

TBT, SPS and PS:

are the wolves of protectionism disguised under sheep skin?

Vera Thorstensen¹
Andreia Costa Vieira²

Summary: 1 – Introduction. 2 – A brief history of the development of TBT and SPS Agreements. 3 – TBT and SPS: a complement of Article XX GATT - highlighting main principles. 4 - Regulatory barriers and scope of each Agreement. 5 – MFN and National Treatment under TBT and SPS. 6 – The requirement for necessity tests. 7 – Process and Production Methods (PPMs). 8 - When regulatory measures are obstacles to international trade. 9 – A quest for harmonization – mutual recognition, equivalency and regulatory coherence. 10 – The Precautionary Principle. 11 – Transparency – Notifications and Enquiry Points. 12 – TBT and SPS Committees and the Specific Trade Concerns. 13 – A briefing on Private Standards (PS). 14 - Conclusions.

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 issues³ 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

¹ Vera Thorstensen, PhD in Economics (FGV), is a Professor at the São Paulo School of Economics (EESP) from Getulio Vargas Foundation (FGV), WTO Chair Holder in Brazil and Coordinator of the Center on Global Trade and Investments (CGTI).

² Andreia Costa Vieira, PhD in International Law (USP), Visiting Scholar at University of Cambridge, (2013) and LLM in International Commercial Law (University of Nottingham) is Researcher at the Center on Global Trade and Investments (CGTI), lawyer and Professor of International Law in Brazil.

³ 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).

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.

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 – 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 system⁴.

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

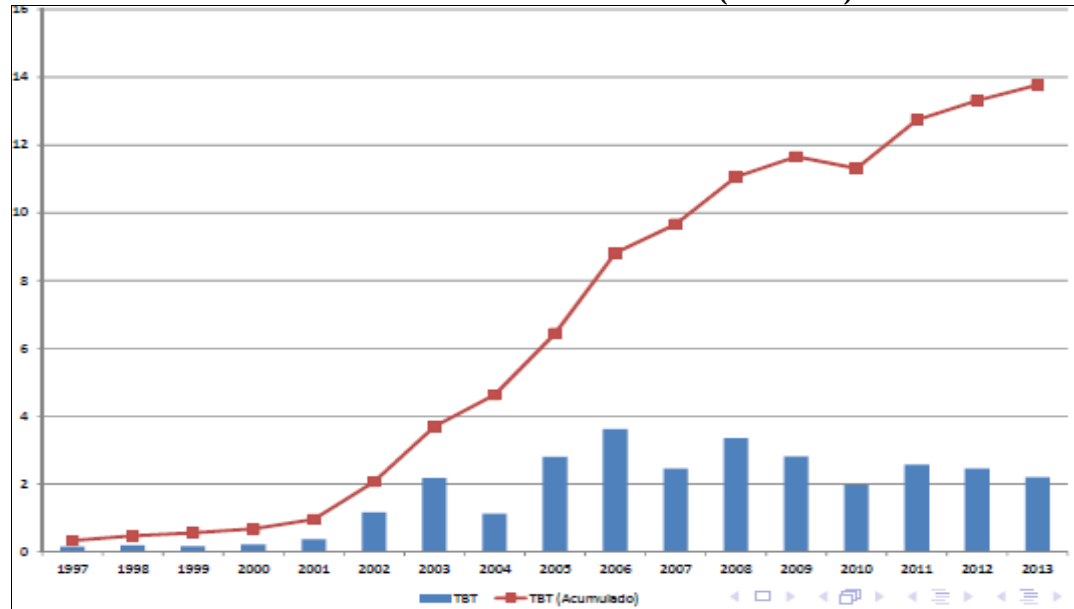
⁴ R. Griffin, History of the Development of the SPS Agreement, In: FAO Documents, Multilateral Trade negotiations on Agriculture – a resource manual, Rome, 2000, In: <http://www.fao.org/docrep/003/x7354e/x7354e01.htm> (Access on 16 June 2014)

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 measures⁵.

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)

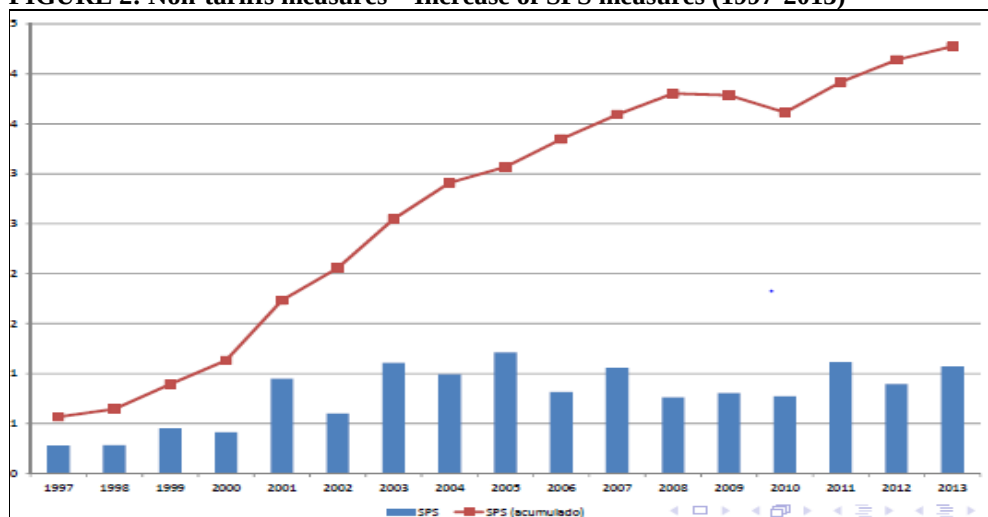


Source: CCGI- FGV, 2014⁶

⁵ 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.

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

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



Source: CCGI- FGV, 2014⁷

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 principle⁸. Therefore the TBT must relate to the SPS in a harmonious way as well as with any other WTO Agreement.

⁷ Ferraz, L and Ribeiro, M. CCGI-FGV, 2014.

⁸ 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.

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 manner⁹.

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 them¹⁰.

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.

3 – 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 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

⁹ 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.

¹⁰ G. Marceau; J. P. Trachtman, *supra*, at 415.

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.

4 - 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**¹¹.

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

¹¹ TBT Agreement, Preamble, Article 1.6, Annex 1.1, 1.2, 1.3.

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’¹².

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’¹³. 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**¹⁴. However it is not limited to “technical barriers” since it states that it is 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 SPS¹⁵.

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

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

¹³ The WTO Agreements Series, Technical Barriers to Trade, at 15.

¹⁴ Article 1 and Annex A - 1.

¹⁵ Article 1.4.

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 Agreement¹⁶.

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**¹⁷. 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:

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.

¹⁶ “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)

¹⁷ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In:

<http://wto.org/english/tratop_e/sps_e/spsund_e.htm> (Access on 18th June 2014)

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 it¹⁸.

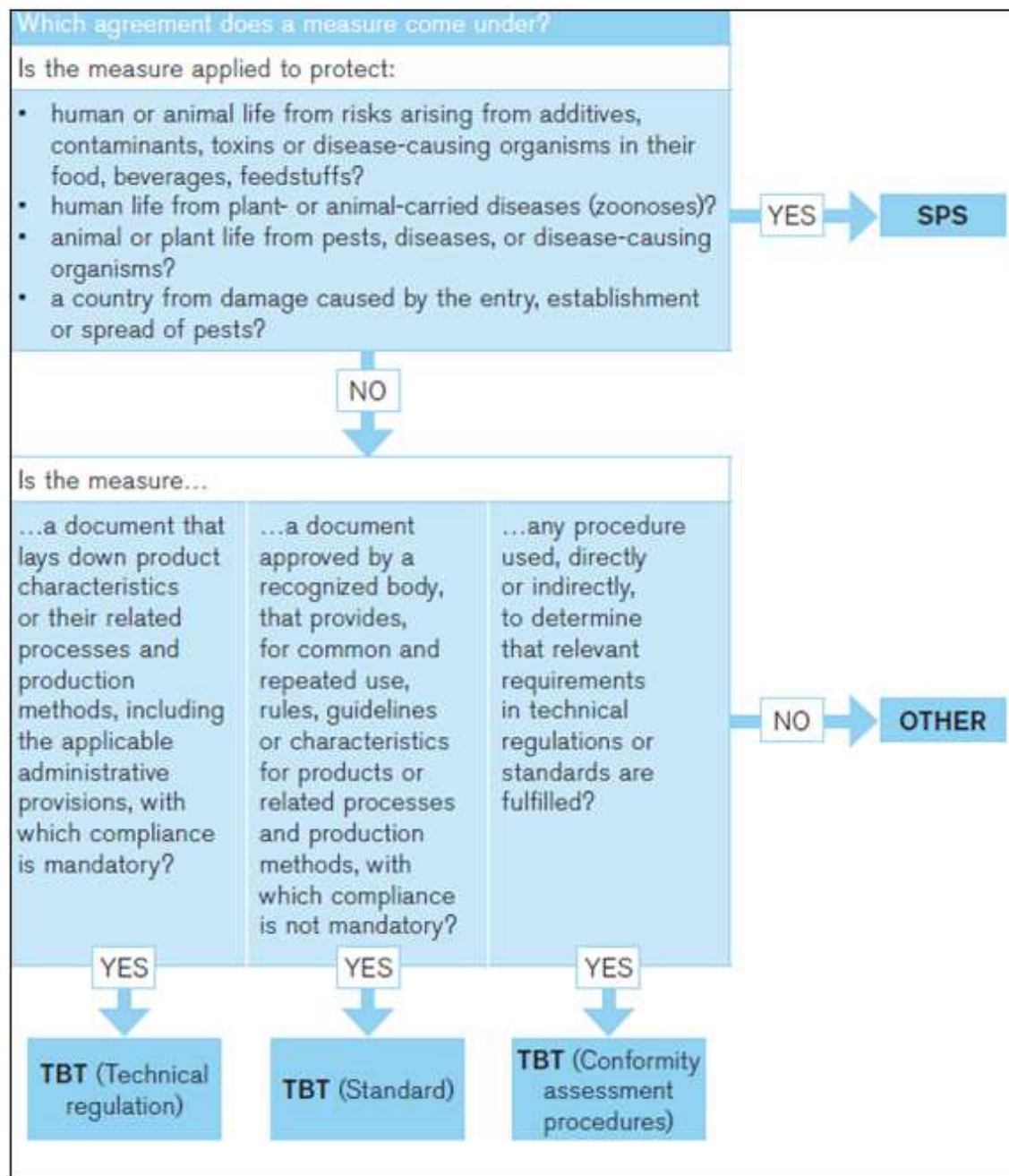
As Horn, Mavroidis and Wijkstrom remark,

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 raised¹⁹.

¹⁸ Ibid.

¹⁹ 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 wide²⁰.

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’²¹. 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)²². (emphasis added)

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

²⁰ Ibid., at 19.

²¹ The WTO Agreements Series, Technical Barriers to Trade, 2014, at 12.

²² Ibid.

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 measure**²³. (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 purpose²⁴. As such, if a regulation is composed of different measures, each measure might be covered by a distinct WTO Agreement.

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

5.1 – Like products in TBT

TBT, Article 2.1, establishes that

²³ 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.

²⁴ VCLT, Article 31.1.

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 rules²⁵.

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 product²⁶.

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;

²⁵ G. Marceau; J. P. Trachtman, *supra*, at 364.

²⁶ US – Clove Cigarettes, *supra*, at 179-182.

ii) their end-uses; iii) consumer tastes and habits vis-à-vis those products; and iv) tariff classification²⁷.

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 it²⁸. (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 2.1²⁹.

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 measure required segregation of meat and livestock according to origin, thus imposing higher segregation costs on 'like' imported livestock³⁰.

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**.

²⁷ Working Party Report, Border Tax Adjustments, adopted 2 Dec. 1970, BISD 18S/97.

²⁸ 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.

²⁹ United States – Measures concerning the importation, marketing and sale of tuna and tuna products. WT/DS381/AB/R.

³⁰ United States – Certain Country of Origin Labelling (COOL) requirements, WT/DS384/AB/R WT/DS386/AB/R

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 price³¹.

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’³².

5.2 – 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 5.5³³. Therefore, **under SPS, there is no ‘like products analysis’ since the focus is the justification for discrimination between situations under the SPS prohibition itself**³⁴.

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.

6 – 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

³¹ See Appellate Body Report, Japan – Alcoholic Beverages II, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, at 26.

³² Appellate Body Report, Korea – Various Measures on Beef, WT/DS161/AB/R and WT/DS169/AB/R, at 137.

³³ Australia – Salmon (Article 21.5 DSU), WT/DS18/RW, adopted 20 Mar. 2000, at para. 7.112.

³⁴ G. Marceau and J. P. Trachtman, *supra*, at 368.

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 available³⁵.

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*³⁶.

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 case³⁷.

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 necessary³⁸. In *Brazil- Retreated Tyres*, the Appellate Body considered that a measure’s degree of contribution must, at minimum, be “material”. Such a “material contribution” requirement has become ever since an important element in the analysis of the necessity test³⁹.

6.1 – 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

³⁵ G. Marceau and J. P. Trachtman, *supra*, at 378.

³⁶ 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’).

³⁷ G. Marceau and J. P. Trachtman, *supra*, at 368.

³⁸ *Korea - Beef* – *supra*, at para. 163.

³⁹ *Brazil – Tyres*, *supra*, at para. 210.

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 alternatives⁴⁰.

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 2.1⁴¹.

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 discrimination⁴².

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 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.

6.2 – 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.

⁴⁰ 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).

⁴¹ Appellate Body Report, US – COOL Requirements, WT/DS384/AB/R at para. 171.

⁴² US – Clove Cigarettes, supra, at 179-182.

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-restrictive⁴³.

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, 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 health⁴⁴.

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 Members⁴⁵.

⁴³ Appellate Body Report, *Australia – Salmon*, WT/DS18/AB/R, supra, at para. 194.

⁴⁴ Appellate Body Report, *EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, at para. 214-215.

⁴⁵ G. Marceau and J. P. Trachtman, supra, at 399.

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*⁴⁶’.

7 – 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.

7.1 – 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.

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**⁴⁷.

7.2 – 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** (...)

⁴⁶ G. Marceau and J. P. Trachtman, *supra*, at 410.

⁴⁷ *US – Clove Cigarettes*, *supra*, at 179-182.

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'⁴⁸.

8 - 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.

8.1 – 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 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 protection⁴⁹.

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 objectives⁵⁰.

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

⁴⁸ G. Marceau and J. P. Trachtman, *supra*, at 414.

⁴⁹ US – Tuna II, Panel Report, para. 7.379-7.623.

⁵⁰ US - Tuna II, AB Report, WT/DS381/AB/R, 2012, para. 333.

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.

8.2 - 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.

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 trade⁵¹.

⁵¹ EC – Hormones, AB Report, , supra, para. 214.

The Appellate Body, in the EC Hormones, also noted that the three elements are cumulative in nature⁵².

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 5.5⁵³.

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'.

9 – 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 (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

⁵² Ibid. , para. 215.

⁵³ *Australia-Salmon*, supra, para. 155.

product standards (particularly for food and chemicals), and are primarily trade-promoting rather than environment-enhancing concepts⁵⁴.

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-setting⁵⁵.

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 mechanisms⁵⁶.

The ‘working language’ in the TTIP⁵⁷ negotiations is ‘regulatory coherence’⁵⁸. Whether the stage of negotiations will pass to the stage of treaty signatures is a matter of whether a treaty 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’⁵⁹.

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 system⁶⁰. Such harmonization wording is also included in the TBT and SPS Agreements.

⁵⁴ Stevens, C. 1993. Harmonization, trade and the environment. *International Environmental Affairs* 5 (1): 42-49.

⁵⁵ Ibid.

⁵⁶ 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>

⁵⁷ EU-US Transatlantic Trade and Investment Partnership.

⁵⁸ European Commission Directorate-General for Trade. State of Play of TTIP negotiations ahead of the 6th round of the negotiations, 11th July, 2014.

⁵⁹ 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)

⁶⁰ Griffin, *supra* at note 1.

9.1 – 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 all Members’⁶¹. 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 dimension⁶².

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 consensus⁶³. 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

⁶¹ United States Tuna II, AB Report, WT/DS381/AB/R, 2012, para. 396-399.

⁶² 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”).

⁶³ European Communities - Trade Description of Sardines AB Report, WT/DS231/AB/R, para. 222.

inconsistent with TBT since it was not based on a ‘relevant international standard’ from the FAO/WHO-administered Codex Alimentarius Commission⁶⁴.

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.

9.2 – 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 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;

⁶⁴ 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.

(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**⁶⁵.

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 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 level⁶⁶.

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’⁶⁷.

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

⁶⁵ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In: http://wto.org/english/tratop_e/sps_e/spsund_e.htm

⁶⁶ Appellate Body Report, *EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, at para. 165.

⁶⁷ G. Marceau and Joel Trachtman, *supra*, at 388.

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.

10 – 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.

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' one⁶⁸.

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.

⁶⁸ 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.

10.1 – 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’⁶⁹.

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 law⁷⁰. 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:

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 uncertainty⁷¹. 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

⁶⁹ Appellate Body Report, *EC – Hormones*, supra, at para. 124.

⁷⁰ Ibid., at para. 123.

⁷¹ “Understanding the WTO Agreement on Sanitary and Phytosanitary Measures”. In: http://wto.org/english/tratop_e/sps_e/spsund_e.htm

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 time⁷².

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, insufficient⁷³.

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’⁷⁴.

10.2 – 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 situation⁷⁵.

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 rule⁷⁶.

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.

⁷² Appellate Body Report, *Japan – Agricultural Products II*, WT/DS76/AB/R, para. 89.

⁷³ Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, para. 621.

⁷⁴ *Ibid.*, para. 685-688.

⁷⁵ Appellate Body Report, *EC Asbestos*, *supra*, at para. 168.

⁷⁶ G. Marceau; J. P. Trachtman, *supra*, at 401.

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 approaches⁷⁷.

Regulation in Europe, such as REACH – Registration, Evaluation, Assessment of Chemicals⁷⁸, has equated the Precautionary Principle with an increase in health and 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’⁷⁹.

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 environment⁸⁰.

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

⁷⁷ 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.

⁷⁸ REACH - Official Journal L 136 (2007), at. 3.

⁷⁹ Lucas Bergkamp and Lawrence Kogan, *supra*, at 499.

⁸⁰ L. A. Kogan. REACH and International Trade Law, 2013, at para12.11.

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'⁸¹.

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 science⁸² 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.

11 – 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 transparency⁸³.

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.

⁸¹ L. A. Kogan., 2013, *supra*, at para12.11.

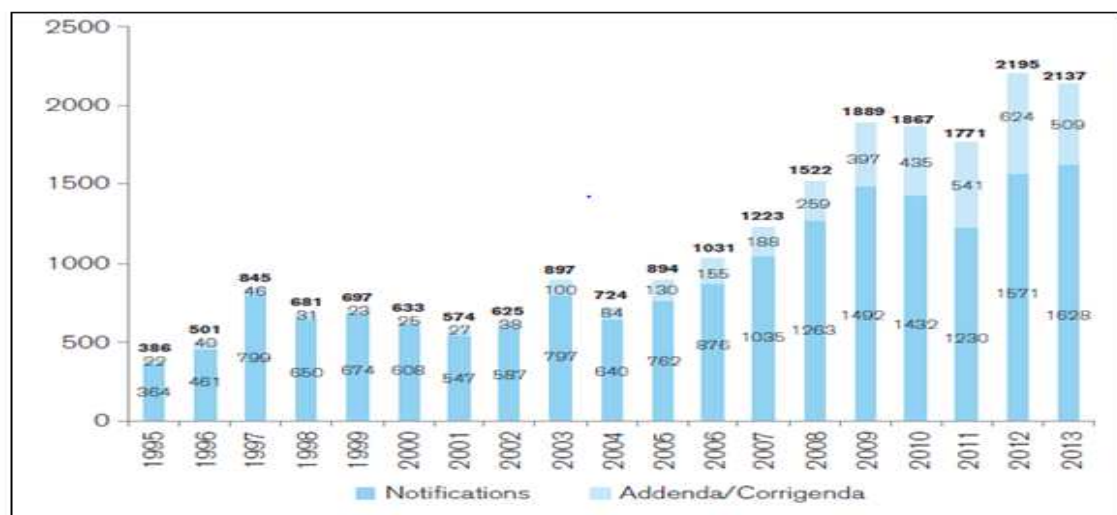
⁸² Lucas Bergkamp and Lawrence Kogan, *supra*, at 500.

⁸³ R. Griffin, *supra*, at note 1.

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’⁸⁴. 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 requirements⁸⁵.

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.

⁸⁴ The WTO Agreements Series, Technical Barriers to Trade, 2014, at 24.

⁸⁵ Ibid.

FIGURE 5: Notifications Objectives



Source: CCGI-FGV, 2014⁸⁶

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 INMETRO⁸⁷, 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 trade⁸⁸.

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.

⁸⁶ Thorstensen, V. Giancesella, F., CCGI, 2014.

⁸⁷ 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.

⁸⁸ Information available on <http://www.inmetro.gov.br/english/institucional/index.asp> (Access on 3rd November 2014).

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 country⁸⁹.**

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.

12 – 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 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 Agreement⁹⁰.

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.

⁸⁹ While INMETRO is the TBT focal point, MAPA (Ministério da Agricultura, Pecuária e Abastecimento) is the SPS focal point, in Brazil.

⁹⁰ World Trade Organization, The WTO Agreement Series – Technical Barriers to Trade, 2014.

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.

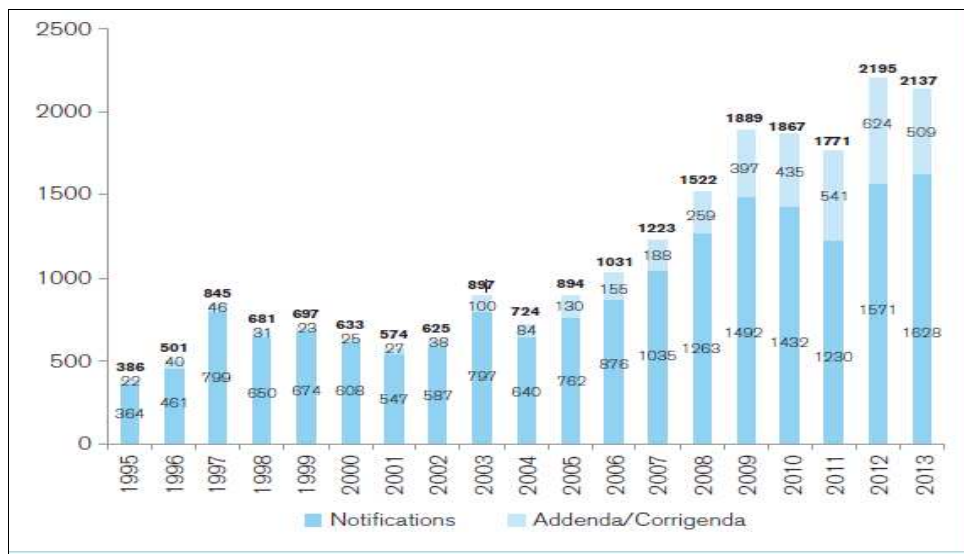
One of the tasks of both TBT and SPS Committees is to manage the specific trade concerns (STCs) that Members might raise before them. STCs are neither disputes raised under the Dispute Settlement Understanding (DSU) before Panels and Appellate Body nor pre-requisites for raising a dispute under the DSU⁹¹. They 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 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 concerns⁹².

⁹¹ 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.

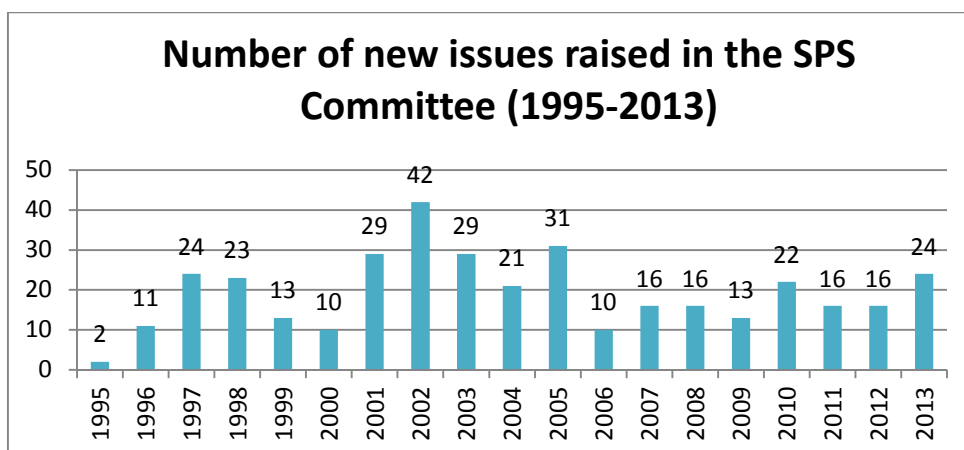
⁹² Henrik Horn, Petros C. Mavroidis and Erik N. Wijkstrom. In the Shadow of the DSU: addressing specific trade concerns in the WTO SPS and TBT Committees. Research Institute of Industrial Economics, IFN Working Paper, n. 960, 2013.

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



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

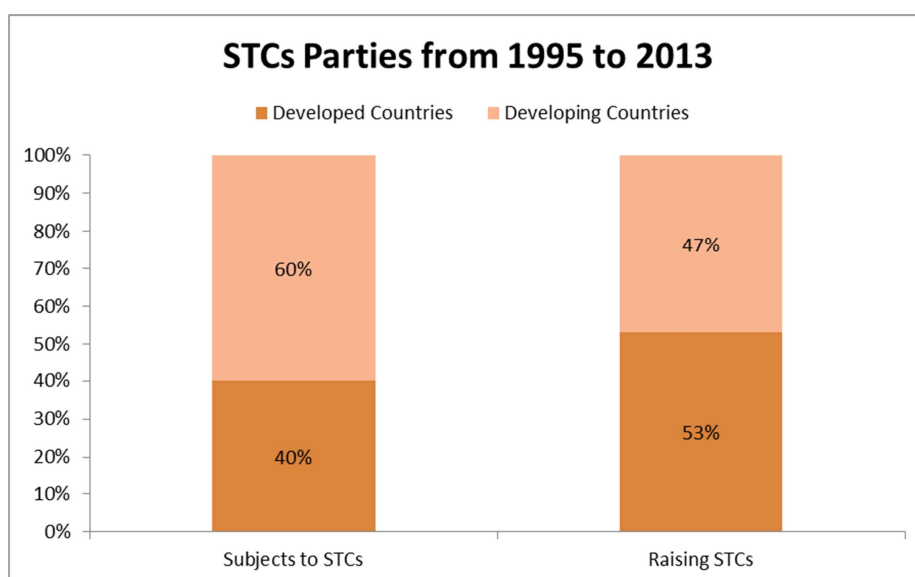
FIGURE 7: Number of specific trade concerns in the SPS Committee



Source: CCGI-FGV, 2014⁹³.

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

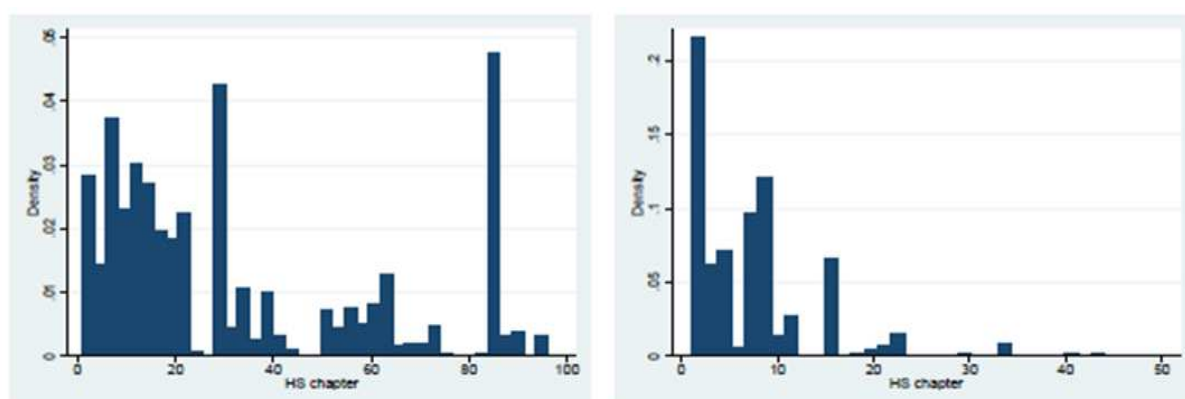
FIGURE 8: STCs Parties from 1995 to 2013



Source: CCGI-FGV, 2014⁹⁴

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.

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 efficient⁹⁵.

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

⁹⁴ Thorstensen, V. and Giancesella, F. CCGI-FGV, 2014.

⁹⁵ WTO Doc. G/TBT/1/Rev.10, page 43.

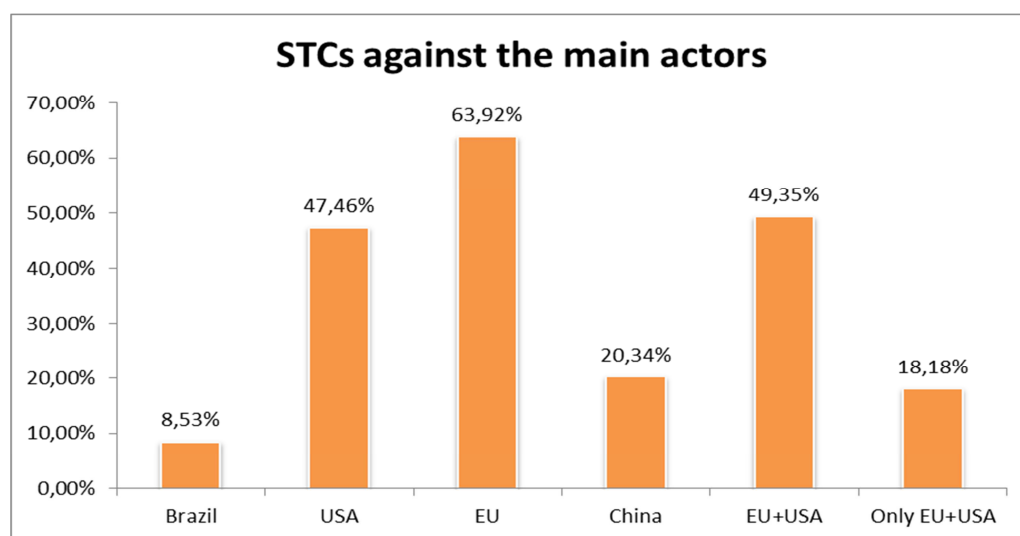
whether TBT STCs have been settled since the official record only indicates ‘not reported’ for all concerns⁹⁶.

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 DSU⁹⁷.

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)⁹⁸. 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 settlement⁹⁹.

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 Vietnam (See Figure 10). The Members that most frequently face SPS STCs are: Australia, Japan, USA, China, South Korea, Indonesia, Canada, Argentina and Brazil¹⁰⁰.

FIGURE 10: STCs against the main actors



Source: CCGI-FGV, 2014¹⁰¹

⁹⁶ Henrik Horn and others, *supra*, at 29.

⁹⁷ *Ibid.*, *supra*, at 2.

⁹⁸ 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.

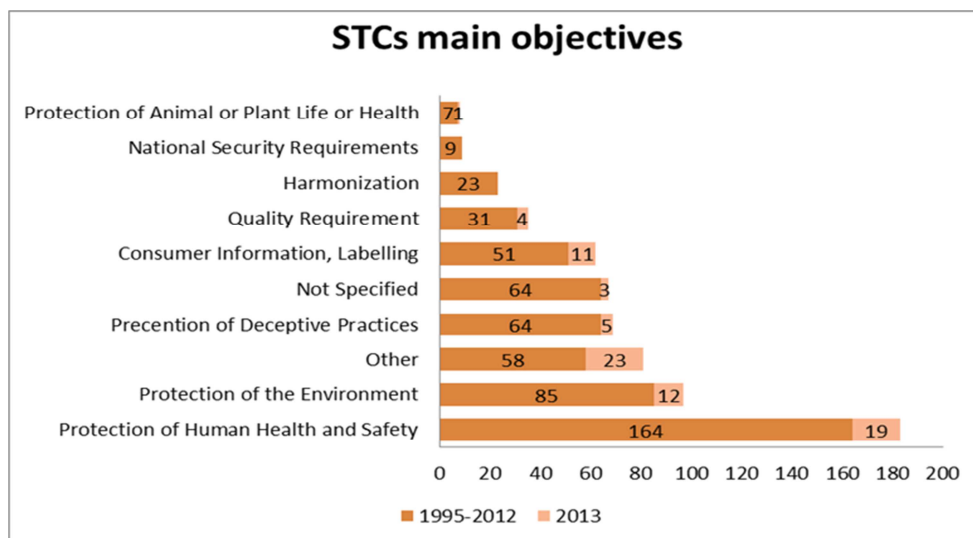
⁹⁹ Henrik Horn and others, *supra*, at 8.

¹⁰⁰ *Ibid.*, at 9-10.

¹⁰¹ Thorstensen, V. and Giancesella, F. CCGI-FGV, 2014.

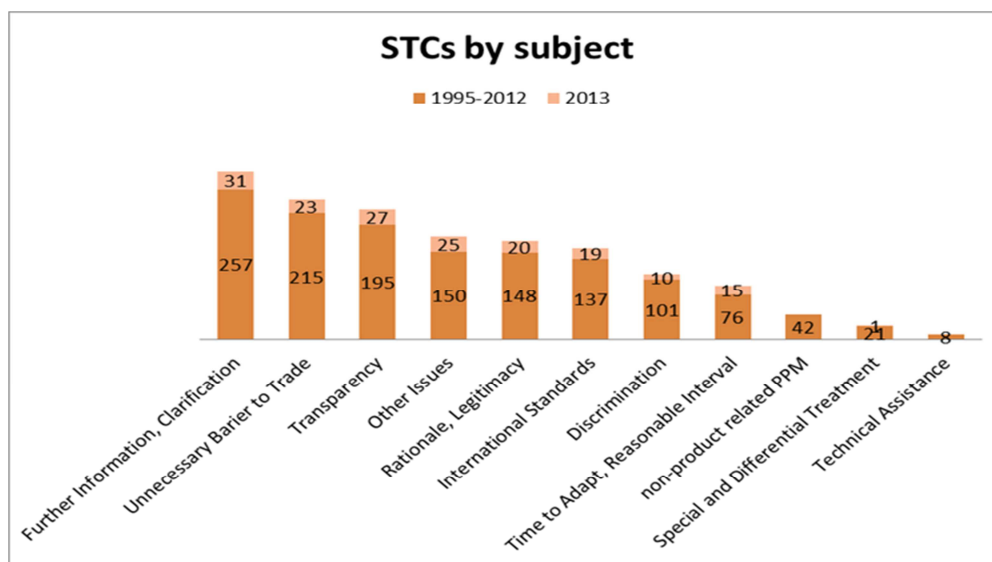
Having a look at the sort of issues that have been raised under both SPS and TBT Committees, some scholars have reached a conclusion that ‘as many as 66% of all STCs, the stated objectives of protecting human health or safety, or the protection of the environment or both are at the root of the concern being addressed’ (Figures 11 and 12)¹⁰².

FIGURE 11: STCs main objectives



Source: CCGI-FGV, 2014¹⁰³.

FIGURE 12: STCs by subject



Source: CCGI-FGV, 2014¹⁰⁴.

Such results ‘contrast sharply with the corresponding figures in the Dispute Settlement system, where a significantly smaller fraction of disputes concern measures falling

¹⁰² Ibid., at 19-20.

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

¹⁰⁴ Thorstensen, V. and Ganesella, F. CCGI-FGV, 2014.

under these two categories’ – protection of human health and protection of the environment¹⁰⁵.

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

13 – A briefing on Private Standards

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.

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 Quality 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 Streekproductie Vlaams Brabant	

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

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.

¹⁰⁵ Henrik Horn and others, supra., at 8., at 20.

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).

Examples of Private Standards:



Source: Nature's Choice, TESCO (2014)¹⁰⁷



Source: Forest Stewardship Council (2014)¹⁰⁸



Source: GlobalGAP (2013)¹⁰⁹



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



Source: United Laboratories (2014)

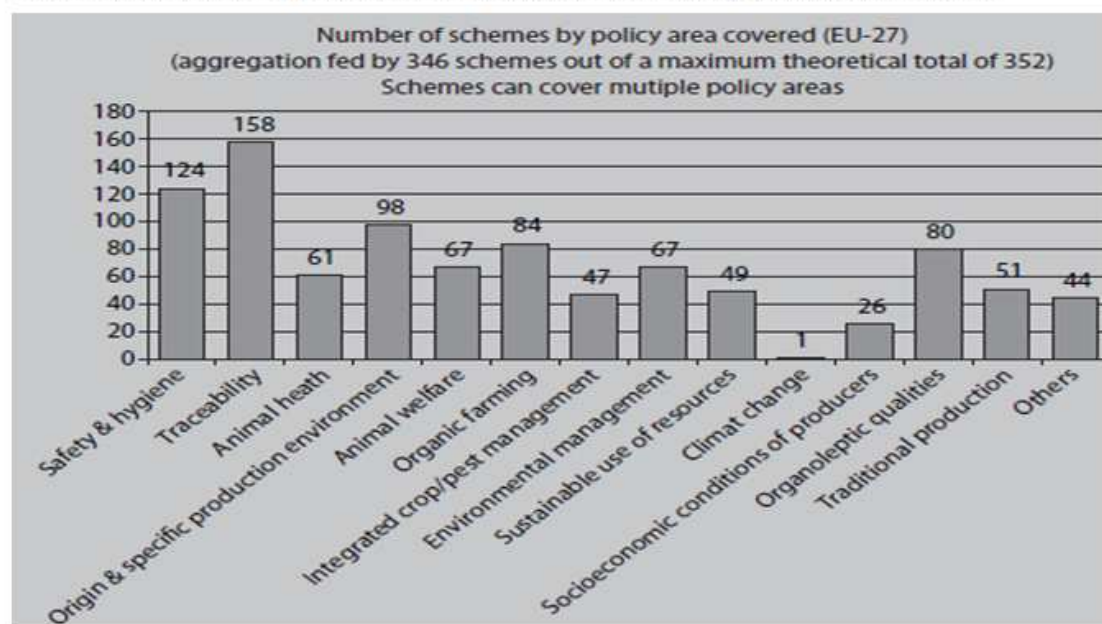
In the last decade, there has been an increase in private standards and they have become one of the most common contemporary trade barriers (See Figures 13 and 14).

¹⁰⁷ Available in <http://www.tesco.com/csr/g/g4.html> (access on 7th November 2014).

¹⁰⁸ Available in <http://br.fsc.org/> (Access on 7th November 2014).

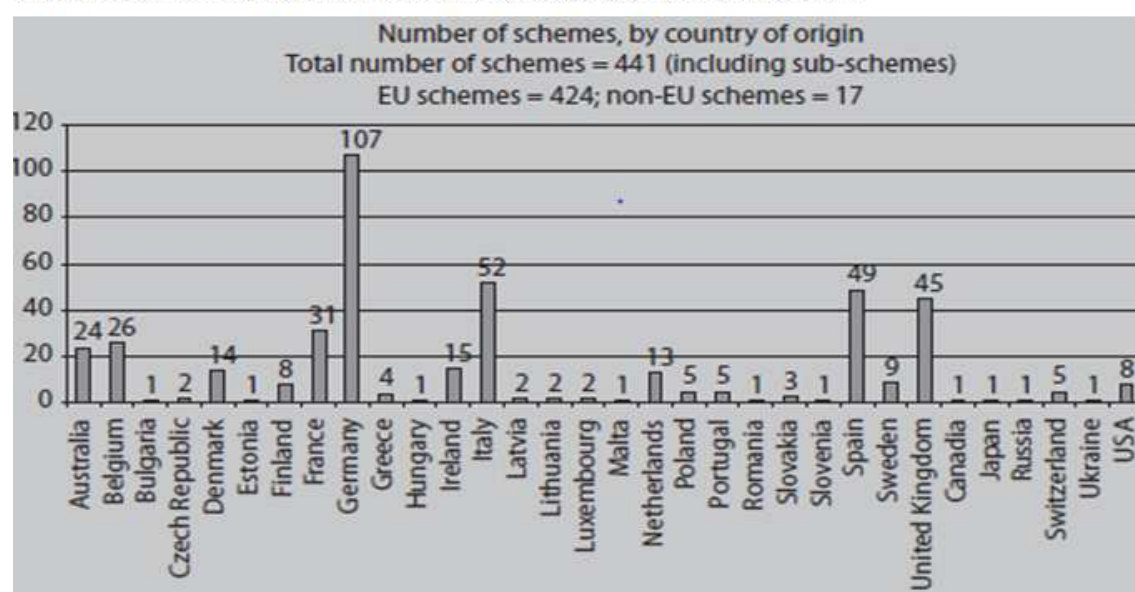
¹⁰⁹ Available in: http://www.globalgap.org/uk_en/ (Access on 7th November 2014).

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



Source: Inventory of Private Food Law, EFLA, 2011¹¹⁰

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



Source: Inventory of Private Food Law, EFLA, 2011¹¹¹

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:

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**

¹¹⁰ Theo Appelhof and Ronald van den Heuvel, Inventory of Private Food Law, In: Bernd van der Meulen (ed.), Private Food Law, 2011, at 113.

¹¹¹ Theo Appelhof and Ronald van den Heuvel, Inventory of Private Food Law, In: Bernd van der Meulen (ed.), Private Food Law, 2011, at 113.

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 sectors¹¹². (emphasis added)

Even though private standards are not legally mandatory, they might become *de facto mandatory* ever since a majority of large buyers demand them¹¹³. 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 Committee¹¹⁴. Another discussion was raised in 2006¹¹⁵. 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'¹¹⁶. 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'¹¹⁷.

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 market¹¹⁸. For example, the search for production of

¹¹² 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.

¹¹³ Ibid.

¹¹⁴ G/SPS/R/37, 11 August 2005.

¹¹⁵ G/SPS/R/39, 21 May 2006.

¹¹⁶ G/SPS/W/256, 3 March 2011.

¹¹⁷ G/SPS/W/265, Proposed Working Definition on SPS-Related Private Standards. 6, March 2012.

¹¹⁸ Rodrigo C. A. Lima. Padrões Privados e Responsabilidade do Estado na OMC. 2014, at 7. (Forthcoming publication).

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 cultivated¹¹⁹.

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 procedures¹²⁰. 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 GATT¹²¹.

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’¹²².

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.

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

¹¹⁹ Ibid., at 9.

¹²⁰ Ibid., at 10.

¹²¹ Ibid., at 11.

¹²² G/SPS/GEN/1334/Rev.1, circulated on 5 August 2014.

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 either¹²³. The core of the discussions on the TBT Committee is the adoption of the Code of Good Practices by private bodies¹²⁴.

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 violation¹²⁵.

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 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 bodies¹²⁶.

14. 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,

¹²³ Manuela K. Amaral, *supra*, at 244.

¹²⁴ G/TBT/13; G/TBT/26; G/TBT/32.

¹²⁵ Manuela k. Amaral, *supra*, at 248.

¹²⁶ Rodrigo C. Lima, *supra*, at 23.

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 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 sheep skin' - 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 clerly 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)

