

REGULATORY BARRIERS TO TRADE: TBT, SPS AND SUSTAINABILITY STANDARDS

VERA THORSTENSEN

ANDREIA COSTA VIEIRA



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REGULATORY BARRIERS TO TRADE: TBT, SPS AND SUSTAINABILITY STANDARDS

**VERA THORSTENSEN
ANDREIA COSTA VIEIRA**



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VT Assessoria Consultoria e Treinamento Ltda.

Tel.: (11) 3799-7926

<http://ccgi.fgv.br>

ccgi@fgv.br

The Authors

Vera Thorstensen

Professor at São Paulo School of Economics of Fundação Getúlio Vargas (EESP-FGV), Head of the Center for Global Trade and Investments Studies (CGTI), and Holder of the WTO Chair in Brazil since 2014. President of the Brazil's Governmental Committee on Coordination of Technical Barriers to Trade (CBTC) of INMETRO since 2014. She served as economic advisor for the Brazilian Mission to the WTO from 1995 to 2010 and editor-in-chief of *Carta de Genebra*, published by the Brazilian Mission to the WTO from 2001 to 2008. She also served as Chairperson of the WTO Committee on Rules Origin from 2004 to 2010.

Andreia Costa Vieira

Professor of International Economic Law and the Environment at the Masters and PhD Program of the Catholic University of Santos – São Paulo, Post-Doctoral Fellow at the Center for Global Trade and Investments (CCGI-FGV), PhD in International Law (University of São Paulo – USP), Masters in International Trade Law (University of Nottingham, UK) and Visiting Scholar at the Lauterpacht Centre for International Law (University of Cambridge, UK, 2013). Legal Adviser.

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1.Introduction

There are new challenges facing the international trade in the 21st century.

For many years, the logic of trade protection was based on tariffs, determined by each government and established at the border of each country. The history of the GATT – General Agreement on Tariff and Trade, created in 1947, can be summarized as a series of negotiation to reduce tariffs. Only in 1978, the Parts of the GATT agreed on the first non-tariff barrier code, the Code of Technical Barriers to Trade, now the Agreement on TBT. With the end of the Uruguay Round, in 1994, and the creation of the World Trade Organization – WTO, a new agreement was negotiated, the Agreement on Sanitary and Phytosanitary Measures. Other agreements on rules were introduced as services and intellectual property. These are agreements on rules to balance the management of discriminatory practices with the legal right of government to protect its citizens.

With the surge of preferential agreements, new rules were introduced in the international trade system: investment, competition, environment and labor. There was a shift from the proliferation of tariff measures, which are already under control in the multilateral trade system, to regulatory measures, which must deserve careful consideration since they might represent another attempt of protection to the developed world and can have, overall, a deep disruptive effect on trade policies.

The best example of this regulatory barriers is presented by the WTO Technical Barriers to Trade and Sanitary and Phytosanitary Agreements which aim at ruling, on a multilateral level, over measures that are created to protect human, animal or plant life or health, or the environment, but have become the 21st century model of new protectionist measures – the new regulatory barriers to trade.

The present study came out of a real interest from the Brazilian industry better understanding of the real logic behind technical barriers and sanitary and phytosanitary barriers: what is discrimination and what is the real need of protection. Many of these questions were raised on several meetings in São Paulo, with the Brazilian industrial associations, and organized by INMETRO (the Brazilian Institute of Metrology, Quality and Technology, under the Ministry of Development, Industry and Foreign Trade) and the Center of Studies on Global Trade and Investments of the FGV (Getulio Vargas Foundation)¹. To address such questions, the CCGI decided to develop a research on these questions.

Chapter I intends to draw a parallel between the TBT and the SPS Agreements in order to better understand their common grounds, intersections and distinct issues.

¹ Authors would like to thank INMETRO for the financial support given to the development of this research, especially the Coordination of International Articulation Division (Caint).

Chapter II aims to raise the issue of Sustainability Standards (SS), which are the latest post-modern kind of regulatory measures that, let without international control, can distort trade. WTO rules were created to regulate public rules, but a ‘new kind’ of rule has become a regulatory barrier to trade – sustainability standards, which reflect a contemporary international relations on global governance – plurality of actors, plurality of institutions and plurality of norms and rules governing international society and consequently international trade. Even though private standards are not legally mandatory, they might become a *de facto* mandatory rule since a majority of large buyers imposes them to producers.

The new words on rules are harmonization and equivalence. They are ‘keywords’ in the contemporary trade negotiations. They both have been introduced in the negotiation of the multilateral trade. At the same time, provisions related to technical barriers to trade and to sanitary and phytosanitary standards and regulations have become core issues in the negotiations of preferential trade agreements and harmonization and equivalence have been a call for common ground among parts.

The TBT and the SPS have introduced harmonization and equivalence on a multilateral level. Harmonization is one of the main features of eliminating or diminishing technical barriers to trade. Equivalence is a complementary approach to technical harmonization – it is one of the instruments for the coordination process in the new mega agreements. Both TBT and SPS encourage members to recognize each other’s procedures for assessing whether a product conforms to the regulation or not.

Since the Rio Declaration, the precautionary approach has been incorporated into the wording of many treaties, not only in the environmental sphere. For the EU and its followers, international trade treaties have adopted the ‘precautionary language’. The US, on the other hand prefers to base regulation on science. In the WTO, the SPS is on the top list whenever precaution is on debate. Under the SPS Agreement, it is adopted the ‘safety first’ approach to deal with scientific uncertainty, enshrined in its preamble and in other clauses. There is not such an explicit precautionary wording in TBT. However, in an interpretation of GATT, Article XX, the Appellate Body ruled, in the EC Asbestos case, that it is undisputed that WTO members have the right to determine the level of protection of health, which they consider appropriate in a given situation. If such a right is recognized, each member may determine their appropriate level of protection and this is in itself an evidence of a precautionary rule. Nevertheless, even a precautionary principle recognized under the WTO system has to obey the principles governing both TBT and SPS preambles and, as such, precautionary measures cannot be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between members where the same conditions prevail or a disguised restriction on international trade.

Chapter III analyses one of the most significant example of a distortion imposed by the EU regulation of the chemistry sector, that of REACH – the European Regulation on Chemicals, which has been a real challenge for the industry to overcome. This chapter aims at identifying REACH’s most basic and controversial element and its consistency under the World Trade Organization System, in context of the Agreement on Technical Barriers to Trade.

A brief comparative study between REACH and the United States, Canada, and Japan's regulations on chemicals is also presented as a way of identifying other ways of reaching similar goals of protection, such as the Canadian CPM, in terms of a cost-benefits model.

In summary, in this new world, there is a preoccupation to ask whether: Are the wolves of protectionism disguised under new sheepskin? On matters of regulatory barriers to trade, we intend to answer such a questioning within this study. Trade and regulation are on the battlefield. Within such a trade and regulatory war, if the masks fall, the true face of regulators might show off 'wolves disguised under sheepskin' - a return to the desire of domination and protectionism. Good and evil are battling on the same stage, in order to conquer what might be a disguised new level playing field.

Vera Thorstensen

Andreia Costa Vieira

2.TBT, SPS and PS: Are the wolves of protectionism disguised under sheepskin?

Summary

Introduction. A brief history of the development of TBT and SPS Agreements. TBT and SPS: a complement of Article XX GATT - highlighting main principles. Regulatory barriers and scope of each Agreement. MFN and National Treatment under TBT and SPS. The requirement for necessity tests. Process and Production Methods (PPMs). When regulatory measures are obstacles to international trade. A quest for harmonization – mutual recognition, equivalency and regulatory coherence. The Precautionary Principle. Transparency – Notifications and Enquiry Points. TBT and SPS Committees and the Specific Trade Concerns. A briefing on Private Standards (PS). Conclusions.

2.1. Introduction

The WTO Technical Barriers to Trade and Sanitary and Phytosanitary Agreements aim at ruling, on a multilateral level, over measures that are created to protect human, animal or plant life or health, or the environment, but have become the 21st century model of trade barriers – the regulatory barriers to trade. The scope of the present study is to draw a parallel between the TBT and the SPS Agreements (hereinafter, TBT and SPS) in order to better understand their common grounds, intersections and distinct issues² and, at the end, bring about a discussion on Private Standards (PS), which are the latest post-modern kind of regulatory measures that have distorted trade.

In order to achieve the scope, first, the present essay presents a brief history of the development of the TBT and the SPS, introducing their common origins - the Tokyo Round Standards Code. It will be remarked that the TBT and SPS are extensions of Article XX of GATT and, as such, an overview will be drawn on some of the main principles that are highlighted in GATT and have become core wording in the regulatory barriers to trade agreements. At this point, the aim is to show that, in practice, there is an artificial distinction between TBT and SPS.

In order to better understand the specific object of each Agreement, there will be introduced the regulatory barriers dealt with by them and their scope.

An overview of the MFN principle and National Treatment, within the clauses of the TBT and the SPS, as well as some of the main rulings from the Panels and the Appellate Body related to necessity tests and PPMs will be covered to better understand the way these agreements have been interpreted under the Dispute Settlement System of the WTO. On this matter, the Appellate Body has also given a better understanding on ‘when measures are obstacles to international trade’, under TBT and SPS distinctively.

² This essay was inspired by the landmark work of Gabrielle Marceau and Joel P. Trachtman, A Map of the World Trade Organization Law of Domestic Regulation of Goods: The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade’. *Journal of World Trade* 48, no. 2 (2014).

This study will also cover a quest for harmonization. TBT and SPS point out to the importance of reaching common ground on international regulation as well as the importance of transparency.

Moreover, the precautionary principle will be brought to the light, since its interpretation has been one of the latest concerns whenever one talks about TBT and SPS measures. On this matter, there will be a closer look at the European Regulation on Chemicals (REACH), in order to check the extent to which the precautionary principle has been interpreted and applied in the construction of legislation in Europe.

The TBT and SPS Committees have been a discussion forum for specific trade concerns (STCs), which have served, by large, as a conciliation forum, avoiding disputes under the DSM of the WTO. Therefore, STCs will also be covered in this essay.

Last, but not the least, the issue of private standards will be presented since it has been one of the latest concerns on 'innovative' regulatory barriers to trade. It will be briefly investigated to what extent TBT and SPS might cover these new private rules.

2.2. A brief history of the development of TBT and SPS Agreements

In 1979, after eight rounds of negotiations, the Standards Code came into existence and was signed by 43 Contracting parties in the Tokyo Round. Since 1948, the negotiations focused on tariff barriers. In the Tokyo Round, there was a first major attempt to negotiate non-tariff barriers. The Standards Code dealt with mandatory and voluntary technical specifications, mandatory technical regulations and voluntary standards for industrial and agricultural goods. It also covered technical requirements related to food safety and animal and plant health measures, including inspection requirements, labelling and pesticide residue limits. Relevant international standards were agreed to be used by the 1979 Standards Code signatories, except when they were not adequate to protect health. That was the launch of the principle of harmonization for non-tariff barriers in the multilateral system³.

Pending the 1980s, there was a pressure to increase non-tariff negotiations and include agricultural issues. Three areas in the agricultural sector were claimed: market access, direct and indirect subsidies and sanitary and phytosanitary measures. In relation to sanitary and phytosanitary measures, harmonization was proposed on the basis of international organizations standards and scientific evidence.

Most of the signatories agreed that the Standards Code failed to deal with trade of agricultural products and that there was an increase in technical restrictions. In the beginning of the Uruguay Round, negotiations surrounded amendments to the Standards Code. In 1988, a separate Working Party was created to deal with sanitary and phytosanitary measures since negotiators understood that rules related to circumstances under which countries could adopt risk-reducing trade measures that were a breach of GATT Most Favored Nation and National Treatment principles could not be accommodated within the same Code on technical barriers to trade. There was a claim for a multilateral agreement that could deal specifically with sanitary and phytosanitary measures⁴.

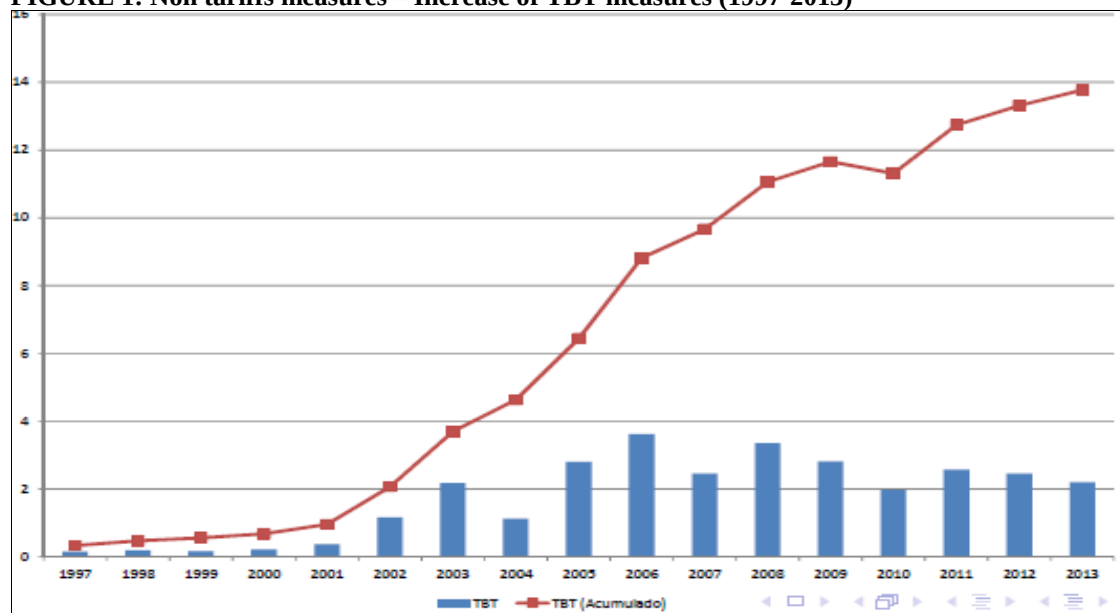
³ R. Griffin, History of the Development of the SPS Agreement, In: FAO Documents, Multilateral Trade negotiations on Agriculture – a resource manual, Rome, 2000, In: <http://www.fao.org/docrep/003/x7354e/x7354e01.htm> (Access on 16 June 2014)

⁴ Gabrielle Marceau and Joel P. Trachtman, A Map of the World Trade Organization Law of Domestic Regulation of Goods: The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade'. Journal of World Trade 48, no. 2 (2014), at 355.

Therefore, in 1995, in the end of the Uruguay round, the TBT and the SPS came into force as separate multilateral agreements under the auspices of the just born World Trade Organization. Prior to the SPS, Members brought claims against each other on food safety and plant and animal health laws as artificial barriers to trade under the 1979 Standards Code. The SPS makes more explicit not only the basis for food safety and animal and plant health requirements that affect trade but also the basis for challenges to those requirements.

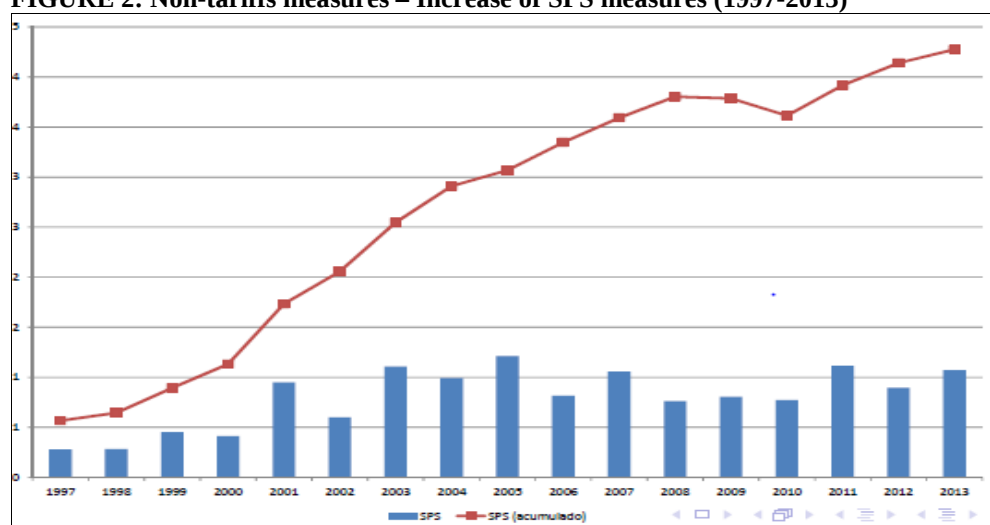
TBT and SPS measures have grown sharply since the 1990s and have become the main substitutes of tariff barriers in the world scenario (See Figures 1 and 2).

FIGURE 1: Non tariffs measures – Increase of TBT measures (1997-2013)



Source: CCGI- FGV, 2014⁵

FIGURE 2: Non-tariffs measures – Increase of SPS measures (1997-2013)



Source: CCGI- FGV, 2014⁶

⁵ Ferraz, L and Ribeiro, M. CCGI-FGV, 2014.

⁶ Ferraz, L and Ribeiro, M. CCGI-FGV, 2014.

All the agreements that came into force in the end of the Uruguay Round were negotiated under separate Working Parties. Such a practice followed a GATT custom well known as *GATT a la carte*, which led to negotiations of plurilateral agreements binding only signatories, imposing a sort of ‘fragmentation’ of the GATT system.

The Marrakesh Agreement, which established the WTO, has in the annexes all multilateral agreements negotiated in the Uruguay Round, presupposing a single treaty. Even though negotiated under separate Working Parties, the WTO agreements have to obey one of the principles that underlined the Uruguay Round negotiations - the WTO single undertaking concept, which avoided fragmentation of the system and differentiated the just born WTO from the old GATT system.

The single undertaking principle must be taken into consideration in the interpretation of the WTO agreements since all of them are part of a single system – a single treaty. According to Gabrielle Marceau and Joel P. Trachtman, the wholeness of the WTO must be reflected in the relationship of its agreements and that is also an interpretation of the single undertaking principle⁷. Therefore the TBT must relate to the SPS in a harmonious way as well as with any other WTO Agreement.

In the 2012 US Clove Cigarettes case, the Appellate Body made reference to the interpretative context of the preamble of TBT and, comparing it to GATT, went on to say that GATT and TBT should be interpreted in a coherent and consistent manner⁸.

Moreover it must be said that all the WTO multilateral treaties hold equally binding force and were entered into force at the same time. Therefore there is no claim of *lex posterior* among them⁹.

The relationship between the rules of TBT and SPS is the main scope of this essay. Issues related to objectives, principles, non-tariff barriers dealt with, harmonization, equivalence, transparency, risks assessment and others will be herein analyzed as a means of affirming the single undertaking principle of the WTO system and of pointing out to the specificities of each of these two agreements.

1.1. TBT and SPS: a complement of Article XX GATT - highlighting main principles

TBT and SPS complement Article XX of GATT. Both try to identify how to meet the need to apply rules concerned with health and environment and, at the same time, avoid protectionism in disguise. In the Uruguay Round, it was not possible to amend Article XX of GATT. Some

⁷ Gabrielle Marceau and Joel P. Trachtman, 2014, *supra*, at 352 and 356. ‘During the Uruguay Round negotiations the concept of a single undertaking was widely used. It refers to two different concepts: the ‘single political undertaking’, referred to the method of negotiations (‘nothing is agreed until everything is agreed’, which was not inconsistent with the possibility of early implementation (early harvest)); and the ‘single legal undertaking’ which refers to the notion that the results of the negotiations would form a ‘single package’ to be implemented as one single treaty. Both concepts are reflected in the Part I:B (ii) of the Uruguay Round Declaration: ‘The launching, the conduct and the implementation of the outcome of the negotiations shall be treated as parts of a single undertaking. However, agreements reached at an early stage may be implemented on a provisional or a definitive basis by agreement prior to the formal conclusion of the negotiations. Early agreements shall be taken into account in assessing the overall balance of the negotiations.’ BISD 33S/19.

⁸ Appellate Body Report, United States – Measures Affecting the Production and Sale of Clove Cigarettes (‘US – Clove Cigarettes’), WT/DS406/AB/R (4 Apr. 2012), at paras. 94-95.

⁹ G. Marceau; J. P. Trachtman, *supra*, at 415.

of the agreements negotiated in that Round – for instance, TBT and SPS – represented ‘interpretation notes’ of the rules enshrined in the exceptions of Article XX.

The chapeau of Article XX is developed in the preambles of TBT and SPS. Both agreements recognize that no country should be prevented from taking measures necessary for the protection of human, animal or plant life or health, or the environment, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade.

Treaty preambles usually set principles and objectives. The treaty is written upon them and its content should be a spell of such principles and objectives. The Vienna Convention on the Law of Treaties establishes a general rule of treaty interpretation in Article 31:

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, *including its preamble and annexes* (...) (emphasis added)

The TBT is broader than the SPS in matter of objectives. Besides enshrining the importance of measures for the protection of human, animal or plant life or health and of the environment, it also highlights, in the preamble, measures necessary to ensure quality of exports, prevention of deceptive practices and measures necessary for the protection of essential security interest. This is a non-exhaustive list and its broadness is verified mainly in the last part of its wording: when it includes measures to ensure ‘quality of its exports’, prevention of ‘deceptive practices’ and those related to ‘essential security interests’. Such a wording is not within the range of SPS.

The SPS establishes, in the preamble, that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

In addition to the preamble, under a topic titled “Basic rights and obligations”, Article 2.4 of the SPS Agreement establishes that sanitary or phytosanitary measures which conform to its relevant provisions, shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994, which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b) that excepts measures necessary to protect human, animal or plant life or health. It is crystal clear, in such provision, the extension function that is played by SPS in relation to GATT Article XX.

2.3. Regulatory barriers and scope of each Agreement

At first, defining the range, coverage and scope of each agreement seems to be a mere technical issue, since the text of each agreement should cover its broadness. Nevertheless, as it will be demonstrated in this essay, that is not such a simple issue. Treaty interpretation has had to be used in order to better understand the coverage of both TBT and SPS.

The TBT Agreement covers regulatory barriers to trade, which consists of **technical regulations, standards and conformity assessment procedures**¹⁰.

In TBT, Annex 1.1, **technical regulations** are defined as measures which lay down product characteristics or their related processes and production methods with which **compliance is mandatory**, including the applicable administrative provisions.

In Annex 1.2, **standards** are defined as documents approved by a recognized body that provides rules, guidelines or characteristics for products or related processes and production methods, for common and repeated use, with which **compliance is not mandatory**.

Either technical regulations or standards may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Conformity assessment procedures are defined in Annex 1.3 as procedures used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Under the TBT, the difference between a standard and a technical regulation lies in compliance. Conformity with standards is voluntary. Technical regulations are by nature mandatory. Conformity assessment procedures are technical procedures, such as testing, verification, inspection and certification, which confirm that products fulfil the requirements laid down in regulations and standards. The TBT Agreement establishes that the procedures used to decide whether a product conforms with relevant standards have to be fair and equitable.

In the TBT, standards are addressed in a separate Code of Good Practice (Annex 3). This Code is a guide for the process of setting standards and the Members should ensure that their central government standardizing bodies adopt it (TBT, Article 4). Moreover, TBT requires governments to “take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories ... accept and comply with this Code of Good Practice”. As such, the TBT, to certain extent, makes Members responsible to ensure that ‘non-governmental entities within their territories abide by disciplines laid out within the Code that, to a large degree, mirror the principles in the TBT’¹¹.

Recently, it has been discussed, in the TBT and SPS Committees, the proliferation of private standards, which have been developed by non-governmental entities in order to manage supply chains or attend consumer concerns. In general, private standards include environmental, social and food-safety concerns and, since they are not enforced by law, they are considered ‘voluntary’, ‘yet they may *de facto* affect market access’¹². A briefing on private standards will be presented later on in this essay.

The SPS Agreement also deals with regulatory barriers, which may comprise technical regulations, standards or conformity procedures, but it is more specific since it comprises **only sanitary and phytosanitary measures that may, directly or indirectly, affect international trade**¹³. However it is not limited to “technical barriers” since it states that it is

¹⁰ TBT Agreement, Preamble, Article 1.6, Annex 1.1, 1.2, 1.3.

¹¹ The WTO Agreements Series, Technical Barriers to Trade, at 15.

¹² The WTO Agreements Series, Technical Barriers to Trade, at 15.

¹³ Article 1 and Annex A - 1.

related to “all sanitary and phytosanitary measures”. It excludes measures that fall within the scope of the TBT Agreement, stating that SPS shall not affect the rights of Members under the TBT with respect to measures not within the scope of SPS¹⁴.

Under the SPS Agreement, the meaning of sanitary and phytosanitary measures is set on Annex A 1.1. Therein it is stated that

Sanitary or phytosanitary measure - Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

The SPS, Annex A, defines the broadness of sanitary and phytosanitary measures stating that

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Therefore, it might be said that it is the type of measure that determines whether it is covered by the TBT Agreement, which could cover any technical subject. The TBT is broader than the SPS in its coverage. In relation to food, TBT could cover labelling requirements, nutrition claims and concerns. Quality and packaging regulations are generally not to be considered sanitary or phytosanitary measures and hence are normally subject to the TBT Agreement¹⁵.

On the other hand, **it is the purpose of the measure that is relevant in determining whether a measure is subject to the SPS Agreement**¹⁶. Any sanitary or phytosanitary measure shall be applied only to the extent necessary to protect human, animal or plant life or health and **must be based on scientific principles and not maintained without sufficient scientific evidence**. That is the wording of SPS, Article 2.2, wherein it is disposed that:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 or Article 5. Article 5 provides that:

¹⁴ Article 1.4.

¹⁵ “Technical Information on Technical barriers to trade”. In: http://wto.org/english/tratop_e/tbt_e/tbt_info_e.htm (Access on 18th June 2014)

¹⁶ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In: http://wto.org/english/tratop_e/spse/spsund_e.htm (Access on 18th June 2014)

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

From Article 5.7, it must be observed that, in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. Nevertheless, such provision also states an obligation for the Member to look for additional information in order to reach a more objective assessment of risk and also to assess the sanitary and phytosanitary measure within a reasonable period of time.

The SPS covers regulations which address microbiological contamination of food or set allowable levels of pesticide or veterinary drug residues, or regulation that identifies permitted food additives. Some packaging and labelling requirements whenever directly related to safety of food are also subject to it¹⁷.

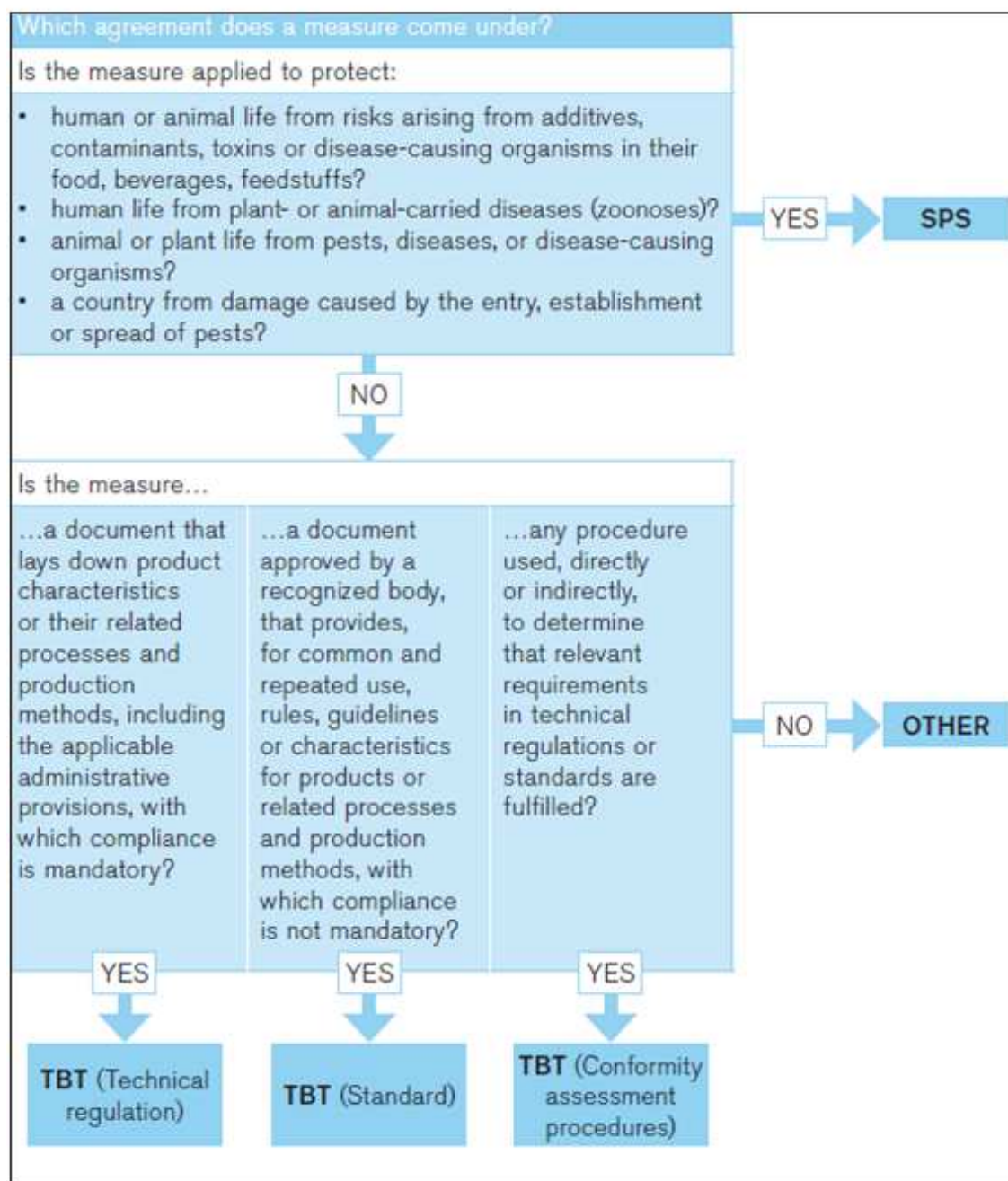
As Horn, Mavroidis and Wijkstrom remark,

Both industrial and agricultural products fall within the scope of the TBT and SPS Agreements. But in practice there is a strong dominance of agricultural products in the SPS area: for instance, 94% of all products addressed in trade concerns raised before the SPS Committee affect trade in agricultural products. This reflects the fact that the SPS Agreement is focused on risks related to food safety, plant and animal health – and that the Agreement was, at least to some extent, negotiated to ensure that concessions made on domestic support and market access under the 1995 WTO Agreement on Agriculture would not be undermined by other types of non-tariff barriers. For the TBT Agreement, about 30% of the products affected by trade concerns raised for discussion are in the agricultural sector, and the rest in other sectors. Overall, trade in farm goods emerges as the single most important area where STCs are being raised¹⁸.

¹⁷ Ibid.

¹⁸ Henrik Horn, Petros C. Mavroidis and Erik N. Wijkstrom. In the Shadow of the DSU: addressing specific trade concerns in the WTO SPS and TBT Committees. Research Institute of Industrial Economics, IFN Working Paper, n. 960, 2013, at 3.

Figure 3: TBT or SPS?



Source: The WTO Series, Technical Barriers to Trade, 2014.

Having in mind the two most prominent objectives – protection of human health and protection of the environment, it must be said that both TBT and SPS raise both concerns. The TBT Agreement expressly lists these objectives in the preamble and clauses. However, while the protection of human health is very explicit in the SPS, environmental protection is not that straight forward in this Agreement (See Figure 3). Some scholars have pointed out the importance of highlighting also protection of the environment in the SPS:

This is mainly because the SPS Agreement was crafted with a specific focus on a set of circumscribed risks for human, animal and plant life or health. So

while the agreement does not explicitly refer to the protection of the environment, many of the measures coming under its purview are effectively relevant to the protection of environment either predominantly so, or as well. We will count the following types of measures to be relevant to the protection of environment: measures aiming to protect plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; and measures taken to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. We believe that with this approach, although we are most likely under-estimating the total number of measures that are relevant to the protection of the environment, had we also included measures relevant to food safety and pest and disease risk to animal health, we might have been casting the net too wide¹⁹.

Besides, it is important to remark that, under the TBT Agreement, all products, including industrial and agricultural products, are included. That is the wording of Article 1.3.

On the other hand, under the SPS Agreement, Article 1.1, it applies to all ‘international trade’ affected by sanitary or phytosanitary measures. With a broader expression, the SPS Agreement does not specify ‘products’ but, in general, ‘trade’.

Moreover, it should be noted that the scope of measures covered by the two agreements is broad. According to TBT, Article 1.5, and SPS, Article 1.4, there is no overlap between the Agreements with regard to scope, which means that a measure cannot be covered by both agreements.

Article 1.5 of TBT provides that

The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Article 1.4 of SPS provides that

Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Each agreement establishes its coverage, which means that ‘a TBT measure cannot be an SPS measure and vice versa’²⁰. Nevertheless, as it has been remarked:

In practice, this is an artificial distinction. Governments sometimes draft and implement broad regulations that contain some requirements covered by the TBT Agreement and others by the SPS Agreement. For example, a single regulation on food products could establish a requirement concerning the treatment of fruit to prevent the spread of pests (relevant to the SPS Agreement) and other requirements, unrelated to the pest risk, concerning the quality, grading and labelling of the same fruit (relevant to the TBT Agreement)²¹. (emphasis added)

¹⁹ Ibid., at 19.

²⁰ The WTO Agreements Series, Technical Barriers to Trade, 2014, at 12.

²¹ Ibid.

Thus, a regulation might be composed of distinct measures related to distinct subjects and, as such, that regulation might fall under the SPS and the TBT Agreements, at the same time, wherein each Agreement would apply to a distinct measure of the same regulation. As such, supported on the concept of cumulative obligations under the WTO general Agreement, a regulation might, for instance, be partially based on health concerns and even so be subject to the SPS Agreement, which means that a regulation might be under the coverage of both TBT and SPS Agreements.

In the EC Biotech case, the Panel reached a conclusion that regulations might be ‘split’ between the SPS and the TBT Agreements. The decision was not appealed to the Appellate Body. The Panel’s Report wording clarifies the real intention of the construction of Article 1.5 of TBT and Article 1.4 of SPS:

In our assessment, the better and more appropriate view is that of the European Communities. Hence, we consider that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1), it may be properly viewed as a measure which falls to be assessed under the *SPS Agreement*; to the extent it is applied for a purpose which is not covered by Annex A(1), it may be viewed as a separate measure which falls to be assessed under a WTO agreement other than the *SPS Agreement*. It is important to stress, however, that our view is premised on the circumstance that the requirement at issue could be split up into two separate requirements which would be identical to the requirement at issue, and which would have an autonomous *raison d’être*, *i.e.*, a different purpose which would provide an independent basis for imposing the requirement.

We recognize that, formally, the requirement at issue constitutes one single requirement. **However, neither the *WTO Agreement* nor *WTO jurisprudence* establishes that a requirement meeting the condition referred to in the previous paragraph may not be deemed to embody two, if not more, distinct measures which fall to be assessed under different WTO agreements. We note that Annex A(1) of the *SPS Agreement*, which defines the term “SPS measure”, refers to “[a]ny measure” and to “requirements”. But these references do not imply that a requirement cannot be considered to embody an SPS measure as well as a non-SPS measure²².** (emphasis added)

It must be remarked that such a position breaks out the preconception that a regulation cannot be under both Agreements’ coverage. In fact, although each Agreement has its own area of coverage, they must be seen under the lens of the single undertaking principle and their wording should not be interpreted in such a manner that would not be the real intention of the Members. According to the Vienna Convention on the Law of Treaties, the ordinary meaning of the Treaty terms must be taken in the context and in the light of its object and purpose²³. As such, if a regulation is composed of different measures, each measure might be covered by a distinct WTO Agreement.

2.4. MFN and National Treatment under TBT and SPS

Under the TBT Agreement, Articles 2.1, 5.1.1, 5.2.4 and 5.2.5 set the rules for National Treatment and Most Favored Nation principles – **the principle of non-discrimination under TBT. In TBT, just as in other WTO agreements, discrimination is intimately related to**

²² Panel Report, European Communities – Measures Affecting the Approval and Marketing of Biotech Products (‘EC – Biotech’), WT/DS291/R, WT/DS292/R, WT/DS293/R (29 Sep. 2006), at para. 7.165-7.166.

²³ VCLT, Article 31.1.

the likeness of products. Under the SPS, there is not a specific clause related to ‘likeness’.

2.4.1. Like products in TBT

TBT, Article 2.1, establishes that

Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded **treatment no less favorable** than that accorded to **like products** of national origin and to **like products** originating in any other country. (emphasis added)

Article 5.1.1 provides that

Conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under **conditions no less favorable** than those accorded to suppliers of **like products** of national origin or originating in any other country, in a comparable situation; access entails suppliers’ right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system. (emphasis added)

Moreover, Art. 5.2.4 and 5.2.5 provide that

4. The confidentiality of information about products originating in the territories of other Members arising from or supplied in connection with such conformity assessment procedures is respected in the same way as for domestic products and in such a manner that legitimate commercial interests are protected;

5. Any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of **like products** of national origin or originating in any other country, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body (...) (emphasis added)

In the 2012 US Clove Cigarettes, **it was the first time that the Appellate Body gave an interpretation on the meaning of National Treatment and MFN from TBT as enshrined in Article 2.1**, whose wording is closely related to GATT Articles I and III. However TBT does not bring about a set of exceptions such as the ones established in GATT Art. XX. The dispute concerned a prohibition of the American government on the production or sale of cigarettes that contain flavors other than tobacco or menthol. The measure aimed at reducing youth smoking. Indonesia complained that the measure hindered its exports of clove-flavored cigarettes while, at the same time, allowed the sale of menthol cigarettes produced in the US, which were, for trade matters, ‘like’ products. The Appellate Body interpreted TBT taking into consideration a ‘GATT balance’ between preventing protectionism and allowing Members to regulate their economies under Article 2.1 and it ruled on the ‘likeness’ of clove and menthol cigarettes and discrimination under TBT rules²⁴.

²⁴ G. Marceau; J. P. Trachtman, *supra*, at 364.

The Appellate Body determined, in the US Clove Cigarettes, the “less favorable treatment” approach under the TBT Agreement and went on to say that TBT and GATT should be interpreted in a coherent and consistent manner. Looking at the TBT, Article 1, the Appellate Body ruled that, in the absence of a rule similar to GATT Article XX in TBT, it must be analyzed whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction rather than spelling discrimination against an imported product²⁵.

We turn to the concept of ‘likeness’ in TBT. In 1970, the Border Tax Adjustment Report set out **the four classic requirements for ‘likeness’ and a ‘competitive relationship between products’**: i) the physical properties of the products in question; ii) their end-uses; iii) consumer tastes and habits vis-à-vis those products; and iv) tariff classification²⁶.

Such a Border Tax Adjustment test is usually criticized on the basis of not taking into consideration the elements that motivated regulation. In fact, regulation is the key approach for understanding what is going on in the multilateral trade scenario. Two main economic theories are raised whenever one talks about regulation, despite in modern times, other theories have been developed. Richard A. Posner explains that:

A major challenge to social theory is to explain the pattern of government intervention in the market - what we may call "economic regulation." Properly defined, the term refers to taxes and subsidies of all sorts as well as to explicit legislative and administrative controls over rates, entry, and other facets of economic activity. Two main theories of economic regulation have been proposed. One is the "public interest" theory, bequeathed by a previous generation of economists to the present generation of lawyers. This theory holds that regulation is supplied in response to the demand of the public for the correction of inefficient or inequitable market practices. It has a number of deficiencies that we shall discuss. The second theory is the "capture" theory - a poor term but one that will do for now. Espoused by an odd mixture of welfare state liberals, Marxists, and free-market economists, this theory holds that **regulation is supplied in response to the demands of interest groups struggling among themselves to maximize the incomes of their members**. There are crucial differences among the capture theorists. I will argue that the economists' version of the "capture" theory is the most promising but shall also point out the significant weaknesses in both the theory and the empirical research that is alleged to support it²⁷. (emphasis added)

In the US – Tuna II, the dispute was related to some US measures that affected tuna products, discriminating against those that had not a ‘dolphin-safe’ label. Mexico, which is a purse-seine net country – not dolphin-safe, complained against this US measure. WTO adjudicators understood that **the US measures were not ‘even-handed’** since they were related to risks to dolphins arising from different fishing methods in different areas of the ocean and, as such, were in violation of Article 2.1²⁸.

The US-COOL dispute, in a similar factual circumstance, was related to a US measure that set out country of origin labelling (COOL) for some meat products. Canada and Mexico complained on the basis of discrimination. The WTO Appellate Body understood that although the US measures did not mandate discrimination, in practice, compliance with that

²⁵ US – Clove Cigarettes, *supra*, at 179-182.

²⁶ Working Party Report, Border Tax Adjustments, adopted 2 Dec. 1970, BISD 18S/97.

²⁷ Richard A. Posner. Theories of Economic Regulation. Center for Economic Analysis of Human Behavior and Social Institutions. National Bureau of Economic Research Inc. New York, May, 1974.

²⁸ United States – Measures concerning the importation, marketing and sale of tuna and tuna products. WT/DS381/AB/R.

measure required segregation of meat and livestock according to origin, thus imposing higher segregation costs on ‘like’ imported livestock²⁹.

From Posner’s remarks, it is possible to identify two main features of regulation: i) correcting the market for public interests; and ii) helping some specific groups’ demands to maximize their interests and incomes. Both features have been applied nowadays. Nevertheless, it must be said that the ‘multilateral trade crisis’ has undergone by a process of substitution for modern regulatory barriers and **regulation has become the main instrument to protect domestic industry in the name of public health, consumer’s protection and the environment.**

In the case Japan Alcoholic Beverages II, a “competitive relationship” between “said to be like products” was constructed on the economic concept of “cross-elasticity of demand”, looking at a shift of consumption to another good every time there is the rise of a product price³⁰.

On the other hand, in Korea Beef, the Appellate Body **accepted a differential treatment** between domestic and imported products **as far as it was not ‘less favorable’**. That ruling related to Article III, GATT, which, according to the Appellate Body only prohibits discriminatory treatment that ‘modifies the conditions of competition in the relevant market to the detriment of imported products’³¹.

2.4.2. Like products in SPS

Under SPS, Article 2.3:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members.

On the other hand, SPS Article 5.5 states that

With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision.

In Australia – Salmon (2000), the Panel understood that SPS Article 2.3, despite its wording that is quite similar to GATT Article XX, rules out discrimination between both similar and different products, having, as such, a broader scope than the one set in Article 5.5³².

²⁹ United States – Certain Country of Origin Labelling (COOL) requirements, WT/DS384/AB/R WT/DS386/AB/R

³⁰ See Appellate Body Report, Japan – Alcoholic Beverages II, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, at 26.

³¹ Appellate Body Report, Korea – Various Measures on Beef, WT/DS161/AB/R and WT/DS169/AB/R, at 137.

³² Australia – Salmon (Article 21.5 DSU), WT/DS18/RW, adopted 20 Mar. 2000, at para. 7.112.

Therefore, **under SPS, there is no ‘like products analysis’ since the focus is the justification for discrimination between situations under the SPS prohibition itself**³³.

As already pointed out, under TBT, the ‘like products’ analysis applies and it is expressed in all the articles listed for MFN and National Treatment.

2.5. The requirement for necessity tests

In GATT, Article XX (a), (b) and (d), the measure has to be ‘necessary’ in order to fulfil the requirements of the chapeau. Article XX establishes:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

- (a) **necessary** to protect public morals;
- (b) **necessary** to protect human, animal or plant life or health;
- (d) **necessary** to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices. (emphasis added)

The ‘necessity requirement’, under GATT, is an ‘affirmative defense’. The provisions of GATT Article XX become relevant only after a violation of another GATT provision is found. The burden of proof is on the defendant to convince that the measure at stake is necessary and no less trade restrictive alternatives are reasonably available³⁴.

For quite a long time, the evaluation of a ‘necessary measure’ was interpreted as being the least trade restrictive method of achieving the desired goals. The shift in interpretation has been made in *EC – Asbestos*, *Korea – Various Measures on Beef* and *Brazil – Tyres*³⁵.

Differently from GATT Article XX that applies the necessity requirement as a ‘justification’ for restrictions found to violate other provisions, including basic market access rights, the TBT and SPS Agreements have made it a ‘positive requirement’ on all relevant regulations not to be more restrictive than necessary. Proof of necessity is framed as an obligation of the defendant and the complainant is required to bring out a *prima facie* case³⁶.

In evaluating whether a measure was really necessary, in *Korea – Various Measures on Beef*, the Appellate Body ruled that the greater the contribution to the realization of the end pursued, the more easily a measure might be considered to be necessary³⁷. In *Brazil-Retreated Tyres*, the Appellate Body considered that a measure’s degree of contribution must,

³³ G. Marceau and J. P. Trachtman, *supra*, at 368.

³⁴ G. Marceau and J. P. Trachtman, *supra*, at 378.

³⁵ Appellate Body Report, *EC Asbestos*, WT/DS135/AB/R; *Korea - Beef*, *supra*; Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (3 Dec. 2007) (‘Brazil – Tyres’).

³⁶ G. Marceau and J. P. Trachtman, *supra*, at 368.

³⁷ *Korea - Beef* – *supra*, at para. 163.

at minimum, be “material”. Such a “material contribution” requirement has become ever since an important element in the analysis of the necessity test³⁸.

2.5.1. The necessity requirement in TBT

In interpreting the TBT Agreement, Article 2.2, the Appellate Body defined the necessity test in US – Tuna II (2012).

Article 2.2 establishes that

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of **creating unnecessary obstacles to international trade**. For this purpose, technical regulations **shall not be more trade-restrictive than necessary to fulfil a legitimate objective**, taking account of the risks non-fulfilment would create. **Such legitimate objectives are, inter alia:** national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information related processing technology or intended end-uses of products.

The preamble of TBT clearly states that the agreement should ‘further the objectives of GATT 1994’ and therefore it should be interpreted harmoniously with the necessity requirements from GATT Article XX.

In US – Tuna II, the Appellate Body affirmed that it should be undertaken a ‘relational analysis’ comparing the measure at stake and its degree of contribution to a legitimate objective, the risks that non-fulfilment of this legitimate objective would create and the trade restrictiveness of the measure to potentially available alternatives³⁹.

In analyzing TBT, Articles 2.1 and 2.2, the Appellate Body set out, in the US Cool Case, a ‘balancing requirement’. The balance would be achieved comparing the determination of ‘non-discrimination’ from Article 2.1 with the ‘necessity requirement’ of Article 2.2. Article 2.1 contains wording related to GATT, Articles I and III (‘like products’ and ‘less favorable treatment’). The Appellate Body found that ‘where a regulatory distinction is not designed and applied in an even-handed manner (...) that distinction cannot be considered ‘legitimate’ under Article 2.1⁴⁰.

Nevertheless, to date, under the Appellate Body’s scrutiny, no Member was found in breach of Article 2.2 of TBT.

In the US-Clove Cigarettes, WTO adjudicators understood that Indonesia had not demonstrated less trade-restrictive alternatives available and the US measure at stake could, in fact, make a ‘material contribution’ to the objective of public health (reducing youth smoking in the US). However, the measure was caught on the basis of discrimination⁴¹.

In the US- Tuna II, the ‘dolphin-safe label’ was found not more trade-restrictive than necessary to fulfil its legitimate objective (protection of the animal health and the

³⁸ Brazil – Tyres, *supra*, at para. 210.

³⁹ Robert Howse & Petros C. Mavroidis, Europe’s Evolving Regulatory Strategy for GMO – the Issue of Consistency with WTO Law: of Kine and Brine, 24 *Fordham Intl. L. J.* 317, 324 (2000).

⁴⁰ Appellate Body Report, US – COOL Requirements, WT/DS384/AB/R at para. 171.

⁴¹ US – Clove Cigarettes, *supra*, at 179-182.

environment – since the measure discouraged the use of fishing techniques that are harmful to dolphins). Nevertheless, the measure at stake was also caught on the basis of discrimination.

In the US-COOL dispute, the WTO Appellate Body was unable to determine whether the US measures were more trade-restrictive than necessary to fulfil a legitimate objective. The measure was caught, once more, on the basis of discrimination only.

2.5.2. The necessity requirement in SPS

SPS Article 5.4 to 5.6 establish that

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

In *Australia – Salmon*, the Appellate Body understood that, in order to establish a violation under SPS, Article 5.6, the complaining party must prove that i) a measure is reasonably available, considering technical and economic feasibility; ii) an alternative measure does not achieve the Members' appropriate level of sanitary or phytosanitary protection; or iii) the measure at stake would be consistent with Article 5.6 if it is not significantly less trade-restrictive⁴².

In the *EC - Hormones*, the Appellate Body identified three elements, which cumulatively must be demonstrated for a violation of Article 5.5 and pointed to 'warning signals':

214. The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those levels of protection exhibit arbitrary or unjustifiable differences ('distinctions' in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the measure embodying or implementing a particular level of protection as resulting, in its application,

⁴² Appellate Body Report, *Australia – Salmon*, WT/DS18/AB/R, supra, at para. 194.

in discrimination or a disguised restriction on international trade. . . .

215. We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element – the arbitrary or unjustifiable character of differences in levels of protection considered by a Member as appropriate in differing situations – may in practical effect operate as a ‘warning’ signal that the implementing measure in its application might be a discriminatory measure or might be a restriction on international trade disguised as an SPS measure for the protection of human life or health⁴³.

It seems that the test under SPS, Article 5.5, is more sophisticated than the one under the chapeau of Article XX, GATT. The Members’ rights to adopt SPS measures are conditional ones and such conditions are stringent. Under GATT, Article XX, Members have an exceptional right to adopt measures therein listed and such conditions are less stringent, but such a right has to be balanced in face of the market access rights of other Members⁴⁴.

In an analysis of SPS, Article 5.6, the Appellate Body, in *Australia – Apples*, confirmed that a violation of Article 5.6 requires proof by the complainant that ‘a proposed alternative measure to the measure at issue: (i) is reasonably available taking into account technical and economic feasibility; (ii) achieves the Member’s appropriate level of sanitary or phytosanitary protection; and (iii) is significantly less restrictive to trade than the contested SPS measure’. That seems to be a “call for a necessity/balancing test under Article 5.6 of the SPS Agreement fairly similar to that developed in *Korea – Various Measures on Beef* and *EC-asbestos*”⁴⁵.

2.6. Process and Production Methods (PPMs)

Discrimination based on Process and Production Methods (PPMs) were ruled out of the WTO in many circumstances. However, new interpretations of TBT and SPS have accepted PPMs based on legitimate objectives.

2.6.1. PPMs under TBT

TBT, Annex 1, sets the technical regulation definition, which includes related process and production methods. Technical regulations are therein defined as documents which

Lay down product characteristics or their related processes and production 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 product, process or production method.

The Standards Code did not include PPMs.

⁴³ Appellate Body Report, *EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, at para. 214-215.

⁴⁴ G. Marceau and J. P. Trachtman, *supra*, at 399.

⁴⁵ G. Marceau and J. P. Trachtman, *supra*, at 410.

In the *US Clove Cigarettes*, the Appellate Body understood that **technical regulations may create distinctions based** on differences between **process and production methods as far as the trade barriers they create are based on legitimate objectives**⁴⁶.

2.6.2. PPMs under SPS

The SPS Agreement, Annex A, sets out a definition of sanitary and phytosanitary measures, wherein it is stated that SPS are measures applied:

- (a) to protect animal or plant life or health **within the territory** of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
 - b) to protect human or animal life or health **within the territory** of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
 - (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
 - (d) to prevent or limit other damage **within the territory** of the Member from the entry, establishment or spread of pests.
- Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; **processes and production methods** (...)

Annex A clearly rules out of the SPS coverage measures to protect health or to prevent or limit damage outside the Member's territory.

Therefore measures that address PPMs out of the Member's territory would not be under the SPS coverage. Nevertheless it 'includes measures of importing states regulating PPMs outside of their territory, where the goal is to protect health within the territory; for example, regulation of foreign slaughterhouse practices may be considered SPS measures. Most SPS PPMs will be product-related since they focus on the health risk of imported food products'⁴⁷.

2.7. When regulatory measures are obstacles to international trade

A measure might be an obstacle to international trade depending on its nature or objective, risk assessment and other issues. Under TBT and SPS, a measure might be an obstacle to trade within different circumstances.

2.7.1. Obstacle to trade within TBT

The TBT Agreement, Article 2.2, establishes that **a measure is an unnecessary obstacle to trade** if it is **more restrictive than necessary to achieve a legitimate objective**. Nevertheless, the wording of that Article requires Members to take into account the risks non-fulfilment would create.

The text of the TBT Agreement exemplifies whether an objective is legitimate and states that 'legitimate objectives' are, *inter alia*: 'national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the

⁴⁶ US – Clove Cigarettes, *supra*, at 179-182.

⁴⁷ G. Marceau and J. P. Trachtman, *supra*, at 414.

environment’ (Article 2.2, second part). The wording ‘inter alia’ means that this is a non-exhaustive list.

In the US Tuna II, Mexico raised a claim, under Article 2.2, complaining against a US measure, which had established conditions for use of a ‘dolphin-safe’ label on tuna products. Such conditions were related to the access to the US Department of Commerce official ‘dolphin-safe’ label, only available under the presentation of certain documentary evidence, which varied depending on the area where tuna is harvested and also on the fishing techniques that are used.

The Panel understood that the measures had a legitimate objective (consumer information and dolphin protection) but that they fulfilled only partially those objectives and that Mexico had identified less trade-restrictive alternatives for the same level of protection⁴⁸.

However, the Appellate Body reversed the Panel’s finding on that specific matter, upholding that Mexico did not demonstrate that the labelling provisions were more trade restrictive than necessary to fulfil the US legitimate objectives⁴⁹.

Moreover, if a technical regulation is adopted, it should only be maintained if the circumstances or objectives giving rise to its adoption are kept. Otherwise they will also be considered obstacles to international trade even though the original reasons for its adoption were legitimate ones. That is the wording of Article 2.3.

There is also a **presumption of conformity with the TBT Agreement of technical regulations based on international standards and**, therefore, a presumption of not being an obstacle to international trade. That is the combination of Article 2.4 and Article 2.5 of the TBT Agreement. In the last part of the Article 2.5, it is very clear that:

Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph two (as set above), and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

Nevertheless, standards might be ineffective or inappropriate and, as such, Members may deviate from their adoption, according to Article 2.4.

2.7.2. Obstacles to trade within SPS

The SPS Agreement, in Article 5.1, disposes that Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. Otherwise, they may constitute unnecessary obstacles to trade.

Under the SPS Agreement, in the assessment of risks, Members shall take into account: available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment, according to Article 5.2.

⁴⁸ US – Tuna II, Panel Report, para. 7.379-7.623.

⁴⁹ US - Tuna II, AB Report, WT/DS381/AB/R, 2012, para. 333.

Moreover, under the SPS Agreement, Article 5.3, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

In order to achieve consistency in the application of an ‘appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health’, a Member shall, according to Article 5.5 of the SPS Agreement:

5.5 (...) avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

In the *EC-Hormones*, the Appellate Body found that three elements must be demonstrated to establish an inconsistency with Article 5.5:

- a) The Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations;
- b) Those levels of protection exhibit arbitrary or unjustifiable differences (‘distinctions’ in the language of Article 5.5) in their treatment of different situations.
- c) The arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade⁵⁰.

The Appellate Body, in the *EC Hormones*, also noted that the three elements are cumulative in nature⁵¹.

Moreover, in the *Australia-Salmon*, the Appellate Body noted that distinctions in the level of protection can be said to be arbitrary or unjustifiable whenever the risk is, at least, equally high between the different situations at issue. In this specific case, the distinctions in levels of sanitary protection reflected in Australia’s treatment of ocean-caught Pacific Salmon and, on the other, herring used as bait and live ornamental finfish, which was considered by the AB ‘arbitrary or unjustifiable’, according to the wording of Article 5.5⁵².

Besides, **there is also a presumption of conformity with the SPS Agreement** whenever it is adopted **a measure that conforms to international standards, guidelines or recommendations**. That is the wording of Article 3.2.

Notwithstanding such a provision, Article 5.6 states that a Member should take into account ‘technical and economic feasibility’ whenever ‘establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection’ and that they should ensure that ‘such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection’.

2.8. A quest for harmonization – mutual recognition, equivalency and regulatory coherence

Provisions related to technical barriers to trade and to sanitary and phytosanitary standards and regulations have become core issues in the negotiations of preferential trade agreements

⁵⁰ EC – Hormones, AB Report, , supra, para. 214.

⁵¹ Ibid. , para. 215.

⁵² Australia-Salmon, supra, para. 155.

(PTAs). Among such provisions, harmonization and equivalence are ‘keywords’ in the contemporary trade negotiations. They both have become a ‘mandate’ for the 21st century international trade.

In general, harmonization stands for replacement of different domestic product standards and domestic regulatory policies by uniform standards, but that is not its sole meaning for contemporary negotiations. Many international trade agreements – such as the SPS and the TBT – encourage or enquire members to harmonize standards or accept different ones on the basis of equivalence.

Stevens remarks that:

The term "harmonization" is inexact and now encompasses the different processes for enhancing the use of policy instruments internationally. For the most part, the purpose of these efforts is not so much to achieve identical regulations or standards, but to converge international methods for developing and administering standards. Such approaches include pre-market harmonization, mutual recognition, equivalency, and reference standards. To date, these approaches have been applied almost solely to product standards (particularly for food and chemicals), and are primarily trade-promoting rather than environment-enhancing concepts⁵³.

Therefore Equivalence is an instrument for a harmonization procedure, despite it has been used in the construction of many treaties as if it was a separate issue. Stevens also further develops a specific definition for equivalence:

Equivalency assumes that if two different standards have an equivalent effect, then a country should allow goods to enter its market based on these standards. Equivalency affords the same degree of protection to each country, but allows regulations or standards to be quantitatively different. It has the advantage of recognizing the different circumstances under which countries protect their consumers and environments, while at the same time recognizing the different conditions and factors that influence standard-setting⁵⁴.

Moreover, harmonization methods have differed from one PTA to the other. Andrew Stoler points out that:

There are, broadly, two models for dealing with standards measures in PTAs. Where the European Union (EU) is a party to a PTA, the agreement often calls for the partner country to harmonize its national standards and conformity assessment procedures with those of the EU. PTAs in the Asia-Pacific region and those in which the United States is a partner typically seek to address problems resulting from different national standards and conformity procedures through a preference for international standards or through the use of mutual recognition mechanisms⁵⁵.

The ‘working language’ in the TTIP⁵⁶ negotiations is ‘regulatory coherence’⁵⁷. Whether the stage of negotiations will pass to the stage of treaty signatures is a matter of whether a treaty

⁵³ Stevens, C. 1993. Harmonization, trade and the environment. *International Environmental Affairs* 5 (1): 42-49.

⁵⁴ Ibid.

⁵⁵ Andrew L. Stoler. TBT and SPS Measures, in practice. Jean Pierre Chauffour and Jean-Christophe Maur (eds). *Preferential Trade Agreement Policies for Development: a handbook*. The World Bank Group, 2011, at 216. <http://siteresources.worldbank.org/INTRANETTRADE/Resources/C11.pdf>

⁵⁶ EU-US Transatlantic Trade and Investment Partnership.

⁵⁷ European Commission Directorate-General for Trade. State of Play of TTIP negotiations ahead of the 6th round of the negotiations, 11th July, 2014.

is really envisaged by the two negotiating nations. Nevertheless, Parker and Alemanno have already pointed out that the TTIP negotiations have enhanced regulatory coherence and cooperation between the EU and the US, by ‘providing negotiators, stakeholders and the public with a comparative overview of the US and EU legislative and regulatory processes in their current form, highlighting differences and similarities’⁵⁸.

Governments that were signatories to the 1979 Standards Code agreed to use relevant international standards, such as those for food safety developed by the Codex Alimentarius Commission, except when they considered that these standards would not adequately protect health. This represented the beginning of the principle of harmonization in the multilateral system⁵⁹. Such harmonization wording is also included in the TBT and SPS Agreements.

2.8.1. Harmonization under TBT

Harmonization is one of the main features of eliminating or diminishing technical barriers to trade. In the TBT Agreement, Article 2.4 encourages Members to use existing International Standards for their national regulations:

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

Under the TBT Agreement, international standards should not be applied whenever they are ineffective or inappropriate for the fulfilment of the legitimate objectives pursued. Article 2.4 exemplifies for instance because of fundamental climatic or geographical factors or fundamental technological problems.

For the purposes of its application, the TBT Agreement defines standards on Annex 1:

1.2. Standard

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production 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 product, process or production method.

In the *US Tuna II*, the Agreement on International Dolphin Conservation Program (AIDCP) was not considered by the Appellate Body an ‘international standardizing organization’, for the purposes of the TBT Agreement. The Appellate Body reversed the Panel’s finding that the ‘dolphin-safe’ definition and certification developed within the framework of the AIDCP is a relevant international standard within the meaning of Article 2.4 of the TBT Agreement, concluding that the AIDCP, acceded only by invitation, is not an international standardizing organization since it is not ‘open’ to relevant bodies of any country; it is not ‘open to at least

⁵⁸ Richard Parker and Alberto Alemanno, Towards Effective Regulatory Cooperation under TTIP: a Comparative Overview of the EU and US Legislative and Regulatory Systems. European Commission. DG TRADE. Reported on 13 May 2014, Available on <http://ec.europa.eu/trade/policy/infocus/ttip/resources/> (Access on 27th August 2014)

⁵⁹ Griffin, *supra* at note 1.

all Members'⁶⁰. A standardizing body should obey the six principles established by Decision G/TBT/9 – transparency, openness, impartiality and consensus, effectiveness and relevance, coherence and development dimension⁶¹.

In the *EC Sardines*, the Appellate Body accepted the Panel's interpretation on the explanatory note to Annex 1.2 of the TBT Agreement, wherein, in order to have a standard, it is not necessary to have 'consensus' on the approval of the document. Standards do not have to be based on consensus⁶². The measure at stake included a specification that only products made out of *Sardina Pilchardus Walbaum*, fished in European waters, could be labeled 'preserved sardines'. Peruvian sardines – *Sardinops sagax sagax*, fished in South American Waters, were prevented from being marketed as 'preserved sardines'. The Appellate Body found that the measure at stake was inconsistent with TBT since it was not based on a 'relevant international standard' from the FAO/WHO-administered Codex Alimentarius Commission⁶³.

On the other hand, in the *US – Tuna II*, where WTO Appellate Body found that the 'dolphin-safe' definition and certification, under the framework of the Agreement on the International Dolphin Conservation Program (AIDCP), to which new parties can accede only by invitation, was not a relevant international standard. Therefore, the US was not under the obligation to base its measures on it. In this dispute, there was reference to the 'Six Principles' in the recognition of standardizing bodies for the purposes of the TBT Agreement.

As already pointed out, Equivalence is a complementary approach to technical harmonization – it is one of the instruments for the harmonization process. Both agreements encourage WTO Members to recognize each other's procedures for assessing whether a product conforms.

Under TBT, members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations. That is the wording of Article 2.7.

A similar rule is stated in Articles 6.1 and 6.3 of the TBT Agreement for mutual recognition of conformity assessment procedures.

2.8.2. Harmonization under SPS

The SPS Agreement, Article 3.1, encourages governments to establish national sanitary and phytosanitary measures consistent with international standards, guidelines and recommendations, as such:

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on

⁶⁰ United States Tuna II, AB Report, WT/DS381/AB/R, 2012, para. 396-399.

⁶¹ G/TBT/9, 13 November 2000, para. 20 and Annex 4. The Six Principles were a Decision of the TBT Committee (G/TBT/9, 13 November 2000, para. 20, Annex 4) on principles for development of international standards, guides and recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement. It aimed at guiding members in the development of international standards and they consisted of a means of informing the understanding of certain terms and concepts contained in the TBT Agreement (such as "open" and "recognized activities in standardization").

⁶² European Communities - Trade Description of Sardines AB Report, WT/DS231/AB/R, para. 222.

⁶³ This was an international standard for preserved sardines and sardine-type products that allowed, under certain conditions, both *Sardinops sagax sagax* and *Sardina pilchardus Walbaum* to be marketed as sardines.

international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

Moreover, in the preamble, the SPS states that there is a desire to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including **the Codex Alimentarius Commission, the International Office of Epizootics**, and the relevant international and regional organizations operating within the framework of the **International Plant Protection Convention**.

In Annex A, the SPS brings a definition of what it considers to be an international standard:

4.3. International standards, guidelines and recommendations

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

There is a presumption rule set in Article 3.2 of the SPS, wherein it is stated that:

- 2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations *shall be deemed to be necessary* to protect human, animal or plant life or health, and *presumed to be consistent* with the relevant provisions of this Agreement and of GATT 1994. (emphasis added)

Encouragement to use international standards do not constitute a floor or a ceiling on national standards, which means that **national standards are not in breach of the SPS Agreement just because they differ from international norms**⁶⁴.

The SPS Agreement clearly permits governments to set **more rigid requirements than the ones set in international standards**, since they justify it **on the basis of scientific evidence and the risks involved** and since they are not inconsistent with other provisions of SPS. That is the provision set in Article 3.3:

- 3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.(2) Notwithstanding the above, all

⁶⁴ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In: <http://wto.org/english/tratop_e/sps_e/spsund_e.htm>

measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

The statutes of these International organizations mentioned in the SPS agreement make clear that their standards and recommendations are not binding.

In the *EC Hormones*, The Appellate Body understood that the terms ‘based on’ (SPS, Article 3.1) have a narrow meaning, which is ‘derived from’, giving the Members a flexibility necessary to the application of the rest of the agreement. On the other hand, the term ‘in conformity with’ (SPS, Article 3.2) does not establish an absolute presumption, since Members may adopt domestic rules that set higher standards than the ones applied on international level⁶⁵.

Nevertheless, as it is observed by Marceau and Trachtman, ‘this is a refined system of applied subsidiarity, subtly allowing national autonomy subject to certain constraints. Prior to the advent of the SPS Agreement, Codex standards had no particular binding force unless accepted for application by national legislation’⁶⁶.

Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. That is the wording of the SPS Agreement, Article 4.1.

The SPS Agreement, Article 4.1, is very clear in matters of transparency for equivalence: reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

It should also be noted that the wording of the SPS is more imperative than in the TBT Agreement. Under SPS, ‘Members shall accept the sanitary or phytosanitary measures of other Members as equivalent (...)’ (Art. 4.1).

On the other hand, under the TBT agreement, Members simply ‘shall give positive consideration to accepting as equivalent technical regulations of other Members (...)’ (Article 2.7).

The imperativeness of SPS is highlighted by the expression “shall accept...” as equivalent sanitary or phytosanitary measures of other Members that sounds like a commandment, while the lighter approach of the TBT Agreement might be remarked on the wording “shall give positive consideration to...”. That does not diminish the importance of equivalence in the TBT Agreement but it certainly makes the SPS Agreement more rigid on this issue.

2.9. The Precautionary principle

The Precautionary Principle (PP) has been articulated since the 1960s, but it gained international agenda only in the 1990s. In the 1992 Rio Declaration, the PP was established as a principle of International Environmental Law, which has also been quoted as its main definition.

⁶⁵ Appellate Body Report, *EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, at para. 165.

⁶⁶ G. Marceau and Joel Trachtman, *supra*, at 388.

Principle 15

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Wiener remarks that “controversial, it is variously viewed as salvation or blunder. Different summaries of what the PP means include ‘better safe than sorry’, ‘uncertainty is no excuse for inaction’ and ‘uncertainty requires action’”. Moreover, the PP may be the most pervasive, innovative and significant ‘new principle’ of environmental policy, but ‘it may also be the most reckless, arbitrary and ill-advised’ one⁶⁷.

Since the Rio Declaration, the precautionary approach has been incorporated into the wording of many treaties, not only in the environmental sphere. Some international trade treaties have also adopted a ‘precautionary language’. In the WTO, the SPS is on the top list whenever precaution is on debate.

2.9.1. Precaution under SPS

Under the SPS Agreement, the Precautionary Principle is enshrined in the Preamble, Articles 3.3 and Article 5.7. However, it has been understood by the Appellate Body that the inclusion of the precautionary principle in the SPS Agreement is not a ‘ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement’⁶⁸.

In fact, in the *EC Hormones*, the Appellate Body understood that it is very uncertain whether the precautionary principle can be recognized a general principle of international law⁶⁹. Moreover, in this case, the European Commission failed to provide enough evidence that the precautionary principle could set the basis for restriction of imported beef treated with hormones.

The Preamble of the SPS Agreement, in its 6th paragraph, states that:

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, **without requiring Members to change their appropriate level of protection of human, animal or plant life or health.** (emphasis added)

Article 3.3 states that:

⁶⁷ Jonathan b. Wiener. The Rhetoric of Precaution, In: J. B. Wiener, M. D. Rogers, J. K. Hammitt and P. H. Sand, *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe*, Washington, 2001, at 04.

⁶⁸ Appellate Body Report, *EC – Hormones*, supra, at para. 124.

⁶⁹ Ibid., at para. 123.

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.(2) Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement. (emphasis added)

Article 5.7 disposes that:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. (emphasis added)

The wording of the SPS Agreement is very clear in the sense that it does not require Members to ‘change their appropriate level of protection’; it allows them to introduce or maintain a higher level of protection or even a different level of protection where relevant scientific evidence is insufficient.

Under the SPS Agreement, it is adopted the ‘safety first’ approach to deal with scientific uncertainty⁷⁰. Nevertheless, under Article 5.7, the Agreement allows Members to adopt a ‘different level of protection approach’, but at the same time it commands them to seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure within a reasonable period of time. This last provision indicates that such ‘different level of protection measure’ might be provisory unless conditions are kept, since they must be reviewed within a reasonable period of time.

In *Japan – Agricultural Products II*, the Appellate Body interpreted Article 5.7 of SPS and ruled that it can be satisfied if four cumulative requirements are met: i) relevant scientific evidence is insufficient; ii) the measure is adopted on the basis of available pertinent information; iii) the Member seeks to obtain the additional information necessary for a more objective assessment of risk and iv) the Member reviews the measure accordingly within a reasonable period of time⁷¹.

An interpretation of ‘insufficient scientific evidence’ was given by the Panel in the *US Hormones – Continued Suspension*, mentioned in the *EC- Hormones*, wherein a provisional ban on certain hormones was enacted by the EC. The Panel understood that the respective EC Directive was in violation of Article 5.7 of the SPS Agreement since the available scientific evidence was not, in fact, insufficient⁷².

⁷⁰ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In: http://wto.org/english/tratop_e/sps_e/spsund_e.htm

⁷¹ Appellate Body Report, *Japan – Agricultural Products II*, WT/DS76/AB/R, para. 89.

⁷² Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, para. 621.

If there is scientific evidence and it is available, it might be considered sufficient for the purpose of that SPS provision. Nevertheless, the Appellate Body reversed the Panel's findings and ruled that even so the Member has the right to set a higher level of protection under the SPS, but it 'may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard'⁷³.

2.9.2. Precaution under TBT

There is not such an explicit precautionary wording in TBT. However, in an interpretation of GATT Article XX, the Appellate Body ruled, in the *EC Asbestos*, that it is undisputed that WTO Members have the right to determine the level of protection of health, which they consider appropriate in a given situation⁷⁴.

If such a right is recognized, each Member may determine their appropriate level of protection and this is in itself an evidence of a precautionary rule⁷⁵.

Moreover, despite the encouragement TBT gives to the use of international standards, it sets the rule for ineffectiveness or inappropriateness of such standards for the objectives pursued and allows Members, in such a case, not to use standard norms, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

Under TBT, Article 2.4:

Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

Nevertheless, even a precautionary principle recognized under the WTO system has to obey the principles governing both TBT and SPS preambles and precautionary measures cannot be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

It must be said that a closer look at the precautionary principle and the way it has been applied in the construction of regulation in Europe reflects dissatisfaction with a slow decision-making process based on conventional scientific approaches⁷⁶.

Regulation in Europe, such as REACH – Registration, Evaluation, Assessment of Chemicals⁷⁷, has equated the Precautionary Principle with an increase in health and

⁷³ *Ibid.*, para. 685-688.

⁷⁴ Appellate Body Report, *EC Asbestos*, *supra*, at para. 168.

⁷⁵ G. Marceau; J. P. Trachtman, *supra*, at 401.

⁷⁶ Lucas Bergkamp and Lawrence Kogan, Trade, the Precautionary Principle, and Post-Modern Regulatory Process. Regulatory Convergence in the Transatlantic Trade and Investment Partnership. *EJRR* 04 (2013), at. 499.

⁷⁷ REACH - Official Journal L 136 (2007), at. 3.

environmental protection. ‘It is unclear, however, how the PP’s application could have any such salutary effects (...). It has been argued, however that the PP is not merely useless, but positively harmful. The PP’s adverse implications are their most visible in its ‘strongest’ version, which is triggered once there is at least *prima facie* scientific evidence of a hazard rather than a risk’⁷⁸.

The REACH registration/data gathering requirement obeys the precautionary principle and reflects a shift on regulatory paradigm, reversing the burden of proof from regulator to producer or importer on the basis of an only substance’s hazardous properties not taking into consideration the actual risk that such substances poses on human health or the environment⁷⁹.

In the preamble of REACH, it has been disposed that:

(69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, *in accordance with the precautionary principle*, be subject to careful attention. *Authorization should be granted where natural or legal persons applying for an authorization demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled.* Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority. (Emphasis added)

And REACH, Article 1 (3) disposes that:

This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. *Its provisions are underpinned by the precautionary principle.* (Emphasis added)

As one recently released report observed, although the EU Commission's Communication on the Precautionary Principle provides that ‘the precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data’, it fails to discuss how serious the risk or its consequences must be in order to trigger the application of the precautionary principle.

While ECJ case law is helpful, it does not appear determinative. According to the report, such case law holds, for example, that it is not sufficient to make a generalized presumption about a putative risk or to make reference to a purely hypothetical risk in the absence of scientific (data) support. The report concludes that, in the absence of further direction, ‘it cannot be deduced that the precautionary principle only applies where a potentially serious risk is identified’ and consequently, ‘the burden of proof necessary to justify such application may be lower’⁸⁰.

⁷⁸ Lucas Bergkamp and Lawrence Kogan, *supra*, at 499.

⁷⁹ L. A. Kogan, REACH and International Trade Law, 2013, at para12.11.

⁸⁰ L. A. Kogan., 2013, *supra*, at para12.11.

It has been crystal clear that, in Europe, a ‘post-modern skepticism’ towards empirical evidence and universal reason has legitimated culture and social values instead of science⁸¹ and, as such, the precautionary principle has been used as a way of setting regulations standards that reflect much more the interests of specific groups –such as industry, rather than reflecting health, consumer’s or environmental protection.

2.10. Transparency - Enquiry points and Notifications

In the negotiations of the 1979 Standards Code, a provision was set for notification of other governments, through the GATT Secretariat, of any technical regulations, which were not based on international standards. Such a provision initiated what would develop into procedures based on the principle of transparency⁸².

Transparency is one of the main principles established in TBT. Throughout the agreement, the expressions “Members shall publish a notice” or “Members shall notify” are commandments related to transparency for standards, technical regulations or conformity assessment procedures. In TBT, Articles 2.9, 2.10, 3.2, 5.6, 5.7 and 7.2 set such a wording.

Article 2.9 of TBT, for instance, provides that:

Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;

2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;

2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

The notification provisions in the TBT show how members intend to regulate in order to achieve specific policy goals and what are the trade effects of their regulations. Notifications have grown in importance in the last years. ‘Receiving information about new regulations or standards at an early stage, before they are finalized and adopted, gives trading partners an opportunity to provide comments either bilaterally or in the TBT Committee, and to receive feedback from industry’⁸³. Early notifications might help to improve the quality of the draft

⁸¹ Lucas Bergkamp and Lawrence Kogan, *supra*, at 500.

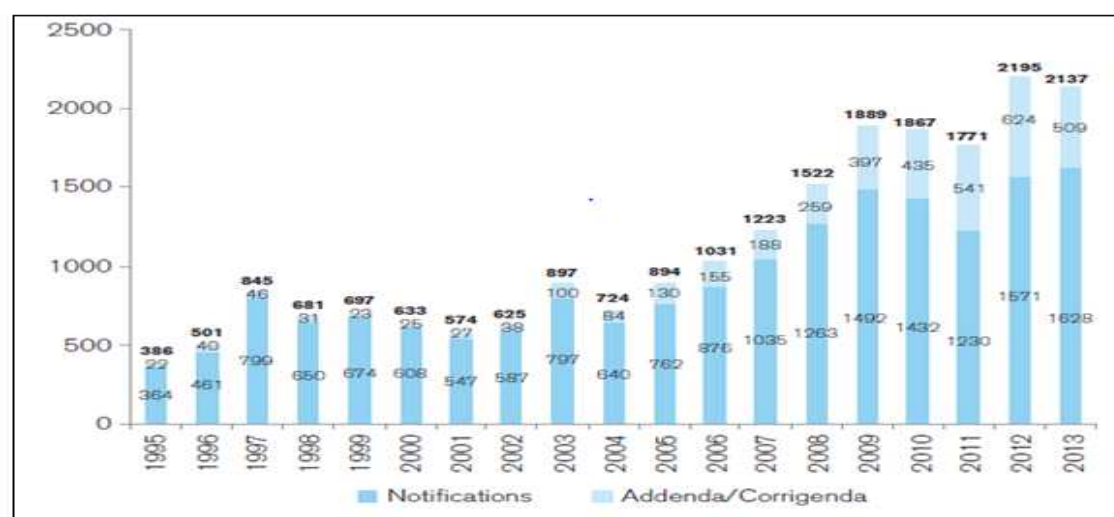
⁸² R. Griffin, *supra*, at note 1.

⁸³ The WTO Agreements Series, Technical Barriers to Trade, 2014, at 24.

regulation, thus avoiding potential trade problems, as well as to assist producers and exporters in adapting to the changing requirements⁸⁴.

Since 1995, it has been observed a growing tendency of notifications in the TBT Committee, which demonstrates its importance within the WTO system and, at the same time, it demonstrates that regulatory measures have been more adopted by Members, in general, in substitution of the old tariffs measures (See Figures 4 and 5).

FIGURE 4: Total number of notifications from WTO members (1995-2013)



Fonte: The WTO Agreement Series, Technical Barriers to Trade, 2014, at 26.

FIGURE 5: Notifications Objectives



Source: CCGI-FGV, 2014⁸⁵

Besides “notification expressions”, TBT Article 10 points out to the importance of establishing enquiry points in each Member. An enquiry point is a national body or institution

⁸⁴ Ibid.

⁸⁵ Thorstensen, V. Giancesella, F., CCGI, 2014.

which must be able to answer all reasonable enquiries from other Members as well as for the provision of related documents. All WTO Members are required to establish national enquiry points to keep each other informed about barriers that would fall under the TBT Agreement.

In Brazil, the focal point is INMETRO⁸⁶, which is the National body responsible for the Brazilian WTO/TBT Enquiry Point, providing information on technical requirements to Brazilian exporters as well as supporting the Brazilian government in all international negotiations on technical barriers to trade⁸⁷.

The same rule about enquiry points is established in the SPS (Annex B (3)).

Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

- (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
- (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
- (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
- (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

Enquiry points are very important to assure transparency. **In some countries, the TBT and SPS enquiry points are the same bodies. In Brazil, they differ and there is an overlapping of competence between some Brazilian bodies, which difficult transparency in the country⁸⁸.**

Under the SPS, Exporting Members claiming that areas within their territories are pest — or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest— or disease—free areas or areas of low pest or disease prevalence, respectively. For this purpose, under Article 6.3 of SPS, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2.11. TBT and SPS Committees and the Specific Trade Concerns

The TBT Committee is the major ‘clearing house’ for members to share information and the major forum to discuss concerns about regulations and their implementation. In fact, the TBT

⁸⁶ National Institute of Metrology, Quality and Technology (INMETRO) was created by law in December, 1973, to support t Brazilian enterprises, to increase their productivity and the quality of goods and services.

⁸⁷ Information available on <http://www.inmetro.gov.br/english/institucional/index.asp> (Access on 3rd November 2014).

⁸⁸ While INMETRO is the TBT focal point, MAPA (Ministério da Agricultura, Pecuária e Abastecimento) is the SPS focal point, in Brazil.

Committee is an instrument to assure transparency within the WTO. It has two to three official meetings per year.

Article 13 of TBT disposes that a Committee is established and composed of representatives from each of the Members for:

13.1 (...) the purpose of affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objectives, and shall carry out such responsibilities as assigned to it under this Agreement or by the Members.

13.2 The Committee shall establish working parties or other bodies as may be appropriate, which shall carry out such responsibilities as may be assigned to them by the Committee in accordance with the relevant provisions of this Agreement.

The TBT Committee's work is divided into two distinct functions: i) Reviewing of specific measures - being a forum of discussions on specific trade concerns, laws, regulations or conformity procedures; ii) Strengthening implementation - wherein Members might exchange experiences on implementation of the Agreement⁸⁹.

For similar purposes, the SPS Committee was established and, according to Art. 12.1 of the SPS Agreement, its main function is

12.1 (...) to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

The description of the Committee's functions is broader in the SPS Agreement. Article 12 has seven long paragraphs compared to only three short paragraphs of Article 13 of TBT Agreement.

The SPS establishes that a function of the Committee is to encourage the use of international standards, guidelines and recommendations by all Members, having the objective of increasing coordination and integration between international and national systems, having the aim of approving the use of food additives or establishing tolerances for contaminants in foods, beverages or feedstuffs. Moreover, with the objective of securing the best available scientific and technical advice for the administration of the SPS Agreement and to avoid duplication of efforts, the Committee, according to Article 12.3, shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention.

One of the tasks of both TBT and SPS Committees is to manage the specific trade concerns (STCs) that Members might raise before them. STCs are neither disputes raised under the Dispute Settlement Understanding (DSU) before Panels and Appellate Body nor prerequisites for raising a dispute under the DSU⁹⁰. They might be simply search for information

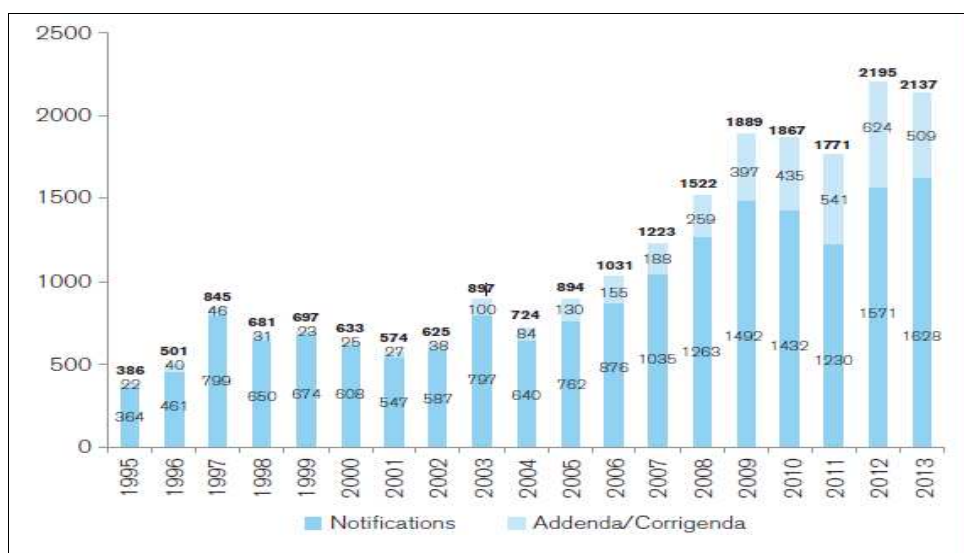
⁸⁹ World Trade Organization, The WTO Agreement Series – Technical Barriers to Trade, 2014.

⁹⁰ Since its first meeting, Members have used the TBT Committee as a forum to discuss issues related to specific measures (technical regulations, standards or conformity assessment procedures) maintained by other Members. These are referred to as "specific trade concerns" and relate variously to proposed measures notified to the TBT Committee in accordance with the notification requirements in the Agreement, or to measures currently in force. Committee meetings, or informal discussions between Members held in the margins of such meetings, afford

concerning other Member's domestic measures on technical regulations or sanitary and phytosanitary policies. Nevertheless, STCs have often addressed conflicts of positions between Members under TBT and SPS. Under STCs, Members might not be just demanding information or clarification, but, at the same time, they might be pointing out that there are reasons to think that some rights and obligations under the SPS and the TBT Agreements have not been met.

Studies on STCs have pointed out the growing importance of such mechanism for resolution of trade conflicts (See Figures 6 and 7), both for developing and developed countries (See Figure 8), concluding that the mechanism of STCs has significantly contributed to minimize trade tensions in TBT and SPS concerns⁹¹.

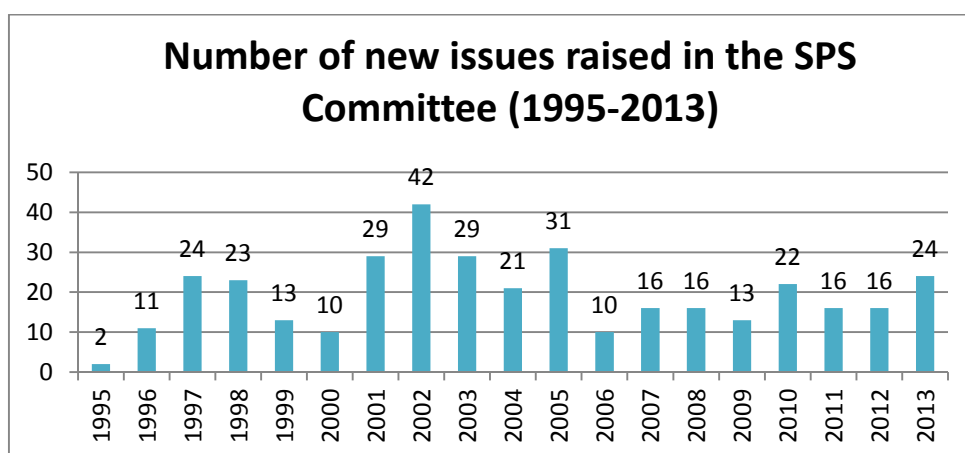
FIGURE 6: Number of specific trade concerns in the TBT Committee



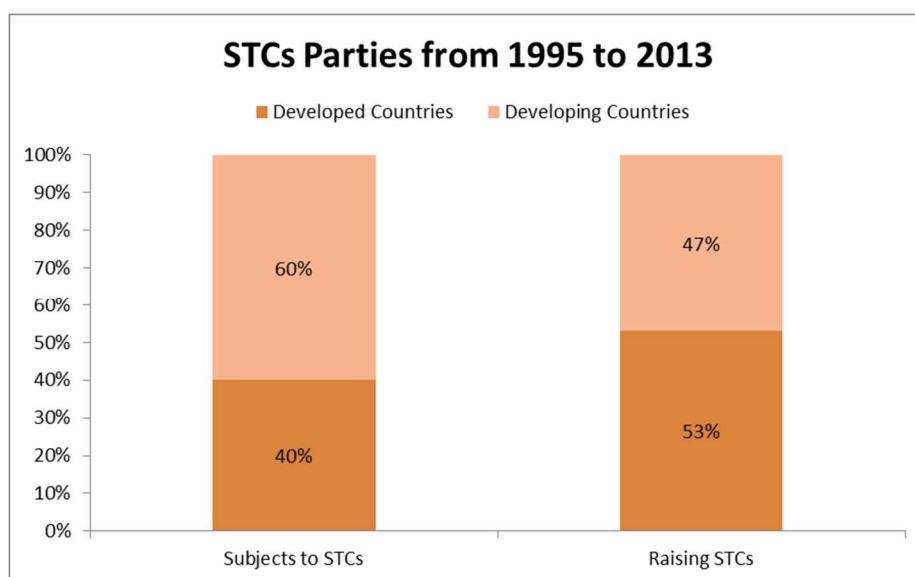
Source: The WTO Agreements Series, Technical Barriers to Trade, at 29.

Members opportunity to review trade concerns in a bilateral or multilateral setting and to seek further clarification'. In: WTO, G/TBT/GEN/74/Rev.9, 17 October 2011, Note by the Secretariat.

⁹¹ Henrik Horn, Petros C. Mavroidis and Erik N. Wijkstrom. In the Shadow of the DSU: addressing specific trade concerns in the WTO SPS and TBT Committees. Research Institute of Industrial Economics, IFN Working Paper, n. 960, 2013.

FIGURE 7: Number of specific trade concerns in the SPS Committee

Source: CCGI-FGV, 2014⁹².

FIGURE 8: STCs Parties from 1995 to 2013

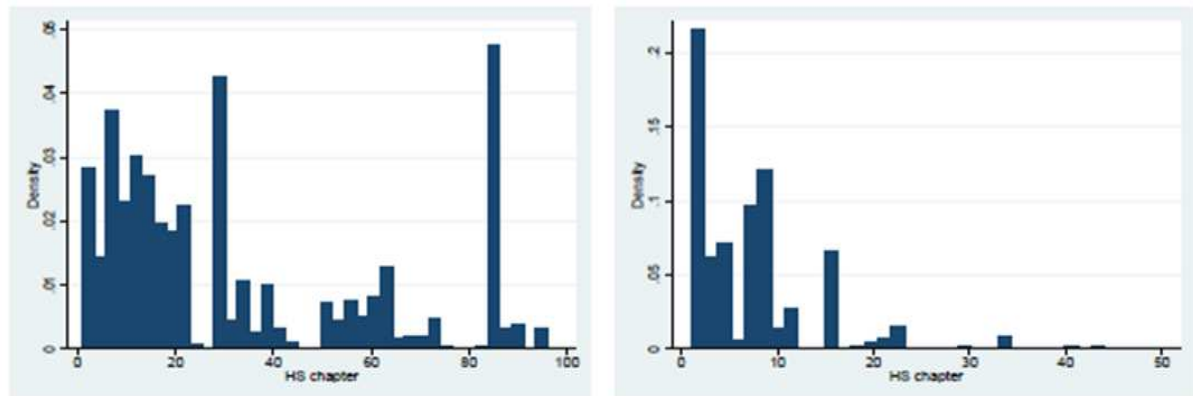
Source: CCGI-FGV, 2014⁹³

Moreover, STCs have grown in distinct sectors – from agricultural to industry concerns. Figure 9 shows the sectorial distribution, under the Harmonized System, of TBT and SPS concerns.

⁹² Thorstensen, V. and Giancesella, F., CCGI-FGV, 2014.

⁹³ Thorstensen, V. and Giancesella, F. CCGI-FGV, 2014.

FIGURE 9: Sectorial distribution of TBT concerns (left panel) and of SPS concerns (right panel)



Source: C. Beverelli, WTO, Working Paper ERSD-2014-18, 2014

The procedure for discussions of STCs, in the TBT Committee, was only formalized in 2009 to cope with a growing agenda, reaching an agreement on a set of guidelines related *inter alia* to sequencing and time limits, creating a due process to make it more efficient⁹⁴.

In relation to trade concerns, the Committees operate in a different manner. While the SPS Committee reports the concerns as ‘partially resolved’ or ‘resolved’, the TBT Committee does not make reference to ‘resolutions’. It is more difficult to assess whether TBT STCs have been settled since the official record only indicates ‘not reported’ for all concerns⁹⁵.

Nevertheless, such difference in procedure has not hindered settlements on the concerns raised since most of the concerns raised under the STC’s approaches have not been raised as formal disputes under the DSU⁹⁶.

Usually STCs are raised and discussed within successive meetings in one of the Committees. The most challenged regulation under STCs has been the European Union Regulation on Chemicals (REACH)⁹⁷. It has been on the TBT agenda for over ten years, having more than thirty Members involved in its discussions. Despite no resolution has been met on REACH in the TBT Committee, such concern has not been raised as a formal dispute settlement⁹⁸.

In fact, the EU is the target of more than 40% of the STCs raised in both TBT and SPS Committees. Besides the EU, the Members that most frequently face TBT STCs are respectively: China, USA, Brazil, South Korea, Canada, India, Australia, Indonesia and

⁹⁴ WTO Doc. G/TBT/1/Rev.10, page 43.

⁹⁵ Henrik Horn and others, *supra*, at 29.

⁹⁶ *Ibid.*, *supra*, at 2.

⁹⁷ REACH is the European Union Regulation that governs the safe use of chemicals (EC 1907/2006). It entered into force on 1 June 2007 and deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances

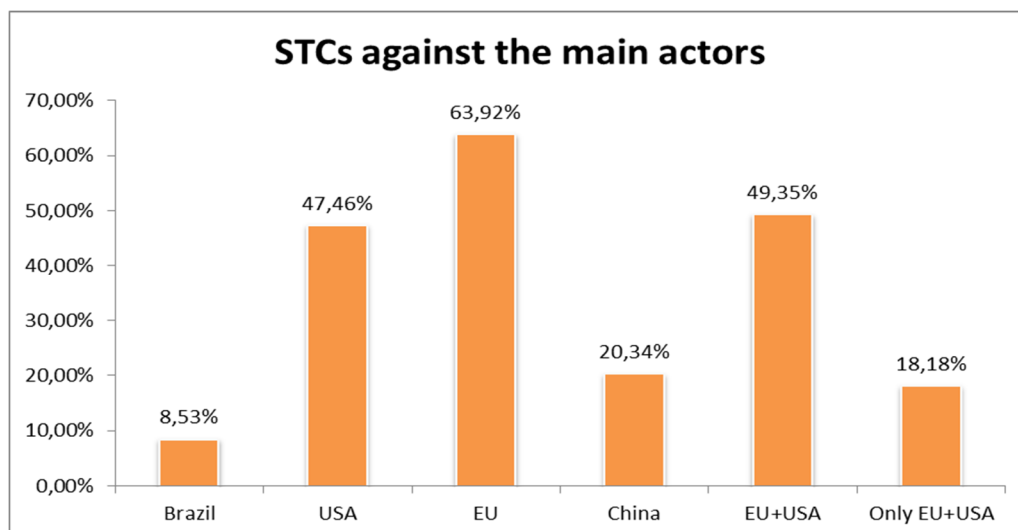
(http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm).

REACH was first raised in the TBT Committee in March 2003, after the first UE notification.

⁹⁸ Henrik Horn and others, *supra*, at 8.

Vietnam (See Figure 10). The Members that most frequently face SPS STCs are: Australia, Japan, USA, China, South Korea, Indonesia, Canada, Argentina and Brazil ⁹⁹.

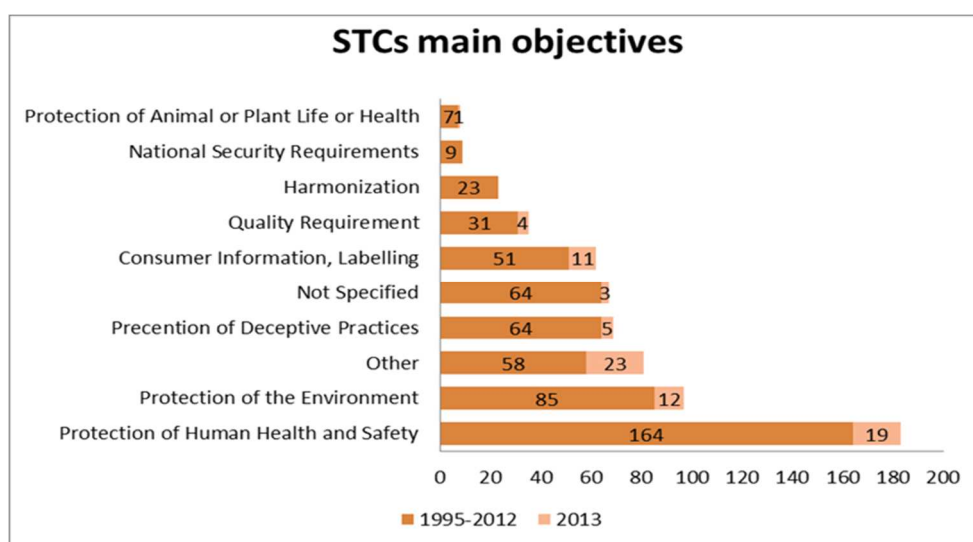
FIGURE 10: STCs against the main actors



Source: CCGI-FGV, 2014¹⁰⁰

Having a look at the sort of issues that have been raised under both SPS and TBT Committees, some scholars have reached a conclusion that ‘as many as 66% of all STCs, the stated objectives of protecting human health or safety, or the protection of the environment or both are at the root of the concern being addressed’ (Figures 11 and 12)¹⁰¹.

FIGURE 11: STCs main objectives



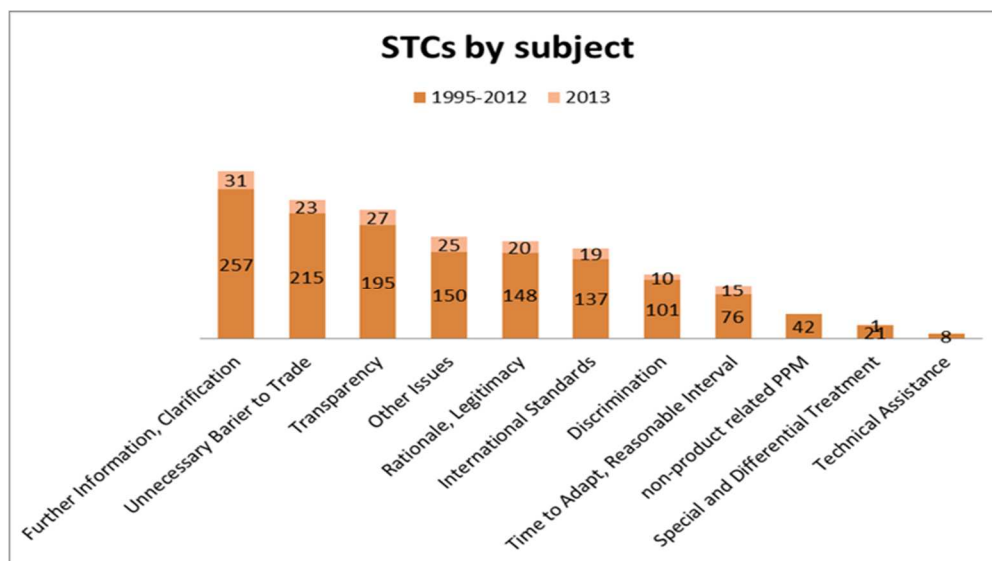
Source: CCGI-FGV, 2014¹⁰².

⁹⁹ Ibid., at 9-10.

¹⁰⁰ Thorstensen, V. and Ganesella, F. CCGI-FGV, 2014.

¹⁰¹ Ibid., at 19-20.

FIGURE 12: STCs by subject



Source: CCGI-FGV, 2014¹⁰³.

Such results ‘contrast sharply with the corresponding figures in the Dispute Settlement system, where a significantly smaller fraction of disputes concern measures falling under these two categories’ – protection of human health and protection of the environment¹⁰⁴.

One might conclude that STCs have been efficient mechanisms for conciliation under the WTO TBT and SPS Committees.

2.12. A briefing on Private Standards¹⁰⁵

Private standards are those created by private entities, such as companies, associations and other non-governmental organizations. They are not mandatory, in nature, unless government backs their compliance¹⁰⁶. Nowadays, there is a range of private standards in different sectors and some of the most well-known are identified in Table 1.

Even though they are not mandatory, non-compliance with them might mean exclusion from a specific market. Some of them are created by individual companies, such as Nature’s Choice, from TESCO; others are created by national or international chains, such as GlobalGAP and Forest Stewardship Council.

In the last decade, there has been an increase in private standards and they have become one of the most common contemporary trade barriers. However, unless private standards are ‘backed by governments’, they do not fall under the TBT or the SPS agreements. Pascal Liu, from FAO, remarks that:

¹⁰² Thorstensen, V. and Giancesella, F. CCGI-FGV, 2014.

¹⁰³ Thorstensen, V. and Giancesella, F. CCGI-FGV, 2014.

¹⁰⁴ Henrik Horn and others, *supra.*, at 8., at 20.

¹⁰⁵ Next chapter of this book will deal with Private Standards in a more detailed manner.

¹⁰⁶ See Manuela Kirschner do Amaral, ‘Padrões Privados e Outras Fontes não tradicionais de governança no âmbito dos regimes multilateral de comércio da OMC e de Mudança Climática: Conflito ou Convergência?’ UNB, Brasília, 2014 (PhD thesis).

The number of private standards and their influence on trade have risen steadily since the early 1990s under the combined forces of globalization, policy liberalization, changing consumer preferences and progress in information technology. There is a wide array of private standards, each with its own objectives, scope, advantages and constraints, **which makes it difficult to treat these standards as a homogeneous category**. The type of organization that develops the standard and the development process may have significant implications for the standard's suitability to producers. It is difficult to assess the market penetration of private standards, as national customs agencies do not monitor this information. However, there is evidence that the market for foods certified to private standards has expanded rapidly over the past decade, in particular in the fair-trade and organic sectors¹⁰⁷. (emphasis added)

Even though private standards are not legally mandatory, they might become *de facto* mandatory ever since a majority of large buyers demand them¹⁰⁸. As such, small-scale producers will bear the risk of exclusion from the market if they do not comply with them.

Compliance with private standards, in this sense, becomes *de facto* mandatory and becomes an ever growing problem mainly for developing countries, which lack infrastructure and public revenue to help their domestic producers. However, even so, in order to raise such issue under the WTO multilateral trade system, it would be necessary to show evidence that the government is directly or indirectly involved with a specific private standard.

In 2005, a discussion on private standards was raised on the SPS Committee¹⁰⁹. Another discussion was raised in 2006¹¹⁰. In both, the discussions centered on whether the government had backed the private sector's standards (EurepGap/GlobalGAP and Nature Choice's, respectively). In both, once demanded, the EC Commission only confirmed the existence of the standards and that they were indeed private ones, but that they neither conflict with EC legislation nor with WTO.

In 2008, a Working Group was established on private standards, which handed in, in 2011, a report on 'Possible actions for the SPS Committee regarding SPS-Related Private Standards'¹¹¹. From this report, some policies were approved by the Committee, *inter alia*: a need to define private standards and exchange of information on whether private standards could be ever compared to regulation.

In 2012, there was a long debate in the Committee related to a definition of private standards, but divergences between the Members did not allow a final conclusion on it. The definition that was presented in 2012 was not approved. It had been proposed that:

'SPS-related private standards are [voluntary] requirements which are [formulated, applied, certified and controlled] [established and/or adopted and applied] by non-governmental entities [related to] [to fulfill] one of the four objectives stated in Annex A, paragraph 1 of the SPS Agreement and which may [directly or indirectly] affect international trade'¹¹².

¹⁰⁷ Pascal Liu, Private standards in international trade: issues and opportunities, WTO's Workshop on Environment-related private standards, Certification and Labelling Requirements, Geneva, 9 July 2009.

¹⁰⁸ Ibid.

¹⁰⁹ G/SPS/R/37, 11 August 2005.

¹¹⁰ G/SPS/R/39, 21 May 2006.

¹¹¹ G/SPS/W/256, 3 March 2011.

¹¹² G/SPS/W/265, Proposed Working Definition on SPS-Related Private Standards. 6, March 2012.

According to Rodrigo Lima, the definition of private standards as voluntary ones is highly questionable. Since the exporter does not conform to the standard, it cannot sell its products on the importing market¹¹³. For example, the search for production of renewable energy has led to establishment of private standards on the sector. Most of these standards were established in fulfillment of government directives, such as EC Directive 2008/28/CE, which established a goal of 20% for consumption of renewable energy by 2020 (from this total, 10% has to be in the transports sector), and EC Directive 2009/28/CE, that established sustainability goals, such as reduction on emissions of 35%, which must be, at least, of 50% from 2017 onwards and 60% from 2018 onwards.

Moreover, this Directive also establishes that biofuels and bioliquids cannot be produced from raw materials extracted from land rich in biodiversity, which from January 2008 has the following characteristics: being primary forest or wooded land, indigenous areas protected under law, endangered species protection areas or pastures areas rich in biodiversity, either natural or cultivated¹¹⁴.

Fulfillment of the Directive requirements is expected from the economic operators that might comply with it through voluntary regimes or bilateral or multilateral agreements, including certification procedures¹¹⁵. Nevertheless, the main issue regarding the multilateral trade system, is whether the EC Directives have adopted a trustful scientific model, which would allow impact measurements consistent with the side effects that it has provoked, which makes it open to dispute under the WTO Dispute Settlement System, mainly the TBT Agreement and GATT¹¹⁶.

In 5 August 2014, the SPS Committee agreed to pursue its work on a definition of SPS-related private standards, based on the working definition tabled in the document G/SPS/W/276:

‘An SPS-related private standard is a written requirement or a set of written requirements of a non-governmental entity which are related to food safety, animal or plant life or health and for common and repeated use’¹¹⁷.

From this definition, the term ‘voluntary’ was excluded. This last definition, which is still under scrutiny in the Committee, is much more objective than the earlier one. One should remark that it includes the term ‘for common and repeated use’, which excludes other kinds of documents for internal uses within the non-governmental entity.

Moreover, with such a definition, the excuses that private bodies would not fall under the requirements for a ‘non-governmental entity’ would come to an end.

¹¹³ Rodrigo C. A. Lima. *Padrões Privados e Responsabilidade do Estado na OMC*. 2014, at 7. (Forthcoming publication).

¹¹⁴ *Ibid.*, at 9.

¹¹⁵ *Ibid.*, at 10.

¹¹⁶ *Ibid.*, at 11.

¹¹⁷ G/SPS/GEN/1334/Rev.1, circulated on 5 August 2014.

One of the discussions in the SPS Committee was based on the wording of Article 13 of the SPS Agreement and the Member's duty towards the behavior of non-governmental entities within their territories. The second part of Article 13 establishes that:

(...) **Members** shall take such reasonable measures as may be available to them **to ensure that non-governmental entities within their territories**, as well as regional bodies in which relevant entities within their territories are members, **comply with the relevant provisions of this Agreement**. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement. (emphasis added)

A parallel requirement is also established in the TBT Agreement. Article 3 of TBT demands that:

With respect to their local government and **non-governmental bodies within their territories**:

3.1 Members shall take such reasonable measures as may be available to them to **ensure compliance by such bodies with the provisions of Article 2**, with the exception of the obligation to notify as referred to in paragraphs 9.2 and 10.1 of Article 2. (...)

3.4 Members **shall not take measures which require or encourage** local government bodies or **non-governmental bodies within their territories to act in a manner inconsistent with the provisions of Article 2**.

3.5 Members are fully responsible under this Agreement for the observance of all provisions of Article 2. Members **shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of Article 2 by other than central government bodies**. (emphasis added).

In the TBT Committee, negotiations on private standards have not reached further results either¹¹⁸. The core of the discussions on the TBT Committee is the adoption of the Code of Good Practices by private bodies¹¹⁹.

Recently, it has been observed either implicit or explicit government support for private standards and they have become, mainly in matters of certification, a regulatory barrier to trade. **Some of them have been mentioned even on State's regulation or public procurement contracts**. The grey area between the State's involvement and the private sector's only involvement makes it more difficult to point out a violation issue under the WTO system. Nevertheless, it seems that whenever it is possible to show evidence of State's involvement in the private standard implementation, it might be possible to raise an issue of violation¹²⁰.

The difficulty would be, in any case, to establish what would be the level and deepness of State's involvement in order to establish that a private standard has become a 'private standard backed by government' and, as such, 'mandatory under law'.

¹¹⁸ Manuela K. Amaral, *supra*, at 244.

¹¹⁹ G/TBT/13; G/TBT/26; G/TBT/32.

¹²⁰ Manuela k. Amaral, *supra*, at 248.

In the EC Directives above mentioned, the EU has accepted private standards as a way of complying with the requirements of EU legislation. It seems reasonable that it could be raised a claim for State's responsibility under the TBT and SPS agreements, since Members shall ensure compliance to these agreements by non-governmental bodies¹²¹.

2.13. *Conclusions*

The single undertaking principle that, according to Marceau and Trachtman (2014), also refers to the notion that the results of the negotiations would form a 'single package' to be implemented as one single treaty, must be taken into consideration in the interpretation of the WTO agreements since all of them are part of a single treaty and, therefore, the wholeness of the WTO must be reflected in the relationship of its agreements. As such, the TBT must relate to the SPS in a harmonious way and some differences that have been pointed out between TBT and SPS measures are, in fact, artificial ones, constructed under legislation.

Since TBT and SPS must be interpreted as a 'single package', domestic governmental bodies in charge of applying their measures and complying with their rules should also work together in order to prevent unnecessary barriers to trade, both for domestic producers and foreigners. Thus, TBT and SPS coordinating bodies and decision making procedures should have common ground.

The present study came up with meaningful first conclusions: i) both TBT and SPS are extensions from GATT, Article XX, and they have common origins (the Standards Code from the Tokyo Round), dealing with regulatory barriers to trade; ii) in fact, their differences, similar in nature, have been determined under WTO law, after a separation of working groups in the Uruguay Round; iii) one of the main differences between them is that the TBT is broader than the SPS in its objectives, since besides enshrining the importance of measures for the protection of human, animal or plant life or health and of the environment, it also highlights, in the preamble, measures necessary to ensure quality of its exports, prevention of deceptive practices and measures necessary for the protection of its essential security interest.

In the 21st century, there was a shift from proliferation of tariff measures, which are already under control in the multilateral trade system, to regulatory measures, which have deserved careful consideration since the globalization of regulation might be representing another attempt of domination from the developed world and might have, overall, a deep disruptive effect on free trade policies. TBT deals with regulatory barriers to trade, which comprise of technical regulations, standards and conformity assessment procedures. Under TBT, the difference between a standard and a technical regulation lies in compliance. The SPS Agreement also deals with regulatory barriers to trade, but it is more specific since it comprises only sanitary and phytosanitary measures that may, directly or indirectly, affect international trade. However SPS excludes measures that fall within the scope of the TBT Agreement and vice versa. In general, it is the type of measure that determines whether it is covered by the TBT and it is the purpose of the measure that is relevant in determining whether a measure is subject to the SPS.

Nevertheless, a regulation might be composed of distinct measures related to distinct subjects and, as such, it might fall under SPS and TBT, at the same time, wherein each Agreement would apply to a distinct measure of the same regulation. It must be remarked that such a

¹²¹ Rodrigo C. Lima, *supra*, at 23.

position breaks out the preconception that a regulation cannot be under both Agreements' coverage. In fact, although each Agreement has its own area of coverage, they must be seen under the lens of the single undertaking principle and their wording should not be interpreted in such a manner that would not be the real intention of the Members.

Another important issue is that the scope of TBT and SPS has been broadened with the expansion of private standards. The WTO rules were created to apply to public rules, but a 'new kind' of rule has become a regulatory barrier to trade – the so called private standards, which reflect a contemporary period of international relations so called global governance – plurality of actors, plurality of institutions and plurality of norms and rules governing international society and consequently international trade.

Even though private standards are not legally mandatory, they might become *de facto* mandatory since a majority of large buyers impose them to producers. However, in order to raise such issue under the WTO multilateral trade system, it would be necessary to show evidence that the requirement for compliance with a private standard has been backed by government. That has been a continuous discussion under the SPS and the TBT Committees, wherein a definition of private standards has been pursued. An analysis of both Agreements wording lead to a conclusion that private standards might be challenged under the WTO dispute settlement system whenever there is a 'commandment' or an 'encouragement' from governments for compliance with them and implementation of their requirements.

Having a closer look on the interpretations of TBT and SPS given by the Appellate Body, the analysis of 'likeness' undertaken from the TBT wording is not made for the SPS by the AB. Under the SPS, there is no "like products analysis" since the focus is the justification for discrimination between situations under the prohibition clause itself. Under TBT, the 'like products' analysis applies and it is expressed in all the clauses listed for MFN and National Treatment. The initial interpretation of 'like products', under TBT, from the 1970s rulings, has been broadened in the last ones to accommodate some features of contemporary regulation – such as consumer's tastes and habits. Moreover, the 'necessity test' under TBT and SPS, differently from GATT, Article XX - that applies it as a 'justification' for restrictions found to violate other provisions - has been a 'positive requirement' on all relevant regulations not to be more restrictive than necessary. Proof of necessity is framed as an obligation of the defendant and the complainant is required to bring about a *prima facie* case.

The TBT Agreement, Article 2.2, establishes that a measure is an unnecessary obstacle to trade if it is more restrictive than necessary to achieve a legitimate objective. Nevertheless, the wording of that Article requires Members to take into account the risks non-fulfilment would create. On the other hand, the SPS Agreement, in Article 5.1, disposes that Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. Otherwise, they may constitute unnecessary obstacles to trade.

Harmonization and equivalence are 'keywords' in the contemporary trade negotiations. They both have become a 'mandate' for the 21st century international trade. At the same time, provisions related to technical barriers to trade and to sanitary and phytosanitary standards and regulations have become core issues in the negotiations of preferential trade agreements and harmonization and equivalence have been a call for common ground. The TBT and the SPS have called for harmonization and equivalence on a multilateral level. Harmonization is one of the main features of eliminating or diminishing technical barriers to trade. Equivalence

is a complementary approach to technical harmonization – it is one of the instruments for the harmonization process. Both TBT and SPS encourage WTO Members to recognize each other's procedures for assessing whether a product conforms.

Since the Rio Declaration, the precautionary approach has been incorporated into the wording of many treaties, not only in the environmental sphere. Some international trade treaties have also adopted a 'precautionary language'. In the WTO, the SPS is on the top list whenever precaution is on debate. Under the SPS Agreement, it is adopted the 'safety first' approach to deal with scientific uncertainty, enshrined in its preamble and in other clauses. There is not such an explicit precautionary wording in TBT. However, in an interpretation of GATT, Article XX, the Appellate Body ruled, in the EC Asbestos case, that it is undisputed that WTO Members have the right to determine the level of protection of health, which they consider appropriate in a given situation. If such a right is recognized, each Member may determine their appropriate level of protection and this is in itself an evidence of a precautionary rule. Nevertheless, even a precautionary principle recognized under the WTO system has to obey the principles governing both TBT and SPS preambles and, as such, precautionary measures cannot be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

Whenever there are grounds for precaution, harmonization, equivalence, 'likeness', 'no less favorable treatment' and other issues co-related to TBT and SPS, transparency is a commandment. Throughout the TBT, the expressions 'Members shall publish a notice' or 'Members shall notify' are commandments related to transparency for standards, technical regulations or conformity assessment procedures. The same transparency principle underlines the SPS agreement.

Whenever transparency policies are not adopted by Members, the TBT and SPS Committees have had an important role, through the procedures of Specific Trade Concerns (STCs). STCs might be simply search for information concerning other Member's domestic measures on technical regulations or sanitary and phytosanitary policies. Nevertheless, STCs have often addressed conflicts of positions between Members. Under STCs, Members might be pointing out that there are reasons to think that some rights and obligations under the SPS and the TBT Agreements have not been met and studies have pointed out the growing importance of STCs for resolution of trade conflicts, concluding that the STC mechanism has significantly contributed to minimize trade tensions in SPS and TBT claims, mainly related to protection of human health and the environment.

In conclusion, it should be remarked that:

1. TBT and SPS should be interpreted, on common grounds, bearing in mind that their main function is to deal with the dichotomy: avoiding the unnecessary 21st century regulatory barriers to trade and, at the same time, supporting domestic policies related to environmental protection and human, animal and plant life and health;
2. TBT and SPS domestic implementation bodies should pay more attention to the mechanism of Specific Trade Concerns, which have reflected a contemporary international law nature of efficient soft power within the WTO;
3. The greatest TBT/SPS contemporary challenge has been private standards. In many circumstances, public authorities have transferred, in a very discrete way, to the private sector the 'power to regulate' and there have had an spaghetti bowl of private standards creating

unnecessary obstacles to trade, in the name of 'legitimate', but 'disguised' environmental protection and health. Whenever the objectives of such standards are really legitimate, they should be kept, since they are not more restrictive than necessary to achieve the desired goals. Nevertheless, the present generation has witnessed a not sustainable manner of creating and exporting regulation that have disrupted fair trade rules and have created uneven competition.

Trade and regulation are on the battlefield. Within such a trade and regulatory war, if the masks fall, the true face of regulators might show off 'wolves disguised under sheepskin' - a return to the desire of domination and protectionism.

Paraphrasing Ivan Karamazov, in the masterpiece of Dostoyevsky, 'the awful thing is that beauty is mysterious as well as terrible'; good and evil are battling on the same stage, in order to conquer what might be a disguised level playing field.

	TBT Agreement	SPS Agreement	Critical Analysis/Remarks
When it came into force	Standards Code was in existence since 1979. In the Uruguay Round, the TBT Agreement (1995) came into force	The SPS Agreement, created in the Uruguay Round, came into force in 1995.	Before the SPS Agreement, Members brought claims against each other's on food safety and plant and animal health laws as artificial barriers to trade under the 1979 Standards Code. The SPS Agreement makes more explicit not only the basis for food safety and animal and plant health requirements that affect trade but also the basis for challenges to those requirements.
In relation to GATT, Art. XX	The TBT Agreement complements GATT, Article XX (Preamble)	SPS Agreement complements GATT, Article XX (Preamble and Art. 2.4)	Both try to identify how to meet the need to apply standards and at the same time avoid protectionism in disguise.
Principles set in the Preamble/ Objectives	No country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade. No country should be prevented from taking measures necessary for the protection of its essential security interest.	No Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade	The TBT is broader in its objectives in the sense that it comprises measures for the protection of environment, prevention of deceptive practices, necessary to ensure quality of its exports and measures necessary for the protection of its essential security interest, in its Preamble. Nevertheless it should be noted that this is a non-exhaustive list , mainly when it includes measures to ensure quality of its exports, prevention of deceptive practices and those related to essential security interests. Such a wording is not within the range of SPS, which is limited to measures necessary to protect human, animal or plant life or health.
Non-tariff barriers dealt with	The TBT Agreement deals with non- tariff barriers to trade, which consists of technical regulations, standards and conformity assessment procedures (Preamble, Art. 1.6, Annex 1 – 1,2,3)	All sanitary and phytosanitary measures which may, directly or indirectly, affect international trade (Art. 1 and Annex A - 1). The SPS shall not affect the rights of Members under the TBT Agreement with respect to measures not within the scope of this Agreement (Art. 1.4).	Under the TBT Agreement, the difference between a standard and a technical regulation lies in compliance . Conformity with standards is voluntary. Technical regulations are by nature mandatory. Conformity assessment procedures are technical procedures (such as testing, verification, inspection and certification, which confirm that products fulfil the requirements laid down in regulations and standards). The TBT Agreement says that the procedures used to decide whether a product conforms with relevant standards have to be fair and equitable . Under the SPS Agreement, the meaning of sanitary and phytosanitary measures is set on Annex A (1). Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Scope	It covers all technical regulations, voluntary standards and the procedures to ensure that those are met, except when there are sanitary or phytosanitary measures as defined by the SPS Agreement . Governments may introduce TBT regulations when necessary to meet different objectives, such as national security or the prevention of deceptive practices.	It covers all measures whose purpose is to protect: a) human and animal health from food-borne risks; b) human health from animal or plant-carried diseases; c) animals or plants from pests or diseases (Annex A – 1). Therefore Sanitary and phytosanitary measures may be imposed only if they are necessary to protect human, animal or plant health on the basis of scientific information.	It is the type of measure which determines whether it is covered by the TBT Agreement, which could cover any subject (TBT is broader than SPS in coverage). In terms of food, it could cover labelling requirement, nutrition claims and concerns. Quality and packaging regulations are generally not considered to be sanitary or phytosanitary measures and hence are normally subject to the TBT Agreement. It is the purpose of the measure that is relevant in determining whether a measure is subject to the SPS Agreement. Any sanitary or phytosanitary measure shall be applied only to the extent necessary to protect human, animal or plant life or health and must be based on scientific principles and not maintained without sufficient scientific evidence (Art. 2.2., except as provided for in Art. 5.7: In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members). Regulations which address microbiological contamination of food or set allowable levels of pesticide or veterinary drug residues, or identify permitted food additives fall under the SPS Agreement. Some packaging and labelling requirements, if directly related to the safety of the food are also subject to it.
Products dealt with	All products, including industrial and agricultural products (Art. 1.3)	All “international trade” affected by sanitary or phytosanitary measures (Art. 1.1).	With a broader expression, the SPS says that it applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect “ international trade ”. It does not specify “products” but, in general, “trade”.
Harmonization	The TBT Agreement encourages Members to use existing International Standards for their national regulation (Art. 2.4).	The SPS Agreement encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations (Art. 3.1). Moreover, Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether all of a country, part of a country, or all or parts of several countries — from which the product originated and to which the product is destined (Art. 6.1).	Under TBT, international standards should not be applied whenever they are ineffective or inappropriate for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems (Art. 2.4). In its preamble, the SPS says that it desires to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994 (Art. 3.2). Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification (Art. 3.3), or as a consequence of the level of sanitary or phytosanitary protection a Member

			determines to be appropriate in accordance with the relevant provisions of Art. 5 (rules that determine the appropriate level of sanitary or phytosanitary protection).
Equivalence	Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations (Art. 2.7). Mutual Recognition of conformity assessment procedures (Arts. 6.1 and 6.3).	Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. (Art. 4.1).	Equivalence is a complementary approach to technical harmonization. Both agreements encourage WTO Members to recognize each other's procedures for assessing whether a product conforms. The SPS is very clear in matters of transparency for equivalence: reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures (Art. 4.1) It should also be noted that the wording of the SPS is stronger in the sense that Members "shall accept...". Under TBT, Members simply "shall give positive consideration to..."
Committee	The TBT Committee is the major clearing house for members to share the information and the major forum to discuss concerns about the regulations and their implementation. It has two to three official meetings per year (Art. 13).	The SPS Committee - Governments which have an observer status in the high level WTO bodies (such as the Council for Trade in Goods) are also eligible to be observers in the SPS Committee. It has three meetings per year (Art. 12).	The SPS Committee has agreed to invite representatives of several intergovernmental organizations as observers. Ex.: Codex, OIE, IPPC, WHO, UNCTAD, ISO and others. Sometimes the SPS Committee has meetings together with the TBT Committee.
Transparency/ Enquiry points	Arts. 2.9 and 5.6; Arts. 2.10 and 5.7; Art. 3.2 and 7.2; Art. 15.2 Art. 10 – All WTO Members are required to establish national enquiry points to keep each other informed about barriers that would fall under the TBT Agreement.	All WTO Members should establish national enquiry points (Annex B).	Enquiry points are very important to assure transparency. In some countries, the TBT and SPS enquiry points are the same bodies. In Brazil, they differ and there is an overlapping of competence between some Brazilian bodies, which difficult transparency in the country (INMETRO, ANVISA, MAPA). Under the SPS, Exporting Members claiming that areas within their territories are pest — or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest— or disease—free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures (Art. 6.3). Moreover, Annex B deals specifically with transparency of sanitary and phytosanitary regulations (publication of regulations, enquiry points and notification procedures).
Precautionary principle	No express precautionary language. However, the TBT encourages the use of international standards. Governments may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors (Art. 2.4).	Art. 5.7 allows precautionary measures. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members.	Under the SPS Agreement, it is adopted the "safety first" approach to deal with scientific uncertainty. Nevertheless, the Agreement takes it as a provisory measure: Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time (Art. 5.7). Moreover, encouragement to use international standards does not mean that these constitute a floor or a ceiling on national standards. National standards are not in breach of the SPS Agreement just because they differ from international norms. The SPS Agreement clearly permits governments to

			set more stringent requirements than the international standards, since they justify it on the basis of scientific evidence and the risks involved. Cases related: EC Hormones, Japan Agricultural Products, Japan – Apples II.
Code of Good Practice	Annex 3 of the TBT Agreement brings a Code of Good Practice	There is not a Code of Good Practice. However Art 13 sets out rules of good practices (similar to the TBT Code of Good Practice) when it regulates implementation	The TBT Code of Good Practice states that it is open to acceptance by any standardizing body within the territory of a Member of the WTO, whether a central government body, a local government body, or a non-governmental body; to any governmental regional standardizing body one or more members of which are Members of the WTO; and to any non-governmental regional standardizing body one or more members of which are situated within the territory of a Member of the WTO (referred to in this Code collectively as “standardizing bodies” and individually as “the standardizing body”)
MFN/ National Treatment	Art. 2.1, Art. 5.1.1/5.2.4 and 5.2.5	Art. 2.3, Annex C 1(a) and 5.5	Under TBT, the “like products” rules applies and it is expressed in all the articles listed for MFN and National Treatment. Under SPS, Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members (Art. 2.3).
When measures are obstacles to international trade	Under the TBT, a measure is an unnecessary obstacle to trade: a) if it is more restrictive than necessary to achieve a given objective policy; or b) if it does not fulfil a legitimate objective (Art. 2.2)	Under the SPS, Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations (Art. 5.1). Otherwise, they may constitute unnecessary obstacles to trade.	Under the TBT, in order to avoid measures that could be unnecessary obstacles to trade, Members should specify, wherever possible, technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. Under the SPS, in the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment (Art. 5.2). Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks (Art. 5.3)
Special and differential treatment	Article 12 sets general provisions of a special and differential treatment for developing countries.	Art 10 sets special and differential treatment for both developing countries and least-developed countries.	Under the TBT, developing countries may adopt technical regulations, standards or tests methods aimed at preserving indigenous technologies and production methods and processes compatible with their development needs (Art. 12.4). Under the SPS, it is specifically determined that longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports. For the least developed countries, it was given a “grace period” of five years following the date of entry into force of the WTO Agreement.
Technical	Members shall, if requested, advise other Members,	Members agree to facilitate the provision of technical	Under TBT, such a technical assistance should regard: a) the establishment of

Assistance	especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions (Art. 11).	assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations (Art. 9).	national standardizing bodies and participation in the international standardizing bodies; b) the establishment of regulatory bodies, or bodies for the assessment of conformity with technical regulations; c) the methods by which their technical regulations can best be met; d) establishment of bodies for the assessment of conformity with standards adopted within the territory of the requesting Member; e) the steps that should be taken by their producers if they wish to have access to systems for conformity assessment operated by governmental or non-governmental bodies within the territory of the Member receiving the request; f) the establishment of the institutions and legal framework which would enable them to fulfil the obligations of membership or participation in such systems (Art 11 and its paragraphs). Under the SPS, such a technical assistance should regard: the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets (Art. 9.1)
Consultations and Dispute Settlement	Application of the WTO DSU and GATT rules (Art. 11)	Application of the WTO DSU and GATT rules (Art. 11)	Under the TBT, a panel may establish a technical expert group to assist in questions of a technical nature, requiring detailed consideration by experts (Art. 14.2) and it must follow Annex 2, which establishes procedures to be followed by technical experts. Under the SPS, in a dispute involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute and when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations (Art. 11.2)
Assessment Level/ Sufficient basis – Scientific basis	Each Member may determine the level of protection it finds appropriate (Marceau, p. 385)	SPS measures must be based on scientific principles and may not be maintained without sufficient scientific evidence, excepts as permitted under Art. 5.7.	SPS, Art. 5.6 addresses measures themselves, but does not limit itself to the manner in which the measure is applied (Marceau and Trachtman, p. 384)
Balancing	Balancing Art. 2.1 (non-discrimination requirements) with Art. 2.2 (necessity requirement)	The balancing test under Art. 5.6 does not appear to call for an assessment of the degree of the measures' contribution to the end.	US Clove Cigarettes While Art. 2.1 clearly contains language akin to GATT Arts. I and III, including both a like products determination and an assessment of less favourable treatment, it has been interpreted as requiring a "legitimate regulatory distinction" and "even-handedness" in its design and application. In US Cool Case, the AB found that where a regulatory distinction is not designed and applied in an even-handed manner (...) that distinction cannot be considered "legitimate" under Art. 2.1. For this reason, it has been suggested that Art. 2.1 may ultimately operate as a check against arbitrary or unjustifiable

			discrimination or disguised restrictions on trade guaranteed both under the chapeau of GATT Art. XX and in TBT preamble (Marceau, p. 409). In Australia-Apples, the AB confirmed that a violation of Art. 5.6 requires proof by the complainant that a “proposed alternative measure to the measure at issue: i) is reasonably available taking into account technical and economic feasibility; ii) achieves the Member’s appropriate level of sanitary or phytosanitary protection; and iii) is significantly less restrictive to trade than the contested SPS measure (Marceau, p. 410)
PPMs	Annex 1 sets the technical regulation definition, which includes related process and production methods.	Annex A includes in the definition of “SPS measures” regulations concerned with “relevant requirements associated with transport of animals and plants”.	The Standards Code did not include PPMs. Technical regulations may create distinctions based on differences between process and production methods, so long as the trade impediments they create are based on legitimate objectives (US – Clove Cigarettes case). What is less clear is whether this provision is limited to product-based PPMs or whether it also includes non-product based PPMs (Marceau and Trachtman, p. 413)
Extraterritoriality		Annex A excludes from its coverage measures addressing health outside the regulating Member’s territory.	SPS Annex A leaves importing state regulation seeking to regulate processes and production methods in the exporting state, with the goal of protecting health outside the territory of the importing state, with the goal of protecting health outside the territory of the importing state, outside the coverage of the SPS Agreement, but potentially subject to GATT or TBT. Importantly, it includes measures of importing states regulating PPMs outside of their territory, where the goal is to protect health within the territory; for example, regulation of foreign slaughterhouse practices may be considered SPS measures. Most SPS PPMs will be product-related since they focus on the health risk of imported products. Yet it is worth noting that Annex A includes in the definition of “SPS measures” regulations concerned with “relevant requirements” associated with transport of animals and plants” (Marceau and Trachtman, p. 414)

3.New Barriers to Trade: the surge of Private Standards

Summary: Introduction. Main features: definition, terminology and interplay between regulation, private standards and international standards. Different types, categories and examples of private standards. Private Standards by sectors and initiatives: The Organic Sector; The ISEAL project; The GLOBALG.A.P Initiative; The JO-IN Initiative. Legitimacy and accountability for market/private standards. Legitimacy and accountability for market/private standards: Legitimacy; General Accountability and State responsibility. Meta and Transnational governance on Market/Private Standards: The Role of ISO; The Role of UNFSS and the building up of domestic VSS platforms: The UNFSS; The building up of domestic VSS platforms: The building up of a VSS platform in India; The building up of a VSS platform in China; The need of a VSS focal point in Brazil. ITC: Standards Map. Conclusion.

3.1. Introduction

In the last decades, many have discussed the impacts of globalization and the spread of a new phenomenon that comes with it – global governance, which means multiplication of international actors, proliferation of distinct norms and manifestation of different concerns from such a multiplicity of ‘regulators’ and ‘regulation’.

Multilateral and governmental initiatives have been incapable of addressing these global challenges that have spread with the ‘emergence of new non-state market regulatory initiatives’, which are aimed at governing ‘production, production process and supply chains across the globe according to a set of non-governmental private standards’ – rules that regard different and complex issues, such as food safety, environmental protection, labour conditions, human rights protection and others¹²².

There are many arguments for and against private standards, but none of them can ignore the fact that private standards have become a reality on global trade. Therefore it is urgent the need to better understand and analyse the institute of private standards from a developing country perspective, in order to maximize their positive points and minimize their negative ones, overcoming policy inertia as well as market failures.

In general, private standards have faced many concerns and have become a big challenge for the multilateral trade system – challenges may be listed as such:

i) multiplicity of interoperability of private standards, which implies lack of harmonization and equivalence on similar standards;

¹²² Axel Marx, Miet Maertens, Johan Swinnen & Jan Wouters, *Private standards and global governance*, Leuven Global Governance Series (2012) 01.

- ii) marginalization of small holders and developing and least developed countries due to complex, rigorous and multi-dimension standards;
- iii) concerns that private standards undermine the structure of the WTO Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS);
- iv) a risk that private standards are disguised and arbitrary measures that undermine all the globalized structure of free trade;
- v) multiplication of private standards that may put at risk their sustainability objectives and create confusion to producers and consumers ('green-washing');
- vi) lack of a multi-dimensional approach on addressing risks for the composition of private standards since many of the standards set are not science-based;
- vii) effects of many private standards that are part of global supply chains, which generates concerns on national policies and priorities and respect to natural trade intensity of exporting countries¹²³.

In order to deal with these concerns, this essay intends to cover: the main features related to private standards, definition, terminology and interplay between regulation, Private Standards by sectors and initiatives (the organic sector, the ISEAL project, the GLOBALG.A.P initiative, the JO-IN initiative), legitimacy and accountability for market/private standards, meta and transnational governance on market/private standards, the role of ISO, the role of UNFSS and the building up of domestic VSS platforms, the ITC Standards Map.

Firstly, this paper proposes a new terminology for private standards – 'market standards', with the purpose of differentiating them from other well established international private standards.

Secondly, it comes up with the conclusion that, in order to deal with the overall problems associated with the proliferation of private standards, the negotiation of a meta-regulation to deal with their complexity is urgently necessary, mainly for the observance of the rule enshrined in the TBT Agreement that whenever a regulation is in accordance with relevant international standards, it 'shall be rebuttably presumed not to create an unnecessary obstacle to international trade'. It analyses some distinct initiatives such as the Organic Sector, the ISEAL project, the GLOBALG.A.P Initiative and the JO-IN Initiative.

Thirdly, it defends the creation of an international body on private standards, which will be responsible for the negotiation of such basic rules as well as for the representation of their stakeholders in international trade fora, such as the WTO.

Fourth, it argues that the significant work of some private bodies such as ISO, IEC and UNFSS and the main private standards platforms have to be taken into consideration, as well as the work of several governmental bodies, such as Codex and OIE. Transparency, non-discrimination, accountability and supervision must be negotiated within these new set of standards.

Fifth, it encourages the creation of national platforms in all interested countries, with the support of private and public bodies, in order to organize the information and offer a focal

¹²³ UNFSS Forum on Sustainability Standards, Geneva (2013), <http://www.unfss.org> (last visited February 2, 2015).

point to the interested ones, with the objective of increasing transparency and diminishing trade barriers, besides enhancing effectiveness in all considered sectors.

Finally, facing the significant impact of private standards on trade, it is imperative to recognize that they must be seriously discussed in the WTO, in joint meetings of the SPS and TBT Committees, since the separation of the two categories of measures is a false dilemma. The political manoeuvre not to face the problems they are creating is a huge strategic misconception. At the end, the effects of private standards on international trade are clearly responsibility of governments and it has to be treated as such. In this paper, such responsibility will be analysed much more on a preventative and policy perspective within the WTO, suggesting Specific Trade Concerns on the matter.

Such a political attitude of negligence should not endure. Otherwise, private – market – non-governmental – transnational standards, whatever the chosen name, will be transformed into significant threat that can undermine the whole meta-structure of the WTO, created by a huge effort of its members along the last seventy years.

3.2. Main features: definition, terminology and interplay between regulation, private standards and international standards

Standard is a document that provides guidelines, characteristics, requirements or specifications in order to ensure that products, processes, services and materials are suitable for their aim¹²⁴. Theoretically, standards should help companies to get access to markets as well as developing countries in levelling the playing field, besides facilitating international trade¹²⁵.

Under the WTO, the definition of standard is provided by the Agreement on Technical Barriers to Trade (TBT), in Annex 1, paragraph 1(2), as a document

‘Approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which **compliance is not mandatory** (...)’
(emphasis added).

Standards may be set by public or private entities. Private standards differ from public ones since they are not prepared by regulatory authorities, but instead by non-governmental entities.

Many publications on private standards have often confused the terms and have employed ‘private standards’ as synonyms for ‘voluntary standards’. Voluntary standards are those that are not mandatory¹²⁶. Often, public authorities produce mandatory standards, but there are some voluntary standards that have been produced by public authorities too¹²⁷.

¹²⁴ ISO/EIC Guide 2, <http://www.iso.org/iso/home/standards.htm> (last visited Oct. 31, 2014).

¹²⁵ Id.

¹²⁶ Henson, S. & Humphrey, J. (2010), *Understanding the Complexities of Private Standards in Global Agri-Food Chains as They Impact Developing Countries*, Journal of Development Studies, 46, 9, (2010), 1628 - 1646.

¹²⁷ P. Liu, World Trade Organization, *Private Standards in International Trade: Issues and Opportunities*, WTO’s Workshop on Environment-related Private Standards, Certification and Labelling Requirements, Geneva (2009).

In 2005, a discussion on private standards was raised on the SPS Committee¹²⁸. Another discussion was raised in 2006¹²⁹. In both, the arguments centred on whether the government had backed the private sector's standards (EurepGap/GlobalGAP and Nature Choice's, respectively). In both, once demanded, the EC Commission only confirmed the existence of the standards and that they were indeed private ones, but that they neither conflict with EC legislation nor with WTO law.

In 2008, a Working Group was established on private standards, which handed in, in 2011, a report on 'Possible actions for the SPS Committee regarding SPS-Related Private Standards'¹³⁰. From this report, some policies were approved by the Committee, *inter alia*: a need to define private standards and exchange of information on whether private standards could be ever compared to regulation.

In 2012, there was a long debate in the SPS Committee related to a definition of private standards, but divergences between the Members did not allow a final conclusion on it. The definition that was presented in 2012 was not approved. It had been proposed that:

'SPS-related private standards are [voluntary] requirements which are [formulated, applied, certified and controlled] [established and/or adopted and applied] by non-governmental entities [related to] [to fulfil] one of the four objectives stated in Annex A, paragraph 1 of the SPS Agreement and which may [directly or indirectly] affect international trade'¹³¹.

The definition of private standards as voluntary ones is highly questionable. Since the exporter does not conform to the standard, it cannot sell its products on the importing market, which would make the standard *de facto* mandatory. In 5 August 2014, the SPS Committee agreed to pursue its work on a definition of SPS-related private standards, based on the working definition tabled in the document G/SPS/W/276:

'An SPS-related private standard is a written requirement or a set of written requirements of a non-governmental entity which are related to food safety, animal or plant life or health and for common and repeated use'¹³².

From this definition, the term 'voluntary' was excluded. This last definition, which is still under scrutiny in the Committee, is much more objective than the earlier one. One should remark that it includes the term 'for common and repeated use', which excludes other kinds of documents for internal uses within the non-governmental entity. Moreover, with such a definition, the excuses that private bodies would not fall under the requirements for a 'non-governmental entity' would come to an end¹³³.

Pascal Liu presents private standards as standards that are elaborated by non-governmental entities, which belong to them, whether they are profit oriented (private companies) or non-profitable bodies¹³⁴.

¹²⁸ G/SPS/R/37, 11 August 2005.

¹²⁹ G/SPS/R/39, 21 May 2006.

¹³⁰ G/SPS/W/256, 3 March 2011.

¹³¹ G/SPS/W/265, Proposed Working Definition on SPS-Related Private Standards. 6, March 2012.

¹³² G/SPS/GEN/1334/Rev.1, circulated on 5 August 2014.

¹³³ See a discussion on non-governmental entities under the topic of Legitimacy.

¹³⁴ P. Liu, *supra*, 2.

On matters of terminology, a proposal has been the expression ‘transnational standards regulation’, referring to the same kind of ‘private standards’¹³⁵. The term “transnational” has been adopted under international law pointing, in general, as main actors multinationals, supermarket chains and NGOs.

Our proposal for terminology would be ‘market standards’ in order to point to the kind of private standards that are prepared by multinationals, supermarket chains and NGOs, but are out of the scope of formal international standardization such as ISO. ‘Market standards’ would make a good distinction whenever discussions related to legitimacy and accountability are on the stage.

From the above discussions on definition, we can track some of the main features related to market standards/private standards - their voluntary nature and their non-governmental status.

There are some private voluntary standards that have become mandatory under legislation – some market standards elaborated by some non-governmental organizations and private companies of organic products, such as Soil Association and Demeter, have been adopted under domestic legislation, such as the European Union, or by recognized international bodies, such as the Codex Alimentarius¹³⁶.

The International Organization for Standardization (ISO is a non-governmental entity and, at the same time, has 165 member countries represented by their national standards bodies, whether they are private or public ones¹³⁷. Despite, in general, ISO standards are voluntary ones, many of the standards prepared by ISO have become mandatory under domestic legislation.

Voluntary market standards prepared by private companies might become *de facto* mandatory, such as in the food sector, supermarket chains, producers and cooperatives¹³⁸. Even though they are not binding on producers, the only option left besides fulfilling the standard requirement is to leave out the market¹³⁹. Since a standard has gained the international market, it also gains international recognition but issues related to legitimacy are still a concern. Therefore, in practice, the difference between a private and a public standard might not be important, at the end, for producers, since they both create heavy burdens in the production process and overall barriers to international trade¹⁴⁰.

For example, the search for production of renewable energy has led to establishment of private standards on the sector. Most of these standards were established in fulfilment of government directives, such as EC Directive 2008/28/CE, which established a goal of 20% for consumption of renewable energy by 2020 (from this total, 10% has to be in the transports sector), and EC Directive 2009/28/CE, which established sustainability goals, such as

¹³⁵ See L. Dobusch, P. Mader & S. Quack, *Governance across borders. Transnational fields and Transversal themes. A Blogbook* (2013).

¹³⁶ P. Santacoloma, FAO/UNEP Programme, *Nexus Between Public and Private Food Standards: Main Issues and Perspectives*, Workshop of the FAO/UNEP Programme on Sustainable Food System – Voluntary Standards for Sustainable Food Systems: Challenges and Opportunities (2014).

¹³⁷ ISO, <http://www.iso.org/iso/home/about.htm> (last visited Oct. 31 2014).

¹³⁸ Wouters, J. & Geraets, D., *Private Food Standards and the World Trade Organization: Some Legal Considerations*, World Trade Review, 11, 3, 479 (2012).

¹³⁹ Id.

¹⁴⁰ Engler, A., Nahuelhual, L., Cofré, G., Barrena, J. (2012), *How Far from Harmonization are Sanitary, Phytosanitary and Quality-related Standards? An Exporter's Perception Approach*, Food Policy, 37, 162-170 (2012).

reduction on emissions of 35%, and must be, at least, of 50% from 2017 onwards and 60% from 2018 onwards¹⁴¹.

Moreover, despite they do not become mandatory; they are used all along the value chain, which makes suppliers' options very limited¹⁴². In many circumstances, the private standards become part of the culture of a specific market and they represent increase of power for some retailers and, as such, they have a *de facto* mandatory force¹⁴³.

Some researchers have focused on a summary of the main motivations for private standards:

Table 1: A summary of the main motivations for private standards

Main Motivations
Responses to food risks/Increase of real risks acknowledged by consumers
Transfer of responsibility on food safety in the public and private sectors
Globalization of production chains
Social and demographic changes and increase in the consumers interests on food production processes
Proliferation of premium trade marks
Need of differentiation in products

Source: L.R. A. Rua, FEP, 2014 (Free Translation)¹⁴⁴

3.3. Different types, categories and examples of private standards

Market/Private standards can be separated into different types, according, *inter alia*, to sectors, categories and subjects. As remarked by Arcuri, 'within the far-reaching category of transnational private regulation, at least four types of regulatory schemes can be distinguished: i) private food safety standards; ii) 'civil regulation' or private codes and standards to control environmental and social aspects of business operations; iii) technical and quality standards; and iv) private meta-regulatory frameworks'¹⁴⁵.

¹⁴¹ Lima, Rodrigo C. A. *Novas Barreiras ao comércio e desafios para a OMC*. In: Dantas, Adriana (org.). *Os desafios Regulatórios que afetam o agronegócio exportador: casos práticos e lições de como enfrenta-los*, 7 (2014).

¹⁴² Rua, L. R., *Os Padrões Privados no Contexto do Comércio Internacional – Percepção dos Exportadores Brasileiros de Carne de Frango*, Masters Dissertation, FEP- Porto-Portugal, 14 (2014).

¹⁴³ P. Liu, *supra*.

¹⁴⁴ L. R. A. Rua, *Os Padrões Privados no Contexto do Comércio Internacional – Percepção dos Exportadores Brasileiros de Carne de Frango*, FEP (dissertação de mestrado), 2014, at 13. (Free translation from the original, which was prepared in Portuguese).

¹⁴⁵ Arcuri, Alessandra, *The TBT Agreement and private standards*, In Tracey Epps and Michael J. Trebilcock (org.), *Research Handbook on the WTO and Technical Barriers to Trade*, 488 (2013).

The major voluntary sustainability standards

	Business to Business	Consumer label
Niche standards	SA8000	Organic Fairtrade
Meta-standards for good agricultural practice (GAP)	GLOBALGAP Utz Certified	Rainforest Alliance
Commodity-specific standards	RSPO RTRS	MSC
Individual company standards	WM Sustainability Index Tesco Nurture	

Source: UNFSS, 2015

Private food safety standards were established as a way to deal with responsibility for food safety to retailers and as a response to some food crises that affected the food sector¹⁴⁶. Such reasons for the development of private food safety standards are legitimate ones; however, their effects are contested. The problem is that some few large supermarket chains dominate food products markets and retailers require compliance with some private standards; meanwhile, small producers, mainly from developing countries, may not always afford certification costs and, as such, they might be *de facto* excluded from these markets¹⁴⁷.

‘Civil regulation’ is the term that has been used to define the structure of private regulation that deals with social and environmental impacts of business operations, being influenced by citizens-consumers - private codes and standards to control environmental and social aspects of business operations. It can be seen as ‘a mechanism that extends the political realm to markets, enabling acts of political consumerism’¹⁴⁸.

On the other hand, technical and quality standards are the primary standards *par excellence*, which were created for trade facilitation. In 1947, ISO was established with the aim to focus on technical standards thus facilitating trade, since voluntary but worldwide recognized standards were followed by industries all over the world¹⁴⁹. ISO has observer status in the TBT Committee and the Codex Alimentarius Commission. Under the TBT Agreement, compliance with ISO standards is compliance with WTO law (TBT, Annex 3). In the same

¹⁴⁶ Cafaggi, Fabrizio, EUI RSCAS, *Private Regulation, Supply Chain and Contractual Networks, The Case of Food Safety*, Private Regulation Series, 03, 490 (2010).

¹⁴⁷ Arcuri, *supra* at 491.

¹⁴⁸ Id. at 488.

¹⁴⁹ ISO, <http://www.iso.org/iso/home.html> (last visited Jan. 9 2015).

way, in the field of electronics, the International Electrotechnical Commission (IEC), founded in 1906, helped to spread compatibility of electronic devices worldwide¹⁵⁰.

Many market standards have been pointed out as examples of private standards that have had a large effect on global markets. The tables bellow show some of these standards and their respective ‘creators’.

Table 1: Examples of private standards

Created by Individual companies	Created by national chains	Created by international chains
Nature’s Choice (TESCO)	Assured Food Standards (UK)	GlobalGAP
Filières Qualité (Carrefour)	British Retail Consortium Global Standard	International Food Standard
Field-to-Fork (marks & Spencer)	Freedom Food (UK)	Safe Qaulity Food (SQF) 1000/2000
Filière Contrôlée (Auchan)	Qualitat Sicherheit (QS)	Marine Stewardship Council (MSC)
P.Q.C. (Percorso Qualità Conad)	Assured Combinable Crops Scheme (UK)	Forest Stewardship Council (FSC)
Albert Heijn BV: AH Excellent	Farm Assured British Beef and Lamb	
	Sachsen Ahrenwort	
	QC Emilia Romagna	
	Stichting Streekproduction Vlaams Brabant	

Source: WTO, SPS Committee and M. K. Amaral (2014)

Examples of Private Standards:



Source: Nature’s Choice, TESCO (2014)¹⁵¹



Source: Forest Stewardship Council (2014)¹⁵²



Source: GlobalGAP (2013)¹⁵³



Source: The Marine Stewatdishps Council, Private Food Law (2011)

¹⁵⁰ IEC, <http://www.iec.ch/> (Jan. 9 2015).

¹⁵¹ Available in <http://www.tesco.com/csr/g/g4.html> (access on 7th November 2014).

¹⁵² Available in <http://br.fsc.org/> (Access on 7th November 2014).



Source: United Laboratories (2014)

Max Havelaar Fair Trade (2014)¹⁵⁴

Last, private meta-regulatory frameworks have also been developed on ‘how to produce and manage private regulatory schemes’¹⁵⁵. Meta-regulation has also been produced by ISO. One such example is ISO Guide 65, published in 1996, on the general requirements for bodies operating product certification systems.

3.4. Private Standards by sectors and initiatives

3.4.1. The Organic Sector

Organic agriculture and trade afford the world a high level of agro-ecosystem services, and present social and economic opportunities for people, especially those in need of food security and ways out of poverty.

Among the foremost challenges for the further development of organic agriculture is that trade pathways have become entangled with multiple organic standards and technical regulations. A product produced according to one set of organic standards and certification requirements may also need to comply with other organic standards and requirements in order to be traded. The labyrinth of requirements in both government and private sectors constitutes an obstacle to trade, which constrains organic market development and denies market access to many, including hundreds-of-thousands of small producers in developing countries.

The Global Organic Market Access (GOMA) project has the aim to simplify the process for trade flow of organic products among various regulatory and/or private organic guarantee systems¹⁵⁶. GOMA focuses on harmonization and equivalence of organic standards and certification performance requirements as mechanisms for clearing trade pathways. It provides two practical tools for this purpose. The tools were developed by the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF), comprised of representatives from governments, intergovernmental organizations and private sector representatives, and subjected to international consultation. The Guide for Assessing Equivalence of Standards and Technical Regulations (EquiTool) and the International Requirements for Organic Certification Bodies (IROCB) can be used by any government or

¹⁵³ EurepGAP was launched in 1999 as a European Initiative, comprised of 16 retailers setting Good Agriculture Practices. EurepGAP was renamed Available in: http://www.globalgap.org/uk_en/ (Access on 7th November 2014).

¹⁵⁴ Max Havelaar label is the first fair trade certification scheme. Available on: <http://www.fairtrade.org.uk/> (Access on 8th January 2015).

¹⁵⁵ Arcuri, *supra*, at 495.

¹⁵⁶ <http://www.ifoam.bio/> (access on 17th April 2015)

private sector organic label scheme as tools for recognizing other organic standards and certification performance requirements as equivalent to their own.

THE ORGANIC WORLD IN 2012¹⁵⁷

Indicator	Global Totals	Leading Countries
Countries with data on certified Organic Agriculture	162 (2008: 154; 2000: 86)	
Organic agricultural land	37.2 mil. ha (2006: 30.7; 1999: 11)	Australia (12 mil. ha), Argentina (3.8), US (1.9)
Countries with > 5% organic agricultural land	25 (2008: 22)	Falklands (35.9%), Liechtenstein (29.3%), Austria (19.7%)
Further, non-agricultural organic areas	32.5 mil. ha (2010: 43)	Finland (7 mil. ha), Zambia (5.9), India (4.5)
Producers	1.8 million (2010: 1.6)	India (574,591), Uganda (188,625 as of 2010), Mexico (169,570)
Organic market size	\$US 62.9 bn. (2008: 50.9; 1999: 15.2)	US (\$US 29 bn.), Germany (9.2), France (5.2)
Organic per capita consumption per year	\$US 9 (2009: 8)	Switzerland (\$US 250), Denmark (226), Luxemburg (187)
Countries with organic regulations	86 (2008: 73)	
Organic certifiers	576 (as of 2012) (2010: 523)	South Korea, Japan, US
Number of IFOAM Affiliates (as of 01.01.2013)	766	Germany (96), India (46), China (41)

Source: The World of Organic Agriculture 2013, IFOAM and FiBL

Note: Data as of 31.12.2011

The project activities include:

- i) outreach to share knowledge about the tools and possibilities for cooperation;
- ii) pilot projects to test the tools in various environments;
- iii) technical assistance to governments and private sector stakeholders to implement the tools and related recommendations;
- iv) facilitation of new regional initiatives for cooperation on harmonized organic standards development and multi-lateral equivalence;
- v) analysis of the organic trade system and evaluation of the trade-facilitating tools¹⁵⁸.

GOMA is overseen by a steering committee comprised of representatives from FAO, IFOAM and UNCTAD. The project is funded by the Norwegian Agency for Development Cooperation (Norad)¹⁵⁹.

¹⁵⁷ http://www.ifoam.bio/sites/default/files/page/files/ifoam_annual_report_2012.pdf (access on 17th April 2015)

¹⁵⁸ <http://www.ifoam.bio/> (access on 17th April 2015)

¹⁵⁹ Ibid.

It is probable that GOMA's success will depend on the interest and participation of stakeholders from governments, intergovernmental institutions and the private sector.

GOMA is divided into workspaces, which have focused on the adoption and implementation of the two equivalence tools, IROCB and EquiTool, that were produced by the ITF. It has also fostered the development of harmonized regional standards, promoted work and conclusions to ISO and Codex Alimentarius, conducted ongoing analysis of the situation for enhancing trade by reducing trade barriers, and assessed and revised other tools¹⁶⁰.

The 3-year GOMA project started in June 2009 and ended in 2012 with a major conference on harmonization and equivalence.

Although The Organic Standard has a broader scope than Harmonization and Equivalence, it covers topics of interest to GOMA. Since the topic has a relatively small group of stakeholders, it has been considered it better to partner than to compete. It also endeavors to find other ways to expose third interested parties to the Organic Standard, because it considers it to be a relevant and even necessary material for many organic government regulators and certification bodies.

3.4.2. The ISEAL project

The International Social and Environmental Accreditation and Labelling Alliance (now just referred to as the ISEAL Alliance) was founded in 2002 by a group of sustainability standard-setters. Today, ISEAL's Codes of Good Practice are seen as global references for developing credible standards¹⁶¹.

At the end of the 1990s, four certification organizations – Forest Stewardship Council (FSC), the International Federation of Organic Agriculture Movements (IFOAM Accountability International – were on board and in 2002 the International Social and Environmental Accreditation and Labelling Alliance (now just referred to as the ISEAL Alliance) was registered in the UK as not-for-profit organization¹⁶².

The aim of the newly formed ISEAL Alliance was to enable collaboration between its members and coordinate and represent their common interests to government and other key stakeholders. The creation of an independent organization also provided an opportunity to develop a common understanding of the best practices for setting sustainability standards. This resulted in the first of ISEAL's Codes of Good Practice, the Standard-Setting Code, which was launched in 2004¹⁶³.

In 2010, it was launched the ISEAL Impacts Code, which provides a process for how standard systems can effectively measure and evidence their contribution to social and environmental impacts on the ground. The third code, the ISEAL Assurance Code, was launched at the end

¹⁶⁰ Ibid.

¹⁶¹ The ISEAL Code of Good Practice, Assessing the Impacts of Social and Environmental Standards Systems, December 2014, <http://www.isealliance.org/sites/default/files/ISEAL%20Impacts%20Code%20v2%20Dec%202014.pdf> (access on 17th April 2015).

¹⁶² <http://www.isealliance.org/> (access on 17th April 2015)

¹⁶³ Ibid.

of 2012. This code provides guidance on how to ensure that certification to standards is both rigorous but also accessible and affordable to small scale enterprises¹⁶⁴.

All full members of ISEAL must meet the requirements of the ISEAL Codes of Good Practice. Associate members have one year to come into full compliance. Our associate membership program was launched in December 2007 to give newer standards an opportunity to work towards full ISEAL membership¹⁶⁵.

Since the beginning, ISEAL's community has expanded beyond members in order to include representatives from business, government, civil society and academia. In 2010 it was established the ISEAL Stakeholder Council, bringing together leaders that have sustainability knowledge and experience. The aim of the Stakeholder Council is to incorporate the voices and ideas of people that use and care about credible standards, into the development of our good practice codes and strategic planning. Some of the most important ISEAL's reports include the ISEAL 100 and the Scaling Up Strategy, which were both published in 2011¹⁶⁶.

ISEAL's community continues to grow with a broad range of individuals and organizations entering into the ISEAL subscriber pool (called the ISEAL "affiliates" prior to 2013). Each year, ISEAL subscribers and members get together at the ISEAL's conference.

ISEAL members



Source: ISEAL, 2015

¹⁶⁴ Ibid.

¹⁶⁵ Ibid.

¹⁶⁶ Ibid.

In 2012 ISEAL expanded its reach further by beginning a program of work in emerging economies; identifying opportunities for standards to be used to address sustainability issues in Brazil, India and China.

3.4.3. The GLOBALG.A.P Initiative¹⁶⁷

Two organizations that cover different sectors - Fairtrade and Marine Stewardship Council (MSC) – timber, fish, organic and fair-trade agriculture - came together to discuss the feasibility and benefits of working in closer collaboration. They recognized areas where their systems overlapped and in November 2000 they agreed to create a formal organization. Soon, other organizations joined in – International Organic Accreditation Service, Marine Aquarium Council, Rainforest Alliance in order to create GlobalGAP.

GLOBALG.A.P.'s roots began in 1997 as EUREPGAP, an initiative by retailers belonging to the Euro-Retailer Produce Working Group. British retailers working together with supermarkets in continental Europe become aware of consumers' growing concerns regarding product safety, environmental impact and the health, safety and welfare of workers and animals. Their solution: harmonize their own standards and procedures and develop an independent certification system for Good Agricultural Practice (G.A.P.)¹⁶⁸.

The EUREPGAP standards helped producers comply with Europe-wide accepted criteria for food safety, sustainable production methods, worker and animal welfare, and responsible use of water, compound feed and plant propagation materials. Harmonized certification also meant savings for producers, as they would no longer need to undergo several audits against different criteria every year¹⁶⁹.

Over the next ten years the process spread throughout the continent and beyond. Driven by the impacts of globalization, a growing number of producers and retailers around the globe joined in, gaining the European organization global significance¹⁷⁰.

To reflect both its global reach and its goal of becoming the leading international G.A.P. standard, EurepGAP changed its name to GLOBALG.A.P. in 2007.

GLOBALG.A.P. today is the world's leading farm assurance program, translating consumer requirements into Good Agricultural Practice in a rapidly growing list of countries – currently more than 100¹⁷¹.

In general, GLOBALG.A.P offers 16 standards for 3 scopes: Crops, Livestock, and Aquaculture. It has more than 228 certified products and over 140.000 certified producers in more than 118 countries and it works with more than 1700 trained inspectors and auditors working for 136 accredited certification bodies to perform independent third-party producer audits and issue our certificates¹⁷².

¹⁶⁷ http://www.globalgap.org/uk_en/ (access on 17th April 2015)

¹⁶⁸ GLOBALGAP., In: http://www.globalgap.org/uk_en/ (access on 17th April 2015)

¹⁶⁹ Ibid.

¹⁷⁰ Ibid.

¹⁷¹ Ibid.

¹⁷² Ibid.

GLOBAG.A.P. CERTIFICATION

Food safety and traceability
Environment (including biodiversity)
Workers' health, safety and welfare
Animal welfare
Integrated Crop Management (ICM), Integrated Pest Control (IPC), Quality Management System (QMS), and Hazard Analysis and Critical Control Points (HACCP)

Source: GLOBALG.A.P., 2015

GLOBALG.A.P has developed a harmonization program to benchmark schemes and standards around the world. And this is why it has had one of the most widely accepted private sector food safety certification systems.

Since November 2011, the GLOBALG.A.P. Stakeholder Committee on Animal Welfare has worked on the establishment of criteria for animal welfare which go beyond legal requirements, and which define the contents of complementary and voluntary add-on certifications for livestock producers. Members worked on two sets of criteria – one for broilers and one for finishing pigs. The criteria they developed are science based, feasible, economically viable and auditable.

According to Norbert Rank, Chairman of the GLOBALG.A.P. Stakeholder Committee on Animal Welfare “Sustainable agricultural practices are essential to successful and responsible business development. Animal welfare is a critical component of this and is very much in the minds of our customers and stakeholders. Their expectations go often beyond legal requirements. The GLOBALG.A.P. voluntary add-on on animal welfare is highly welcomed as a tool to help to monitor animal welfare practices that go beyond legislation at farm level.”

In collaboration with the Friend of the Sea consumer label, GLOBALG.A.P. is now offering the Friend of the Sea Add-On Module for Aquaculture. Therefore, GLOBALG.A.P. certified producers who successfully comply with the four criteria defined in the Friend of the Sea Add-On at farm level will be allowed to use a special consumer label, consisting of both the Friend of the Sea consumer label and the GLOBALG.A.P. Number - GGN. The FoS Add-On criteria cover the impact on water body sediment, the effect on the local community regarding access to drinking water and fishing areas, and social criteria by requiring GRASP. This add-on can be audited during the GLOBALG.A.P. Certification audit.

Friend of the Sea is a non-profit non-governmental organization for the conservation of marine habitats by means of market incentives. Friend of the Sea has created a leading international certification project to certify and promote seafood and products from sustainable fisheries and aquaculture. This consumer label follows the FAO - Guidelines for the Ecolabelling of Fish and Fishery Products from Marine Capture Fisheries.

3.4.4. The JO-IN Initiative ¹⁷³

Codes of conduct have been an important part of efforts to improve labor standards in global supply chains. Over the last ten years these codes and systems for their implementation have

¹⁷³ <http://www.jo-in.org/english/index.html> (access on 17th April 2015)

proliferated. Brands and retailers are faced with multiple industry standards and suppliers are confused by the numerous codes and initiatives. Local organizations are frustrated by the many initiatives making demands on their time. Better co-ordination and co-operation is essential to address this confusion. It is also important to develop a shared understanding of the ways in which voluntary codes of conduct contribute to better working conditions¹⁷⁴.

Representatives of the six organizations met during 2003 and 2004 and agreed the broad outline of a 'trial project' which would pose and test various aspects of the overall collaborative effort (the 'Joint Initiative')¹⁷⁵. The Joint Initiative (also called JO-IN Initiative) is the first effort to bring together key organizations different aspects of code implementation and/or enforcement in a program of collaborative work. These are: Clean Clothes Campaign, Ethical Trading Initiative, Fair Labor Foundation, Social Accountability International and Workers Rights Consortium ("the organizations"). Each of these organizations is involved in the global effort to improve working conditions in global supply chains. It seems that all believe that codes of conduct can only make an effective and credible contribution to this effort, if their implementation involves a broad range of stakeholders, including governments, trade unions, employers' associations and civil society¹⁷⁶.

The aims of the Joint Initiative are: i) to maximize the effectiveness and impact of multistakeholder approaches to the implementation and enforcement of codes of conduct, by ensuring that resources are directed as efficiently as possible to improving the lives of workers and their families; ii) to explore possibilities for closer co-operation between the organizations; iii) to share learning on the manner in which voluntary codes of labor practice contribute to better workplace conditions in global supply chains¹⁷⁷.

The project has received funding from the European Commission (DG Employment), the US State department, ICCO (Interchurch Organisation for Development Co-operation) as well as some funding from two of the brands involved in the project. An International Steering Committee consisting of representatives of the six-organizations, and an independent Chair meet twice a year to provide strategic direction, make policy decisions and assess progress¹⁷⁸.

3.5. Legitimacy and accountability for market/private standards

One of the big challenges faced by the proliferation of market standards has been legitimacy on creation and setting of such standards as well as accountability and State responsibility towards the behaviour of the bodies that have issued them.

Concerns related to legitimacy intend to answer questions such as: i) 'who produces the standards?' and ii) 'where such authority comes from?'

Concerns related to accountability are related to: i) are there scientific basis for the creation of such standards?; ii) who responds for the setting of private standards under a market/government failure and a multilateral trade system perspective?

¹⁷⁴ Ibid.

¹⁷⁵ <http://www.jo-in.org/turkeyproject.htm> (access on 17th April 2015)

¹⁷⁶ http://www.jo-in.org/english/resimiler/080623_JO-IN_Final_Report.pdf (access on 17th April 2015)

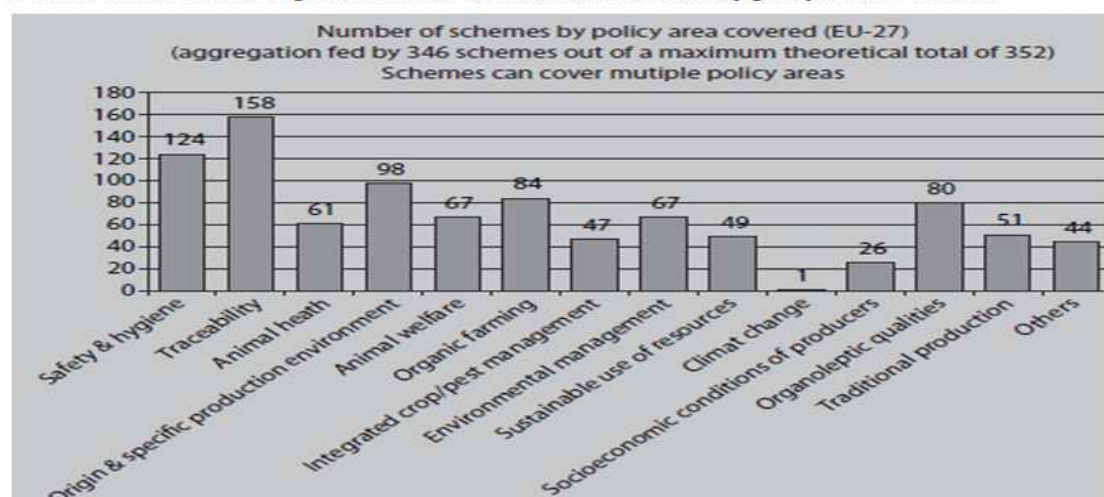
¹⁷⁷ Ibid.

¹⁷⁸ Ibid.

3.6. Legitimacy

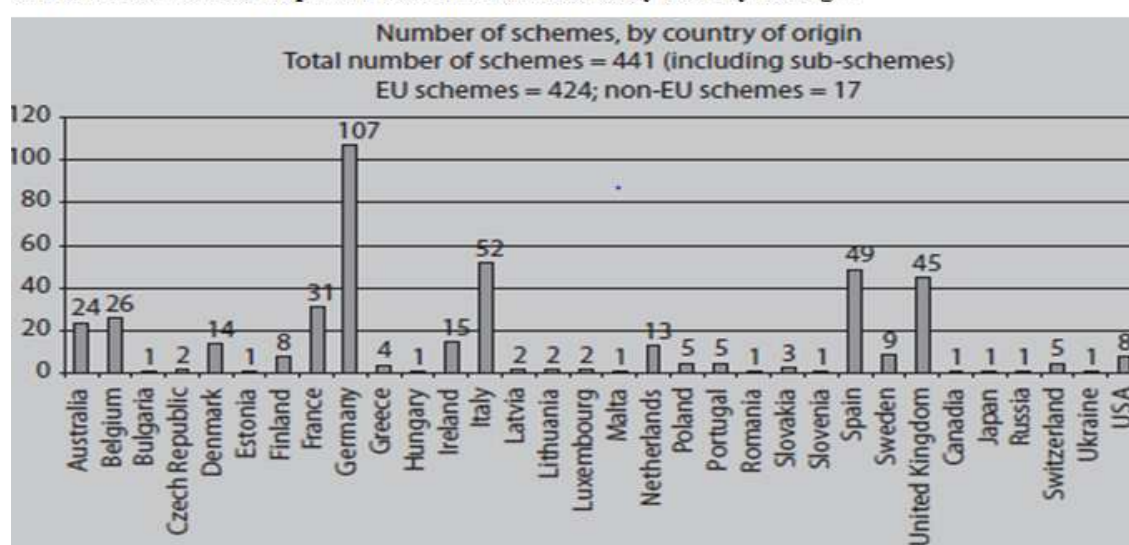
Market standards have been issued by non-governmental bodies based on many different reasons. Concerns have existed on legitimacy of such standards creators and how the market has accommodated such new ‘trustworthiness’.

FIGURE 13: Number of private standards certificates covered by policy areas in the EU



Source: Inventory of Private Food Law, EFLA, 2011¹⁷⁹

FIGURE 14: Number of private standards certificates by country of origin



Source: Inventory of Private Food Law, EFLA, 2011¹⁸⁰

Under the TBT agreement, standardizing bodies have to comply with a Code of Good Practice (Annex 3) and Members should not take measures which have the effect of, directly or indirectly, require or encourage such standardizing bodies to act in a manner inconsistent with such Code. In this sense, any standard created by a standardization body, ‘irrespective of a

¹⁷⁹ Theo Appelhof and Ronald van den Heuvel, Inventory of Private Food Law, In: Bernd van der Meulen (ed.), Private Food Law, 2011, at 113.

¹⁸⁰ Theo Appelhof and Ronald van den Heuvel, Inventory of Private Food Law, In: Bernd van der Meulen (ed.), Private Food Law, 2011, at 113.

governmental mandate', fall within the scope of the TBT agreement, and, as such, is also a 'clear case of private regulation' under TBT¹⁸¹.

As remarked by Arcuri, 'the remaining question concerns which private regulatory bodies fit within the definition of the TBT Agreement. Given the open-ended definition of a non-governmental body provided in Annex I (8) of the TBT Agreement, some doubts may remain as regards bodies that do not set routine standards, and doubts have also been raised as to whether all typologies of standards are covered by Article 3'¹⁸².

From the very definition of standards, under the TBT Agreement (See definition above) one could ask what kind of bodies would fit within such definition. No doubt as for International bodies, regional, local or central government ones. But what about non-governmental bodies? Annex 1, paragraph 8 expressly states that a non-governmental body is a :

Body other than a central government body or a local government body, including a nongovernmental body which has legal power to enforce a technical regulation.

Would it include bodies that are not regulatory ones, but that develop standards occasionally, in a random fashion?

It is important to note that, in the explanatory note to the definition of 'standard' developed in the building up of the TBT Agreement, pending the Tokyo Round, it was settled that the definition does not cover technical rules made by individual companies for its own production and consumption requirements¹⁸³. In the final text of the TBT Agreement, such exclusion was not included, which may indicate that the definition of a non-governmental body, pending the Uruguay round, is much broader than what was initially intended in the Tokyo Round¹⁸⁴.

That would also lead to another question related to the acceptance of international standards, within TBT and other WTO Agreements, as a bench for compliance with WTO law. As TBT has no definition of 'international standards', the one that is adopted by scholars and WTO jurisprudence is the definition set in ISO, taking into consideration that ISO standards are pointed up in the introductory clause of TBT, Annex1¹⁸⁵. Thus, the answer comes in ISO/IEC Guide 2. 'Standard that is adopted by an international standardizing/standards organization and made available to the public'.

In US-Tuna II, the Appellate Body understood that such definition 'suggests that it is primarily the characteristics of the entity approving a standard that lends the standard its "international" character'¹⁸⁶.

On the other hand, in the TBT Agreement, Annex 1, paragraph 4, an international body is a: 'Body or system whose membership is open to the relevant bodies of at least all Members'.

What exactly such 'openness' mean? 'Should it be open at the moment a standard is negotiated, or is it sufficient that it is open once the standard has already been adopted?'¹⁸⁷

¹⁸¹ Id. at 501.

¹⁸² Id.

¹⁸³ Id. at 505.

¹⁸⁴ Id.

¹⁸⁵ Id. at 507.

¹⁸⁶ United States – Measures concerning the importation, marketing and sale of tuna and tuna products.

WT/DS381/AB/R., para. 353.

¹⁸⁷ Arcuri, *supra* at 508.

The answer came with the 2000 TBT Committee Decision, which interpreted, in section 2, ‘openness’ as:

Membership of an international standardizing body should be open on a non-discriminatory basis to relevant bodies of at least all WTO Members. This would include openness without discrimination with respect to the participation at the policy development level and at every stage of standards development, such as the:

- a. Proposal and acceptance of new work items;
- b. Technical discussion on proposals;
- c. Submission of comments on drafts in order that they can be taken into account;
- d. Reviewing existing standards;
- e. Voting and adoption of standards; and
- f. Dissemination of the adopted standards¹⁸⁸.

Besides openness, the 2000 TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement lists also transparency, impartiality and consensus, effectiveness and relevance, coherence and development dimension and principles to be observed in the construction of international standards.

In the *US Tuna II*, the Appellate Body understood that a ‘TBT Committee Decision can be considered as a ‘subsequent agreement’ within the meaning of Article 31 (3) (a) of the Vienna Convention. The extent to which this Decision will inform the interpretation and application of a term or provision of the TBT Agreement in a specific case, however, will depend on the degree to which it “bears specifically” on the interpretation and application of the respective term or provision’¹⁸⁹.

Arcuri remarks that ‘if, on the one hand, the Decision introduces principles that could enhance the transparency and participatory dimensions of international standard bodies, on the other hand, it has been criticized as attempting to ‘shape and constrain international standard setting in the light of the norms and priorities of Geneva’¹⁹⁰.

From an economics point of view, many certification rules would fit the 2000 Decision terms ‘market needs’ as ‘regulatory needs’, since a need for regulation, whenever read from a neoclassical economics standpoint, happens when there is market failure and many international labelling standards would fit such requirement since they deal with asymmetry issues¹⁹¹.

Moreover, in *US - Tuna II*, the Appellate Body, in an interpretation of the term ‘recognized body’, understood that the meaning should be a broad one by linking its interpretation to the ISO/IEC definition: ‘the definition in the ISO/IEC Guide 2: 1991 adds to and complements the definition in the TBT Agreement, specifying that a body must be ‘recognized’ with respect to its activities in standardization’¹⁹². However, the Appellate Body understood that the broad participation on standards development might constitute evidence that a body has a

¹⁸⁸ G/TBT/9, 13 November 2000, para. 20 and Annex 4.

¹⁸⁹ *US – Tuna II* (Appellate Body Report), *supra*, para. 372.

¹⁹⁰ Arcuri, *supra*, at 509.

¹⁹¹ *Id.*

¹⁹² *US-Tuna II* (Appellate Body Report) *supra*, para. 357.

recognized role on standardization¹⁹³. Nevertheless, at the same time, an organization that has developed a single standard might also have ‘recognized activities in standardization’¹⁹⁴.

In the SPS Agreement, the only clause that could accommodate private standards is the definition set in Annex A, paragraph 1, wherein it is brought a specific definition of a sanitary and phytosanitary measure.

Sanitary or phytosanitary measure - Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures (...)

Many scholars have questioned whether or not such definition would include non-governmental measures within the features of private standards. Some would say that ‘all relevant laws, decrees, regulations, requirements and procedures’ do not include non-governmental measures, within an interpretation of Panel’s not specific rulings¹⁹⁵.

Moreover, the Preamble of SPS refers to Members, which would suggest that only Members’ measures would fit in the agreement¹⁹⁶.

However, such views would only stand if the SPS Agreement could be seen as a separate agreement, totally dissociated from the rest of WTO law, which is not the case. Marceau and Trachtman well remember that WTO Agreements comprehend a single treaty – under the single undertaking principle¹⁹⁷ and as such, in those matters that are not specificity of the SPS agreement, principles and definitions from other parts of WTO law could be accommodated in SPS measures through a dialogue of complementary¹⁹⁸. The definition of standards provided in the TBT Agreement could be easily transposed to SPS since it is the only agreement that sets a definition of standard, which does not mean that it would break the specificity exclusion of TBT, Article 1.5, which clearly excludes the application of the ‘TBT provisions’ to ‘SPS measures’, but do not exclude definition of terms.

¹⁹³ Id, para. 357.

¹⁹⁴ Id, para. 394.

¹⁹⁵ See Arcuri and the mention to unpublished work on this subject, *supra* at 517.

¹⁹⁶ Id at 516.

¹⁹⁷ Gabrielle Marceau & Joel P. Trachtman, *A Map of the World Trade Organization Law of Domestic Regulation of Goods: The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade*, *Journal of World Trade* 48, 2 (2014).

¹⁹⁸ See Vieira, Andreia Costa, *International Trade and the Environment: a dialogue of sources or fragmentation of international law?*, In: PEPA/SIEL Proceedings, Goettingen (2013).

Besides, the SPS Agreement, Article 13, establishes a rule on implementation of the agreement, which extends Members' measures to non-governmental ones, as such:

(...) Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement (...).

Although some scholars have argued that such a clause rules out private standards from SPS¹⁹⁹, we do not understand it in this way; quite the opposite. Such a narrow interpretation of the clause does not go with the ongoing work developed in the SPS Committee on a definition of private standards, as we have remarked earlier. Therefore, private standards do not stand alone under the auspices of the TBT structure, but it is also accommodated within the SPS provisions. Under the single undertaking principle, they should be interpreted together in the name of coherence and harmony within WTO law.

Alessandra Arcuri ends up her comments on private standards by raising the question that 'from a normative point of view, it may be complex to draw a line between private standards that could legitimately be subjected to WTO law and standards that may not. These considerations highlight the fact that the binary question (is it desirable/undesirable to bring private standards under the purview of WTO law) may not be easily answerable. Instead, the question could be reformulated as one of the degree: to what extent can the existing WTO legal framework address the trade-related problems created by the emergence and operation of private standards, without losing legitimacy?'²⁰⁰.

Besides WTO, the market itself has provided legitimacy to the many private standards that have proliferated and been accommodated within global value chains. The problem has been to sustain such legitimacy for a longer time, since proliferation of new rules and new certificates have been common ground on distinct sectors and, as such, have created confusion for producers and consumers, delegitimizing them with a certain period of time. Sustainability of legitimacy for most private standards already existent could be found in meta-regulation, as it will be presented later on in this essay. The issue of accountability adds concerns to legitimacy since, under law, security is a matter of certainty.

3.7. General Accountability and State responsibility

In 2005, the small Caribbean island of St. Vincent, a sovereign State Member of the WTO, raised a Specific Trade Concern, under the WTO Committee on Sanitary and Phytosanitary Measures (SPS Committee), complaining about restrictions on the sale of bananas to the European Union. Such concerns were not about the official pesticide residue requirements of the EU, but instead on the requirements of a private, non-profit organization so called GLOBALG.A.P. (in 2005, known as EUREPGAP)²⁰¹. That was the first time that the issue of private standards was raised for discussions in the WTO.

In general, WTO only takes into consideration voluntary standards when they belong to international standardization bodies, such as ISO or Codex, and the WTO agreements refer to

¹⁹⁹ See Arcuri, *supra* at 520.

²⁰⁰ *Id.* at 522.

²⁰¹ G. H. Stanton, *Food safety-related private standards: the WTO perspective*, in A. Marx, M. Maertens, J. Swinnen and J. Wouters (org.), *Private Standards and Global Governance. Economic, Legal and Political Perspectives*, 235 (2012).

them as a means of harmonization (See TBT and SPS Agreements²⁰²). Whenever countries use these international standards for products entering their territory, there is a 'presumption of conformity'.

In the TBT and SPS Committees, the issue of private standards have been raised on the basis of Specific Trade Concerns (STCs), which are instruments that have grown in importance in the WTO, whose role has diversified in the last years and has accommodated preventive and policy discussions on the basis of eliminating barriers even before they become violations.

One of the tasks of both TBT and SPS Committees is to manage the STCs that Members might raise before them. STCs might be simply search for information concerning other Member's domestic measures on technical regulations or sanitary and phytosanitary policies. Nevertheless, STCs have often addressed conflicts of positions between Members under the TBT and SPS agreements. Under STCs, Members might not be just demanding information or clarification, but, at the same time, they might be pointing out that there are reasons to think that some rights and obligations under the SPS and the TBT Agreements have not been met.

Studies on STCs have pointed out the growing importance of such mechanism for resolution of trade conflicts, both for developing and developed countries, coming to a conclusion that the mechanism of STCs has significantly contributed to minimize trade tensions in TBT and SPS concerns²⁰³.

As we have remarked earlier, the definition of market/private standards as voluntary ones is highly questionable. Since the exporter does not conform to the standard, it cannot sell its products on the importing market²⁰⁴.

For example, the above mentioned 2009 EU Directive establishes that biofuels and bioliquids cannot be produced from raw materials extracted from land rich in biodiversity, which from January 2008 has the following characteristics: being primary forest or wooded land, indigenous areas protected under law, endangered species protection areas or pastures areas rich in biodiversity, either natural or cultivated²⁰⁵.

Fulfilment of the Directive requirements is expected from the economic operators that might comply with it through voluntary regimes or bilateral or multilateral agreements, including certification procedures²⁰⁶. Nevertheless, the main issue regarding the multilateral trading system, is whether the EC Directives have adopted a trustful scientific model, which would allow impact measurements consistent with the side effects that it has provoked, which makes it open to dispute or STCs under the WTO system²⁰⁷.

Moreover, irrespective of having or not scientific basis, the creation of such standards also raise concerns on accountability under a market/government failure and a multilateral trade system perspective.

²⁰² See TBT, Code of Good Practices (Annex 3) and SPS, Preamble and Article 3(1).

²⁰³ See Thorstensen, Vera and Vieira, Andreia Costa, TBT, SPS and PS: are the wolves of protectionism disguised under sheep skin?, CCGI-FGV, 2015.

²⁰⁴ See Lima, *supra*, at 7.

²⁰⁵ *Id.* at 9.

²⁰⁶ *Id.* at 10.

²⁰⁷ *Id.* at 11.

International standards are encouraged, in general, under TBT. In order to harmonize regulations on a broad scale, Members should play a full part

2.6. [I]n the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

If a regulation is prepared, adopted or applied in accordance with relevant international standards, according to Article 2.5, ‘(...) [I]t shall be rebuttably presumed not to create an unnecessary obstacle to international trade’.

Besides, the TBT Agreement also provides for circumstances when there is not a relevant international standard or when a regulation is not in accordance with the technical content of relevant international standard and, according to Article 2.9, Members should proceed to notifications at an early appropriate stage, when amendments can still be introduced and comments taken into account, identifying, whenever applicable, the parts which in substance deviate from relevant international standards.

Annex 3 of TBT provides for a Code of Good Practice for Preparation, Adoption and Application of Standards. In the General Provisions of the Code of Good Practice, it is provided that the Code is open to acceptance by any standardizing body – whether a central government body, a local government body or a non-governmental body – within the territory of a WTO Member.

TBT, Article 4, demands Members to ensure that their central government standardizing bodies as well as non-governmental bodies within their territories accept and comply with the Code of Good Practice. Moreover, it also provides that the obligation of Members in relation to compliance of standardizing bodies with the commandments of the Code of Good Practice ‘shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice’.

In the Code of Good Practice, paragraph E, it is provided that the standardizing body, which might be a non-governmental one (See definition of a non-governmental body above), shall ensure that standards are not prepared, adopted or applied ‘with a view to or with the effect of creating unnecessary obstacles to international trade’.

One of the discussions in the SPS Committee was based on the wording of Article 13 of the SPS Agreement. The requirements for Members are clear-cut: they shall take reasonable measures to ensure that non-governmental bodies comply with the provisions of the SPS Agreement (See full text of Article 13 above).

A parallel requirement is also established in the TBT Agreement. Article 3 of TBT demands that:

With respect to their local government and **non-governmental bodies within their territories:**

3.1 Members shall take such reasonable measures as may be available to them to **ensure compliance by such bodies with the provisions of Article 2** (...) (emphasis added)

In the TBT Committee, negotiations on private standards have not reached further results²⁰⁸. The core of the discussions on the TBT Committee is the adoption of the Code of Good Practices by private bodies²⁰⁹.

Recently, it has been observed either implicit or explicit government support for market standards and they have become, mainly in matters of certification, a regulatory barrier to trade. Some of them have been mentioned even on State's regulation or public procurement contracts. The grey area between the State's involvement and the private sector's only involvement makes it more difficult to point out a violation issue under the WTO system. Nevertheless, it seems that whenever it is possible to show evidence of State's involvement in the private standard implementation, it might be possible to raise an issue of State's responsibility²¹⁰. Such an understanding cannot be ignored under Specific Trade Concerns in the TBT and SPS Committees.

On matters of violation, the difficulty would be, in any case, to establish what would be the level and deepness of State's involvement in order to establish that a private standard has become a 'private standard backed by government' and, as such, 'mandatory under law'.

In the EC Directives above mentioned, the UE has accepted market standards as a way of complying with the requirements of its legislation. It seems reasonable that it could be raised a claim for State's responsibility under the TBT and SPS Committees, under STCs, since Members shall ensure compliance to these agreements by non-governmental bodies²¹¹.

Governments can be responsible for actions of private parties. In Japan-Film, it was argued that although it might not be easy to determine 'bright-line rules', whenever there is 'sufficient government involvement' with it, it might be found that such measure is governmental²¹². Such understanding was adopted under the GATT/WTO system but it could also be extended to other matters.

On matters of scientific evidence, for instance, proliferation of market standards have spread sometimes with no scientific basis but instead for pure market preference concerns pointing out to 'holdings' on global value chains. As such, accountability concerns within the WTO system and within other plurilateral or regional arrangements might be detected and might be dealt with under State's responsibility for non-governmental bodies.

3.8. Meta and Transnational governance on Market/Private Standards

'Social compliance' is for most contemporary businesses on the 'order of the day' due to a spread of private standards initiatives to regulate working conditions in the industries' global supply chains, considering an ongoing quest for best practices. 'From the company perspective, this multiplicity also makes for a "crowded and costly market in social

²⁰⁸ M. K. Amaral, 'Padrões Privados e Outras Fontes não tradicionais de governança no âmbito dos regimes multilateral de comércio da OMC e de Mudança Climática: Conflito ou Convergência?' UNB, Brasília, 2014 (PhD thesis), 244.

²⁰⁹ G/TBT13; G/TBT/26; G/TBT/32.

²¹⁰ M. K. Amaral, *supra*, at 248.

²¹¹ Lima, *supra*, at 23.

²¹² Panel Report, Japan – Measures Affecting Consumer Photographic Film and Paper, WT/DS44/R, adopted 22 April 1998, para. 10.56.

compliance”, as factories supplying several brands may have to deal with various codes and certifiers and their sometimes conflicting demands²¹³.

In 2003, some key members of civil society and multi-stakeholder entities in the worker’s rights field gathered together to create the Joint Initiative on Corporate Accountability and Worker’s Rights (JO-IN)²¹⁴. Each one of these entities has been involved in the task of improving working conditions mainly in the apparel global supply chains, by reducing duplication of efforts as well as identifying best practices²¹⁵. The last efforts on this project were undertaken in 2007, since the joint operations did not manage to come to a consensus on an appropriate system for code implementation and compliance verification²¹⁶.

Another sector that joined efforts to have meta-governance on market standards was the sector of organic agriculture²¹⁷. The multiplicity of private labels and certification and assessment procedures had a deep impact on organic producers, mainly on smallholders that were engaged in international trade. The International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) was launched in 2003, in a joint effort of UNCTAD, FAO and International Foundation for Organic Agriculture (IFOAM)²¹⁸. Between 2003 and 2008, many agreements between public and private sectors individuals were achieved on how to reduce barriers to organic trade. ITF Tools were developed in 2008 – the International Requirements for Organic Certification Bodies IROCB and the Tool for Equivalence of Organic Standards and Technical Regulations (EquiTool)²¹⁹. The ITF work was enhanced by the project Global Organic Market Access (GOMA) that took place from 2009 to 2012, aiming at facilitating and giving support to regional harmonization and equivalence processes on the sector²²⁰.

ITF and GOMA have had their history of success. First, they have indeed enhanced public-private collaboration on the establishment of market standards in the organic sector. Second, they have supported harmonization and equivalence among stakeholders. Third, some high quality tools, i.e. EquiTools, have been developed under their auspices²²¹. However, ‘on the whole, the uptake of the ITF’s tools has remained rather limited so far’ and there are ‘few indications that the Task Force’s various recommendations have already had tangible impacts on the decision making processes of the regulatory arena’s major players’²²². Nevertheless, ‘as the ITF was an outward-oriented institution, aiming to change the wider regulatory environment rather than merely the practices and standards of its participants, the effective set up and implementation of the process was not by itself enough to bring about the desired amounts of regulatory change’²²³.

²¹³ Boudewijn Derkx, UNFSS, *Meta-governance in the Realm of Voluntary Sustainability Standards: early experiences and their implications*, UNFSS Discussion Papers, 1, 2 (2013).

²¹⁴ The six private entities are: Clean Clothes Campaign, Ethical Trading Initiative, Fair Labor Association, Fair Wear Foundation, Social Accountability International and Workers Rights Consortium (“the organizations”).

²¹⁵ Worker’s Rights JO-IN, <http://www.jo-in.org/english/about.html> (last visited Feb. 5 2015).

²¹⁶ Derkx, *supra* at 3.

²¹⁷ See Diane Bowen & Ulrich Hoffmann, UNFSS, *Review of Key Systemic Issues and Findings Resulting from Activities of the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) and the Global Organic Market Access (GOMA) Project*, UNFSS Discussion Papers, 2, (2013).

²¹⁸ ITF, <http://www.organic-world.net/itf.html> (last visited Feb. 5 2015).

²¹⁹ Tool for Equivalence of Organic Standards and Technical Regulations (EquiTool), <http://www.organic-world.net/itf.html> (Feb. 5 2015).

²²⁰ GOMA <http://goma.tops.net/about/project/> (Feb. 5 2015).

²²¹ Derkx, *supra* at 7.

²²² *Id.*

²²³ *Id.* at 8.

In 2002, some certification organizations – Forest Stewardship Council (FSC), the International Federation of Organic Agriculture Movements (IFOAM), Fairtrade and Marine Stewardship Council (MSC), the International Organic Accreditation Service, Marine Aquarium Council, Rainforest Alliance and Social Accountability International - created the International Social and Environmental Accreditation and Labelling Alliance (ISEAL Alliance)²²⁴. In 2010, it was established the ISEAL Stakeholder Council, joining together other representatives from business, government, civil society and academia and, in 2012, ISEAL expanded its programme of work to address sustainability issues in Brazil, India and China.

After an elaborated work on best practices for sustainability standards, ISEAL launched its Codes of Good Practice (2004), the ISEAL Impacts Code (2010) and the ISEAL Assurance Code (2012), which provide procedures on how standards systems may effectively measure and evidence contribution to social and environmental impacts²²⁵.

However, 'ISEAL's other work programs combining conceptual work on the development of good practice guidance with related shared learning and capacity building activities have progressed a lot slower and been less effective. Cooperation within ISEAL has thus far also yielded relatively little in terms of successful tangible collaboration on concrete projects²²⁶.

In general, there has been an urge for meta-regulation on general market standards, in order to resolve concerns related to legitimacy and accountability, which were a summary of the problems faced by the meta-regulation attempts presented above by sectors. The difficulty is to reach a common ground on which body could play such a role.

3.8.1. The Role of ISO

ISO is the International Organization for Standardization²²⁷ and it categorizes private standards into distinct ways according to ISO work on standards: i) PS in the Information and Communication Technologies sector (ICT); ii) PS in the agri-food sector; and iii) PS related to social and environmental aspects²²⁸.

ISO has been pointed out as a possible body to meta-regulate private standards. 'In the environment and related areas, ISO provides international standards addressing such subjects as environmental management (ISO 14001/4) ; environmental labelling (ISO 14020/21/24/25), lifecycle assessment (ISO 14040/44) ; greenhouse gas measurement, verification and validation (ISO 14064/65) ; and drinking water and wastewater services (ISO 24510/11/12)'. Moreover, ISO has recently engaged in the development of new standards – the ISO 26000 – on social responsibility²²⁹.

Notwithstanding the acknowledgeable standardizing role developed by ISO, there is a good amount of criticism on the status that ISO has in the WTO. ISO has been 'stigmatized as a club dominated by private industrial groups, where civil society has no real role to play. ISO members are national standards bodies; many of which in turn are private non-profit groups, often dominated by private companies. Not only is civil society excluded from the decision-making process – it may not even exercise a critical role, as proposed standards are difficult to access. Even adopted ISO standards cannot be accessed free of charge but must be purchased.

²²⁴ ISEAL Alliance <http://www.isealalliance.org/about-us/our-history> (last visited Feb. 6 2015).

²²⁵ ISEAL Assurance Code (2012), <http://www.isealalliance.org/about-us/our-history> (last visited Feb. 5 2015)

²²⁶ Derkx, 2013, at 10.

²²⁷ ISO at <http://www.iso.org/iso/home/about.htm> (last visited Jan. 27 2015).

²²⁸ See ISO, International Standards and Private Standards, Geneva, 6 (2010).

²²⁹ ISO, International Standards and Private Standards, Geneva, 7 (2010).

Such legitimacy and accountability issues may appear irreconcilable with the privileged status that ISO standards seem to have at the WTO,²³⁰.

As above remarked, meta-regulation has also been produced by ISO. However, it is highly questionable, due to the reasons mentioned in the last paragraph, that ISO would be the right standardizing body to deal with meta-regulation on market standards. Since market standards have dealt with changes in global production markets and have highly influenced the way producers work in developed as well as in developing countries, perhaps an institution that would be more concerned with the social and environmental impacts of private standards, mainly in developing countries, would be a better option for meta-regulation on this matter.

3.8.2. The Role of UNFSS and the building up of domestic VSS platforms

3.8.2.1. *The UNFSS*

The United Nations Forum on Sustainability Standards is a joint initiative of FAO, ITC, UNCTAD, UNEP and UNIDO, consisting of a platform of International Dialogue on Voluntary Sustainability Standards (VSS), which are related to environmental, social, occupational safety and animal welfare issues²³¹.

In the UNFSS platform, private standards are termed VSS and are defined in a broad but directed way. Thus, ‘voluntary sustainability standards (VSS) are standards specifying requirements that producers, traders, manufacturers, retailers or service providers may be asked to meet, relating to a wide range of sustainability metrics, including respect for basic human rights, worker health and safety, environmental impacts, community relations, land-use planning and others’²³².

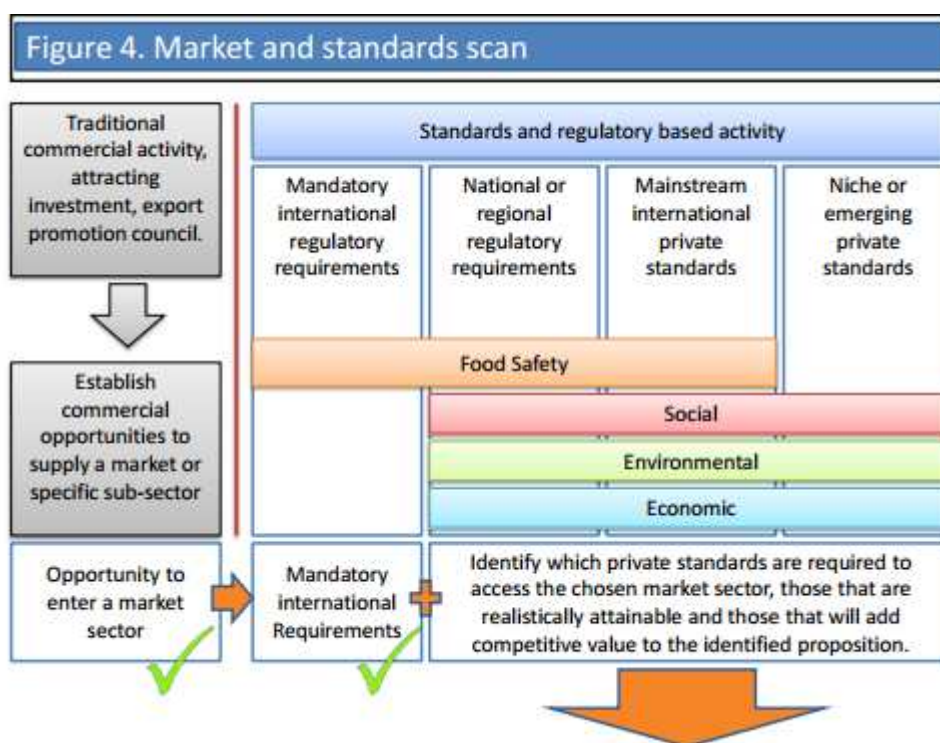
In 2013, there were presented the following rational for creating the UNFSS: ‘i) VSS as means to sustainable development, not as ends in themselves; ii) Contextualize VSS into the macro-economic development perspective (i.e. not only market access and market shares agenda); iii) UNFSS should focus on public interest and public goods related to VSS; iv) VSS need to be recognized as strategic policy issue (mitigating economic, food, climate and water crises); v) understood within overall life cycle of products and related services (and within context of avoidance, minimization and management of ‘real’ risks); vi) also of increasing importance for South-South trade; vii) VSS represent a new meta-governance system for international supply chains, largely outside WTO rules’²³³.

²³⁰ Arcuri, *supra*, at 495.

²³¹ See information on UNFSS on <http://unfss.org/about-us/objectives/> (Access on 18th December 2014).

²³² UNFSS Platform, available at http://unfss.files.wordpress.com/2012/05/unfss-report-issues-1_draft_lores.pdf (Access on 15th January 2015).

²³³ UNFSS Forum on Sustainability Standards, Geneva, 2013.



Source: UNFSS, 2015

Taking into consideration the growing concerns on VSS - related to their potential on becoming a trade barrier and the obstacles to development that they may create, mainly for small-scale producers and developing and least developed countries - the UNFSS has become a forum for State actors to dialogue with each other and with some core groups, such as traders, consumers, producers, certification bodies, diplomats, NGOs and scholars. 'The overall goal of UNFSS activities is to make VSS a driver and avoid it being an obstacle to sustainable development in developing countries'²³⁴.

Moreover UNFSS intends to drive attention to the marginalization of smallholders and small and medium-sized enterprises²³⁵. Such work might be accomplished through analytical procedures and activities, having exchanges of experiences and constructing a network among stakeholders²³⁶.

The UNFSS Forum works taking into account the three pillars of sustainable development – environmental, social and economic standards, with a first emphasis on the agri-food standards and energy/ resources/climate-change-related VSS, considering the interaction between food production and climate change (mitigation-adaptation) as well as energy efficiency and carbon footprint²³⁷.

Despite special concerns towards developing countries, the UNFSS has an open membership with no minimum requirements to UN Member States. It is composed of a Steering Committee and an Advisory Panel. The Steering Committee comprehends the five

²³⁴ UNFSS, available on <http://unfss.org/about-us/objectives/> (Access on 18th December 2014).

²³⁵ UNFSS.

²³⁶ UNFSS.

²³⁷ UNFSS.

collaborating UN Agencies - FAO, UNIDO, ITC, UNEP and UNCTAD, and is in charge of facilitating management and coordination of the Forum. The Advisory Panel, for instance, is composed of 20 experts representatives of the core groups - i.e. producers, consumers, traders, trade diplomats, standard setters, certification bodies, NGOs and scholars and has the role of providing guidance on development of the forum, as well as information gathering and analytical, empirical and capacity building support for stakeholders. The Advisory Panel is in charge of setting direction, presenting main tasks and priorities in the meetings²³⁸.

Besides, the UNFSS has a support team, hosted by UNCTAD and coordinated by the UNCTAD Secretariat.

Structure of the United Nations Forum on Sustainability Standards (UNFSS)



Source: UNFS (2014)

The primary focus of the UNFSS activities is on VSS developed by non-governmental organizations and private companies, which have been categorized into distinct categories: i) business-to-business standards; ii) consumer-oriented standards; iii) meta standards covering different issues and groups of products; iv) issue and commodity specific standards; and v) company-specific standards.

In general, the expectations of the UNFSS is that it ‘will contribute to poverty alleviation, strengthening of food security, improvement of resource/ material/ energy efficiency and enhanced mitigation of and adaptation to climate change’²³⁹.

The UNFSS intends to take into account that ‘adoption of VSS tends to be favored in contexts where: i) the type of product has high requirements regarding traceability, ii) in extractive businesses; iii) where commodities are identifiable in end-products, or iv) where there are shorter supply chains with fewer actors; v) VSS tend to be more viable in contexts with higher levels of producer and institutional preparedness’²⁴⁰.

In 2013, several briefing sessions were organized and took place in Geneva (February 18th 2013), China (March 4th 2013); Thailand (March 13th 2013), Kenya (March 2013) Panama (May 9th 2013), Cameroon (June 27th 2013) and in the Philippines (October 24th 2013).

²³⁸ UNFSS. In: <http://unfss.org/about-us/structure/>

²³⁹ UNFSS, available on <http://unfss.org/work-areas/> (access on 18th December 2014).

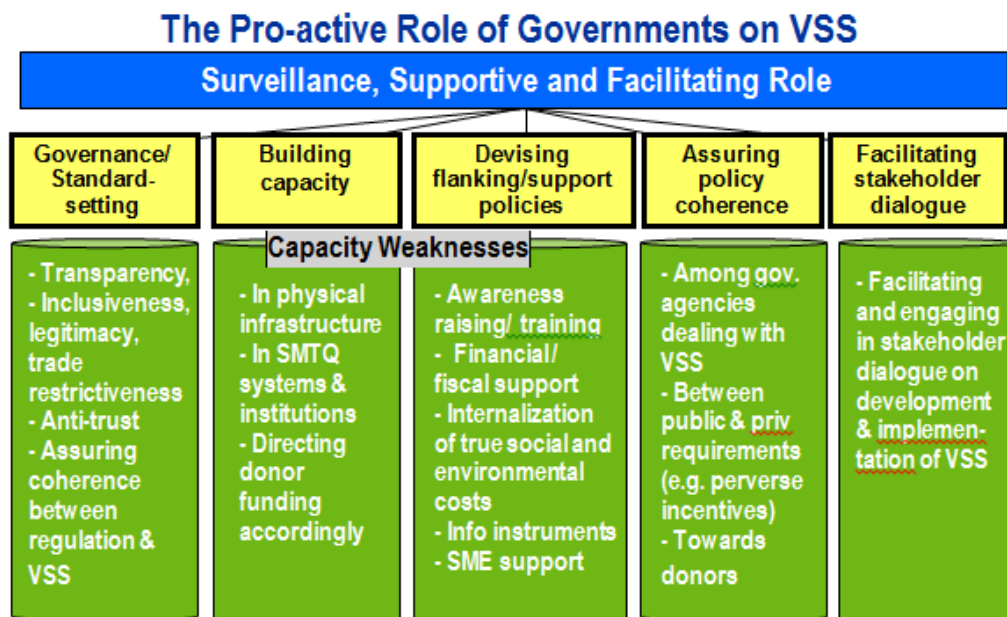
²⁴⁰ Joseph Wozniak, Taking Stock of the current research on the impacts of voluntary sustainability standards, Based on a 4-part literature review series published by the International Trade Centre (ITC), March 2013.

One of the main roles of the UNFSS: taking into consideration asymmetries on establishment of standards, since the optimum level of sustainability is different in different countries. See VSS Part 1 (Issues), at 10.

3.8.2.2. The building up of domestic VSS platforms

The UNFSS is the only intergovernmental forum that proposes to deal specifically with private standards, on a multi-stakeholder level. It is intended to be a ‘demand-driven forum’ to address concerns and interests of decision makers based on developing countries.

According to the UNFSS, national governments have a tripartite role on VSS platforms – surveillance, supportiveness and facilitation that can be detailed in the table below:



Source: UNFSS, 2013.

In the UNFSS launching conference that took place in Geneva, in 2013, titled ‘Policy Making and Sustainability Standards: How can governments and the private sector work together to achieve sustainable development goals?’, there was acknowledgment of the importance of a national dialogue between key stakeholder groups VSS policies. Therefore, there was a proposal for the establishment of national multi-stakeholder platforms for policy studies and dialogue, under the supervision of the UNFSS.

3.8.2.2.1. The building up of a VSS platform in India

India was the first country to have launched its national VSS platform under the auspices of the UNFSS, envisaging the building of technical and institutional capacity (i.e. standards, metrology, testing and quality assessment procedures) as well as policy structuring, taking into account the true social and environmental costs²⁴¹.

²⁴¹ See <http://unfss.org/2014/08/20/unfss-in-ciiissd-conference-new-delhi-india/> (access on 29 January 2015)

The Indian platform is intended to promote a dialogue based on case studies and technical reports on VSS distinct subjects. The primary concern is the conduction of a dialogue with the ASEAN Task Force on Horticultural and Food Product Standards, besides establishing a direct connection with the West African International Cocoa Organization to work on schemes of sustainable cocoa certification²⁴².

In India, some of the most important VSS already implemented are ECOMark, AgroMark, IndGAP, Fruit Product Order (FPO) and mandatory farming production standards implemented under the National Programme for Organic Production²⁴³. Differently from other countries, in India, VSS systems and approaches are implemented under integrated government management schemes, even though they seem to be focused on needs and demands of the industry²⁴⁴.

According to the Indian government, there are the following envisaged objectives for such a national platform on VSS:

Envisaged objectives for a national platform on VSS in India

1	To conduct a dialogue on a regular basis within a core group of public and private stakeholders and build a more institutionalized structure to facilitate and strengthen an informed policy dialogue on how to pro-actively use VSS to fulfil specific sustainable policy objectives, strengthen competitiveness and facilitate market access.
2	To gather and exchange information on key issues and concerns related to VSS in India and assess the information needs of Indian policy makers and other stakeholders. This will include discussions on best cases/practices and learning from successful examples in India and other countries.
3	To assist Indian standard setting organizations in arranging for training and developing effective VSS frameworks and how to prepare the domestic users for effective VSS use. Special attention should be paid to assist small-scale producers in complying with VSS.
4	To identify key areas of research interest and assist in conducting such research in collaboration with selected national and international partners.
5	Strengthening cooperation between relevant stakeholder groups to the benefit of more inclusive standards development and more effective VSS implementation, based on better policy coherence and public-private dialogue.
6	Assist policy makers in framing effective pro-active policies to reach specific sustainable development goals, including better market access and strengthened competitiveness.
7	Study specific success examples of VSS development, use and supportive government action in India, such as the National Programme for Organic Production, and explore in what way such examples can be emulated.

Source: UNFSS, 2014²⁴⁵

In general, the main objective of the platform is helping to create a UNFSS focal point in India, in order to coordinate between UN Geneva, UNFSS India platform composed of public/private sector, industry etc. and Indian policymakers, thus establishing a feedback system that would build on a whole scenario for private standards²⁴⁶.

In India, the public institutions involved in the platform are the Ministry of Commerce and Industry (focal point), the Ministry of Agriculture, the National Accreditation Board for Certification Bodies, the Council of India, the Bureau of Indian Standards, the Agriculture Processing Export Development Authority, the National Agriculture Innovation Project, the

²⁴² UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 1.

²⁴³ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 4.

²⁴⁴ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 4.

²⁴⁵ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 6.

²⁴⁶ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 6.

Indian Council for Sustainable Agriculture and other commodity boards. On the other hand, the elements of the private sector involved are the Confederation of Indian Industry, the Federation of Indian Chambers of Commerce and Industry, the Energy and Resource Institute, some certification companies and relevant NGOs that work with VSS, such as SARSO, OXFAM, ISEAL, ANSI and HIVOS India, besides some Small and Medium-sized Enterprises (the platform would be kept open to other key decision-makers on VSS and VSS implementation strategies)²⁴⁷.

3.8.2.2.2. The building up of a VSS platform in China

China also proposed the construction of a VSS platform, under the auspices of the UNFSS. The primary concern, in China, is also the conduction of a dialogue with the ASEAN Task Force on Horticultural and Food Product Standards²⁴⁸. In general, with such a structure, China pretends to harness the benefits of VSS and increase competitiveness as well as to have an overview of the strategically important VSS issues for the country²⁴⁹. The focus of China would be private sustainability standards in the fields of food safety and quality as well as their interplay with Chinese standards and Chinese quality control systems in the agricultural area²⁵⁰.

The bases for the Chinese platform are the same as the ones for the Indian VSS platform. The objectives envisaged by the national platform on VSS in China are about the same as in India as well as the possible platform format and approach²⁵¹.

Both in China and India, the platform is financially supported by co-funding – by UNFSS and public and private bodies. The building up of a platform is a way of creating a UNFSS focal point in China in order to coordinate public/private sector as well as international actions towards policymaking on VSS, providing a kind of roadmap for governments and a mechanism of continuous feedback on VSS. In fact, the idea is to construct a network of national platforms that will benefit of co-sharing information, which might be, in the end, a good structure for developing countries in a world full of developed countries' private standards.

In China, the institutions involved in the platform are the Ministry of Commerce (**WTO Department as the focal point**), the Ministry of Agriculture, the Ministry of Environmental Protection, the National Development and Reform Commission, the General Administration for Quality Supervision, Inspection and Quarantine, the China Administration for Accreditation and Certification, the China Administration for Standardization, the China Certification and Accreditation Institute and other correlated scholarly bodies²⁵².

The Chinese comments on the proposal of a platform remark the importance of harmonization and equivalence in the area of private standards, which is really the key point on this matter. 'Consistency, harmonization and equivalence between Chinese standards and those of ASEAN countries as well as the private sustainability standards applied by both trading

²⁴⁷ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 6.

²⁴⁸ UNFSS, National Platform on Private Sustainability Standards in India, Concept Note, 2014, at 1.

²⁴⁹ UNFSS, National Platform on Private Sustainability Standards in China, Concept Note, 2014, at 1.

²⁵⁰ UNFSS, National Platform on Private Sustainability Standards in China, Concept Note, 2014, Annex.

²⁵¹ See Table on Indian Envisaged objectives above.

²⁵² UNFSS, National Platform on Private Sustainability Standards in China, Concept Note, 2014, at 6.

partners are therefore of increasing strategic importance for market access, competitiveness and sustainability impact'²⁵³.

Moreover, remarks have also pointed out that the VSS platform may also make an important contribution to debates on free trade agreements (e.g. the Trans-Pacific Partnership Agreement or Regional Comprehensive Economic Partnership) and that it could represent the involvement of China into ASEAN discussions about related regional standards for the ASEAN common market (mutual interest/ coherence of standards agenda); e.g. private GAP standards in ASEAN countries could be harmonized with Chinese standards, the new ASEAN GAP (+China) could offer an important opportunity for exchange in agricultural trade²⁵⁴.

3.8.2.2.3. The need of a VSS focal point in Brazil

The building up of VSS platforms is matter of transparency as well as of governance and strategic planning. Governments should not ignore the urgency of the matter and should plan in advance, before the concern becomes an unmanageable political problem for the country.

In the negotiations of the 1979 Standards Code, a provision was set for notification of other governments, through the GATT Secretariat, of any technical regulations which were not based on international standards. Such a provision initiated what would develop into procedures based on the principle of transparency²⁵⁵.

Transparency is one of the main principles established in the TBT agreement. Throughout the agreement, the expressions “Members shall publish a notice” or “Members shall notify” are commandments related to transparency for standards, technical regulations or conformity assessment procedures. In TBT, Articles 2.9, 2.10, 3.2, 5.6, 5.7 and 7.2 set such a wording.

Article 2.9 of TBT, for instance, provides that:

Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;

2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;

²⁵³ ‘Couching the National Platform on Voluntary Sustainability Standards into the Development and Export Strategy of the PR of China’, In: UNFSS, National Platform on Private Sustainability Standards in China, Concept Note, 2014, Annex, General Observations.

²⁵⁴ ‘Couching the National Platform on Voluntary Sustainability Standards into the Development and Export Strategy of the PR of China’, In: UNFSS, National Platform on Private Sustainability Standards in China, Concept Note, 2014, Annex, General Observations.

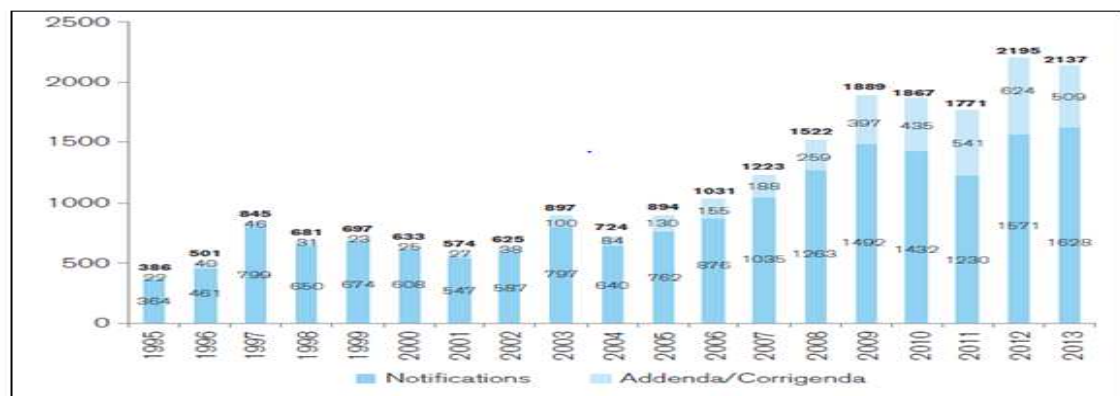
²⁵⁵ R. Griffin, *supra*, at note 1.

2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

The notification provisions in the TBT show how members intend to regulate in order to achieve specific policy goals and what are the trade effects of their regulations. Notifications have grown in importance in the last years. ‘Receiving information about new regulations or standards at an early stage, before they are finalized and adopted, gives trading partners an opportunity to provide comments either bilaterally or in the TBT Committee, and to receive feedback from industry’²⁵⁶. Early notifications might help to improve the quality of the draft regulation, thus avoiding potential trade problems, as well as to assist producers and exporters in adapting to the changing requirements²⁵⁷.

Since 1995, it has been observed a growing tendency of notifications in the TBT Committee, which demonstrates its importance within the WTO system and, at the same time, it demonstrates that regulatory measures have been more adopted by Members, in general, in substitution of the old tariffs measures (See Figures 4 and 5).

FIGURE 4: Total number of notifications from WTO members (1995-2013)



Fonte: The WTO Agreement Series, Technical Barriers to Trade, 2014, at 26.

²⁵⁶ The WTO Agreements Series, Technical Barriers to Trade, 2014, at 24.

²⁵⁷ Ibid.

FIGURE 5: Notifications Objectives



Source: CCGI-FGV, 2014²⁵⁸

Besides “notification expressions”, TBT Article 10 points out to the importance of establishing enquiry points in each Member. An enquiry point is a national body or institution which must be able to answer all reasonable enquiries from other Members as well as for the provision of related documents. All WTO Members are required to establish national enquiry points to keep each other informed about barriers that would fall under the TBT Agreement.

In Brazil, the focal point is INMETRO²⁵⁹, which is the National body responsible for the Brazilian WTO/TBT Enquiry Point, providing information on technical requirements to Brazilian exporters as well as supporting the Brazilian government in all international negotiations on technical barriers to trade²⁶⁰.

The same rule about enquiry points is established in the SPS (Annex B (3)).

Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

- (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
- (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
- (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
- (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within

²⁵⁸ Thorstensen, V. Giancesella, F., CCGI, 2014.

²⁵⁹ National Institute of Metrology, Quality and Technology (INMETRO) was created by law in December, 1973, to support the Brazilian enterprises, to increase their productivity and the quality of goods and services.

²⁶⁰ Information available on <http://www.inmetro.gov.br/english/institucional/index.asp> (Access on 3rd November 2014).

the scope of this Agreement, and the texts of such agreements and arrangements.

Under the SPS, Exporting Members claiming that areas within their territories are pest — or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest— or disease—free areas or areas of low pest or disease prevalence, respectively. For this purpose, under Article 6.3 of SPS, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Enquiry points are very important to assure transparency. **In some countries, the TBT and SPS enquiry points are the same bodies. In Brazil, they differ and there is an overlapping of competence between some Brazilian bodies, which difficult transparency in the country as well as strategic planning towards TBT and SPS common grounds²⁶¹. There should not be forgotten that a focal point is a centralization body, which reminds exporters, importers and investors that the country is under a single government and, as such, decisions should point to the same direction within a coherent and harmonized manner, providing legal and administrative certainty for all.**

As the issue of private standards is an urgent one, as demonstrated above with the construction of VSS platforms in China and in India, the Brazilian government should also be concerned in the building up of a focal point that will gather together all concerns related to private standards – the ones that would be classified as TBT as well as the ones that would be SPS measures in the name of transparency, governance and strategic planning.

Bearing in mind the Ministerial structure of the Brazilian government and having as a good example the composition of the VSS platform in China, a good parallel for Brazil could be having an Inter-ministerial body as a focal point, which could join together INMETRO (a standardization entity under the Ministry of Development, Industry and International Trade) and MAPA (a representative of the Ministry of Agriculture) as well as other Brazilian Ministries and entities - such as the Ministry of Environment, the Ministry of Foreign Affairs and some correlated scholarly bodies that could develop strategic research on the subject.

3.9. ITC: Standards Map

The International Trade Commission (ITC), which was formed in 1964, has been the focal point within the United Nations system for trade related technical assistance (TRTA)²⁶².

In line with a joint mandate from the World Trade Organization (WTO) and the United Nations through the United Nations Conference on Trade and Development (UNCTAD), ITC has supported the parent organizations' regulatory, research and policy strategies and it has focused on implementing and delivering practical TRTA projects²⁶³.

²⁶¹ While INMETRO is the TBT focal point, MAPA (Ministério da Agricultura, Pecuária e Abastecimento) is the SPS focal point, in Brazil.

²⁶² In: <http://www.intracen.org/itc/about/how-itc-works/our-role-in-the-un-and-wto/> (access on 23 April 2015)

²⁶³ Ibid.

Working together



Source: ITC, 2015

ITC's work focuses on the areas of expertise where ITC can have the greatest impact, such as strengthening the integration of the business sector of developing countries and economies in transition into the global economy, and improving the performance of trade and investment support institutions for the benefit of SMEs, besides enhancing the abilities of trade support institutions to better support them²⁶⁴.

Along with the United Nations family and partner organizations, ITC continues to connect ITC projects and programmes with global efforts to achieve the Millennium Development Goals and the Aid for Trade agenda. ITC remains the only international organization focused solely on trade development for developing and transition economies. In order to deliver effective trade-related technical assistance (TRTA) and to achieve the goal of expanding exports requires all the major players, including ITC, to develop effective working partnerships as well as greater levels of coherence and coordination. ITC's goal is to build on our capabilities and that of its partners in order to bring about even greater trade impact for good²⁶⁵.

Trade for Sustainable Development (T4SD) is ITC's partnership-based programme that provides comprehensive, verified and transparent information on voluntary sustainability standards through 'Standards Map', and through the 'Sustainability Marketplace' and 'SustainabilityXchange' web platforms²⁶⁶.

Standards Map enables its users to identify voluntary sustainability standards, generate comparisons between standards' content requirements, and to assess their business' sustainability roadmap to sustainable trade. The Sustainability Marketplace, launched at the end of 2014, intends to be an "e-market" where Standards Map users will share their business' "Sustainability Diagnostic Reports" with buyers and retailers, creating momentum for new

²⁶⁴ Ibid.

²⁶⁵ Ibid.

²⁶⁶ Ibid.

business opportunities²⁶⁷. The main objective of T4SD overarching programme is to strengthen the capacity of producers, exporters, policymakers, and private and public buyers to participate in more sustainable production and trade²⁶⁸.

The ITC Standards Map has served as a tool to identify Standards requirements and standards policies throughout the world. The standards map provides information on over 170 standards, codes of conduct, audit protocols addressing sustainability hotspots in global supply chains²⁶⁹.

A tutorial on identification of World Standards is available on the ITC webpage. As sustainability schemes proliferate, “transparency and comparability between schemes and benchmarking initiatives are driving change”²⁷⁰. Moving “from turf to trust” is the biggest challenge ahead, as a crowded standards marketplace moves towards harmonization, while maintaining some needed diversity²⁷¹.

3.10. Conclusion

Although the definition of ‘private standard’ in itself is not a pacific one, it must be taken into consideration that private standards may be considered ‘international standards’ and their ‘non-governmental character’ does not exclude them from the multilateral trade system; instead they might be well accommodated within the TBT and SPS Agreements. Private standards have been considered voluntary in nature, but they are *de facto* mandatory and whenever they are backed by governments, they might fall within the scrutiny of the TBT and SPS Committees, mainly under Specific Trade Concerns.

The present essay proposes also a new terminology - ‘market standards’, which would better comprehend all the transnational regulatory work that has been on-going, in fact. Nonetheless, a different terminology would not remove the concerns related to proliferation of such standards, which has brought big challenges towards legitimacy on creation and setting of such standards as well as accountability and State responsibility towards the behaviour of the bodies that have issued them.

Concerns related to legitimacy intend to answer questions such as:

- i) ‘who is producing the standards?’; and
- ii) ‘where such authority comes from?’

On the other hand, concerns related to accountability are related to:

- i) are there scientific basis for the creation of such standards?;
- ii) who responds for the setting of market standards under a market/government failure and a multilateral trade system perspective?

²⁶⁷ See more at: <http://www.intracen.org/itc/market-info-tools/voluntary-standards/#sthash.P8D8jmzF.dpuf> (access on 23 April 2015)

²⁶⁸ See more at: <http://www.intracen.org/itc/market-info-tools/voluntary-standards/#sthash.P8D8jmzF.dpuf> (access on 23 April 2015)

²⁶⁹ In: <http://www.standardsmap.org/> (access on 23 April 2015)

²⁷⁰ Schukat, P., In: <http://www.intracen.org/news/Sustainability-Standards-From-turf-to-trust/> (access on 23 April 2015).

²⁷¹ From: <http://www.intracen.org/news/Sustainability-Standards-From-turf-to-trust/> (access on 23 April 2015).

This essay proposes that meta-regulation would be the key to answer such questions and to calm down their related concerns.

Many meta-regulation efforts have been on-going, split in different sectors and strategic areas. This essay pointed out to the work developed under the structure of:

- i) The Organic Sector
- ii) The GLOBALG.A.P Initiative
- iii) The ISEAL project
- iv) The JO-IN Initiative

In general, so far, the existent meta-governance efforts have taken the structure of ‘an internally oriented collaboration between a limited number of like-minded peers active in the same sector’²⁷². In the end, their poor efficiency - as pointed out by some working papers and distinct scholars - is also related to legitimacy and accountability, since they do not diminish the overall problem of proliferation of standards, ‘standardization of standards’, and general confusion among producers and consumers, letting the market too free to decide whatever it wants to do.

Perhaps, a multilateral stakeholder structure, such as ISO or UNFSS would gather together a larger number of stakeholders and could have more legitimacy on the setting of meta-regulation on market standards, which could diminish the problems of ‘greenwashing’, anti-competitive practices and malpractices in the standards- setting business. ITC could also be helpful in the construction of a meta-regulation body, since it has already expertise on its Standards Map.

One of the biggest challenges would be the choice between a model of meta-regulation based on a ‘secretariat’ or based on ‘membership’²⁷³. A membership model – such as the one established by ISO - would generate more support for the meta-governance process among member organizations and States and perhaps would lead more easily to a plurilateral or multilateral collaboration²⁷⁴. On the other hand, a model based on secretariat - such as the one created by the UNFSS – would have more autonomy and as such could lead to a process of meta-regulation that operates faster, more decisively and more productively²⁷⁵. One should not forget that, in the end, the goal is to achieve effectiveness.

ISO has been stigmatized as ‘a club dominated by private industrial groups, where civil society has no real role to play’ and such legitimacy and accountability difficulties may appear irreconcilable with the privileged status that ISO standards seem to have at the WTO²⁷⁶.

Due to ‘their global reach, extensive expertise, strong legitimacy, perceived neutrality and ability to act as a gateway to more government involvement, UN agencies are particularly well-positioned to successfully take up such a meta-governance role (...) UN involvement

²⁷² Derkx, *supra* at 15.

²⁷³ *Id.* at 21.

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ Arcuri, *supra* at 495.

would also be beneficial when it concerns the meta-governance of exclusively private standards setting fields²⁷⁷.

Thus the UNFSS could be well positioned in taking up such a role. In fact, under the auspices of the UNFSS, national platforms have been built in China and in India, which purport to become UNFSS focal points in order to coordinate between standardization composed of public/private sector, and policymakers, thus establishing a feedback system that would build on a whole scenario for private standards.

This essay also proposes the creation of a market standards focal point in all interested countries, particularly emerging countries such as Brazil, so as to accommodate TBT and SPS measures and concerns and become an established structure to deal with issues related to different trade barriers caused by proliferation of market standards.

Such an initiative would certainly enhance legitimacy and accountability, which is one of the main concerns in the punctual efforts of meta-regulating market standards, so far it would involve directly government, non-governmental entities as well as the private sector, thus levelling the playing field among developed and developing countries partners.

In conclusion, standards could be mandatory, non-mandatory, private, governmental, transnational or from any other kind, but if they affect international trade, they must follow basic principles and rules and be represented by their stakeholders. Moreover, they must have an international body to guarantee their legitimacy and their accountability and defend their rules when they create impacts on other established international trading rules.

The WTO SPS and TBT Committees are committing a strategic error not taking more seriously the issue of private standards. Private-market standards are already affecting multilateral trade, and should be scrutinized jointly by the TBT and the SPS Committees, since they are spreading in the grey area between TBT and SPS measures.

It is past the time that one could, on this matter, follow the ancient saying of Hippocrates – ‘prevention is better than cure’. Notwithstanding such lapse of trade strategy, it is not too late to remedy the non-attended multiplication of market standards.

²⁷⁷ Derkx, *supra* at 19.

4. Is REACH a regulation WTO consistent?

Summary

Introduction. REACH: definition and main features. REACH's primary and most controversial element. The Precautionary principle under REACH. Is REACH WTO consistent? REACH and comparative regulation: the United States, Canada, and Japan. REACH and Mega- Regional Trade Agreements. Globalization and multiplication of REACH-likes. Specific Trade Concerns on REACH. Case Law on REACH in the European Court of Justice. Cases under the General Court. Conclusions. Annex: Table – Case Law on REACH in the European System.

4.1.Introduction

This present study analyses the Regulation on Chemicals of the European Union – so called REACH, and some of its main features. Technical barriers to trade have become the new instrument of distorting international trade benefits and creating protection for domestic industry, on the basis of protection of human health and the environment. It aims at identifying REACH's most primary and controversial element and its consistency under the World Trade Organization System, in context of the Agreement on Technical Barriers to Trade.

A brief comparative study between REACH and the United States, Canada, and Japan's regulations on chemicals is also herein presented as a way of identifying other ways of reaching similar goals of protection. According to some Brazilian representatives of the chemicals industry, the Canadian CPM is a better cost-benefits model.

The present study also introduces a brief analysis of the ongoing discussions of mega regional agreements and the negotiations on REACH, which have raised an extended concern in the European Chemicals Agency that fears lowering of levels of protection for human health and the environment.

Last, but not the least, in order to understand REACH's application and to address some possible claims that might be raised - either on negotiations or under international tribunals - for inconsistency of that regulation with international trade rules and principles, the present essay makes an analysis of case law related to REACH, under the European Court of Justice and the European General Court, since there is no specific case law to be analyzed under the WTO system. Post conclusions, in an annex to the present work, a table of cases related to REACH, under the European dispute settlement system is available.

4.2.REACH: definition and main features

REACH is the abbreviation for “Registration, Evaluation, Authorization and Restriction of Chemicals”²⁷⁸. It is a European Union Regulation of 18th December 2006, which came into

²⁷⁸ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

force in June 2007. It addresses production and use of chemical substances and their potential impacts on human health and the environment, promoting alternative methods for the hazard assessment of substances to reduce the number of tests on animals²⁷⁹. Its latest consolidated version is dated 10th April 2014²⁸⁰.

REACH applies to almost all chemicals produced or imported in the EU. The Regulation, as a whole, does not apply to radioactive substances, substances under customs supervision, non-isolated intermediates and carriage of dangerous substances, according to its Article 2.1. Some parts of REACH, such as Registration and Evaluation, do not apply to substances used in medicinal products, food and feedingstuffs, according to its Article 2.4 (b). However, food and feedstuff are under other parts of REACH. REACH, Title IV, (information in the supply chain) does not apply to medicinal products for human or veterinary use, cosmetic products, medical devices which are invasive or used in direct physical contact with the human body and food or feedingstuffs. Other substances within specific conditions (e.g. re-imported and on-site isolated intermediates, according to Article 2.7 and 2.8) are exempted from other parts of the Regulation. The burden of proof is on companies to comply with the regulation and they must identify and manage the risks linked to the substances that they manufacture and market in the EU.

REACH Regulation has 849 pages. It took seven years to pass in the European Parliament and Council and it is one of the strictest and most complex legislations in the European Union dealing with chemical substances. Theoretically, companies established outside the EU are not bound by the obligations of REACH, even if they export their products into the customs territory of the European Union. Under REACH Regulation, the responsibility for fulfilling the requirements, such as pre-registration or registration, lies with the importers established in the EU or with the only representative of a non-EU manufacturer established in the EU²⁸¹. Nevertheless, the EU is one of the most important trade partners for most of the countries in the world, the burden of proof and many of its costs, in practice, lie on the exporter willing to export its products to Europe. Therefore, REACH affects industries all over the world.

One of the “creations” of REACH Regulation was the establishment of the European Chemicals Agency (ECHA) whose main duty is to manage scientific, administrative and technical aspects from its headquarters in Helsinki²⁸².

ECHA set three deadlines for registration of chemicals, which are determined by tonnage manufactured or imported: i) 1000 tons/a. being required to be registered by 1st December

²⁷⁹ See Understanding REACH, In: <http://echa.europa.eu/web/guest/regulations/reach/understanding-reach> (access in 23th June 2014).

²⁸⁰ In: <http://old.eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20140410:EN:HTML> (access on 23rd June 2014).

²⁸¹ Ibid.

²⁸² In the ECHA Webpage: “ECHA is the driving force among regulatory authorities in implementing the EU’s groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern”, in: <http://echa.europa.eu/about-us> (access in 23th June 2014).

2010 (for chemicals of higher concern or toxicity); ii) 100 tons/a. by 1 June 2013; and iii) 1 ton/a. by 1 June 2018.

Pre-registering was a policy undertaken by 1st December 2008 and around 143,000 chemical substances marketed in the European Union were pre-registered even though pre-registering was not mandatory. Substances supply to the European market that has not been pre-registered or registered is illegal and according to the wording in REACH, it is "no data, no market".

ECHA has a special policy for addressing the continued use of chemical substances of very high concern (SVHC)²⁸³. ECHA must be notified, since June 2011, of the presence of SVHCs in articles whenever the total quantity used is more than one ton per year and the SVHC is present at more than 0.1% of the mass of the article²⁸⁴. Some SVHCs may be subject to prior authorization and applicants have to make plans for substituting it with a safer alternative. When a safer substitute is not known, the applicant must work to find one. The identification of a substance as SVHC and its inclusion in the Candidate List is the first step of the authorization procedure. A Candidate List of SVHCs is published and updated often by ECHA. The last list was updated on 16th June 2014 and it contains 155 SVHCs for authorization²⁸⁵.

Under REACH, it is not possible to register a substance if the "Only Representative" consultancy company is not based in the EU, unless it is subcontracted to an EU-based registrant. Only Representatives (O.Rs.) are EU based entities that must comply with REACH, according to Article 8, and should operate standard, transparent working practices. The O.R. assumes responsibility and liability for fulfilling obligations of importers, in accordance with REACH, for substances being brought into the EU by a non-EU manufacturer.

4.3. REACH's primary and most controversial element

The REACH regime is comprised of several elements. However, **its primary and most controversial element is its data gathering and registration requirement²⁸⁶ and, for non-Community manufacturers, the obligation to hire an O. R. to fulfil it.**

This data gathering and registration requirement applies to EU manufacturers, EU importers or EU O.Rs., established within the European Community, that manufactures within or imports into the EU both existing or new substances (on their own, in preparation or in articles), unless otherwise exempt, in a volume of more than 1 ton per year.

²⁸³ Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorization List (<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification>) (access in 23th June 2014).

²⁸⁴ REACH defines an article as an object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. According to REACH, articles are for example; t-shirts, flooring and plastic packaging.

²⁸⁵ SVHCs Candidate List in <http://echa.europa.eu/web/guest/candidate-list-table> (access on 23th June 2014).

²⁸⁶ L. A. Kogan. REACH and International Trade Law, 2013, at para12.11.

An O. R. might be a natural or legal person established in the Community appointed as the non-Community manufacturer's only representative to fulfil the obligations related to registration of substances. The O.R. must comply with all obligations under the REACH Regulation and must have a sufficient background in the practical handling of substances and the information related to them and keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet, according to Article 8.2 of REACH²⁸⁷.

The complexity of this data gathering and registration requirement put non-EU manufacturers at an economic disadvantage since their only option is to choose between an importer and an O.R. registration to protect their intellectual property and to carry on with the burdensome bureaucracy (additional registration costs and burdens, mainly for Small and Medium Enterprises – SMEs and non-EU chemical substance-based product manufacturers at a competitive economic disadvantage, because they are unlike multinationals that have a European presence or to know where to find a competent and reliable O.R.).

4.4. The Precautionary principle under REACH

The REACH registration/data gathering requirement obeys the precautionary principle and reflects a shift on regulatory paradigm, reversing the burden of proof from regulator to producer or importer on the basis of a only substance's hazardous properties not taking into consideration the actual risk that such substances poses on human health or the environment²⁸⁸.

REACH implements a hazard-based version of the precautionary principle through its Preamble, paragraphs 9 and 69 and Article 1(3), which is informed by quasi -quantitative or qualitative risk assessments.

In REACH's preamble, it is disposed that:

(9) The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (4), Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (5), Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (6) and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (7), identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the

²⁸⁷ See REACH O.R. Requirements at Article 8 (1,2,3), In: <http://old.eu-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20140410:EN:HTML> (access on 23rd June 2014)

²⁸⁸ Kogan, supra note 9, para. 12.15.

laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and the need to do more to protect public health and the environment in accordance with the precautionary principle.

(69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorization should be granted where natural or legal persons applying for an authorization demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

REACH, Article 1 (3) disposes that:

This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

As one recently released report observed, although the EU Commission's Communication on the Precautionary Principle provides that 'the precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data', it fails to discuss how serious the risk or its consequences must be in order to trigger the application of the precautionary principle. While ECJ case law is helpful, it does not appear determinative. According to the report, such case law holds, for example, that it is not sufficient to make a generalized presumption about a putative risk or to make reference to a purely hypothetical risk in the absence of scientific (data) support. The report concludes that, in the absence of further direction, 'it cannot be deduced that the precautionary principle only applies where a potentially serious risk is identified' and consequently, 'the burden of proof necessary to justify such application may be lower'²⁸⁹.

4.5. *Is REACH WTO consistent?*

REACH can be described as a "behind-the-border" technical measure intended to address regional health and environmental concerns and impacts. It can also be appropriately classified as a type of non-tariff measure (NTM) that falls within the scope of the TBT Agreement because arguably it distorts and creates uncertainty surrounding international trade flows of chemical substance-based products²⁹⁰.

²⁸⁹ Kogan, *supra* note 9, para. 12.45.

²⁹⁰ Kogan, *supra* note 9, para 12.5

As the WTO itself acknowledges, while the application of NTMs does not always restrict trade, they often result in unnecessary restrictions of undue barriers, which explains why they are referred to as non-tariff barriers (NTBs) and some WTO treaties have dealt with them; e.g. TBT and SPS Agreements.

REACH does affect international trade but the mere presence of effects on international trade is not sufficient for holding that REACH violates the EU's obligations under WTO law. It must be highlighted that some features of REACH might point out to an unlawful technical regulation on chemicals.

An analysis of REACH in light of TBT

REACH does not refer to specific substances unless they are placed on the SVHC "candidate and/or authorization lists" or they are subject to restrictions. Nevertheless, it probably qualifies as a "technical regulation" within the meaning of TBT Agreement²⁹¹, Annex 1, and, as such, it does fall within the coverage of that Agreement²⁹².

In *US Clove Cigarettes*, *Mexico Tuna II* and *US COOL Requirements*, Panels and Appellate Body have recognized that the TBT Agreement assures the right of WTO Members to regulate for the protection of human health and the environment at "their chosen level of protection", as far as that right is not exercised to employ such regulations in "a discriminatory manner or as unnecessary obstacles to trade" (wording from the Preamble of the TBT Agreement)²⁹³.

A country might choose its level of protection as far as two conditions are met:

- 1) the regulation is not employed in a discriminatory manner;
- 2) the regulation does not represent unnecessary obstacle to international trade.

Therefore, an analysis of REACH's "discriminatory power" has to be undertaken on two basis, under TBT: Art. 2.1 (and its "likeness" and "less favorable treatment" analysis) and Art. 2.2 (and its wording "unnecessary obstacles to international trade" and "more trade-restrictive than necessary").

The TBT Agreement, Article 2.1, provides that

Members shall ensure that in respect of technical regulations, like products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.

²⁹¹ It "probably qualifies" because it has never been analyzed by a Panel or Appellate Body of the WTO.

²⁹² Kogan, *supra* note 9, para. 12.24

²⁹³ See Panel Report, *United States-Measures Affecting the Production and Sale of Clove Cigarettes* ('US-Clove'; See Panel Report, *United States-Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna; See Panel Report, United States-Certain Country of Origin Labelling* ('COOL)Requirements ((18 November 2011) WT/DS384R, WT/DS386R Products ('Mexico- Tuna 11') (15 September 2011) WT/DS381/R. Cigarettes') (2 September 2011) WT/DS406/R.

The likeness of imported and domestic products should generally be determined on a case-by-case basis pursuant to four general criteria: a) the properties, nature and quality of the products; b) the end-uses of the products; c) consumers ‘tastes and habits in respect of the products; and d) the tariff classification of the products’²⁹⁴.

An analysis of REACH based on “likeness”, which focuses either on “finished articles containing chemical substances”, chemical substances or mixtures, shows the importance of product-related process and production methods (PPMs) as a possibility of claiming trade discrimination. In other words, within the chemical industry, “how products are made is becoming almost as important as how products perform”²⁹⁵. Discrimination between products has been based on PPMs, under REACH.

Based on a comparison of product characteristics and consumer tastes and habits, which include actual and perceived product-related health risks, groups of imported SVHC products may be distinguished from groups of domestic non-SVHC products, to the extent that they would not be deemed “like products”²⁹⁶. Thus ‘like products’ would become ‘different products’ merely on the substitution of a substance that would be deemed to be of very high concern, even though the rest of components and the performance of the product itself do not change.

That “likeness” would depend, however, on whether ECHA and/or EU Member State competent authorities, when classifying the substances incorporated within such products and later reviewing technical and substance dossiers, employ(s) a semi-quantitative or qualitative rather than a quantitative risk assessment approach. Semi-quantitative or qualitative analyses tend to focus mostly on the health hazards (based on intrinsic substance characteristics) posed by SVHC or non-SVHC products, which entails a lower threshold of potential harm, as compared to a strictly quantitative risk assessment approach. A quantitative approach instead focuses on the health risks engendered by such products, which necessarily takes into account exposure, dosage and actual use²⁹⁷.

As such, some might reach a conclusion that a discrimination claim against the EU, under the TBT Agreement, Article 2.1, would have a greater chance of succeeding if it focused on groups of imported substances that are not SVHCs, not incorporated within articles, and not shown to pose empirical health or environmental risks²⁹⁸. Nevertheless, it could be different on a “less favorable treatment” analysis.

There is evidence that shows that EU Member State implementation of REACH’s registration/data gathering and notification requirements imposes a higher cost structure upon, and thus impairs the competitiveness of “like” chemical substance-based product imports in EU markets. “It does so by subjecting groups of imported non-REACH registered SVHC-containing articles to treatment less favorable than that accorded to like groups of REACH-

²⁹⁴ US Clove and EC Asbestos Cases.

²⁹⁵ Kogan, *supra* note 9, para.12.26

²⁹⁶ *Ibid.*, para.12.27.

²⁹⁷ *Ibid.*, para. 12.28.

²⁹⁸ Kogan, *supra* note 9, para. 12.29.

registered domestic articles and substances”²⁹⁹. Higher costs and higher bureaucracy (as identified in the list of Specific Trade Concerns) count for a ‘less favorable treatment’ for like imported products. Among other factors, EU based manufacturers do not have to contract an O.R. to represent them.

On the other hand, the TBT Agreement, Art. 2.2 provides that

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective taking account of the risks non-fulfillment would create.

Assessing the risks of non-fulfillment of these objectives, there can be found relevant considerations related to available scientific and technical information, related processing technology, or intended end-uses of products³⁰⁰.

Having a look at REACH’s primary objective (‘ensuring a high level of protection of human health and the environment consistent with sustainable development’) one might note that it probably qualifies as a ‘legitimate objective’. The risk of a chemical substance toward human health and the environment does not necessarily have a proportionate relationship with the volume of production. However, volume is used as a proxy for exposure, since it allows a clear, enforceable priority setting for registration which also gives “legal certainty”. Moreover the REACH registration/data gathering and notification requirements’ default reliance upon a volume (hazard)-based exposure proxy can be respected as reflecting the EU’s chosen level of protection³⁰¹. Under REACH, the volume of production was the chosen level for protection in the EU. However it is doubtful whether ‘volume’ is the right proxy for measuring up protection for human health and the environment.

Nevertheless, the REACH registration process may be seen much more as “a system of data collection and warehousing than a procedure for protecting the public and the environment from exposures to hazardous substances (...) A majority of the data submitted under the REACH registration process may never be evaluated”³⁰².

A report published by the EU Commission indicates that REACH registration-related costs for EU and non-EU industries were more than twice the amount previously estimated³⁰³. There were identified several classes of expenditures, such as human resource, ECHA registration, data gathering, supply-chain communication, notification and external consultant

²⁹⁹ Ibid., para. 12.30

³⁰⁰ Ibid., para. 12.32.

³⁰¹ Ibid., 12.11

³⁰² ADK Abelkop, Á Botos, LR Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012) School of Public and Environmental Affairs, Indiana University, 24 In.: http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf (accessed 25th June 2014).

³⁰³ See Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European ChemicalMarket After the introduction of REACH' (2012), iii-iv, 39-40, 45-46, 49, 78, 97, 101, 102, table box 4.1, table 4.16and 105;

In: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf (access on 25th June 2014);

costs – a part of all that was due to excessive vertebrate animal testing that resulted in significantly higher than estimated animal testing costs (an approximate €2.1 billion of costs, in general). These substantially “higher-than-anticipated registration costs” have generated a negative impact on chemicals international trade flows. The report reached a conclusion that such a high bureaucratic cost was the main reason for many large and SME chemicals companies to reduce substance production volumes to a “lower and less expensive tonnage band”, effectively shrinking their EU market share. The report strongly suggests that these responses to REACH and the cost of REACH compliance could very well lead to fewer available substances, somewhat higher prices, and a potentially more concentrated and less competitive EU chemicals market.

It might be said that REACH's registration/data gathering and notification requirements, which includes O.R.'s costs and bureaucracy, are more trade restrictive than necessary to achieve REACH's legitimate objectives, considering the real benefits that REACH, according to the EU Commission itself, has provided.

Therefore, as far as the TBT Agreement is concerned, a violation might be found in distinct situations:

1) Whenever it is possible to ascertain that the compared products - EU domestic and imported - are “like products”, under TBT, Art. 2.1, imported products should receive ‘no less favorable treatment’. The argument that two compared products are not ‘like products’, based only on a hazard-approach of product-related process and production methods (PPMs) should not convince on the basis of the TBT preamble, since Art. 2.1 should also obey the rule not to create ‘unnecessary obstacles to international trade’ and the rule that measures should not be ‘applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade’.

2) Whenever it is possible to ascertain that compared products are not “like products” on a basis of product-related process and production methods (such as SVHC products), TBT preamble and Art. 2.2 should be applied and the rule that ‘technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective’ should be complied with. A country should not be prevented from taking ‘measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate’ (from the preamble wording). Nevertheless, such measures are ‘subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade’ (from the preamble wording). It might be said that, under REACH, the volume of production was the chosen level for protection in the EU. However it is doubtful whether ‘volume’ is the right proxy for measuring up protection for human health and the environment.

3) In general, technical regulations should not be prepared, adopted or applied whenever they create unnecessary obstacles to international trade. From Article 2.2

wording, technical regulations create unnecessary obstacles ever since they are more trade-restrictive than necessary to fulfill a legitimate objective. Moreover such rule also is under TBT preamble. From REACH, it is very clear that its high bureaucracy and registration costs are more than necessary to fulfil the legitimate objectives established in its preamble. Moreover, a majority of the data submitted under the REACH registration process may never be evaluated and the EU Commission has indicated that the registration-related costs were more than twice the amount previously estimated, generating a negative impact on international trade flows of chemicals.

4.6. REACH and comparative regulation: the United States, Canada, and Japan

After the launch of REACH, the United States Congress, in 2007, prepared a document in which it pointed out some of the basic differences in approach between REACH and the US Toxic Substances Control Act (TSCA), 1976³⁰⁴.

The US document highlights that the TSCA places the burden of proof on the Environmental Protection Agency (EPA) to demonstrate that a chemical poses a risk to human health or the environment even before EPA regulate such a chemical's production or use. REACH, instead, generally places a burden on chemical companies to make sure that chemicals do not represent such risks or, if they do so, that there are identified ways for handling them in a safe way.

The EPA may regulate a substance if it shows that there is a reasonable basis to come to a conclusion that it presents or will present an unreasonable risk. The TSCA requires the EPA to find a regulatory measure that is least burdensome but that, at the same time, mitigates the unreasonable risk. Nevertheless, the EPA has declared how difficult it is to regulate under this standard³⁰⁵. On the other hand, REACH requires chemical companies to obtain authorization to use chemicals that are in a list of 'substances of very high concern'. In order to obtain such authorization, companies need to show that they can control risks posed by the substance or they must make sure that the substance is safe for use. The companies, under REACH, must provide and develop information on the physical and chemical properties of the substance and the health and environmental effects of its use for new and existing chemicals produced on certain volumes.

Moreover, under REACH, regulators must require companies to undertake additional test data and information whenever they need to make an evaluation of the risk that a substance poses to human health and the environment. The TSCA, in contrast, puts the burden on the EPA to demonstrate that information on health and environmental effects are needed before requiring chemical companies to develop the data. The TSCA requires companies to make a notification to the EPA before producing or importing a new substance, but it does not require

³⁰⁴ US Government Accountability Office, 'Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals', Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.

³⁰⁵ US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.

companies to develop and provide data on health and environmental effects unless the EPA sets out a rule requiring them to do so³⁰⁶.

The TSCA and REACH both have clauses to protect information that is confidential or sensitive for companies. However, REACH requires a much more public disclosure of certain information, such as primary chemical properties, which includes even melting and boiling points. Moreover REACH restricts substantially the sort of information that the chemical industry may consider confidential³⁰⁷.

REACH requires companies to develop and share with government regulators data on the effects that the substances produce on human health and the environment. The TSCA generally does not.

One of the most notable differences between REACH and TSCA is that TSCA requires the EPA to demonstrate that substances represent a risk to human health or the environment before controlling risks related to their production, distribution or use. REACH, instead, is based on the principle that companies are responsible to demonstrate that the chemicals they market, distribute, or use do not adversely affect human health or the environment. Moreover, under REACH, companies have to obtain authorization to carry on with the use of a substance of very high concern, such as a substance for which there is scientific evidence of likely serious health or environmental effects. In order to obtain such authorization, companies need to demonstrate that it can adequately control risks posed by the substance. The EPA, instead, under TSCA, has distinct bodies to make the control of risks posed by new and existing chemicals. Whenever there is a new chemical, the EPA can restrict the production of such substance or its use if it understands that there is insufficient information to allow a calculated evaluation of the health and environmental effects of that substance. On that matter, EPA, according to TSCA, may choose the least burdensome requirement on the chemical industry that will adequately protect against the risk³⁰⁸.

The TSCA does not require the chemical industry to develop hazard information for existing chemicals. EPA, instead, uses regulatory and voluntary programs to raise data on certain substances. The TSCA does not command the chemical industry to develop information on the harmful effects of existing chemicals for the human health or the environment. On this matter, EPA may request a test rule, that is, it may require such information on a case-by-case basis. Nevertheless, REACH demand companies to make a declaration of hazard information for new and existing chemicals that are within specific production and toxicity levels. On behalf of that command, REACH conceived a sole system for the regulation of new and existing chemicals and it requires companies to provide the registration of substances produced or imported at 1 ton or more per producer or importer per year with the European Chemicals Agency. Under REACH, the amount of information to be included in the study summaries based on the chemical's production volume must be specified (i.e., how much of

³⁰⁶ Ibid.

³⁰⁷ Ibid.

³⁰⁸ US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.

the chemical will be produced or imported each year). The data collection requirements may be fulfilled through a variety of ways, including existing scientific modeling or testing³⁰⁹.

In general, the TSCA requires the EPA to demonstrate that substances will cause unreasonable risk. Such a burden of proof, under REACH, is on the chemical industry, which must demonstrate that the substance has adverse chemical effects.

REACH requires companies to ask for authorization in order to use some hazardous substances and to point out safer substitutes. Moreover, to control chemical risks, REACH creates procedures for both authorizing and restricting the use of chemicals. Under REACH, authorization procedures have three different steps: i) publication of a list of substances that need authorization before they can be used, by the European Chemicals Agency ('the candidate list')³¹⁰; ii) the European Commission will determine the substances, on the candidate list, that will require authorization and which of them will be exempted from the authorization requirements³¹¹; iii) once a substance has been chosen to require authorization, companies will have to apply to the European Commission for an authorization for each use of that substance³¹².

A recent study concludes that a majority of the data submitted under the REACH registration process may never be evaluated³¹³.

Alternative regulation on chemicals management strategies were issued in Canada ('Canada's risk prioritization-based Chemicals Management Plan') and Japan ('Japan's risk prioritization-based chemical substance control law – so called Kashinho Law'), each of which feature 'an iterative screening approach that permits regulators to 'set aside a vast array of

³⁰⁹ Ibid.

³¹⁰ 'The chemical agency will determine which chemicals to place on the candidate list after it has reviewed the information that chemical companies submit to the agency at the time the chemicals are registered under REACH and after considering the input provided by individual EU member states and the European Commission. In making this determination, the agency is to use criteria set forth in REACH, covering issues such as bioaccumulation, carcinogenicity, and reproductive toxicity' (US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

³¹¹ 'According to the Environment Counselor for the Delegation of the European Commission to the United States, some chemicals may be exempted from authorization requirements because, so far, sufficient controls established by other legislation are already in place' (US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

³¹² 'The application for authorization must include an analysis of the technical and economic feasibility of using safer substitutes and, if appropriate, information about any relevant research and development activities by the applicant. If such an analysis shows that suitable alternatives are available for any use of the chemical, then the application must also include a plan for how the company plans to substitute the safer chemical for the chemical of concern in that particular use. The European Commission is generally required to grant an authorization if the applicant meets the burden of demonstrating that the risks from the manufacture, use, or disposal of the chemical can be adequately controlled, except for (1) PBTs; (2) very persistent, very bioaccumulative chemicals (vPvBs); and (3) certain other chemicals including those that are carcinogenic or reproductive toxins. However, even these chemicals may receive authorization if a chemical company can demonstrate that social and economic benefits outweigh the risks' (US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

³¹³ ADK Abelkop, Á Botos, LR Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012) School of Public and Environmental Affairs, Indiana University, 24 In.: http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf (accessed 25th June 2014).

substances/uses at the beginning if they are unlikely to cause unacceptable risk', may qualify as less burdensome alternatives to REACH, in a different way from the TSCA. Such experts have come to a conclusion that an iterative screening approach focuses on a substance's potential for 'risk' rather than 'hazard, it would probably reduce costs and administrative burdens associated with substance registration while ensuring the same high level of protection of human health and the environment pursued by REACH³¹⁴.

Unlike the hazard-based REACH registration/data gathering provision, however, the multiple-level screening mechanisms of Canada's CMP and Japan's Amended Kashinho focus mostly on the exposure risks posed by substances rather than on merely a substance's hazardous intrinsic properties.

According to representatives of the Brazilian chemicals industry, the Canadian CMP offers a better cost-benefit, within a context of national policy for safety in chemicals³¹⁵. The CMP is based on the Domestic Substances List – DSL, which contains around 24 thousand substances. From the DSL, 4,300 substances were separated for analysis up to 2020, under a criterion of prioritization. A key element in the CMP is data collecting on properties and uses of about 200 substances identified in the prioritization procedure. Such policy is so termed 'Challenge'. Industry and interested parties might contribute with additional information, which can be used in the assessment of risk and in the development of better practices for managing risk and substances³¹⁶.

Nevertheless, none of the three chemicals-management regulatory regimes (REACH, CMP, and Amended Kashinho) - besides the amended US TSCA³¹⁷ - have been in operation for more than a few years, and therefore continue to evolve. Consequently, it is probably too soon to draw any definitive conclusions regarding their relative effectiveness such that the CMP or Amended Kashinho can be justified as a less trade-restrictive alternative to REACH that can, partially or completely, fulfill REACH's legitimate objective to the same extent as REACH³¹⁸.

An absence of a risk threshold for action within the EU REACH's precautionary principle would seem to explain the difference between the Canadian CMP prioritized screening approach informed by a quantitative risk assessment-focused precautionary principle and the REACH hazard-based pre-registration/data gathering approach informed by a hazard assessment qualitative risk-focused precautionary principle. Under REACH, the precautionary principle appears already to have been applied in requiring the pre-registration of tens of thousands of substances for which risk assessments have not yet been performed (i.e. at a pre-risk assessment stage), premised only on a 'volume-based exposure proxy' (annual substance manufacturing and import volumes) and, perhaps, also on some qualitative risk data informed by socio-economic analysis ('general scientific acceptance'). By comparison, under the CMP, the precautionary principle would appear to be applied at the risk management stage once a

³¹⁴ Ibid.

³¹⁵ MOURÃO, Nícia Maria Fusaro; ZANATTA, Fernando, 2013.

³¹⁶ MOURÃO, Nícia Maria Fusaro; ZANATTA, Fernando.

³¹⁷ TSCA is still under scrutiny in the US Congress.

³¹⁸ Kogan, *supra* note 9, para. 12.55.

risk assessment has been performed on a medium or high priority substance and has revealed a high likelihood of harm (exposure) to human health or the environment under particular exposure scenarios³¹⁹.

Moreover, Japan's legislation amendment was phased in over a two-year period and effectively facilitated Japan's shift from a hazard-based to a risk-based chemical substance management framework.

4.7. REACH and Mega- Regional Trade Agreements

Regulation on the chemical sector has become more dynamic. Over the past decades, legislators have decided to take different approaches for regulation and dismiss their trade partners' approaches. Different legislation to be fulfilled in each part of the world generates high costs for chemical companies since they must comply with similar requirements more than once ever since they decide to put their products on foreign markets. Identified barriers are, inter alia, different methods for assessment of chemical substances since each partner country has its own method of assessing them. There have been suggestions for harmonization and for avoidance of duplication without compromising some of the protection standards, which include inter alia administrative obligations, reporting requirements and data generation and capture³²⁰.

Besides, in the application and implementation of laws, there are fields where duplication can be reduced with no real effects on protection standards. Efforts have been made to include mutual recognition in the actual agreements negotiations.

The Transatlantic Trade and Investment Partnership (TTIP) is different from other free trade agreements negotiated earlier³²¹ since the two trading partners - The US and the EU - have considered to make a commitment on regulatory cooperation related to trade barriers which might be eliminated and at the same time maintaining the same levels of environmental and consumers protection³²².

Since non-tariff barriers have been identified as the main aim of Mega Regional Agreements, mutual recognition has become one of the main objectives of TTIP and has been feared mainly by the European Environmental Bureau that are afraid of negotiations pushing standards to the bottom in the name of harmonization and mutual recognition³²³. That might be the most difficult issue to negotiate mainly under the TTIP. However it is still difficult to know how legislation like REACH might be affected before the final draft is released.

³¹⁹ Ibid., para. 12.46.

³²⁰ VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

³²¹ Such as the Trans-Pacific Partnership and the former negotiations for the Free Trade Area for the Americas.

³²² VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

³²³ See R. Trager, Fears free trade agréments will hamstring chemical legislation, In:

<http://www.rsc.org/chemistryworld/2014/04/fears-free-trade-agreements-will-hamstring-chemical-legislation> (access on 10th July 2014).

It is not easy to identify concrete proposals from the chemical industry for regulatory cooperation. TTIP has to deal with a big gap in the chemical sector since US and EU have completely different approaches for regulation on chemicals - REACH in the EU and the U.S. Toxic Substances Control Act (TSCA). Therefore mutual recognition is difficult to be envisaged, although cooperation is possible on other basis.

The European Chemical Industry Council (CEFIC) and the U.S. American Chemistry Council (ACC) have proposed some steps for reducing duplication and for getting convergence within time, which include, inter alia:

- a) Cooperating in the prioritization of chemicals that need to undergo assessment;
- b) approximation of methods in chemical assessment;
- c) intensive exchange of information and finding out about possibilities how to cooperate in newly arising topics (e.g. regulation of nanomaterials, combination effects of chemicals, endocrine active substances);
- d) cooperation and exchange of information for data between public agencies in charge of chemicals;
- e) an effort to handle the classification and labeling of chemicals in a similar manner and to implement the already agreed United Nations GHS classification and labeling system uniformly;
- f) protection of registration data and of confidential business information and of trade secrets³²⁴.

There is also a fear that sustainable agriculture and food policies might be endangered under these free trade agreements, since some of their negotiations focus on sanitary and phytosanitary restrictions³²⁵. Countries have been allowed to set their own standards for animal and plant health and food safety that are not based on science under the precautionary principle and REACH has made it its main language.

US companies have described REACH as ‘the biggest trade barrier they face’³²⁶. On this behalf, the European Environmental Bureau fears that TTIP could threaten REACH by ‘introducing confidentiality clauses that would make relevant safety data even harder to obtain, or by creating a system of ‘mutual recognition’ that would mean approval of a chemical in the US would mean it was automatically approved in the EU, where chemical regulation is tighter’³²⁷.

One of the fears, mainly from the European side, is that there is already precedent for chemical industries using free trade agreement clauses, such as the North American Free Trade Agreement (NAFTA), to challenge legislation that infringe their expected profits.

In 1997, the US chemical company Ethyl Corporation successfully challenged a Canadian ban on import and inter-provincial trade of the gasoline additive MMT, a suspected neurotoxin that car makers claim interferes with vehicles’ onboard diagnostic systems. Preliminary tribunal judgments against Canada led its government to repeal the MMT ban, issue

³²⁴ VCI Verband Der Chemischen Industrie . V. Wir Gestalten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

³²⁵ Trager, supra note 104.

³²⁶ Ibid.

³²⁷ Ibid.

an apology to the company and settled out of court with Ethyl for \$13 million (£7.8 million). In 1998, the US waste disposal firm SD Myers challenged a temporary Canadian ban on the export of waste polychlorinated biphenyls. The tribunal awarded the company C\$6 million compensation. A few years later, Crompton, a US-based agro-chemical company, now part of Chemtura, unsuccessfully challenged the Canadian government ban on the sale and use of lindane, an agricultural pesticide now banned under the Stockholm Convention on Persistent Organic Pollutants. Currently, Lone Pine Resources, a US oil and gas company, is challenging a Quebec government ban on hydraulic fracturing in the St Lawrence River basin and seeking damages of C\$250 million, also under NAFTA³²⁸.

TTIP has been accused as an excuse to ‘water down’ REACH in Europe. Nevertheless, as a matter of fact, negotiations have already pointed out that there will be no mutual recognition of REACH and TSCA, since they are too different regimes for chemicals management and their protection standards are quite distinct from each other. Regarding REACH and TSCA, there might have a more intensive data exchange between the chemicals agencies³²⁹.

It has also been discussed to what extent TTIP threatens the WTO system. On this subject, there are positions that point out that WTO, in fact, lays ‘the foundation for how to negotiate multilaterally – somewhere down the road – the many new topics which will be parts of TTIP’ and, therefore, ‘the results of the agreement should be open to third parties too’, which would ‘further multilateral trade liberalization’, in general³³⁰.

4.8. Globalization and multiplication of REACH-like

REACH has become a pattern that has been replicated worldwide. In the chemicals word, the ‘order of the day’ is, more and more, ‘globalization of REACH’. It is interesting to note that compliance with REACH has become much more common place than complains against REACH. What exactly was the convincing European speech to make that happen?

Mourão and Zanata (2013) make a comment on a Press Release of the European Union (MEMO/06/488), which is based on some few questions: i) ‘Will REACH become the world standard for controlling chemicals?’ The answer to this question is that the EU has effectively assumed the constructive role of international leader on chemicals safety and REACH has potential to inspire legislation all over the world; ii) ‘How have European companies and third countries reacted to this European’s desire to ‘globalize’ REACH?’ The answer would be that many European companies have approved such globalization of the EU chemicals regulation since they are not penalized in face of other markets³³¹.

In fact, with such globalization, the European companies keep their competitiveness and, for the rest of the world, REACH might be a good investment as the European market is a large consumer’s market. Moreover, adopting the high standards of REACH might result in

³²⁸ Trager, supra note 104.

³²⁹ VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

³³⁰ Ibid.

³³¹ MOURÃO, Nícia Maria Fusaro; ZANATTA, Fernando. A Globalização da regulação e suas forças motrizes: o caso do REACH. In: Revista Químicos e Derivados, 2013.

substantial gains for all, but mainly for developing countries that will be able to have technological support and investments to adequate their markets under the Stockholm Convention on Persistent Organic Pollutants. The adoption of REACH in a multilateral level brings also gains to all since it reduces the duality of having to comply with different standards³³². Nevertheless, REACH has also its bitter taste.

Despite all these European assumptions that a REACH globalization might bring gains to all, Small and Medium Enterprises (SMEs), which have low technical knowledge and less access to investments, have faced many difficulties in complying with REACH. In Europe itself, such difficulties with compliance have led many SMEs to sell their plants to large companies – a process that is conducting Europe and other markets around the world to concentration, less competition and changes in chemicals overall prices³³³.

Heyvaert (2009), Professor of International Environmental Law, at the London School of Economics and Political Science, argues that the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices. She identifies five challenges that rules-importing countries are likely to face:

First, there is the risk of a mismatch between global norms and local regulatory priorities. The second and third challenges address the risks generated by increasing regulatory uniformity, namely, the development of ‘regulatory monocultures’ and the amplification of both strengths and weaknesses of a dominant regulatory approach. The fourth and fifth challenges consider the process of rules importation as a first step in the development of transnational regulatory governance and contemplate some of the trade-offs between regulatory sovereignty and transnational recognition of domestic rule making³³⁴.

REACH was constructed in such a way that it has become a ‘desirable product’ to be exported to the rest of the world. The rest of the world seems to be keen to ‘buy it’. It represents a chemical regulation that has been promoted as a global standard, probably under the European belief ‘in its inherent superiority as a regime to foster innovation and competitiveness on the chemicals market, while guaranteeing an acceptable high level of health and environmental protection’³³⁵.

Nevertheless, there are other clear motivations, besides public health and environment that are at the front level of this globalization of REACH. ‘If regulatory cost cannot be avoided entirely, then at least the affected industry can try to ensure that none of its competitors escape it, leading it to put pressure on government, first, to strive for uniformity in product regulations and, second, champion the adoption of equally costly regulations abroad, so that

³³² Ibid.

³³³ Ibid.

³³⁴ HEYVAERT, Veerle. Globalizing Regulation: Reaching Beyond the Borders of Chemicals Safety. In: *Journal of Law and Society*, v. 36, N. 1, March, 2009, at 111.

³³⁵ Ibid., at 113.

local rules do not adversely affect the global competitive position of the domestic industry’³³⁶. This is clear-cut a matter of keeping the EU’s competitiveness on the global market.

Moreover, taking REACH beyond EU’s borders legitimatizes its high standards procedures, joining together EU’s allies for that matter. Heyvaert adverts that it would be much more difficult to argue that REACH’s risk management regime is not necessary, or that it is unfair or disproportionate if it is ratified by a considerable share of the world population³³⁷.

However, as the primary goals of REACH are the protection of public health and the environment, all the burdensome costs and bureaucracy that it causes would be considered legitimate if it achieves its goals. ‘A number of leading scientists in Europe take a discouragingly dim view of the quality of the information that will be generated in compliance with the REACH prescriptions as a basis for better health and environmental decision making. For instance, the decision to exclude substances produced below one tonne pm/py causes unease, since production volume is a plausible but still highly imperfect heuristic for expected exposure. A considerable range of chemicals that pose unacceptable risks may continue to escape out notice as they are produced in below-threshold volumes. Even more damningly, the chemical tests prescribed for toxicity and ecotoxicity assessment are no longer state-of-the-art, and can only give the most rudimentary insight into a chemical’s toxicity’³³⁸.

In fact, according to representatives of the Brazilian chemicals industry, the registration procedure of REACH has not brought up surprises or added any value to the scientific knowledge so far that could justify its strictness in the name of protection of human health and the environment³³⁹.

*4.9. Specific Trade Concerns on REACH*³⁴⁰

After the notification of REACH regulation to the TBT Committee, thirty four non-European WTO-Members expressed Specific Trade Concerns (STC) about REACH, most of them comprising of REACH’s registration/data gathering and notification obligations. Some of the main concerns raised in the last years were based on the following arguments:

³³⁶ Ibid., at 114.

³³⁷ Ibid., at 116.

³³⁸ Ibid., at 123.

³³⁹ MOURÃO, N. M. F.; ZANATTA, F., 2013.

³⁴⁰ ‘The Committee on Technical Barriers to Trade ("TBT Committee") was established with the purpose of "affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objectives, and shall carry out such responsibilities as assigned to it under this Agreement or by the Members". Since its first meeting, Members have used the TBT Committee as a forum to discuss issues related to specific measures (technical regulations, standards or conformity assessment procedures) maintained by other Members. These are referred to as "specific trade concerns" and relate variously to proposed measures notified to the TBT Committee in accordance with the notification requirements in the Agreement, or to measures currently in force. Committee meetings, or informal discussions between Members held in the margins of such meetings, afford Members opportunity to review trade concerns in a bilateral or multilateral setting and to seek further clarification’. In: WTO, G/TBT/GEN/74/Rev.9, 17 October 2011, Note by the Secretariat.

- a) SMEs – high costs and bureaucracy for Small and Medium Enterprises; distorting market effects competition; market concentration since these SMEs have been absorbed by large companies;
- b) Developing countries – no available technologies and difficulties to fulfil REACH requirements;
- c) Distinct interpretations of REACH terms – as the implementation of REACH is due in each country of the EU, there have been multiple interpretations of REACH terms, such as ‘articles’ and, therefore, there is an urgent need to harmonize REACH interpretation in Europe;
- d) Nanomaterials – proliferation of registries among the State Members of the EU;
- e) SIEF (Substance Information Exchange Fora – arbitrary and opaque functioning, including costs related to it; large companies have become owners of data within the SIEF system;
- f) ORs (Only Representatives) – discrimination on foreign importers and producers, since they cannot register their products without contracting an European O.R.;
- g) SVHCs (Substances of Very High Concern): lack of a pattern on notification of SVHCs; each EU country proceeds in a different manner³⁴¹.

Nevertheless, REACH has not been challenged at the WTO Dispute Settlement System so far. There have been identified possible nine reasons for that:

- 1) the EC’s submission to the TBT Committee of an “early notification” under TBT Agreement, Article 2.9.1 acquainting Members with the proposed REACH regulation; 2) the EU’s almost simultaneous hosting of a public internet-based consultation that received up to 6,500 comments in response to the REACH proposal; 3) the EU’s granting of a 60-day extension to the REACH comment period; 4) the EU’s willingness to respond in writing and in person to WTO Member’s numerous concerns at several TBT Committee meetings and to engage in private bilateral consultations with some WTO Members; 5) considerable WTO Member government and non-EU industry lobbying; 6) the EU’s willingness to incorporate at least some of the comments and criticisms received into a partial revision of REACH prior to its adoption; 7) the passage of time deemed necessary for the purpose of accurately assessing whether the adopted REACH registration/data gathering obligation has been applied in a WTO-consistent manner; 8) a dedicated *cadre* of academic, civil society and industry advocates/lobbyists who have labored to defuse accusations of REACH WTO non-compliance; and 9) the EU’s likely comprehensive review of the Panel and AB decisions in WTO Shrimp-Turtle case³⁴².

In case of a dispute under the WTO system, the EU is “likely to emphasize that it had engaged in prior efforts to ensure that REACH was complementary to international initiatives, such as the International Council of Chemicals Management” and also that they have undertaken “good faith diplomatic efforts to negotiate with other WTO Members, including those which have raised objections to the proposed measure, for the purpose of concluding bilateral or multilateral agreements that address the perceived (health, environment etc.) threat in a more consensual manner, prior to enforcing said measure”³⁴³.

³⁴¹ WTO, Minutes G/TBT/N/EU/131, G/TBT/N/EEC/52 (+Add.1-7) G/TBT/N/EEC/52/Add.3/Rev.1, G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, G/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1, G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; G/TBT/W/208.

³⁴² Kogan, *supra* note 9, para. 12.17.

³⁴³ *Ibid.*, para. 12.18.

However, after eight years of implementation of REACH, we understand that new STCs can be raised on the following basis:

- i) Many Small and Medium Enterprises (SMEs), in Europe and in the rest of the world, have sold out their business to large companies, which has led the chemicals market worldwide to concentration, less competition and changes in chemicals overall prices³⁴⁴.
- ii) As REACH has been ‘exported’, the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices³⁴⁵.
- iii) Increasing regulatory uniformity leads to the development of ‘regulatory monocultures’ and consequently the amplification of both strengths and weaknesses of a dominant regulatory approach³⁴⁶.
- iv) Leading scientists in Europe have had a discouragingly view in relation to the quality of data that has been generated in compliance with REACH’s prescriptions for better health and protection of the environmental³⁴⁷.

4.10. Case Law on REACH in the European Court of Justice

Since there is no case law under the WTO system specifically related to REACH, it is important to analyze some of the disputes that have been brought before the European Court of Justice and the European General Court³⁴⁸ on this issue.

In an annex to the present work, there are some other disputes that have been listed, which comprise of similar discussions to the ones herein analyzed.

³⁴⁴ MOURÃO, Nícia Maria Fusaro; ZANATTA, Fernando, 2013.

³⁴⁵ HEYVAERT, 2009.

³⁴⁶ Ibid.

³⁴⁷ Ibid.

³⁴⁸ The European General Court (EGC) is a constituent of the European Union’s Court of Justice. The EGC hears actions taken against the institutions of the European Union by individuals and Member States, although certain issues are reserved for the European Court of Justice (ECJ), which is the highest court in Europe. Decisions of the General Court can be appealed to the ECJ, but only on a point of law. Prior to the coming into force of the Lisbon Treaty on 1 December 2009, it was known as the Court of First Instance. In: <http://curia.europa.eu/> (access on 22nd July 2014).

4.10.1. Case C-558/07: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs³⁴⁹

The European Court of Justice interpreted the scope of Article 6(3) of the REACH Legal Text and declared Article 6(3) valid in the European Court of Justice ruling on monomers C-558/07 of 7 July 2009.

The case concerned a request from the High Court of Justice (England & Wales), Queen's Bench Division - Administrative Court, regarding the interpretation and validity of REACH, Article 6(3).

REACH, Article 5, entitled 'No data, no market', provides:

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

REACH, Article 6, entitled 'General obligation to register substances on their own or in preparations', provides as follows:

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the [European Chemicals] Agency.

(...)

3. Any manufacturer or importer of a polymer shall submit a registration to the [European Chemicals] Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, if both the following conditions are met:

a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

Moreover, Article 8 of REACH states:

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation.

³⁴⁹ See in

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=77548&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=524647> (access on 10th July 2014).

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.'

For a preliminary ruling, two questions were raised by the UK High Court: 1) clarification of the concept of 'monomer substance', as used in Article 6(3) of the REACH Regulation; and 2) whether Article 6(3) of the REACH Regulation is invalid in so far as it requires manufacturers and importers of polymers to submit an application for registration of monomer substances.

It must be first clarified that unreacted monomers must, according to Article 6(1) and (2) of the REACH Regulation, be registered inasmuch as they constitute substances on their own. By contrast, polymers are, in accordance with Article 2(9) of that regulation, excluded from the registration obligation. According to Article 3 (5), polymers are composed of monomer units, which are defined as monomer substances in a reacted form. As it can be observed, Article 6(3) of the REACH Regulation concerns monomer substances or any other substances which are constituents of polymers. Therefore, given the definition of polymer as stated in Article 3(5) of the REACH Regulation, registration concerns reacted monomer substances and the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are incorporated in polymers. As such, it is not polymers which are affected by the registration obligation but only monomer substances with their own characteristics as they existed before polymerization. Despite polymers are exempted from registration because of their large number, according to Article 138(2) of the REACH Regulation, that situation is liable to be reviewed as soon as it is possible to establish a practicable and cost-efficient way of selecting polymers.

The ECJ's ruling answered the first question by reaching a conclusion that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are integrated in polymers.

As for the second question, the ECJ found it important to have a look at the principle of proportionality. Under EC Law, the principle of proportionality requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it³⁵⁰. The ECJ found that it was necessary to examine whether the obligation to register monomer substances constitutes a proportionate means to achieve the objectives of that regulation – that is, to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation, as set in Article 1 of the REACH regulation.

In the preamble of REACH, the method to achieve this objective is the registration obligation imposed on manufacturers and importers, which includes the obligation to generate data on the substances that they manufacture or import, to use those data to assess the risks related to

³⁵⁰ Case C-491/01 British American Tobacco (Investments) and Imperial Tobacco [2002] ECR I-11453, paragraph 122 and the case-law cited.

those substances and to develop and recommend appropriate risk management measures. Therefore, the obligation to register monomer substances, which are less numerous than polymers, makes information available not only on the risks specific to those substances but also on those of monomers found as residues after polymerization or in monomer form after the possible degradation of the polymer³⁵¹. The ECJ understood that the registration of reacted monomers in polymers obeyed the precautionary principle and that it is an appropriate means by which to realize the objectives of the REACH Regulation³⁵².

It remains to be determined whether that obligation goes beyond what is necessary. As it was applied for Community manufacturers and importers of monomer substances alike, preventing distortion of competition, the ECJ reached a conclusion that the regulation does not go beyond that which is necessary to meet the objectives of the REACH Regulation³⁵³.

In the proceedings before the UK High Court, the applicants claimed the proportionality of that registration obligation, taking into account that importers are faced with heavier practical difficulties that arise mainly from the fact that first, they do not know the composition of the imported polymer and, second, that the costs of the registration procedure are disproportionate in relation to the results achieved and the quantities of substances concerned³⁵⁴.

Regarding such concerns, the ECJ pointed out that ‘the procedure is identical whether the products are manufactured in the Community or outside it and, consequently, the burden is not heavier for manufacturers not established in the Community or importers than it is for Community manufacturers’³⁵⁵ and therefore, ‘taking account of the limited number of potential monomer substances, the 12-year period of validity for a previous registration of substances, as provided for in Article 27 of the REACH Regulation, and the possibility of sharing information in order to reduce costs, the burden deriving from the obligation to register reacted monomer substances in polymers does not appear to be manifestly disproportionate in the light of the free movement of goods on the internal market open to fair competition. It follows that Article 6(3) of the REACH Regulation is not invalid on the ground that it infringes the principle of proportionality’³⁵⁶.

It was also discussed under the UK High Court that there was an infringement of the principle of equal treatment, since Community manufacturers of polymers were in a position to register those substances more easily than were importers because they know the composition of their products, whereas importers are subject to the good will of their suppliers outside the Community. Regarding such a concern, the ECJ ruled that ‘the identical treatment required in those different situations is objectively justified by compliance with the competition rules applicable in the internal market’ and that ‘no infringement of the principle of equal treatment

³⁵¹ Ibid, para. 53.

³⁵² Ibid., para. 58.

³⁵³ Ibid., para. 63.

³⁵⁴ Case 491/01, Ibid., para. 64.

³⁵⁵ Ibid., para. 67.

³⁵⁶ Ibid, para. 71-72.

can be found and, therefore, that Article 6(3) of the REACH Regulation is not invalid on the ground that that principle has been infringed³⁵⁷.

4.10.2. Case C-358/11: *Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri -vastuualue v Lapin luonnonsuojelupiiri ry*, Judgment of the Court of 7 March 2013³⁵⁸

In 2008, the *Liikenne ja infrastruktuuri -vastuualue* decided to repair the 35 km track between *Raittijärvi village* and the nearest road, part of which crosses a Natura 2000 zone. The repair work was to consist in laying down wooden duckboards to facilitate the passage of quad vehicles in wetland areas outside the winter season besides other provisions. Those duckboards are supported by structures made up of old telecommunications poles which, for their previous use, were treated with CCA solution. The *Lapin luonnonsuojelupiiri*, which is the applicant association in the main proceedings, took the view that those poles constitute hazardous waste and requested the *Lapin ympäristökeskus* (the body responsible for environmental protection) to prohibit the use of those materials. Following the rejection of that request, that association brought an action before the *Vaasan hallinto-oikeus* (Administrative Court), which annulled that decision in 2009. The case was raised before the *Korkein hallinto-oikeus* (Supreme Administrative Court), which brought the requests before the ECJ for a preliminary ruling, as following³⁵⁹:

‘1 Is it possible to deduce directly from the fact that waste is classified as hazardous waste that the use of such a substance or object has overall adverse environmental or human health impacts within the meaning of Article 6(1), first subparagraph, point (d), of ... Directive 2008/98/EC? May hazardous waste also cease to be waste if it fulfils the requirements laid down in Article 6(1) of Directive 2008/98?

2. In interpreting the concept of waste and, in particular, assessing the obligation to dispose of a substance or an object, is it relevant that the re-use of the object which is the subject of the assessment is authorized under certain conditions by Annex XVII as referred to in Article 67 of the REACH Regulation? If that is the case, what weight is to be given to that fact?

3. Has Article 67 of the REACH Regulation harmonized the requirements concerning the manufacture, placing on the market or use within the meaning of Article 128(2) of that regulation so that the use of the preparations or objects mentioned in Annex XVII cannot be prevented by national rules on environmental protection, unless the restrictions [envisaged by those provisions] have been published in the inventory compiled by the Commission, as provided for in Article 67(3) of the REACH Regulation?

4. Is the list in Point 19(4)(b) in Annex XVII to the REACH Regulation of the uses of CCA-treated wood to be interpreted as meaning that that inventory exhaustively lists all the possible uses?

³⁵⁷ Ibid. para 78-80.

³⁵⁸ See in:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=134608&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=557970> (access on 10th July 2014).

³⁵⁹ Case C-358/11, para. 22-23.

5. Can the use of the wood at issue as underlay and duckboards for a wooden causeway be treated in the same way as the uses listed in the inventory referred to in Question 4 above, so that the use in question may be permitted on the basis of Point 19(4)(b) of Annex XVII to the REACH Regulation if the other conditions are met?
6. Which factors are to be taken into account in order to assess whether repeated skin contact within the meaning of Point 19(4)(d) of Annex XVII to the REACH Regulation is possible?
7. Does the word “possible” in the provision mentioned in Question 6 above mean that repeated skin contact is theoretically possible or that repeated skin contact is actually probable to some extent?³⁶⁰

As a preliminary observation, it should be noted that despite the telecommunications poles under stake were treated with a dangerous substance, for the application of REACH, it remains the fact that, under that regulation, such treatment does not preclude, under certain circumstances, the use of those wooden poles for certain purposes that may include duckboards for the track concerned, where appropriate. It should also be observed that, according to REACH, Article 2(2), waste, as defined in Directive 2008/98, is not a substance, mixture or article within the meaning of Article 3 of that regulation.

Moreover, REACH, Article 67(1) and (3) states:

‘1. A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. ...

(...)

3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.’

First, the ECJ examines the third question

So far as Article 67(3) of the REACH Regulation is concerned, while it authorizes a Member State to maintain existing and more stringent restrictions than those in Annex XVII, this is to be done on a transitional basis, until 1 June 2013, and subject to the condition that those restrictions have been notified to the Commission, something which the Republic of Finland, moreover, acknowledges that it has not done. The transitional and conditional nature of that measure cannot call into question the harmonization carried out by Article 67(1) of the REACH Regulation.

Therefore, if a Member State intends to make the preparation, placing on the market or use of a substance which is the subject of a restriction under Annex XVII to the REACH Regulation subject to new conditions, it may do so only in accordance with Article 129(1) thereof, in order to respond to an urgent situation to protect human health or the environment, or in accordance with Article 114(5) TFEU on the basis of new scientific evidence relating inter alia to the protection of the environment. The adoption of other conditions by the Member States is incompatible with the objectives of that regulation (see,

³⁶⁰ Ibid., para. 26.

by analogy, Joined Cases C-281/03 and C-282/03 *Cindu Chemicals and Others* [2005] ECR I-8069, paragraph 44)³⁶¹.

The ECJ concluded that, under those circumstances, the answer to the third question is that Articles 67 and 128 of the REACH must be interpreted as meaning that European Union law harmonizes the requirements relating to the manufacture, placing on the market or use of a substance such as that relating to arsenic compounds which is the subject of a restriction under Annex XVII to that regulation³⁶².

The ECJ goes on to analyze the fourth and fifth questions. The provisions of Annex XVII, point 19(4), to the REACH set out the situations in which there may be a derogation from the provisions of point 19(3) prohibiting the use of arsenic compounds for the protection of wood. Regarding these questions, Annex XVII states, in point 19, column 2, concerning ‘Conditions of restriction’ that:

3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.
4. By way of derogation from paragraph 3:
 - (a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorized in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed.
 - (b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:
 - as structural timber in public and agricultural buildings, office buildings, and industrial premises,
 - in bridges and bridgework,
 - (...)
 - as electric power transmission and telecommunications poles,
 - (...)
 - (d) Treated wood referred to under point (a) shall not be used:
 - in residential or domestic constructions, whatever the purpose,
 - in any application where there is a risk of repeated skin contact,
 - (...)
5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.
6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4:
 - may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
 - may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:

³⁶¹ Case C-358/11, para. 36-37.

³⁶² *Ibid.*, para. 38.

- to be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
- to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).'

The ECJ makes a first point that the provision mentioned in these questions has an exhaustive list and must be necessarily subject to strict interpretation³⁶³. It remains the question whether the use of the telecommunications poles at issue as an underlay for duckboards does in fact come within the scope of the applications listed in that provision. The ECJ understands that it would come within the scope of REACH 'where there is a risk of repeated skin contact', which 'must be interpreted as meaning that the prohibition at issue must apply in any situation which, in all likelihood, will involve repeated skin contact with the treated wood, such likelihood having to be inferred from the specific conditions of normal use of the application to which that wood has been put'³⁶⁴.

For the present essay, it is not important to go through the ECJ's reasoning on the first question. Nevertheless the second question is also related to REACH. The ECJ's answer to second question is therefore that REACH, Annex XVII, 'in so far as it authorizes the use, subject to certain conditions, of wood treated with CCA solutions, is, in circumstances such as those in the main proceedings, relevant for the purpose of determining whether such wood may cease to be waste (...)'³⁶⁵.

Article 2(2) of the REACH Regulation provides that it does not apply to waste. However, it would not be consistent to understand from Article 13 of the Waste Directive requirements concerning the use of waste which the holder does not discard or intend to discard, or no longer discards or intends to discard, which are more stringent than those for identical substances which are not waste. An inconsistency of that kind must in any event be avoided if rules for such substances exist that have a similar objective. It must be reminded that the purpose of the REACH Regulation, under Article 1(1), is to ensure a high level of protection of human health and the environment. Despite that objective, it is not all uses of substances, mixtures or products that would be permissible under that regulation; it is necessarily also to be regarded as permissible recovery of waste, particularly hazardous waste. REACH covers a large number of substances, mixtures and products, but specifically regulates their use in certain cases, which are distinguished by particularly serious risks to human health and the environment. The Member States may restrict the use of such substances to protect workers, human health and the environment unless it has been harmonized under the regulation. According to REACH, such harmonized rules for the use of CCA-treated wood already exist. Such an assessment must serve as guidance on how similar waste may be used³⁶⁶.

On first and second question, the ECJ ruled that the answer to be given to Questions 1 and 2 is that, under Article 6(4) of the Waste Directive, 'hazardous waste is no longer to be regarded as waste if it is to be presumed that the holder no longer discards or intends or is required to

³⁶³ Case C-358/11, para. 41-43.

³⁶⁴ Ibid., para. 52.

³⁶⁵ Ibid., para. 64.

³⁶⁶ Ibid., para. 92-96.

discard it because its recovery corresponds to a use which harmonized rules for the purpose of Article 128(2) of the REACH expressly permit for identical substances which are not waste³⁶⁷.

4.10.3. Cases C-625/11P and C-626/11P: Polyelectrolyte Producers Group (PPG) and SNF v. ECHA, Judgment of the Court in Case C-625/11P and in Case C-626/11P, both of 26 September 2013

The first case concerned ECHA's inclusion of a substance on the list of 'candidate substances'. PPG (Polyelectrolyte Producers Group GEIE) is a European economic interest grouping which represents the interests of companies that are producers and/or importers of polyelectrolytes, polyacrylamide and/or other polymers containing acrylamide, established in Brussels. SNF is one of its member companies, established in Andrézieux-Bouthéon, France.

In 2009, the Netherlands submitted to ECHA a dossier concerning the identification of acrylamide as a substance fulfilling the criteria set out in Article 57(a) and (b) of REACH, which sets out the substances which may be included in Annex XIV to that regulation, entitled 'List of substances subject to authorization' and letters (a) and (b) of Article 57 list the substances which meet the criteria for classification as carcinogenic and mutagenic substances under certain categories.

In the contested decision, ECHA identified acrylamide as fulfilling the criteria set out in Article 57 of REACH and included acrylamide on the candidate list of substances, which was published on the ECHA website, in accordance with Article 59(10) of the REACH Regulation. According to Article 59 of that regulation, entitled 'Identification of substances referred to in Article 57', paragraph (10) establishes that ECHA shall publish and update the list that identifies substances meeting the criteria referred to in Article 57 and establish a candidate list for eventual inclusion in Annex XIV ('candidate list of substances').

PPG and SNF brought an action against that decision and, according to ECHA and the European Commission, the complainants failed to observe the time-limit for bringing an action. On the basis of the alleged failure to comply with the time-limit for bringing an action, the General Court, at first instance, dismissed the action brought by PPG and SNF as inadmissible without considering the other pleas of inadmissibility raised by ECHA and the Commission³⁶⁸.

Leaving aside the time-limit procedural discussions of the case, which were the main issue, it is important to make reference to an interpretation of the ECJ related to the fact that 'it is not disputed that a decision of ECHA concerning the inclusion of a substance on the list of candidate substances constitutes a challengeable act. Article 94(1) of the REACH Regulation provides that an action may be brought against a decision of ECHA, in accordance with the

³⁶⁷ Ibid., para. 97.

³⁶⁸ Case C-625/11P, para. 20.

Treaty on the Functioning of the European Union (TFEU), Article 263, where, *inter alia*, no right of appeal lies before the Board of Appeal of ECHA. That is the case in respect of decisions taken under Article 59 of the REACH Regulation³⁶⁹.

Regarding the main issue, without raising the grounds for that finding, it is important to note that the ECJ overruled the first instance decision, considering that it was not observed the proper procedural time-limit for the complainants to bring an action against ECHA on the grounds that a substance was included in the ‘candidate list’³⁷⁰. This case makes a point for the possibility of challenging ECHA’s decision of including a substance in the candidate list, since it operates within the procedural limits.

In the second Case C-626/11P, an action was brought for annulment prior to the publication of acrylamide on the candidate list of substances of very high concern. ECHA, on 27 November 2009, agreed on the identification of acrylamide as a substance of very high concern, because it fulfilled the criteria set out in Article 57(a) and (b) of the REACH Regulation and, On 7 December 2009, ECHA published a press release announcing it. The candidate list of substances would be formally updated in January 2010. On 30 March 2010, the candidate list of substances, including acrylamide, was published on the ECHA website³⁷¹.

PPG and SNF raised an appeal on the basis that the General Court erred in law in the interpretation and application of the REACH by finding that the identification of a substance as one of very high concern by the ECHA Member State Committee, according to Article 59(8) of REACH, does not constitute a decision intended to produce legal effects *vis-à-vis* third parties before the publication of the candidate list of substances including that substance³⁷². They claimed that it is clear, from the various references to ‘identification’ and ‘inclusion’ in the provisions of REACH defining the obligations regarding information, that the European Union regulation ‘intended to create such obligations arising from the identification of a substance at an earlier stage than its inclusion on the candidate list of substances’³⁷³.

According to Article 59 of REACH, entitled ‘Identification of substances referred to in Article 57’:

‘1. The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV (‘candidate list of substances’). ...

(...)

3. Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to [ECHA].... [ECHA] shall make this dossier available within 30 days of receipt to the other Member States.

³⁶⁹ Ibid., para. 28.

³⁷⁰ Ibid., para. 35.

³⁷¹ Ibid., para. 7-10.

³⁷² Ibid., para. 24.

³⁷³ Ibid., para. 25.

4. [ECHA] shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. [ECHA] shall invite all interested parties to submit comments within a specified deadline to [ECHA].
5. Within 60 days of circulation, the other Member States or [ECHA] may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to [ECHA].
6. If [ECHA] does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. ...
7. When comments are made or received, [ECHA] shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.
8. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, [ECHA] shall include the substance in the list referred to in paragraph 1. ...
- (...)
10. [ECHA] shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.'

On the one hand, under the ECHA, whenever a procedure involves several stages, only measures that lay down the institutional position at the completion of the procedure is a contestable measure. Therefore, according to ECHA, in the present case, the inclusion of acrylamide on the candidate list of substances, published on 30 March 2010, is the only measure that creates potential legal effects and, as such, the agreement of the Member State Committee is a 'preparatory measure' that cannot not produce any legal obligation in itself³⁷⁴.

The Commission itself has found that 'whenever an unanimous agreement of the Member State Committee allows no discretion as to the inclusion of a substance on the candidate list of substances does not mean that that agreement constitutes the final, challengeable measure and is substitutable for the decision of ECHA taken under Article 59(8) of the REACH Regulation'³⁷⁵.

On the other hand, the Commission also understands that no provision of REACH point out to a distinction between the 'identification of a substance' and 'its inclusion on the candidate list of substances'. From Article 59 of REACH, it can be understood that substances are identified as 'substances of very high concern' for the sole purpose of being included on the candidate list³⁷⁶.

On first instance, the General Court was right to find that the legal obligations that arise from the measure identifying a substance as being of 'very high concern', resulting from the procedure referred to in Article 59 of REACH, only bind the persons concerned after publication of the candidate list of substances, which contains that specific substance, just as provided for in Article 59(10), because only then it is possible to ascertain unequivocally what are those person's rights and obligations in order to take the necessary measures accordingly³⁷⁷.

³⁷⁴ Case C-626/11P, para. 26.

³⁷⁵ Ibid., para. 27.

³⁷⁶ Ibid., para. 28.

³⁷⁷ Ibid., para. 31-32.

The ECJ ruled that the General Court was wrong to conclude that an ‘application was inadmissible on the ground that it had been brought before the date of publication of the contested decision by means of the inclusion of acrylamide on the candidate list of substances on the ECHA website, initially scheduled for 13 January 2010, but which finally took place on 30 March 2010’ and, in the light of the foregoing, the appellants’ appeal was upheld. The case went back to the General Court, since the state of the proceedings does not allow the ECJ to give final judgment in such a matter³⁷⁸.

4.11. Cases under the General Court

4.11.1. Case T-93/10: Bilbaína de Alquitranes, SA and Others v ECHA, Judgement of the General Court of 7 March 2013

The case T-93/10, under the European General Court, consisted of an action raised by Bilbaina de Alquitranes, established in Spain, and others, for the partial annulment of the decision of ECHA, which was published on 13 January 2010, to identify pitch, coal tar, high temperature (so called CTPHT) as a substance among the carcinogenic substances (category 2) on account of its persistent, bioaccumulative and toxic properties (‘PBT properties’) and its very persistent and very bioaccumulative properties (‘vPvB properties’), meeting the criteria set out in Article 57(a), (d) and (e) of REACH. The applicants brought an action for partial annulment of the decision of the ECHA, regarding specifically their substance concerned.

ECHA argues inadmissibility of the action because it says that the contested decision is not of direct concern to the applicants. It is not disputed that the applicants, who are the suppliers of a substance provide the recipient of the substance in question with a safety data sheet where that substance meets the criteria for classification as ‘dangerous’(CTPHT has been classified among the carcinogenic substances - Category 2). Nevertheless, it is disputed that the identification of CTPHT as a substance of very high concern, resulting from application of the procedure provided for by Article 59 of REACH, on the ground that that substance has PBT or vPvB properties, constitutes new information capable of triggering the obligation referred to in that provision; that is, the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicants³⁷⁹.

The identification of CTPHT as a ‘substance of very high concern’, on the grounds that it has PBT or vPvB properties, constitutes new information, regarding hazards identification and composition/information on ingredients. The ECHA’s argument that ‘the dangerous nature of the substance at issue is caused by its inherent properties, which the applicants should have assessed and should have been aware of before the adoption of the contested decision, first, it must be observed, that the ECHA refers to the discussions held in a subgroup of the European Chemicals Bureau (ECB) on the question whether the substance at issue met the PBT and vPvB criteria. While it is true that the hazards caused by a substance are the result of its

³⁷⁸ Ibid., para. 41, 44.

³⁷⁹ Case T-93/10, para. 39-40.

inherent properties, those dangers must be assessed and determined in accordance with defined rules of law. In its argument concerning the discussions held in that subgroup, the ECHA does not indicate the rules of law which allowed that subgroup to determine the PBT and vPvB properties. Moreover, the ECHA does not state that the conclusions of that subgroup were binding on the applicants. On the other hand, the applicants pointed out that the conclusions concerning CTPHT were disputed. Second, the ECHA states that the applicants should have assessed the inherent properties of CTPHT and should, as a result, be aware of the PBT and vPvB properties of that substance. As is apparent from the case-file and as the applicants confirmed at the hearing, it is precisely the PBT and vPvB properties of CTPHT which they dispute. Thus they did not conclude, in the context of their assessment concerning CTPHT, that that substance had PBT and vPvB properties'³⁸⁰.

Regarding the 'hazard identification' of the safety data sheet, the identification of CTPHT as a 'substance of very high concern', on the ground that that substance had PBT or vPvB properties, consisted of new information which could allow users to take measures for the protection of human health and safety at work and for the protection of the environment. Such an identification amounts to new information that is capable of affecting the risk management measures, or new information on hazards and, as such, the applicants were obliged to update the safety data sheets concerned. Therefore, the contested decision directly affects the legal situation of the applicants. According to REACH, any actor in the supply chain of a substance must communicate new information on hazardous properties, regardless of the uses concerned, to the next actor or distributor up the supply chain. Therefore it is uncontestable that the contested decision is of direct concern to the applicants ³⁸¹.

Moreover, ECHA has argued that the action is inadmissible because the contested decision is not a 'regulatory act'³⁸². It is true that the contested decision does not constitute a legislative act since it was not adopted according to EU legislative procedure. However the contested decision is an act of the ECHA adopted on the basis of Article 59 of REACH and, as such, the General Court found that it constitutes a regulatory act³⁸³.

It was submitted by the applicants that the identification of CTPHT as a 'substance of very high concern' breaches the principle of equal treatment. It is alleged that that substance is comparable, concerning its content of chemical substances and of competition on the market, to other UVCBs containing anthracene and other polycyclic aromatic hydrocarbons ('PAHs'). Nevertheless, ECHA, with no objective justification, identified only CTPHT, and not those other substances, as a 'substance of very high concern'³⁸⁴.

REACH, Article 59, sets out an identification procedure that does not confer on ECHA the power to choose the substance to be identified. Nevertheless, if a dossier on a substance is prepared by a Member or, at the request of the Commission, by the ECHA, the latter must proceed to identify that substance in accordance with the conditions set out in that article. The

³⁸⁰ Case T-93/10, para. 47.

³⁸¹ Ibid., para. 48-50.

³⁸² Ibid, para. 52.

³⁸³ Ibid, para. 65.

³⁸⁴ Ibid, para. 69.

Great Court understood that the identification procedure was observed and that, in identifying CTPHT and not the allegedly comparable substances as a substance of very high concern, the ECHA did not breach the principle of equal treatment³⁸⁵.

There was also a plea alleging an error of assessment or an error of law in the identification of a substance as PBT or vPvB on the basis of its constituents. The applicants pointed out that the dossier presented by ECHA for CTPHT did not comply with the requirements set out in Article 59(2) and (3) and in Annexes XIII and XV of REACH because it was not based on ‘an assessment of the substance itself but on an assessment of the properties of its constituents’. Besides that, the rule that a substance must be identified as ‘having PBT or vPvB properties provided that it contains a constituent which has PBT or vPvB properties and is present in a concentration of 0.1% or more’ is not provided for in Annex XIII to REACH and therefore has no legal basis³⁸⁶. The Great Court considered that ECHA did not therefore infringe those provisions³⁸⁷ and that it based its approach on scientific reasons³⁸⁸ because ‘that CTPHT was not identified as having PBT and vPvB properties solely because a constituent of that substance has a certain number of PBT and vPvB properties, but that the proportion in which such a constituent is present and the chemical effects of the presence of such a constituent were also taken into account. The applicants’ argument concerning the identification of CTPHT as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1% does not demonstrate that the contested decision is vitiated by a manifest error’³⁸⁹.

It is also observed by the applicants that the assessment of the constituents of the substance at issue is not a ‘sufficient basis’ for its identification as having PBT or vPvB properties since those constituents have not been individually identified as having PBT or vPvB properties in a separate ECHA decision based on a thorough assessment for that purpose³⁹⁰, but the General Court also rejected such a submission.

A third plea was brought up, alleging that the contested decision does not respect the principle of proportionality. REACH’s objective is to ensure a high level of protection of human health and the environment. All the substances that could replace CTPHT also have PBT or vPvB properties. The applicants claim that ECHA could have taken other ‘appropriate and less onerous measures’, which could be ‘the application of risk management measures on the basis of the chemical safety assessment in the registration dossier prepared by the applicants’ or ‘the presentation of a dossier concerning the substance at issue under Title VIII of REACH’³⁹¹.

The principle of proportionality, which is a general principle under EU case law³⁹² and a principle invoked under WTO case law³⁹³, requires that measures adopted by Members do not

³⁸⁵ Case T-93/10, para. 72.

³⁸⁶ Ibid, para. 78.

³⁸⁷ Ibid, para. 81.

³⁸⁸ Ibid, para. 89.

³⁸⁹ Ibid, para. 100.

³⁹⁰ Ibid, para. 102.

³⁹¹ Case T-93/10, para. 113.

³⁹² See Case C-15/10 *Etimine* [2011] ECR I-0000.

exceed the limits of what is supposed to be appropriate and necessary in order to reach the objectives pursued and whenever there is a choice between several appropriate measures, it should be chosen the least onerous one. Besides that, the measure at issue must not be disproportionate to the aims pursued.

Regarding the principle of proportionality, the General Court remarked that the ‘ECHA is to recommend priority substances to be included’ in the annex ‘taking into account the opinion of the Member State Committee and specifying for each substance inter alia the uses or categories of uses exempted from the authorization requirement’. Therefore a substance may be subject to authorization only as a result of a decision by the Commission to include that substance in REACH, Annex XIV. For the purpose of identification of substances of very high concern, REACH lays down an authorization procedure³⁹⁴. On such reasoning, the applicant’s argument was rejected.

Within the claim of proportionality, the applicants argued that the contested ECHA’s decision exceeds the limits of what is necessary to achieve the objectives pursued, since other provisions could be less onerous and at the same time serve to provide a high level of protection of human health and the environment. It was argued that the ECHA could have waited for the presentation of the assessment in order to check the chemical safety report and the proposed risk management measures, instead of identifying the substance at issue as being of very high concern³⁹⁵. The General Court understood that ‘the objective of the authorization procedure’, under REACH, is part, inter alia, ‘progressively to replace substances of very high concern with other appropriate substances or technologies, where they are economically or technically viable’ and therefore ‘the risk management measures’ proposed under REACH ‘do not constitute appropriate measures for the achievement of the objectives pursued’³⁹⁶.

4.11.2. Case T-94/10: Rütgers Germany GmbH and Others v ECHA, Judgement of the General Court of 7 March 2013

The case consisted of an action brought by Rütgers Germany GmbHfor, based in Germany, and others, for the partial annulment of the decision of ECHA to identify anthracene oil³⁹⁷ as a substance of very high concern, under REACH³⁹⁸.

³⁹³ See US – Standards for Reformulated and Conventional Gasoline (US-Gasoline), WT/DS2/9, adopted on 20 May 1996, Section III.B.

³⁹⁴ Case T-93/10, para. 119-120.

³⁹⁵ Ibid, para. 119-123.

³⁹⁶ Ibid, para. 124.

³⁹⁷ Anthracene oil is a combination of polycyclic aromatic hydrocarbons (‘PAHs’) obtained from coal tar, with an approximate distillation range of 300° C to 400° C and a composition primarily of phenanthrene, anthracene and carbazole. Such a substance is among the ‘substances of unknown or variable composition, complex reaction products or biological materials (‘UVCB substances’), because it cannot be fully identified by its chemical composition’ and is used mainly as an intermediate for the production of carbon black, a pigment and a reinforcing filler in rubber products, especially tyres as well as an intermediate for the production of pure anthracene.

³⁹⁸ Case T-94/10, para. 2.

Germany submitted to the European Chemicals Agency ('ECHA'), on 28 August 2009, a dossier that it had prepared on the identification of anthracene oil, on behalf of its persistent, bioaccumulative and toxic properties ('PBT properties') and its very persistent and very bioaccumulative properties ('vPvB properties'). Following the procedure, ECHA stated that anthracene oil is classified as a 'carcinogenic substance' and met the criteria set out in Article 57(a) of REACH. Such an agreement was reached unanimously by the Committee.

One of the first applicants' argument was that it is disputed that the identification of anthracene oil as a substance of very high concern as a result of the procedure provided for by Article 59 of REACH, on the ground that that substance has PBT or vPvB properties, constitutes new information within the meaning of Article 31(9)(a) of REACH capable of triggering the obligation referred to in that provision, that is, the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicant³⁹⁹. The discussion was similar to the one analyzed in the previous case, related to CTPHT.

There were five pleas in law raised in support of the present case: the first two pleas concerned alleged breaches of procedural requirements, related to Article 59(3), (5) and (7) of and Annex XV to REACH. The other three pleas alleged breach of the principle of equal treatment, an error of assessment or an error of law regarding the identification of a substance as having PBT or vPvB properties on the basis of its constituent ingredients and breach of the principle of proportionality⁴⁰⁰. All the pleas were rejected by the General Court and the action in its entirety was dismissed. The arguments were quite similar to the previous case discussed. Therein will be highlighted only the issues that distinguish the cases.

The applicants argued that Germany did not give information on alternative substances even though it had been informed by the applicants of the existence of such substances, namely petroleum-based preparations and ECHA accepted that dossier without alternative substances having been pointed out. According to the applicants, it can be taken into consideration that without that irregularity and if the fact that the alternative substances also contained PBT constituents had been known, the contested decision might not have been adopted and a different procedure might have been triggered⁴⁰¹.

The letter to the competent German authorities of 17 July 2009 from the Coal Chemicals Sector Group did not refer to any alternative substances, but they simply asked the German authorities to adopt 'a more balanced approach not penalizing a single industry sector', since the group pointed out that 'it is well known that many streams of petroleum conversion contain anthracene as well'. The Court understood that that letter makes reference to substances which, according to the group, present a 'comparable level of danger to that of anthracene oil' and not to substances which can be used as 'alternatives' because they are capable of being used instead of anthracene oil to perform the same function and therefore they found that the procedural requirements set out in REACH were respected. Therefore it

³⁹⁹ Ibid., para. 41.

⁴⁰⁰ Ibid., para. 68.

⁴⁰¹ Ibid., para. 69.

does not seem the information on alternative substances is relevant as regards the outcome of that procedure⁴⁰².

In a second plea, the applicants observed that ECHA had no authority to make an amendment on the proposal made by the Germany concerning the inclusion of anthracene oil in the candidate list of substances, which was based solely on the fact that that substance had PBT and vPvB properties. According to that amendment, anthracene oil was identified as a ‘substance of very high concern’ on the basis not only of its PBT and vPvB properties as alleged, but also of its carcinogenic properties. Since that substance could not have been identified as being of very high concern on the basis of its PBT and vPvB properties, the reference to its carcinogenic properties remains the only reason for its inclusion in the candidate list of substances. The dossier prepared by Germany contained only the proposal to identify anthracene oil as a substance with PBT and vPvB properties – and as such of very high concern. It said nothing about its carcinogenic substance, which was an amendment of ECHA. It was argued that ECHA had no authority to amend the proposal. Such a plea was also rejected on the grounds that ECHA is in a position to put forward its point of view effectively and therefore it must be possible to incorporate the comments made by the ECHA in the contested decision⁴⁰³.

The third plea, alleging breach of the principle of equal treatment⁴⁰⁴ was similar to the previous case analyzed and the General Court upheld the position that such a plea should be rejected⁴⁰⁵.

Moreover, very similar arguments to the previous case were: the fourth plea, alleging an error of assessment or an error of law in the identification of a substance as PBT or vPvB on the basis of its constituent. The Court upheld, as in the previous case, that ECHA bases its approach on scientific reasons. The applicants’ argument concerning the identification of anthracene oil as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1% does not demonstrate that the contested decision is vitiated by a manifest error⁴⁰⁶.

The fifth plea of this case brought about the same discussion of the principle of proportionality discussed on the previous case and was also rejected by the General Court.

4.12. Conclusions

The European chemicals regulation policy, REACH, is a main concern for international companies entering into the European market. One of the main creations of REACH was the European Chemicals Agency, which has been in charge of applying such regulation.

⁴⁰² Ibid, para. 73-74 and 77.

⁴⁰³ Ibid, para. 80-88.

⁴⁰⁴ The identification of anthracene oil as a substance of very high concern breaches the principle of equal treatment. That substance is comparable, from the point of view of its content in chemical substances and of market competition to other UVCB substances containing anthracene. However, the ECHA, without any objective justification, identified only anthracene oil, and not those other substances, as a substance of very high concern (para. 90).

⁴⁰⁵ Case T-94/10, para. 95.

⁴⁰⁶ Ibid., para. 121.

REACH's primary and most controversial element is its data gathering and registration requirement and, for non-Community manufacturers, the obligation to hire an O. R. to fulfil it. This has become an economic disadvantage for them since their only option is to choose between an importer and an O.R. registration to protect their intellectual property and to carry on with all the burdensome bureaucracy.

Many WTO Specific Trade Concerns have been raised and most of them comprise of REACH's registration/data gathering and notification obligations, mainly related to its costly and hazard-based approach, threatens to intellectual property rights and mandatory data sharing. Nevertheless, REACH has not been challenged at the WTO Dispute Settlement System. There are some identified reasons for that, which may consist of: the EC's submission to the TBT Committee of an "early notification", under TBT Agreement, acquainting Members with the proposed REACH regulation; the long period of discussions of that regulation and the EU's granting of a 60-day extension to the REACH comment period, although a 60 days period might count exactly in the opposite direction, which is too short a period for the complexity of REACH; considerable WTO Member government and non-EU industry lobbying; and a considerable group of academic, civil society and industry advocates/lobbyists who have labored to defuse accusations of REACH WTO non-compliance.

Nevertheless, an analysis of REACH in light of TBT shows that EU Member State implementation of REACH's registration/data gathering and notification requirements imposes a higher cost structure, and thus impairs the competitiveness of "like" chemical substance-based product imports in EU markets. It subjects groups of imported non-REACH registered SVHC-containing articles to treatment less favorable than that accorded to like groups of REACH-registered domestic articles and substances. Moreover, REACH's registration/data gathering and notification requirements, which includes O.R.'s costs and bureaucracy, are more trade restrictive than necessary to achieve REACH's legitimate objectives, considering the real benefits that REACH, has provided. It has been observed that the REACH registration process may be seen much more as a method of 'data collection and warehousing' than a procedure for protecting the public and the environment from exposures to hazardous substances. It is very true that most of the information submitted under the REACH registration procedure may never be evaluated, given the amount of data submitted.

Therefore, as far as the TBT Agreement is concerned, a violation might be found in the following situations:

- 1) Whenever it is possible to ascertain that the compared products - EU domestic and imported - are "like products", under TBT, Art. 2.1, imported products should receive 'no less favorable treatment'. The argument that two compared products are not 'like products', based only on a hazard-approach of product-related process and production methods (PPMs) should not convince on the basis of the TBT preamble, since Art. 2.1 should also obey the rule not to create 'unnecessary obstacles to international trade' and the rule that measures should not be 'applied in a manner which would constitute a means of arbitrary or unjustifiable

discrimination between countries where the same conditions prevail or a disguised restriction on international trade’.

2) Whenever it is possible to ascertain that compared products are not ‘like products’ on a basis of product-related process and production methods (such as SVHC products), TBT preamble and Art. 2.2 should be applied and the rule that ‘technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective’ should be complied with. A country should not be prevented from taking ‘measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate’ (from the preamble wording). Nevertheless, such measures are ‘subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade’ (from the preamble wording). It might be said that, under REACH, the volume of production was the chosen level for protection in the EU. However it is doubtful whether ‘volume’ is the right proxy for measuring up protection for human health and the environment.

3) In general, technical regulations should not be prepared, adopted or applied whenever they create unnecessary obstacles to international trade. From TBT, Article 2.2, technical regulations create unnecessary obstacles ever since they are more trade-restrictive than necessary to fulfill a legitimate objective. Moreover such rule also is under TBT preamble. From REACH, it is very clear that its high bureaucracy and registration costs are more than necessary to fulfil the legitimate objectives established in its preamble. The EU Commission has indicated that the registration-related costs were more than twice the amount previously estimated, generating a negative impact on international trade flows of chemicals.

Whenever REACH is compared to other regulation that also intends to protect human health and the environment from chemical substances (e.g. US’s TSCA, Canadian CMP and Japanese Kashinoh), it is clear that REACH’s hazardous approach and the shift of burden of proof to manufacturers is too burdensome compared to what would be deemed necessary to reach its legitimate goals.

‘Moves to require mandatory substitution or across the board uniform time limits would cause unnecessary market disruptions without clear environmental benefits. Registration and notification of substances embedded in articles when no potential risks have yet been identified could cause many entities including numerous SMEs from developing countries to forego the EU market without corresponding environmental benefit’⁴⁰⁷.

Although some may say that it might be too late to challenge REACH under the multilateral system or even under other international fora, an analysis of case law that have been brought before the ECJ’s system provides evidence to the contrary. Many cases have been discussed either at the ECJ or at the General Court instances and they show that the highest tribunals in

⁴⁰⁷ EU Economic Observer, in: <http://euobserver.com/economic/21813> (access on 24th July 2014).

Europe are willing to verify the legality of REACH and its complexity under EU law, remarking that some outcomes have been in favor of the complainants.

The ECHA's most recent concerns around the mega-regional trade negotiations, fearing that agreements such as TTIP might lower the level of protection for human health and the environment, on the basis of regulatory cooperation and mutual standards recognition, is evidence that REACH can and might be challenged, either on tribunals or under international negotiations and that its "warehouse approach" may be dully considered an unnecessary barrier to international trade.

Last, but not the least, globalization of REACH – the multiplication of REACH-likes – has raised new concerns. New procedures of STCs can be raised, under the WTO TBT Committee, in the actual stage of implementation of REACH, under the following basis: i) many SMEs, in Europe and in the rest of the world, have sold out their business to large companies, which has led the chemicals market worldwide to concentration, less competition and changes in chemicals overall prices; ii) as REACH has been 'exported', the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices; iii) increasing regulatory uniformity leads to the development of 'regulatory monocultures' and consequently the amplification of both strengths and weaknesses of a dominant regulatory approach; iv) leading scientists in Europe have had a discouragingly view in relation to the quality of data that has been generated in compliance with REACH's prescriptions for better health and protection of the environmental .

ANNEX

TABLE: CASE LAW ON REACH IN THE EUROPEAN SYSTEM⁴⁰⁸

Cases	Court	Outcome
Case C-558/07: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs	ECJ	This reference for a preliminary ruling concerns the interpretation and validity of Article 6(3) of REACH. The concept of ‘monomer substances’ in Article 6(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC relates only to reacted monomers which are integrated in polymers.
Case C-358/11: Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri - vastuualue v Lapin luonnonsuojelupiiri ry	ECJ	This request for a preliminary ruling concerns the interpretation of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, such as REACH. European Union law does not, as a matter of principle, exclude the possibility that waste regarded as hazardous may cease to be waste within the meaning of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives if a recovery operation enables it to be made usable without endangering human health and without harming the environment and, also, if it is not found that the holder of the object at issue discards it or intends or is required to discard it within the meaning of Article 3(1) of that directive, this being a matter for the referring court to ascertain. The REACH Regulation, in particular Annex XVII thereto, in so far as it authorizes the use, subject to certain conditions, of wood treated with CCA solutions, is, in circumstances such as those in the main proceedings, relevant for the purpose of determining whether such wood may cease to be waste because, if those conditions were fulfilled, its holder would not be required to discard it within the meaning of Article 3(1) of Directive 2008/98.
Case C-625/11P :Polyelectrolyte Producers Group and SNF v ECHA	ECJ	By their appeal, Polyelectrolyte Producers Group GEIE (PPG) (‘PPG’) and SNF SAS (‘SNF’) seek to have set aside the order of the General Court of the European Union of 21 September 2011 in Case T-268/10 PPG and SNF v ECHA [2011] ECR II-6595 (‘the order under appeal’), by which that Court dismissed as inadmissible their action for annulment of the decision of the European Chemicals Agency (ECHA), identifying acrylamide (EC No 201-173-7) as a substance meeting the criteria laid down in Article 57 of REACH. The ECJ Sets aside the order of the General Court of the European Union of 21 September 2011 in Case T-268/10 PPG and SNF v ECHA, understanding that the General Court erred in

⁴⁰⁸ See <http://echa.europa.eu/web/guest/regulations/reach/legislation> (access on 24th July 2014).

		law in finding that Article 102(1) applies only to measures published in the Official Journal of the European Union and thus declaring the action brought by PPG and SNF inadmissible.
Case C-626/11P: Polyelectrolyte Producers Group and SNF v ECHA	ECJ	The ECJ understood that the General Court was wrong to conclude that that application was inadmissible on the ground that it had been brought before the date of publication of the contested decision by means of the inclusion of acrylamide on the candidate list of substances on the ECHA website, initially scheduled for 13 January 2010, but which finally took place on 30 March 2010.
Case T-1/10: PPG and SNF v ECHA	General Court	Application for annulment of the decision of ECHA identifying acrylamide (EC No 201-173-7) as a substance fulfilling the criteria referred to in Article 57 of REACH. As the candidate list of substances exists only on the ECHA website, the inclusion of a substance in that list takes place when the updated list is published. It is, therefore, only upon inclusion in the candidate list of substances published on the ECHA website that the act identifying a substance as being of very high concern, resulting from the procedure set out in Article 59 of that regulation, is intended to produce legal effects.
Case T-93/10: Bilbaina de Alquitrane, SA and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify pitch, coal tar, high temperature (EC No 266-028-2) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of REACH, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-94/10: Rütgers Germany GmbH and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil (EC No 292-602-7) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to Regulation No 1907/2006 demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of Regulation No 1907/2006, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-95/10: Cindu Chemicals BV and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil, anthracene low (EC No 292-604-8) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out

		in Article 59 of Regulation No 1907/2006, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-96/10: Rütgers Germany GmbH and Others v ECHA	General Court	ACTION for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil (anthracene paste) (EC No 292-603-2) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of REACH, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-268/10: PPG and SNF v ECHA	General Court	Application for annulment of the decision of ECHA identifying acrylamide (EC No 201-173-7) as a substance fulfilling the criteria referred to in Article 57 of REACH. It follows from the foregoing that the action must be dismissed as inadmissible and that it is unnecessary to consider the other pleas of inadmissibility raised by ECHA and the Commission.
Case T-89/13: Calestep v ECHA	General Court	Available only in French and Spanish: ‘une demande de sursis à l’exécution des rappels de paiement des 23 janvier et 8 février 2013 adressés par l’ECHA à la requérante au motif que celle-ci ne remplissait pas les conditions pour bénéficier de la réduction des redevances prévue pour les petites entreprises. La demande en référé doit être rejetée comme irrecevable’.
Case T-346/10: Borax Europe v ECHA	General Court	Application for annulment of the decision of the ECHA, published on 18 June 2010, identifying boric acid (EC No 233-139-2) and disodium tetraborate, anhydrous (EC No 215-540-4) as substances meeting the criteria referred to in Article 57 of REACH. It is apparent from all of the foregoing that the Court is in a position to rule on the action without ordering measures of inquiry. Furthermore, since the contested decision has been published on the ECHA’s website and produced by the applicant in an annex to the application, this request is irrelevant. The applicant’s request for a measure of inquiry must therefore be refused, and the action dismissed in its entirety.
Case T-368/11: Polyelectrolyte Producers Group and Others v Commission	General Court	Available only in French and Spanish: ‘une demande d’annulation du règlement (UE) n° 366/2011 de la Commission, du 14 avril 2011, modifiant le règlement (CE) n° 1907/2006 du Parlement européen et du Conseil concernant l’enregistrement, l’évaluation et l’autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH), en ce qui concerne l’annexe XVII (acrylamide). Le recours dans son intégralité doivent être rejetés
Case T-456/11: ICdA and Others v Commission	General Court	Application for partial annulment of Commission Regulation (EU) No 494/2011 of 20 May 2011 amending REACH of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (OJ

		2011 L 134, p. 2) in so far as it restricts the use of cadmium pigments in plastic materials other than plastic materials in which that use was restricted before the adoption of Regulation No 494/2011. the first part of this plea in law must be upheld. In the light of the foregoing considerations, and without there being any need to rule either on the second part of this plea in law or on the other pleas in law raised by the applicants, the action must be upheld and the contested regulation must be partly annulled in so far as it restricts the use of the cadmium pigments at issue in mixtures and articles made from plastic materials other than those in respect of which that use was restricted before the adoption of that regulation. On the other hand, the action must be rejected as inadmissible as to the remainder.
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For many years, the logic of trade protection was based on tariffs, determined by each government and established at the border of each country. The history of the GATT – General Agreement on Tariff and Trade, created in 1947, can be summarized as a series of negotiation to reduce tariffs. Only in 1978, the Parts of the GATT agreed on the first non-tariff barrier code, the Code of Technical Barriers to Trade, now the Agreement on TBT. With the end of the Uruguay Round, in 1994, and the creation of the World Trade Organization – WTO, a new agreement was negotiated, the Agreement on Sanitary and Phytosanitary Measures. Other agreements on rules were introduced as services and intellectual property. These are agreements on rules to balance the management of discriminatory practices with the legal right of government to protect its citizens.

In this new world, there is a preoccupation to ask whether: Are the wolves of protectionism disguised under new sheep skin? On matters of regulatory barriers to trade, we intend to answer such a questioning within this study. Trade and regulation are on the battlefield. Within such a trade and regulatory war, if the masks fall, the true face of regulators might show off 'wolves disguised under sheep skin' - a return to the desire of domination and protectionism. Good and evil are battling on the same stage, in order to conquer what might be a disguised new level playing field.

Vera Thorstensen
Andreia Costa Vieira

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