests on samples taken from the producer, followed by a periodic maintenance assessment, by collecting the sample of the product in the factory and in the trade; tests on samples taken from the producer followed by a periodic maintenance assessment by collecting the sample of the product in the factory and/or the trade through audits in the quality system of the producer and audit of the quality management system or inspection, followed by periodic maintenance by repetition of audit procedures¹⁹⁵.

The main Brazilian entities that perform conformity assessment are INMETRO that coordinates its conformity assessment program, ABNT, whose operation encompasses more than 400

¹⁹⁴ All the information in THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁹⁵ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

certification programs on different fields, ANVISA that provides certificates according to the rules set in RDC 39/2013 and MAPA, which has a structure for assessment of organic products. INMETRO is the competent body to perform accreditation according to ISO and IEC international guides, in which are foreseen requisites for its internal organization and for its accreditation activities.

Argentina also presents a broad network of conformity assessment bodies, including testing, calibration laboratories and product certification bodies. It should be pointed out that these evaluating entities are, for the most part, accredited by a private entity, the Argentine Accreditation Body (OAA). Even though it has an important public function and is not for profit, the OAA acts in accordance with the rules of private law, under the laws governing civil society entities¹⁹⁶.

In Argentina, a higher concentration of certification activities is present. INTI performs the main activities, as it offers services of mandatory and voluntary certification in the country. INTI acts as an independent third party to grant the conformity certificate or label according to national and international standards. Moreover, INTI manages a quality policy that reaches all levels of the conformity assessment process. The Accreditation Argentine Body (*Organismo Argentino de Acreditación*, OAA) is competent to accredit certification bodies and laboratories according to standards ISO and IEC, is composed of representatives of the productive sectors, of consumption and of technology and maintains a close union between the private and public spheres that guarantees the impartiality of the institution and its necessary credibility before analogous foreign entities¹⁹⁷.

Argentina encompasses a wide network of conformity assessment bodies that includes testing and calibration laboratories and product certification bodies. It should be emphasized that these evaluating entities are mostly accredited by a private institution, the OAA. Despite its important public function and its non-profitable nature, the OAA performs its functions according to the rules of private law, under the laws governing civil society entities.

In Mexico conformity assessment is also conducted by a network bodies, which can be divided into assessment bodies of management systems and product evaluation body. An important aspect is that accreditation is not a prerogative of a main body, but rather performed by several private bodies, which act according to the specific area of specialty. *Entidad Mexicana de Acreditación* is the largest entity in the Mexican system, but it often competes with other bodies in the accreditation of conformity assessment bodies¹⁹⁸.

In Colombia, the main forms of conformity assessment are calibration, certification, inspection and tests. ICONTEC¹⁹⁹ is the main certifying entity, being recognized worldwide. The National

¹⁹⁶ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁹⁷ THORSTENSEN, V. et al. Convergência Regulatória na Integração Comercial Brasil-Argentina: os impactos da regulação e da normalização técnica sobre o comércio internacional. Texto para Discussão, Rio de Janeiro, v. 2454, n. 1, p. 7-44, mar/2019. Disponível em: <http://www.ipea.gov.br/portal/images/stories/PDFs/TDs/td_2454.pdf>. Acesso em: 23 jul. 2019.

¹⁹⁸ ENTIDAD MEXICANA DE ACREDITACIÓN (EMA. Quiénes somos?. Disponível em: https://www.ema.org.mx/portal_v3/. Acesso em: 23 jul. 2019.

¹⁹⁹ INSTITUTO COLOMBIANO DE NORMAS TÉCNICAS E CERTIFICAÇÃO (ICONTEC). Quiénes somos. Disponível em <https://www.icontec.org/Paginas/Home.aspx>. Acesso em 15/07/2019.

Accreditation Organization of Colombia (ONAC)²⁰⁰, created by Decree No. 4.738 of 2008, under the administrative control of the MinCIT, is the national accreditation body. The accreditation functions were concentrated in only one entity.

The Chilean system presents a post-market nature, in which conformity assessment is performed once products are placed on the market by bodies that are not bound to the supplier and to the buyer and the first party conformity assessment is prohibited. In Chile the conformity assessment process comprises mechanisms of mandatory nature under the control of the competent public institutions for technical regulations and a voluntary accreditation system managed by INN. On the majority of cases, governmental authorities are supported by conformity assessment bodies accredited by INN.

The system comprises national and foreign conformity assessment bodies that include universities, public and private institutions and subsidiaries of transnational companies. A post-market system operates, in which compliance with technical regulations is verified after the products have been placed on the market. The conformity assessment is done mainly by an accredited body independent of the supplier and the buyer. These bodies commonly constitute entities accredited by the INN, although in some cases, the ministry or government authority that issued the technical regulation performs the inspection using its own infrastructure. First party conformity assessment is not performed in Chile.

On the topic of accreditation, the INN, as the accreditation body, operates the national accreditation system, which accredits conformity assessment bodies that comply with internationally accepted requirements and the relevant regulations and directives. The country is also not a party in mutual recognition agreements of technical regulations with its commercial partners. The Electricity and Fuels Supervisory Authority (SEC) does, however, recognize the results of tests and certification by a list of organizations from 14 countries. Above the conformity assessment system, the National Network of Metrology (RNM) is an institution that aims to guarantee and diffuse traceability of measurements performed in Chile and to attain international recognition.

²⁰⁰ ORGANISMO NACIONAL DE ACREDITACION COLOMBIANO. Quiénes somos?. Disponível em: <https://onac.org.co/>. Acesso em: 1 ago. 2019.

Table 2.3 - Accreditation and conformity assessment: Brazil, Argentina, Mexico, Colombia and Chile

ACCREDITATION AND EVALUTATION OF CONFORMITY			
	ACCREDITATION CHARACTERISTICS	CHARACTERISTICS OF THE EVALUATION OF CONFORMITY	CONFORMITY ASSESSMENT BODIES (sample list)
BRASIL	INMETRO, through its General Accreditation Coordination (Cgcre), is the accrediting entity in Brazil. Accreditation, therefore, is promoted by a public entity, linked to the entity of indirect administration	The conformity assessment is carried out by a network of bodies accredited by INMETRO. These bodies are classified according to the type of evaluation service they carry out. In terms of evaluation of material goods, stand out the product certification bodies (OCPs).	A2BR/CATA; ABENDI; ABNT; ABRACE; ABS; APCER; BBV Q; BRICS BRTUV; BVC; CCB; CCP; CTBC; DEKRA; DNVGL; FCAV; ICV BRASIL; IEX; IFBQ; INNAC; INTERTEK; IQA; IQB; LRQA; MR CERTIFICAÇÕES; NACER; NCC; PCN; QC CERT; RINA; SARON Certificações; SAS; SENAI PR; SGS; TUV RHEINLAND; TUV SUD UL; ICV BRASIL
ARGENTINA	In Argentina, the accreditation activity is performed by the Argentine Accreditation Body, a private and non-profit entity	Argentina also presents a broad network of conformity assessment bodies, including testing, testing, calibration and product certification laboratories. It should be emphasized what are the evaluating organizations are, for the most part, accredited by a private entity, the Argentine Accreditation Body (OAA).	Association Control Union Certificates Bureau Veritas Argentina S.A. Bureau Veritas Certification Chile S.A. - CPS-certification of product and systems ltda. Det norske veritas s.a; Food safety s.a Fundación gutenbergl instituto argentino de artes gráficas - certificación gutenbergl Instituto del gas argentino Intertek Argentina Certificaciones S.A. INTI - Instituto Nacional de Tecnología Industrial; IQC S.A.; IRAM - Instituto Argentino de Normalizacion y Certificacion; Lenor chile s.p.a; Lenor s.r.l; Letis s.a. Net connection international s.r.l; Organización Internacional Agropecuaria S.A Primus chile s.p.a; Qetkra s.r.l; Schutter argentina s.a; Sgs argentina s.a; Tüv rheinland argentina s.a; UL de argentina s.r.l

MÉXICO	<i>Entidad Mexicana de Acreditacion</i> is the largest entity in the Mexican system, but it often competes with other bodies in the accreditation of conformity assessment bodies.	In Mexico conformity assessment is also conducted by a network bodies, which can be divided into assessment bodies of management systems and product evaluation body. An important aspect is that accreditation is not a prerogative of a main body, but rather performed by several private bodies, which act according to the specific area of specialty.	
CHILE	The INN, as an accreditation body, operates the national accreditation system, which accredits conformity assessment bodies that meet internationally accepted requirements and relevant regulations and directives. Accreditation is given for a period of four years.	As a general rule, compliance with technical regulations is verified after placing the products on the market. However, for imports of certain products, especially food, beverages, medicines, weapons, radioactive substances, electrical products and fuels, verification takes place at the border. In some cases, the Government authority that issued the technical regulation carries out the inspection.	-Agriculture and Livestock Service (SAG). -Ministry of Economy, Housing and Urban Planning, Labor and Social Assistance. -National Service for Women. -Institute of Public Health (ISP). -Sanitary Services Supervision Authority. - National Customs Service. -National Training and Employment Service (SENCE). -Secretariat of Fisheries and Aquaculture (Underfishing). - National Fishing Service (SERNAPESCA). -Energy and Fuel Supervision Authority (SEC).
COLOMBIA	The aspects to be evaluated in an accreditation process are organization, guarantee of quality and technical competence. Qualified and trained staff perform the accreditation and the final result is evaluated by accreditation entities authorized for this function. ONAC (National Accreditation Body of Colombia) grants accreditation for a three-year period in the case of a conformity assessment body that is accredited for the first time. ONAC is also the sole official source of information about accreditation in Colombia and is	The mechanisms and methods for conformity assessment and proof are in general set out in the technical regulation itself, and depending on the level of risk may consist in certification, inspection or testing carried out by bodies accredited or designated by the regulatory body. In general, the accredited certification bodies subcontract the services of accredited laboratories to assess product conformity. Conformity assessment bodies (certification, inspection, calibration, testing and assays) established in Colombia and accredited in accordance with international practices and rules are grouped in the	-ONAC (National Accreditation Body of Colombia) - Institute of Hydrology, Meteorology and Environmental Studies (IDEAM) -the National Food and Drug Surveillance Institute (INVIMA) -the National Institute of Forensic Medicine and Forensic Sciences, and the ICA - Conformity Certificates Information System (SICERCO) - Colombian Agricultural Institute (<i>Instituto Colombiano de Agricultura</i> – ICA) - ASOSEC (Colombian Association of Safety) is an organization that encompasses conformity assessment entities and seeks to contribute in an

	responsible for granting, maintaining, broadening, restricting, suspending and withdrawing accreditations	National Association of Conformity Assessment Bodies (ASOCEC). The National Institute of Metrology (Instituto Nacional de Metrología de Colombia – INM) performs conformity assessment activities through comparisons between laboratories that provide calibration services. Decree 1595/2015 provides rules applicable to conformity assessment. It establishes that conformity assessment for goods subject to technical regulations is compulsory and that importers and domestic producers are obliged to prove compliance by means of an inspection report or a conformity certificate, which can be a first-party certificate issued by an accredited body or a certificate issued by a designated body before the marketing.	organized manner to the efforts to implement a quality culture in the country. The members of the association can have direct or indirect interests in the conformity assessment.

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

In summary, further convergence of Mercosur and the Pacific Alliance countries should include, after the elimination of tariff barriers, a new and important phase for the elimination of non-tariff barriers. Among them, the most significant is regulatory barriers, mainly technical measures, including regulations, standards and conformity assessment.

With the diversity of regulatory models present in the area and fragmentation of rules, this task will be an arduous negotiation.

3. Comparative sectorial analysis of main aspects of technical regulatory frameworks

BRAZIL, ARGENTINA, COLOMBIA, CHILE AND MEXICO²⁰¹

In this part of the report, the purpose is to compare the main aspects of the quality infrastructure systems of five Latin American countries. In addition to Brazil and Argentina, three countries are included: Colombia, Chile and Mexico.

²⁰¹ The detailed information on Brazil and Argentina is in previous works. A summary of the information concerning these two countries can be found in

http://www.ipea.gov.br/portal/index.php?option=com_content&view=article&id=34629&Itemid=444

The comparison will focus on the three dimensions of quality infrastructure systems (technical regulation, technical standardization and conformity assessment), with emphasis on integration between technical regulations and technical standardization.

3.1.Comparative overview

The tables below contain a comparative summary of regulation, standardization and conformity assessment in selected sectors in the five Latin American countries.

Table 3.1 - Comparison of main regulators

	GENERAL REGULATION (political bodies)				
	ARGENTINA	BRASIL	CHILE	COLOMBIA	MEXICO
OIL AND GAS	Instituto Argentino del Petróleo y del Gás/Ministerio de Hacienda	Agência Nacional do Petróleo, Gás Natural e Biocombustíveis	Ministerio de Transportes y Telecomunicaciones/Ministerio de Energía/Ministerio de Economía, Fomento y Turismo/Ministerio de Minería/Ministerio del Interior y Seguridad Pública	Ministerio de Comercio, Industria y Turismo/Ministerio de Ambiente y Desarrollo Sostenible/Ministerio de Minas y Energía/Ministerio de Transporte	Secretaría de Economía/Secretaría de Energía/Secretaría de Medio Ambiente y Recursos Naturales
VEHICLES	Ministério do Meio Ambiente e Desenvolvimento Sustentável	Ministério das Cidades	Ministerio de Transportes y Telecomunicaciones/Ministerio del Medio Ambiente/Ministerio de Hacienda	Ministerio de Comercio, Industria y Turismo/Ministerio de Ambiente y Desarrollo Sostenible/Ministerio de Transporte	Secretaría de Economía/Secretaría de Comunicación y Transporte/Secretaría de Energía/Secretaría de Medio Ambiente y Recursos Naturales
ELECTRIC AL APPLIANCES	Ministerio de Producción	Ministério da Indústria, Comércio Exterior e Serviços (MDIC)	Ministerio de Energía/Ministerio de Economía, Fomento y Turismo/Ministerio de Hacienda	Ministerio de Minas y Energía/Ministerio de Comercio, Industria y Turismo/Ministerio de Ambiente y Desarrollo Sostenible/Ministerio de Salud y Protección Social	Secretaría de Economía/ Secretaría de Comunicación y Transporte/ Secretaría de Energía
CHEMESTRY: PHARMACEUTICAL	Ministério da Saúde	Ministério da Saúde	Ministerio de Salud/Ministerio de Hacienda	Ministerio de Salud y Protección Social	Secretaría de Salud
FOOD	Ministério da Agroindustria	Ministério da Agricultura, Pecuária e Abastecimento (MAPA) Ministério da Saúde	Ministerio de Agricultura	Ministerio de Comercio, Industria y Turismo/Ministerio de Salud y Protección Social/Ministerio de Agricultura y Desarrollo Rural/Ministerio de Ambiente y Desarrollo Sostenible/Ministerio de Transporte	Secretaría de Economía/Secretaría de Salud/Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación/ Secretaría de Medio Ambiente y Recursos Naturales

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

Table 3.2 - Comparison of specific regulators:

	SPECIFIC REGULATION (technical bodies)				
	ARGENTINA	BRASIL	CHILE	COLOMBIA	MEXICO
OIL AND GAS		INMETRO; ANP	Superintendencia de Electricidad y Combustibles	Superintendencia de Industria y Comercio	n.a.
VEHICLES	Asociación de Ingenieros y Técnicos del Automotor (AITA)	CONTRAN/ Instituto Brasileiro do Meio Ambiente (IBAMA)/ INMETRO	n.a.	n.a.	n.a.
ELECTRICAL APPLIANCES	Associação Eletrotécnica Argentina (AEA)	Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO)	Superintendencia de Electricidad y Combustibles	n.a.	n.a.
CHEMESTRY: PHARMACEUTICALS	Serviço Nacional de Sanidade e Qualidade Agrícola (SENASA)	Agência Nacional de Vigilância Sanitária (ANVISA)	n.a.	Instituto Nacional de Vigilância de Medicamentos y Alimentos (INVIMA)	n.a.
FOOD	Sistema Nacional de Controle de Alimentos (SNCA): Serviço Nacional de Sanidade e Qualidade Agrícola (SENASA)/Instituto Nacional de Vinicultura (INV)/Administração Nacional de Medicamentos, Alimentos e Tecnologia Médica/Comissão Nacional de Alimentos (CONAL)/Administração Nacional de Medicamentos, Alimentos e Tecnologia Médica (ANMAT)	Agência Nacional de Vigilância Sanitária (ANVISA)	Servicio de Agricultura y Ganadería	Instituto Agrícola Colombiano	n.a.

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

Table 3.3 - Comparison: standardization bodies and associations

STANDARDIZATION AND ASSOCIATIONS					
	ARGENTINA	BRASIL	CHILE	COLOMBIA	MÉXICO
OIL AND GAS	Instituto Argentino de Normalización y Certificación (IRAM)	Associação Brasileira de Normas Técnicas (ABNT , http://www.abnt.org.br/):	Instituto Nacional de Normalización (INN)/Instituto Chileno del Petróleo (ICHP)	Asociación Colombiana del Petróleo (ACP); Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)	Asociación de Normalización y Certificación A.C. (ANCE)
VEHICLES	Instituto Argentino de Normalización y Certificación (IRAM)/Asociación de Ingenieros y Técnicos del Automotor (AITA)	Associação Brasileira de Normas Técnicas (ABNT , http://www.abnt.org.br/): Comitê Brasileiro Automotivo (CB n. 5, ANFAVEA)	Instituto Nacional de Normalización (INN)/Asociación Nacional Automotriz de Chile (ANAC), Asociación Gremial de Vehículos Eléctricos de Chile (AVEC) Cámara Nacional de Comercio Automotriz de Chile (CAVEM) and Automóvil Club	Automóvil Club de Colombia (ACC); Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)	Asociación de Normalización y Certificación A.C. (ANCE)
ELETRICAL APPLIANCES	Instituto Argentino de Normalización y Certificación (IRAM)/Asociación Electrotécnica Argentina (AEA)	Associação Brasileira de Normas Técnicas (ABNT , http://www.abnt.org.br/) / Comitê Brasileiro de Eletricidade (COBEI , CB 3)	Instituto Nacional de Normalización (INN)/Asociación de la Industria Eléctrica-Electrónica (AIE)	Nacional de Eléctricos; Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)	Asociación de Normalización y Certificación A.C. (ANCE)
CHEMESTRY: PHARMA CEUTICALS	Instituto Argentino de Normalización y Certificación (IRAM)/Serviço Nacional de Sanidade e Qualidade Agrícola (SENASA)	Associação Brasileira de Normas Técnicas (ABNT , http://www.abnt.org.br/)/A BNT/CB-010 - Comitê Brasileiro de Química (ABIQUIM)	Instituto Nacional de Normalización (INN)	Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)	Asociación de Normalización y Certificación A.C. (ANCE); Facultad de Química y Facultad de Medicina, Academia Nacional de Medicina de México, Asociación Farmacéutica Mexicana, the Asociación Mexicana de farmacovigilancia, Asociación Mexicana de Profesionales en Regulación Sanitaria, Asociación Nacional de Fabricantes de Medicamentos, Asociación mexicana de industrias de investigación farmacéutica

STANDARDIZATION AND ASSOCIATIONS					
	ARGENTINA	BRASIL	CHILE	COLOMBIA	MÉXICO
FOOD	Instituto Argentino de Normalización y Certificación (IRAM)/serviço Nacional de Sanidade e Qualidade Agrícola (SENASA)	Associação Brasileira de Normas Técnicas (ABNT, http://www.abnt.org.br)/A BNT/CEE-104 - Comissão de Estudo Especial de Segurança de Alimentos	Instituto Nacional de Normalización (INN)/Asociación de Empresas de Alimentos de Chile (Chilealimentos)	Asociación Colombiana de Ciencia y Tecnología de Alimentos (ACTA)	Asociación de Normalización y Certificación A.C. (ANCE)

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

Table 3.4 - Comparison: conformity assessment

CONFORMITY ASSESSMENT					
	ARGENTINA	BRASIL	CHILE	COLOMBIA	MEXICO
OIL AND GAS	Organismo Argentino de Acreditação (OAA)/Instituto Nacional de Tecnología Industrial (INTI)	Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO) /Instituto Brasileiro de Petróleo, Gás e Biocombustíveis (IBP)	Instituto Nacional de Normalización (INN)/Superintendencia de Electricidad y Combustibles (SEC)	Organismo Nacional de Acreditación de Colombia (ONAC)/Instituto Colombiano de Normas Técnicas y Certificación (ICONTEC)/Superintendencia de Industria y Comercio (SIC)	Entidad Mexicana de Acreditación (EMA)/Comisión Regulatoria de Energía (CRE)
VEHICLES	Organismo Argentino de Acreditação (OAA)/Instituto Nacional de Tecnología Industrial (INTI)	Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO)	Instituto Nacional de Normalización (INN)	Organismo Nacional de Acreditación de Colombia (ONAC)/Superintendencia de Industria y Comercio (SIC)	Entidad Mexicana de Acreditación (EMA)
ELETRICAL APPLIANCES	Organismo Argentino de Acreditação (OAA)/Instituto Nacional de Tecnología Industrial (INTI)	Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO)	Instituto Nacional de Normalización (INN)	Organismo Nacional de Acreditación de Colombia (ONAC)	Entidad Mexicana de Acreditación (EMA)/Directorio General de Normas (DGN)
CHEMESTRY: PHARMACEUTICALS	Organismo Argentino de Acreditação (OAA)/Instituto Nacional de Tecnología Industrial (INTI)	Agência Nacional de Vigilância Sanitária (ANVISA)	Instituto Nacional de Normalización (INN)	Organismo Nacional de Acreditación de Colombia (ONAC)	Entidad Mexicana de Acreditación (EMA)/Comisión Federal para la Protección contra Riesgos Sanitarios (Cofepris)
FOOD	Organismo Argentino de Acreditação (OAA)/Instituto Nacional de Tecnología Industrial (INTI)	Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO)/Agência Nacional de Vigilância Sanitária (ANVISA)	Instituto Nacional de Normalización (INN)	Organismo Nacional de Acreditación de Colombia (ONAC)/Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Entidad Mexicana de Acreditación (EMA)/Instituto de Nutrición y Tecnología de los Alimentos (INTA)

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaboration: CCGI-EESP/FGV.

3.2.The regulatory bodies

The three countries analyzed share some important characteristics. First of all, it must be highlighted the plurality of sectoral regulatory actors. In other words, it means that the sectors are regulated by a plurality of governmental organisms. The case of vehicles and auto parts is quite emblematic, because at least two types of authorities have regulatory interest in the subject: transit and vehicular security agencies and environmental agencies.

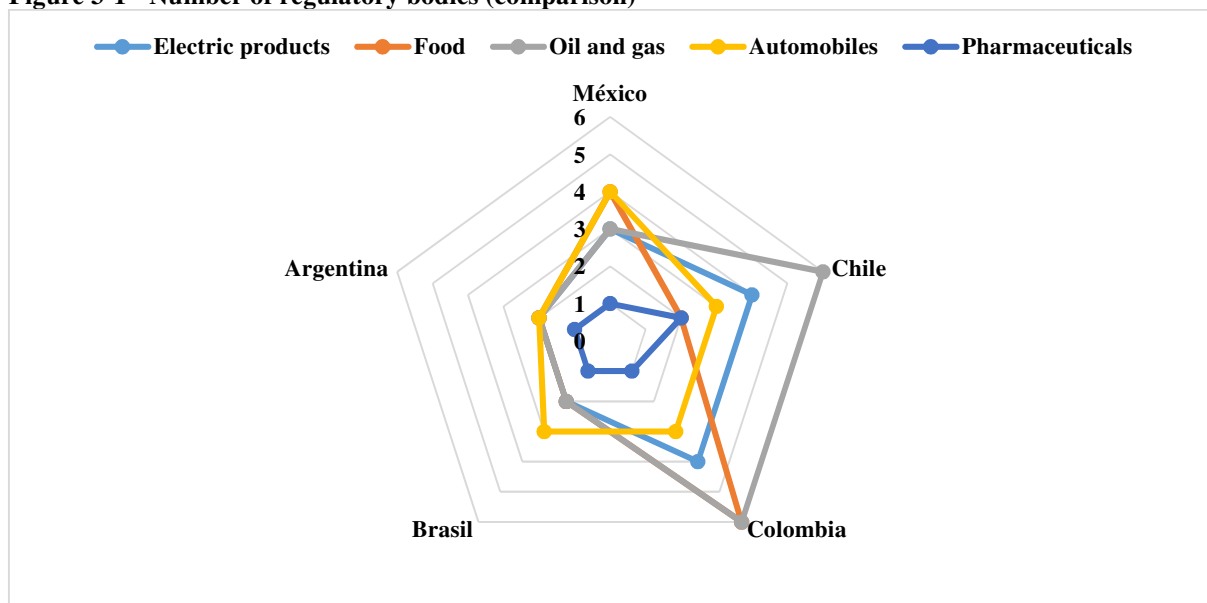
Table 3.5 - Number of regulatory bodies

	Electric products	Food	Oil and gas	Automobiles	Pharmaceuticals
Mexico	3	4	3	4	1
Chile	4	2	6	3	2
Colombia	4	6	6	3	1
Brazil	2	2	2	3	1
Argentina	2	2	2	2	1

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaborated by CCGI-EESP/FGV.

In the table above and in the chart below, there is a comparison between the numbers of regulatory agencies in five different countries, including the three selected countries in this report. It is clear that there is not a quite defined pattern for the number of regulatory bodies. The oil and gas sector in Colombia and Chile (although this country is only an importer of these products) has six different regulatory entities. This same sector has only two regulators in Brazil and Argentina. The pharmaceutical sector, in turn, has regulation concentrated in only one entity in Mexico, Colombia, Brazil and Chile. The vehicles, electric and food sector have more than one regulatory authority in all the five countries.

Figure 3-1 - Number of regulatory bodies (comparison)



Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaborated by CCGI-EESP/FGV.

3.3. The regulatory activities

The number of regulatory authorities does not have direct relationship to the number of technical regulations issued for each sector. A regulatory authority may have a much more intense regulatory activity than that of several aggregate bodies. With regard to the intensity of regulatory activity, based on the number of technical regulations, there is a clear separation of countries into two groups. The organisms of Brazil and Argentina present more intense regulatory activity, when compared with the organs of the other three countries. This characteristic is verified in all five selected sectors. The Brazilian agencies, in particular, have a very intense regulatory activity, with a number of regulations that exceed, in some cases, three hundred.

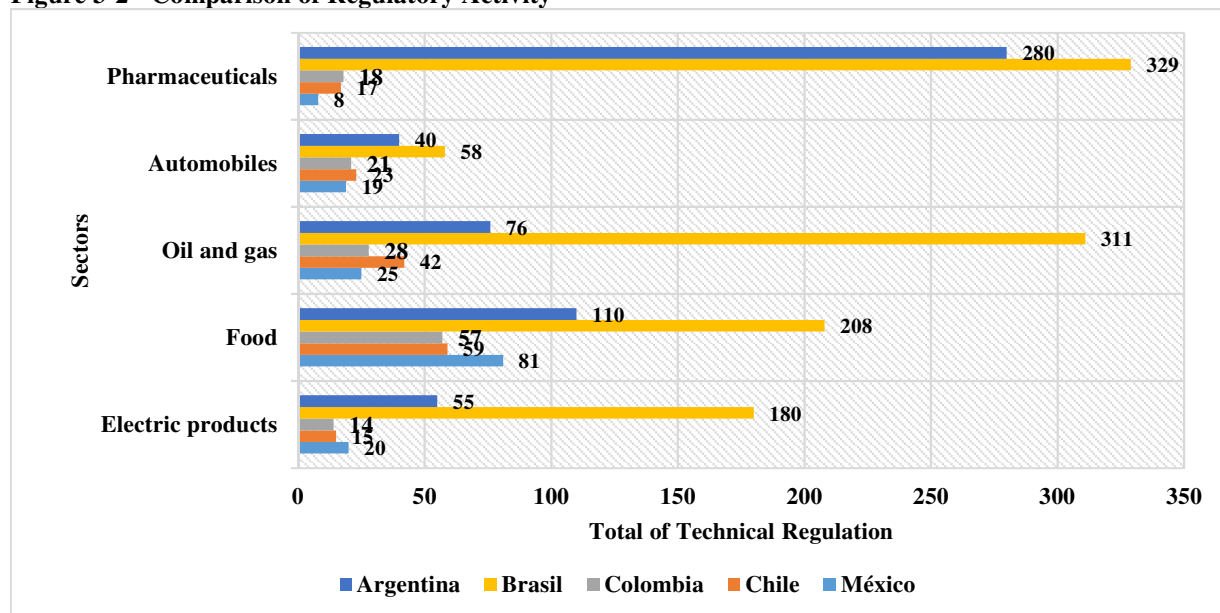
Table 3.6 - Comparison of Regulatory Activity

	Electric products	Food	Oil and gas	Automobiles	Pharmaceuticals
Mexico	20	81	25	19	8
Chile	15	59	42	23	17
Colombia	14	57	28	21	18
Brazil	180	208	311	58	329
Argentina	55 (ver)	110	76		280

Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaborated by CCGI-EESP/FGV.

In the chart below this aspect is more evident. The dark yellow bar always stands out in relation to the others, even in relation to the blue bar of Argentina, which also has high values.

Figure 3-2 - Comparison of Regulatory Activity



Source: WORLD TRADE ORGANIZATION. Trade Policy Review: Argentina, Brazil, Mexico, Chile e Colombia. Elaborated by CCGI-EESP/FGV.

If regulatory frequency is highlighted according to the sector, it is verified that the food sector is more regulated in Colombia, Chile and Mexico. Brazil and Argentina regulate the pharmaceutical sector with greater intensity.

3.4. The standardization activity

The normalization activity is usually complementary to regulatory activity. The intense normalization activity may indicate the strength of the productive sector of a given sector. It should be remembered that the technical standards are volatile, except where expressly mentioned in a technical regulation.

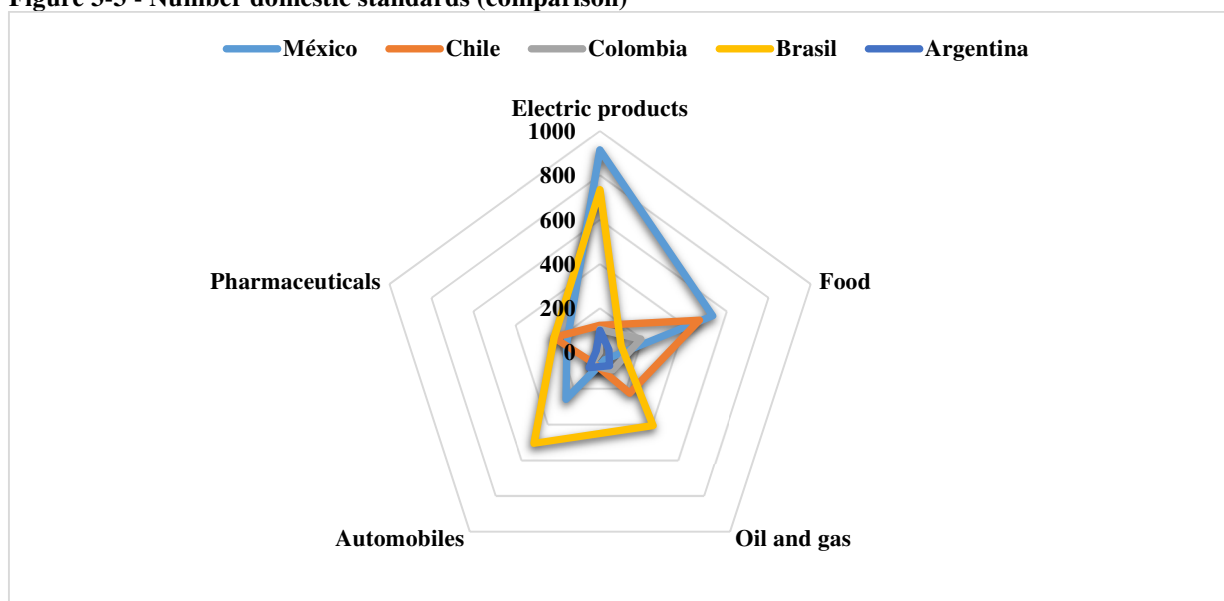
Table 3.7 - Comparison of Standardization Activity

	Electric products	Food	Oil and gas	Automobiles	Pharmaceuticals
Mexico	915	535	39	261	157
Chile	122	472	227	56	220
Colombia	104	194	97	70	2
Brazil	735	100	408	507	217
Argentina	100	42	74	84	19

Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

The standardization bodies of Brazil and México stand out in the production of technical standards for electrical products. Argentina and Chile have more technical standards for processed foods. In the automotive and oil and gas sectors, the Brazilian standardization bodies are more effective. The table below summarizes the differences in standardization activity among the five countries.

Figure 3-3 - Number domestic standards (comparison)



Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Despite being able to present an indirect relation, depending on the will of the regulator, the standardization activity is not reflected in the intensity of the regulatory activity. This activity, if intense, can erect barriers to trade, since they are compulsory prescriptions directed even at imported products.

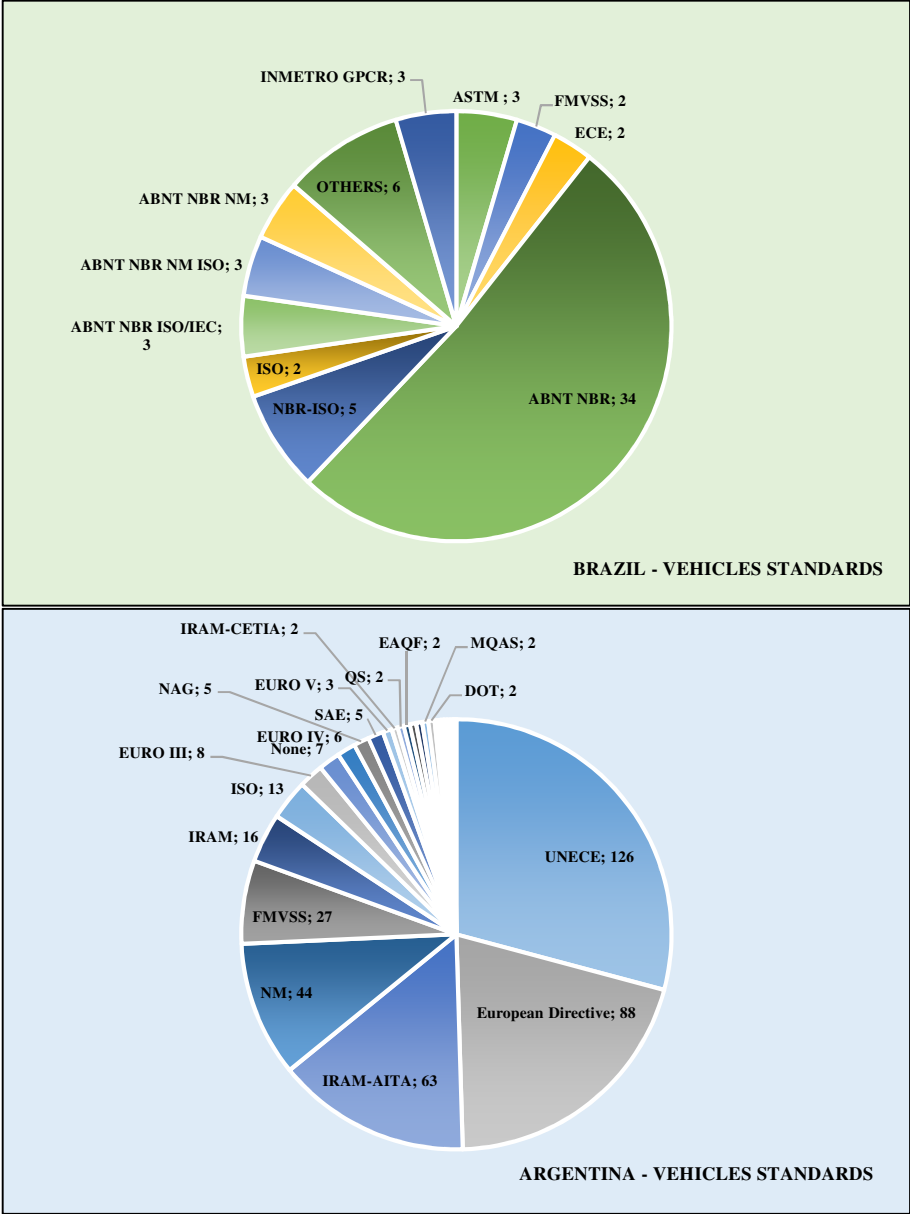
3.5. Use of Supporting Standards in the Technical Regulation

The use of supporting standards may reveal some important features of the set of technical regulations adopted by the countries because they are the pillars of each regulation. In this section, the supporting technical standards referred to in the scope of technical regulations of Colombia, Mexico, Chile, Brazil and Argentina will be identified.

Two aspects should be carefully observed in this identification. The first is the amount of supporting technical standards present in the technical regulations; the second is the variety and origin of the technical standards used to support compulsory rules.

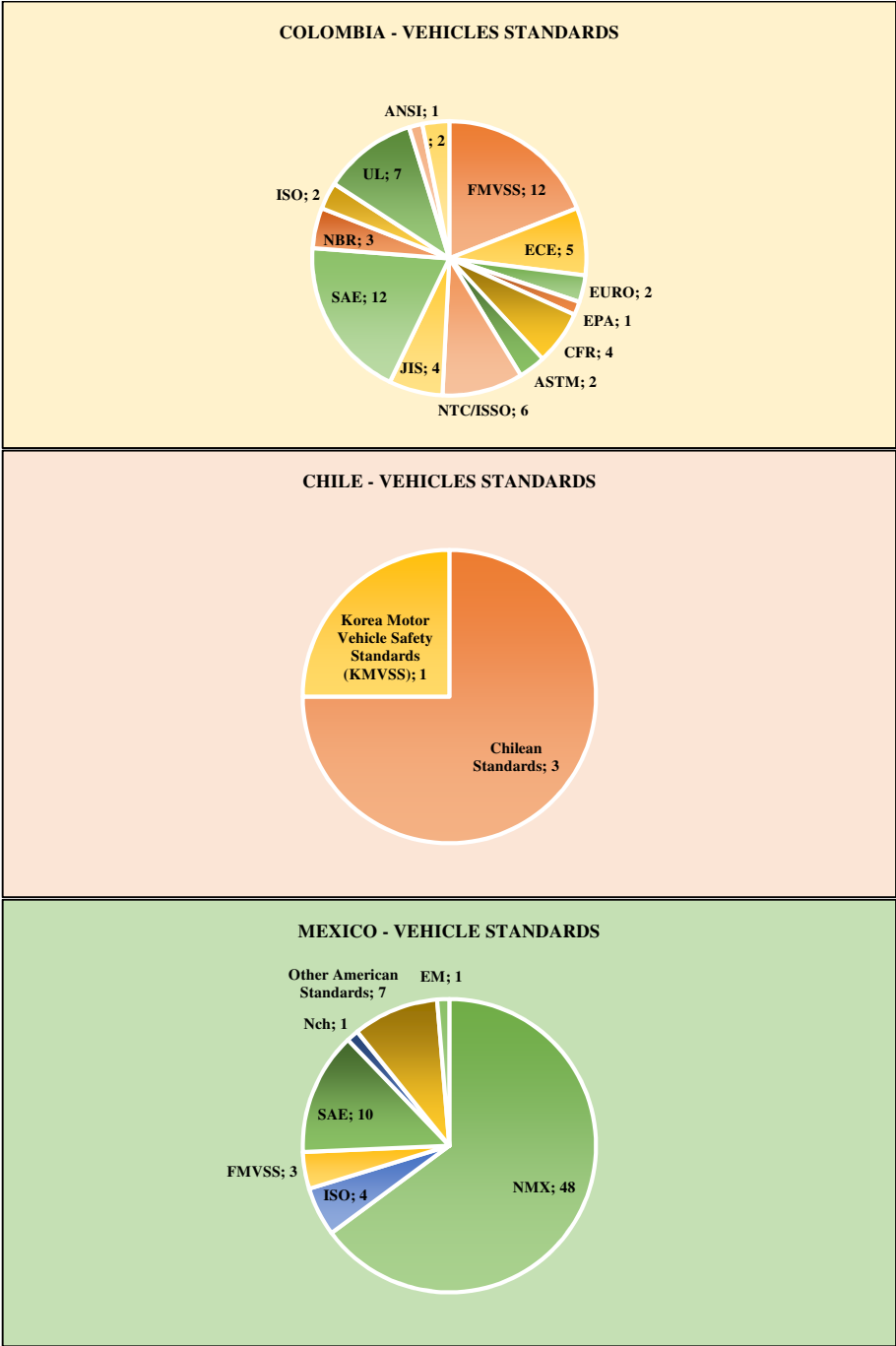
As a direct inference of this identification, the research verifies a very strong presence of technical standards of United States origin in the three countries, independently of the sector. This is not what happens with Brazil and Argentina. Not only the number of US technical standards is high because they sometimes exceed the number of international standards, but also their great variety is apparent, that is another aspect to be highlighted. The following graphs summarize this information.

Figure 3-4 - Brazil and Argentina: Standards in Technical Regulation for Vehicles



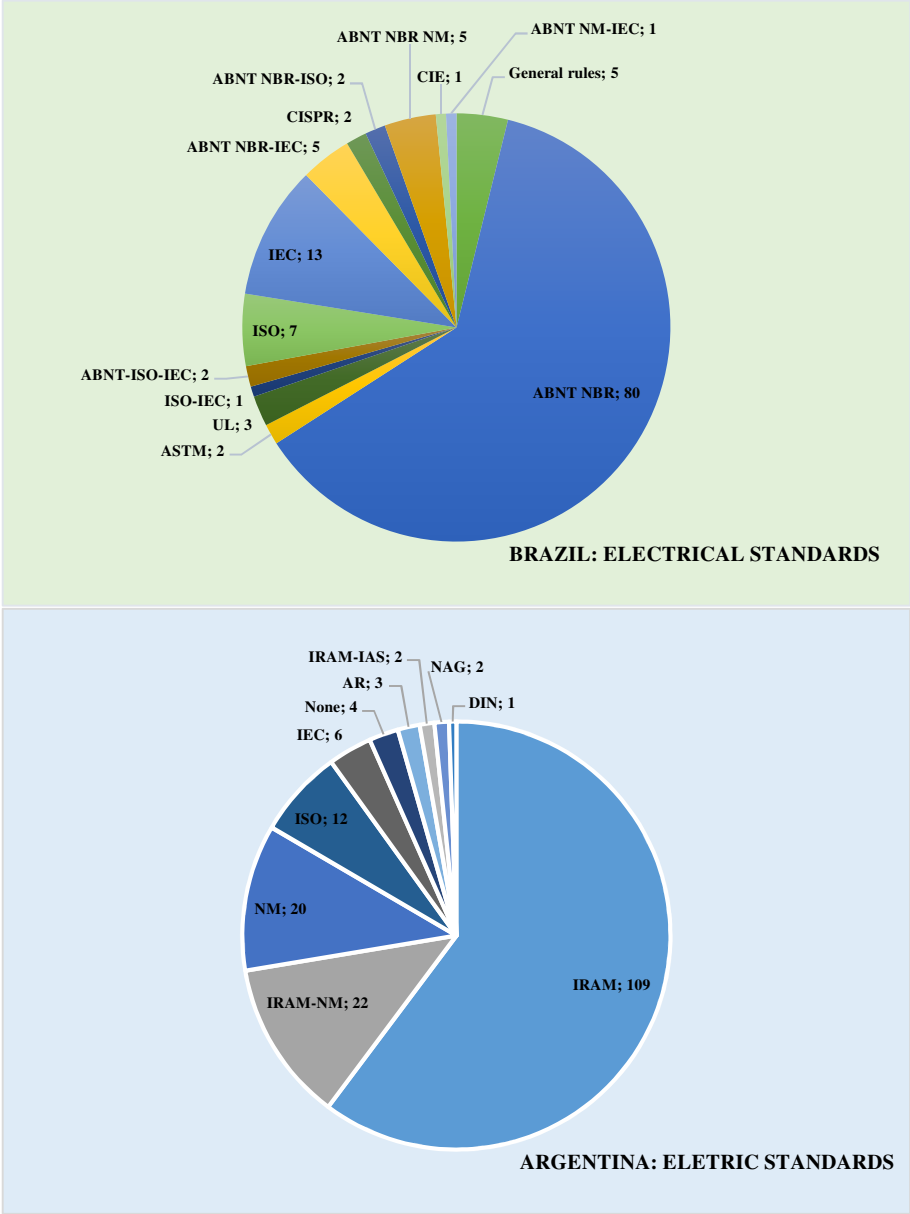
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-5 - Colombia, Chile and Mexico: Standards in Technical Regulation for Vehicles



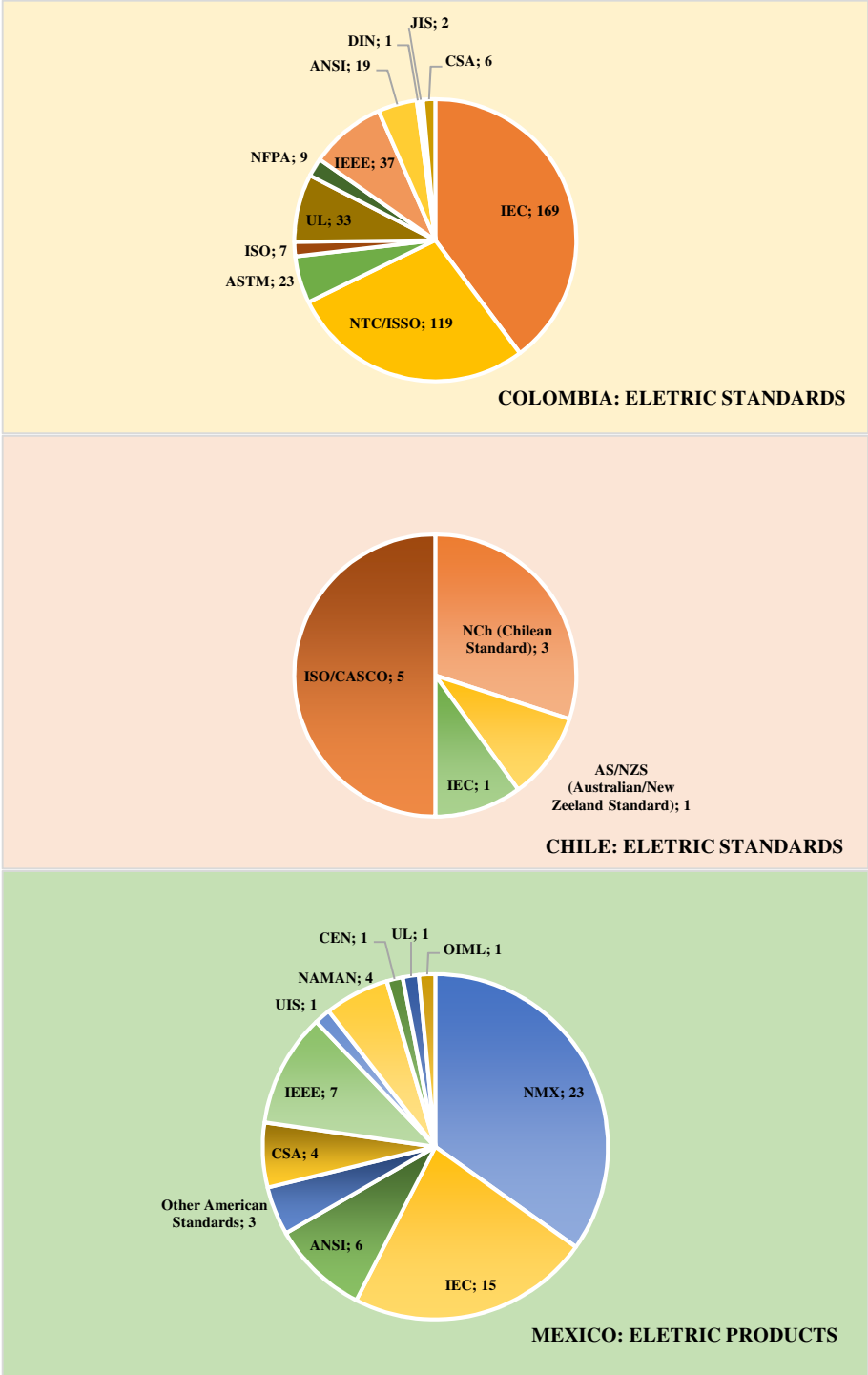
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-6 - Brazil and Argentina: Standards in Technical Regulation for Electric Products



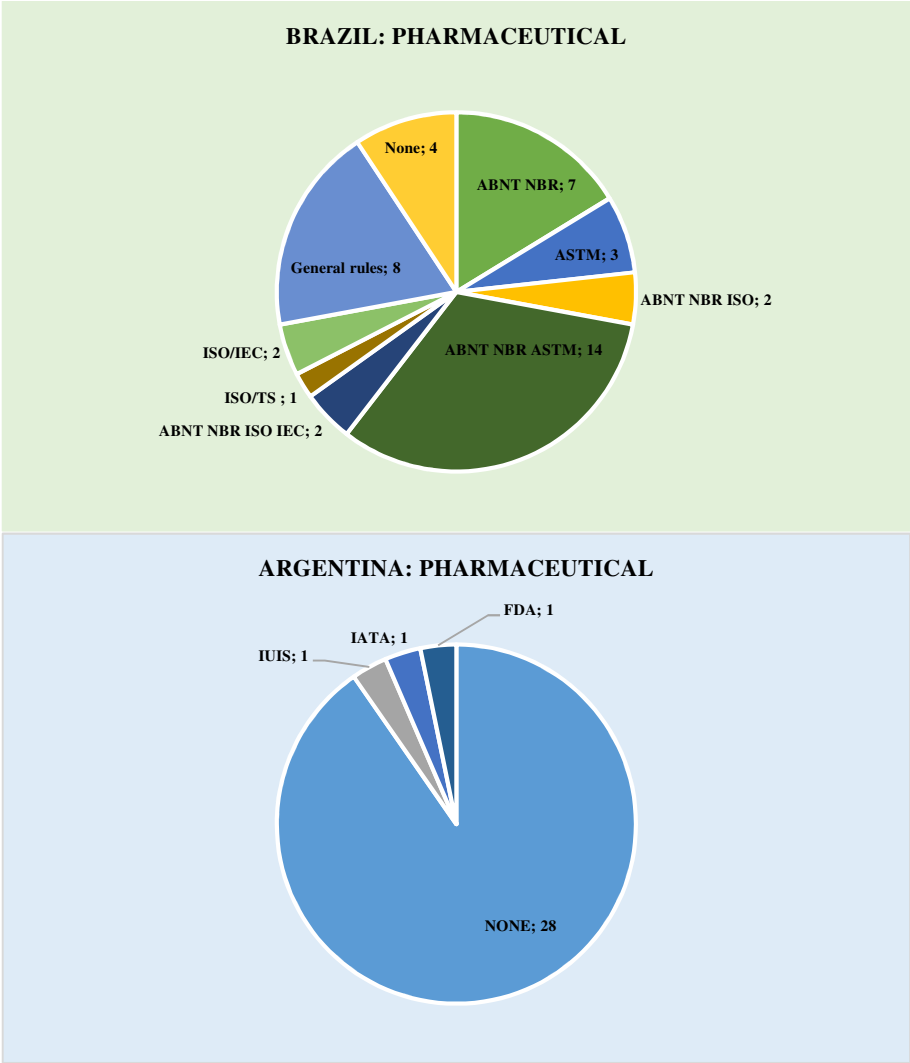
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-7 - Colombia, Chile and Mexico: Standards in Technical Regulation for Electric Products



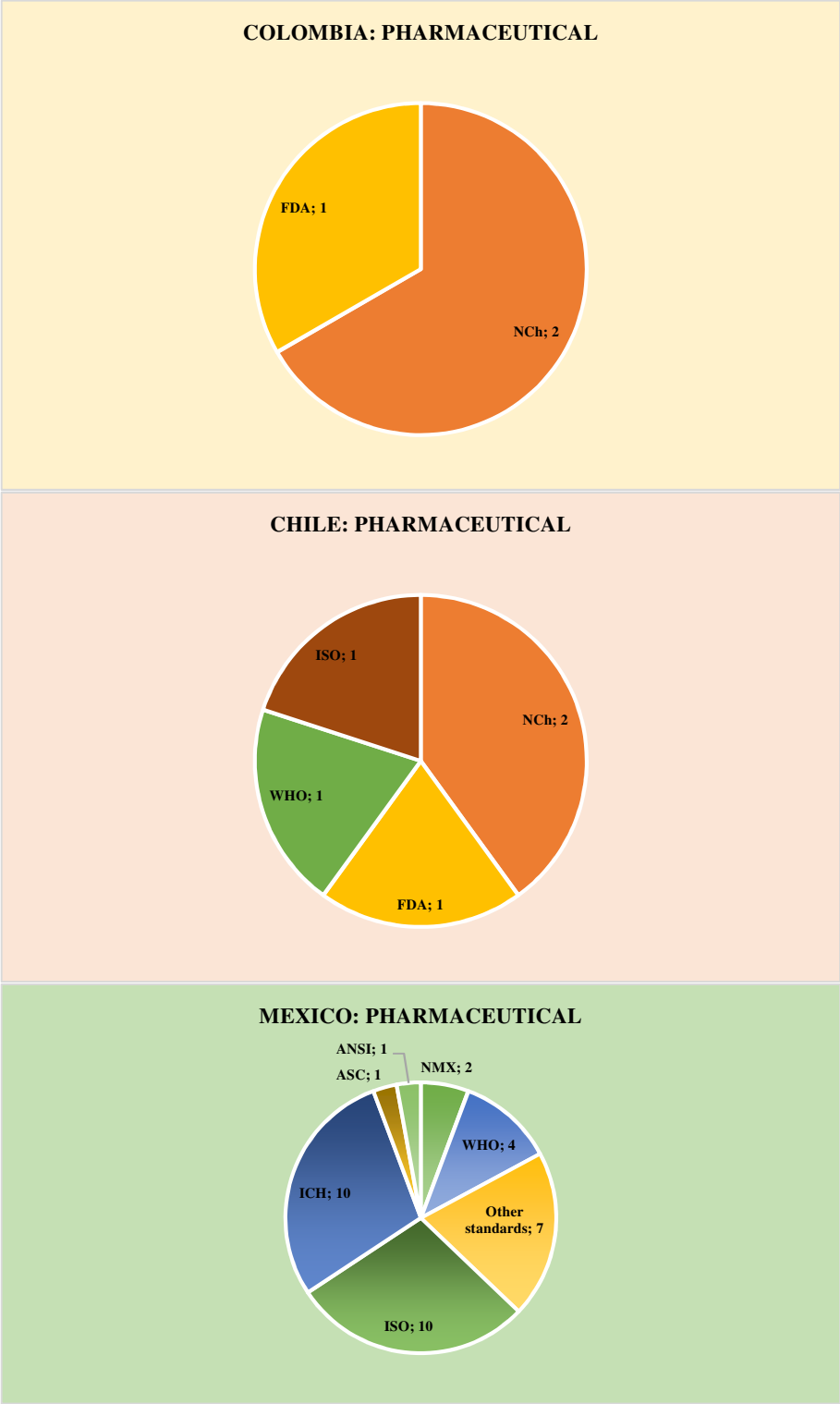
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-8 - Brazil and Argentina: Standards in Technical Regulation for Pharmaceuticals



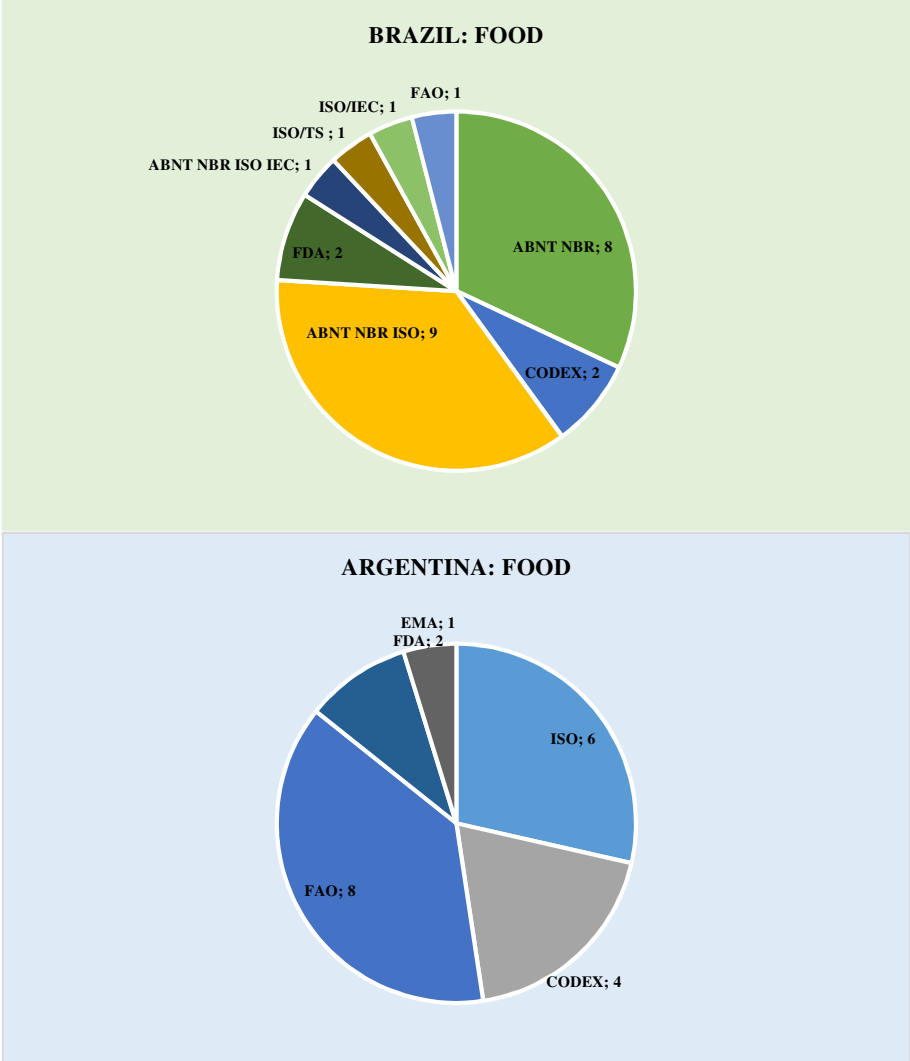
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-9 - Colombia, Chile and Mexico: Standards in Technical Regulation for Pharmaceuticals



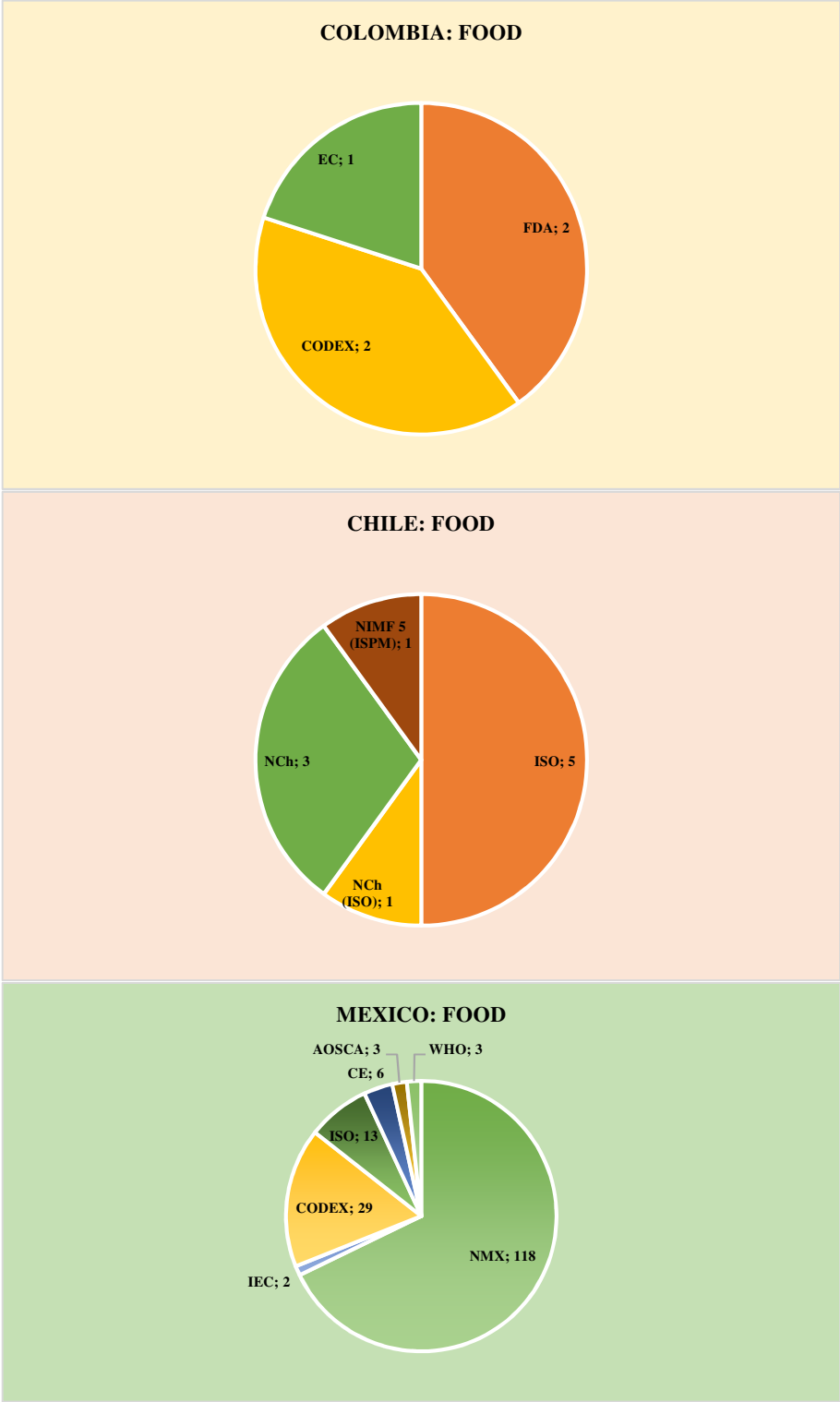
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-10 - Brazil and Argentina: Standards in Technical Regulation for Food



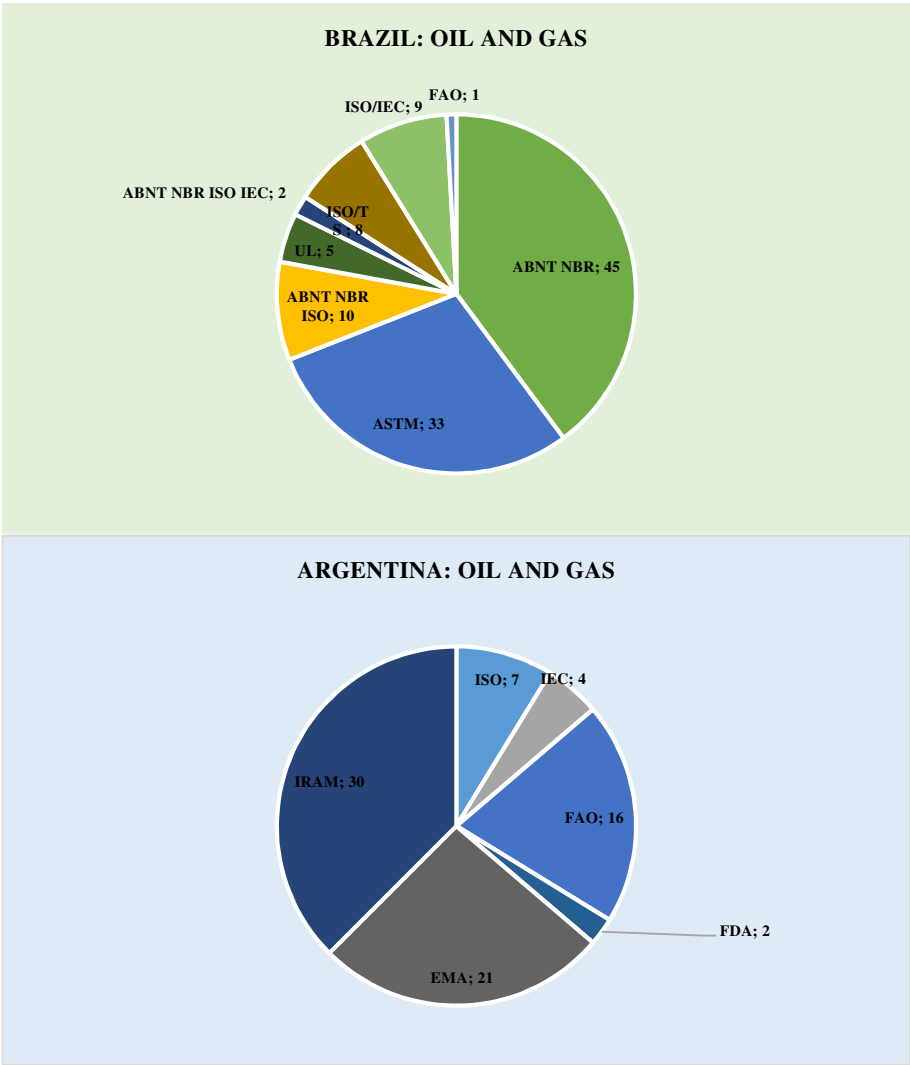
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-11 - Colombia, Chile and Mexico: Standards in Technical Regulation for Food



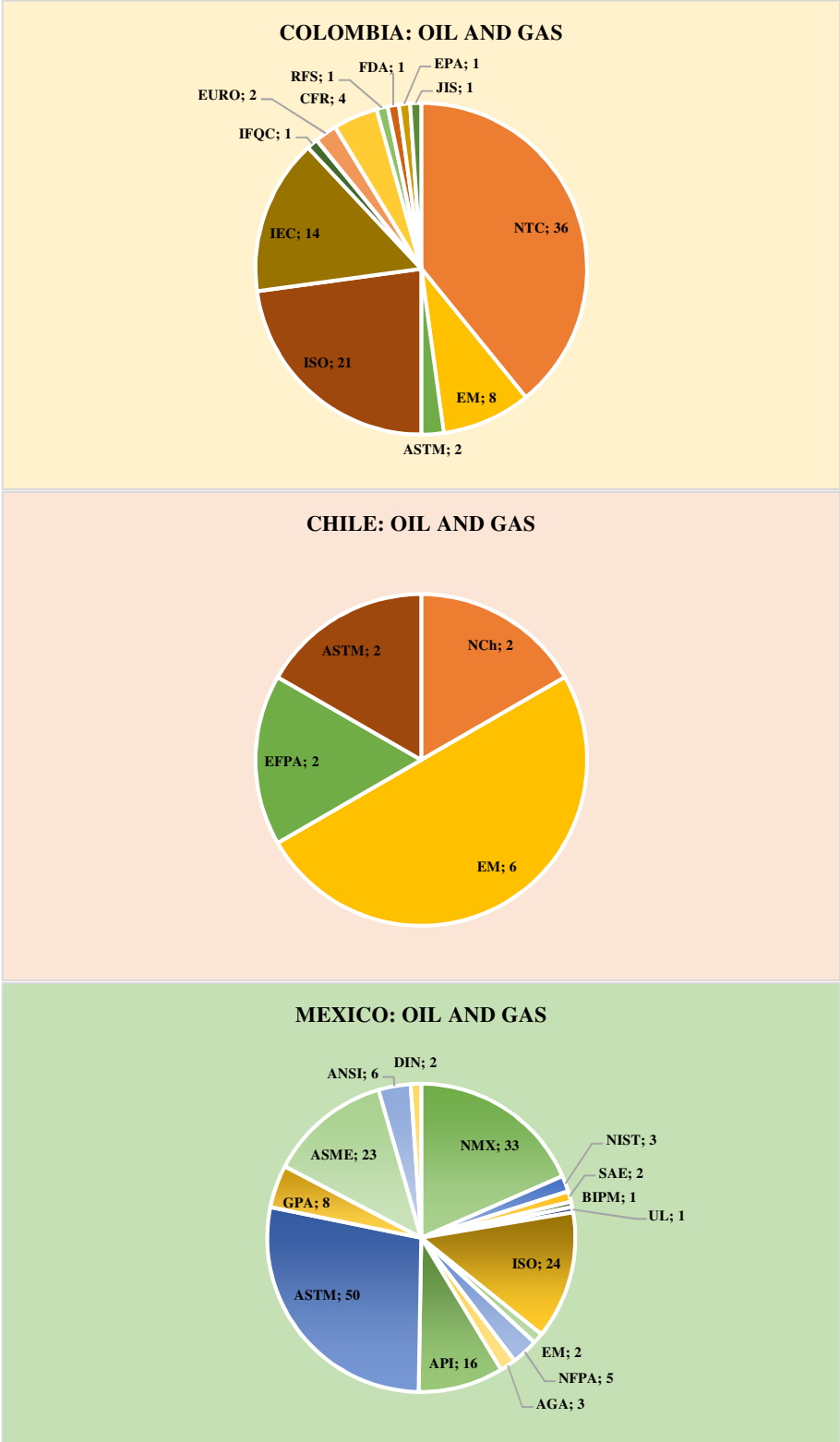
Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-12 - Brazil and Argentina: Standards in Technical Regulation for oil and gas



Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

Figure 3-13 - Colombia, Chile and Mexico: Standards in Technical Regulation for oil and gas



Source: ABNT, IRAM, INN, ICONTEC, Secretaría de Economía. Elaborated by CCGI-EESP/FGV.

4. Conclusion

The aim of this research is to examine how technical regulation, standardization and conformity assessment procedures (quality infrastructure systems) adopted by Brazil, Argentina, Chile, Mexico and Colombia and analyze how these systems could affect the international trade flows of these countries, especially in relation between Mercosur and the Pacific Alliance.

The Center for Global Trade and Investment Studies (CCGI) at EESP-FGV is undergoing several researches on the regulatory policies of relevant international partners, such as US, EU, UK, Canada, Japan, Korea and China and examining the degree of convergence of these policies. Another part of the research is the study on the degree of convergence by sectors for several Latin American countries. The results demonstrate the importance of the topic to the trade relations of the Mercosur countries. They also show one possible cause for the failure of the integration process in Mercosur. The small degree of regulatory convergence of this two main countries can also explain the lack of competitiveness of the Brazilian industries and the decline of exports from Brazil to South America itself.

In the contemporary context of international trade, regulatory barriers are increasingly relevant. After successive multilateral negotiations and preferential trade agreements tariff barriers were consistently reduced. This did not happen with regulatory barriers. The World Trade Organization, in particular the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS), together with international standards and regulatory bodies, prescribe a broader normative framework for regulations, standardization and conformity assessment activities connected to international trade. Simply observing these international rules and recommendations, however, may be insufficient to eliminate barriers to trade. In this case, regulatory convergence initiatives among trading partners become necessary. This is already an important part of a new generation of the trade agreements as USCMA (NAFTA II), CPTPP, EU-Canada, Mercosur-EU, among others.

In view of the relevance of the regulatory theme for international trade, the scope of this research included: the mapping of the regulatory policies and structures for regulations, standardization and conformity assessment in Brazil, Argentina, Chile, Mexico and Colombia, which are important trade partners in Latin America. The main purpose is to identify the degree of convergence of regulatory policies. The research also investigated the possible solutions offered by those countries to mitigate or eliminate the non-tariff barriers through regulatory convergence initiatives.

Regulations, Standards and International Supporting Standards

In order to identify the degree of compatibility among Latin American Countries, this Part of the Project compared the Regulatory Policy of these five countries related to technical regulations for five different sectors of their economies: automotive, electric products, pharmaceutical, food and oil and gas. This comparative examination will include, for each sector: the main regulators, the main technical regulations, their standards and conformity rules.

To make the comparison of technical barriers among these countries, Colombia, Chile and Mexico with Brazil and Argentina, this research identifies the main international supporting standards followed by the national regulators and standardization bodies for each of the sectors.

Some important concepts used in this project are related to the most important standardization models around the world: the international model, the US model and the EU model. As a consequence, it is possible to identify: international standards and sectoral global standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), *Codex Alimentarius Commission*, World Organization for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*. International standards are generally produced in accordance with the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectoral standards are private standards developed by relevant standardizing bodies and are followed by producers and exporters around the world and are relevant to international trade. There are two main sources for these standards: the United States and the European Union.

The United States produce important sectoral global standards, following the logic of a market oriented economy. There are around 300 Standards Bodies in the US. This model can be identified as a *bottom-up* approach. Some standards can be considered as global standards. They are: American Society for Testing and Materials (ASTM), American Petroleum Institute (API), American Society of Mechanical Engineers (ASME), Underwriters Laboratories (UL), Institute of Electrical and Electronics Engineers (IEEE), Society of Automotive Engineers (SAE). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

The EU produces another set of global standards, following the logic of an integrated or common market, produced and used not only regionally but also around the world. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI). They are produced following Directives established by the European Commission under what is called a *top down* approach. European standards are essential for the functioning of the EU integrated market and are widely used as a model influencing many standardization and regulatory work in several countries around the world.

For Latin-American countries, these global standards are important because they are used as supporting standards for technical regulations and technical standards. International and global standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies.

In the case of Mexico, Colombia and Chile, the regulatory system for the technical regulations, the process of standardization and the conformity assessment systems of these selected

countries present some important common characteristics. The fact that the three countries underwent similar liberal administrative reforms, signed a major set of international trade agreements and adopted many of the good regulatory practices advocated by the Organization for Economic Cooperation and Development (OECD), probably approached the systems of these three countries, despite important differences in their production systems and in the development stage of their industries.

In the specific topic of technical regulation, especially in the comparison with Brazil and Argentina, it was clear that the three countries adopt low-intensity regulatory practices, a characteristic that is evident in the relatively small regulatory stock of the three countries. However, the standardization activity appears to be less complementary to the technical regulation of what is observed in the two Mercosur countries – Brazil and Argentina. This can be verified in the few references to the technical standards in the text of the technical regulations of Chile, Colombia and Mexico. Because of the small number of compulsory rules, this lack of support standards in technical regulations is unlikely to create technical barriers to international trade.

Regarding the choice of the technical standards used by the regulatory authorities, it can be noted, alongside domestic and international standards, the strong presence of global sectorial technical standards, with emphasis on standards produced by US entities (SAE, ASTM, UL, IEEE, for example). The presence of these sectoral standards reveals, possibly, the strong economic bond of these countries with the United States, a characteristic that was also among the hypotheses initially proposed in the research.

The main conclusions of this research is the evidence of two regulatory trends in Latin American countries: Pacific countries seem to be progressively moving closer to the US model, with the adoption of supporting technical standards produced by US sectoral organizations, while Mercosur countries have a strong presence of indigenous technical standards and European standards.

The Pacific countries of Latin America are clearly under a strong influence of the US, not only because they have preferential trade agreements with the US, but also because the US is their most important trade partner.

Mercosur countries, mainly Brazil and Argentina, have historically an important trade flow with European countries, and also a relevant share of European investments. They import from Europe mainly industrial products of higher added value. They are much more under the influence of the EU regulatory policy for technical regulation. Some sectors in Argentina show a higher degree of convergence with the EU than Brazil, such as machinery. Other sector presents a dual approach such as automobiles.

The celebration of the EU-Mercosur Agreement is another source of influence. Now, with more interests toward a deeper integration among different sectors of the economies, the use of European regulations and standardization will play a big role among Mercosur countries.

The big question to be answered is about the growing degree of divergence between the regulatory policies of the US and the EU, one of the main reason why the old Trans-Atlantic Agreement was never concluded.

For Brazil, the main consequence of this scenario is that Brazil and Argentina, under the influence of the EU, for the next years, can lose competitiveness toward Latin American markets, under the influence of the US.

To mitigate these negative consequences some suggestion could be advanced:

- Facing the fact that Brazil still has a high level of domestic standards, that are not convergent to international standards, an important initiative for governments and private associations is to defend a strong policy of internationalization for the standards of Brazil.
- As was exposed in the comparison between Brazil and Argentina, there is a low degree of convergence between their global and international supporting standards and a lack of substantial results from the Mercosur Sub-Group of Technical Regulation. It is imperative for industrial sectors to start a serious work in seeking convergence among their technical rules.
- Since the main industrial sectors of Latin American have different historical background and quite diverse interests as producers and consumer countries, it is important that each producer country intensifies its work on bilateral convergence of conformity rules, standardization and technical regulations through an intensive work of mutual recognition arrangements.

In summary, regulatory barriers are now the main barrier to trade. Without a huge effort of the stronger interested parties, governmental agencies and sectors, Latin American countries will lose even more competitiveness and markets toward other Latin American countries and the global market.

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The importance of non-tariff barriers is already identified in the multilateral framework of trade, in several rules and activities of the World Trade Organization (WTO) and in the various preferential agreements, including regional integration projects such as Mercosur.

At the same time, the negative impacts of countries' regulatory policies on their trade can be evaluated by comparative analysis between domestic regulatory regimes of trading partners. Such an analysis makes possible to understand the dynamics of bilateral trade flows, as well as their trade relations with third countries.

This book aims at a comparative analysis between Brazilian and Argentine regulatory systems in the context of international trade and integration.

This research report is divided into three parts: Brazil and Argentina (Part I); Mexico, Colombia, and Chile (Part II); and a comparative study between Mercosur and the Pacific Alliance (Part III).

Part I shows an overview of Brazil and Argentina technical regulatory systems and sectorial analyses for automotive and auto-parts sector; machinery; electrical appliances; medical devices; pharmaceuticals; cosmetics; processed food; plastic and plastic materials; amongst other specific trade issues.

Part II examines the regulatory structure, aspects of regulatory convergence and sectorial analyses for Mexico, Colombia, and Chile.

Part III holds a comparative exercise amongst Brazil, Argentina, Mexico, Colombia, and Chile in terms of technical regulations, technical standards and conformity assessment procedures; and a comparative sectorial analyses to conclude that there is room for improving horizontal regulatory convergence between Brazil-Argentina and Mexico-Colombia-Chile.

It also reveals that some sectors are based on international standards, such as the oil and gas sector for Brazil and Argentina, while others are still heavily based on domestic regulations not necessarily on a basis of international standards such as machinery and electrical equipment for Brazil, Colombia and Mexico.

THE WTO CHAIRS PROGRAMME

The WTO Chairs Programme was launched in 2010. It aims to enhance knowledge and understanding of the trading system among academics and policy makers in developing countries through curriculum development, research and outreach activities by universities and research institutions.

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