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FOOD TRADE AND STANDARDS IN THE SPS AGREEMENT:

NECESSITY AND LEGITIMACY IN A COOPERATION FRAME

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Table of Contents

Introduction…….…….4

Chapter I. The legal nature of international standards under the SPS Agreement…….8

1. Introduction…….....9
2. Setting the scene: a look back from Punta Del Este…….……..……..12
2.1. Negotiators' (different) positions, a request of flexibility?.....16
2.2. The participation of the Codex Alimentarius Commission: the germ of cooperation…….23
2.3. The evolution of the draft texts shaping the harmonization obligations…….26
3. Different tracks for States and distinctive modes of compliance under the SPS Agreement Article 3……...30
3.1. What are international standards under the SPS Agreement?.....31
3.2. Measures conforming to international standards (Article 3 para. 2)…….39
3.3. Basing measures on international standards (Article 3 para. 1)……..…….45
3.4. Measures deviating from international standards (Article 3 para. 3)……49
3.5. Risk Assessment: the turning point for compliance…….……53
3.6. Interim conclusions on Article 3: framing its normative value and opening to the cooperative dimension……55
4. The SPS Committee: the institutionalized dynamism…….……58
4.1. The functions: a forum for consultation beyond Dispute Settlement……60
4.2. The functions (ii): monitoring and shaping standards……..63

Chapter II. The outsourcing of standard-setting to the Codex Alimentarius Commission…….……..……72

5. Introduction…….……73
6. The Codex Alimentarius Commission. ……..……74
6.1. The rise of the Codex - structure and functions. …….…...75
6.2. The Codex: harmonization through standard-setting. …….....80
6.3. The Codex before 1995: a "Gentlemen's Club"..……..……..85
6.4. A new role and status after 1995……...…...87
7. The WTO shaping the Codex: (i) introducing politics. – (ii) hardening science….…...89
8. The WTO-Codex interinstitutional relationship…….....99
8.1. Preliminary remarks: different membership and mandate……...101
8.2. The judicial dimension: the role of Panels and AB……..103
8.3. Applying non-WTO law: the broad picture of public international law……..104
8.4. Applying and interpreting international standards. ……107
8.4.1. An additional option to interpret standards: the role of experts……115
8.4.2. Internal dispute settlement mechanisms: not in the Codex "garden"……120
9. The delegation of regulatory authority……122
9.1. The case of Codex: historical and practical reasons…….124
9.2. The politics of delegation: benefits, limits and legitimacy……...129

Chapter III. Private sector food-safety standards and the SPS Agreement: challenges and possibilities……..……..136

10. Introduction……137
11. The SPS Committee practice: beyond the definitional problem. ……..142
12. The SPS Agreement and private sector standards - which room and which role for private actors. ……..149
12.1. Scope of application of the SPS Agreement. ……150
12.2. Provisions of the SPS Agreement relating to the activities of non-governmental standard-setting organizations – Article 13. ……..153
13. The case for private standards: limits and challenges. ……..156

Conclusion……...…160

Bibliography……165

Introduction

The dropping of tariff levels which started after the Second World War entailed that non-tariff barriers (NTBs) became the most important manmade impediments to international trade. Seven rounds of tariff negotiations dramatically reduced import duties on industrial goods and in 1979 the Tokyo Round Codes expanded GATT discipline to include the far more sensitive field of NTBs as well. In particular, as tariff reductions moved forward under GATT, the realization that differing standardization systems between countries acted as a major NTBs gained ground. To reduce this possibility the Standards Code was concluded. Further developments occurred within the World Trade Organization (WTO), a normative expansion into a host of new regulatory areas, such as health and safety standards. Since standards were essential for smooth trade, WTO Agreements strongly encouraged Governments to harmonize their requirements on the basis of international standards.

The disciplines regarding food hygiene and safety standards established by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) concluded during the Uruguay Round are slightly different from the rules established for harmonization of general standardization and certification by the Agreement on Technical Barriers to Trade (TBT Agreement). The SPS Agreement sets out a framework of rules to achieve a balance between Members' rights to adopt measures to ensure food safety and the goal of limiting the unnecessary effects of such measures on trade. The peculiarity of such Agreement, compared to the other covered Agreements, is that its rules require national measures to be based on scientific findings.

Food standards and trade go hand in hand in ensuring safety products. By setting down a common understanding on different aspects of food for Governments, producers and consumers, standards enable trade to take place. International standards

formulated by international standardizing bodies are in principle recommendations or guides whose adoption is left to the discretion of each Member State.

The expanding international food market in the aftermath of the Second World War necessitated more cooperation in the setting of standards for food. This led to the creation of the core body in charge of international harmonization on safety standards, the Codex Alimentarius Commission (Codex or CAC). In the area of food safety, the SPS Agreement relies on Codex standards by setting them out as the benchmark for harmonization. The importance of international standards is highlighted by the fact that SPS measures conforming to or based on international standards are presumed not to constitute trade barriers. Therefore, the institutional framework that governs the development and application of international food safety standards is based on the Codex and the WTO.

Against this background, contemporary agri-food systems are increasingly pervaded by a plethora of private food safety standards that operate alongside public regulatory rules. Innovations in science and technology, methods of production and processing, as well as the paths that food travels along from farm to fork, are continuously evolving. It is evident that private standards, addressing these issues, are playing an increasing role in the governance of agricultural and food supply chains.

This research questions the current system of sources of law in the SPS Agreement in a legitimacy-related perspective and the actors involved in standard setting activities that cooperate in this frame. The research questions addressed are the following: how and to what extent international standards are binding according to the SPS Agreement? (Chapter I). Which is the role of States, the SPS Committee, Panels and the Appellate Body and, in particular which is the relationship between the Codex and the WTO? (Chapter II). Do the activities of private parties trigger for the application of SPS Agreement provisions? Which are the possibilities and the criticisms when paving the way for private actors in the domain of food safety? (Chapter III).

In this research it will be enquired the entire system of rights and obligations around sanitary and phytosanitary standards that has been object of discussion, negotiation, cooperation and dispute within "soft environments and processes" (the SPS Committee, the Codex Alimentarius Commission, expert meetings) as well as within the "hard context" of the WTO system (the covered Agreements and the Dispute Settlement Mechanism).

While this research comes up with conclusions on food safety standards, before delving into this issue, it is useful to briefly frame the broad WTO context.

In a world that, according to what Wolfgang Friedmann said in 1964, is moving from coexistence to cooperation and even to forms of integration[1], it is alleged that customs, treaties, and general principles of law no longer suffice to catch the processes of norm creation at the international level. In the domain of trade law, we can notice the growing importance of regulatory disciplines, due to the transition process from trade liberalization to trade regulation[2], as the result of the change from classic trade liberalization on tariffs and negative integration to the removal of behind-the-border measures and positive integration[3]. This is also one of Professor Jackson's many legacies in is his role in moving the international trade system from a "power-oriented" to a "rule-oriented" regime[4].

Focusing solely on traditional or formal processes of law-making results in an incomplete understanding of the current nature of the international economic framework, as embodied in WTO law. The relationship between the WTO and other areas of international law has been described as an example of "new legal realism",

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[1] W. FRIEDMANN, *The Changing Structure of International Law*, Columbia University Press, 1964, p. 61 *et seq*.
[2] T. COTTIER, *International Economic Law in Transition from Trade Liberalization to Trade Regulation*, Journal of International Economic Law, Vol. 17, issue 3, 2014, pp. 671–677.
[3] For a general overview on legal tools and free trade see F. ORTINO, *Basic Legal Instruments for the Liberalisation of Trade: A Comparative Analysis of EC and WTO Law*, Bloomsbury Publishing PLC, Studies in International Trade Law, 2004. For a focus on trade liberalization in the food perspective see A. ALEMANNO, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, 2007.
[4] J. H. JACKSON, *The Jurisprudence of GATT and the WTO: Insights on Treaty Law and Economic Relations*, Cambridge University Press, 2000, pp. 6–10.

and the matches with other areas of international law "depend[s] not just on formal doctrinal interpretations, but also on social processes through which formal law gains meaning and is practiced"[5]. Moreover, in the negotiation stalemate, we are addressing stagnation in the formation of traditional treaty rules[6]. Thus, the rise of what has been called the "informal international law-making"[7] is the corresponding trend of the 'crisis' of classic law actors, processes and outputs. Soft law[8], with its rich and complex normative structure and varying degrees of normativity[9], is significative for reflections on the WTO context. Referring specifically to the area of food trade, the current scenario shows a heterogeneous and soft normative reality, which demonstrates how the WTO is moving away from its hard approach and is starting to regulate trade also in non-traditional forms.

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[5] G. SHAFFER, *The New Legal Realist Approach to International Law*, Leiden Journal of International Law, Vol. 28, issue 2, 2015, pp. 207–208. In particular, the author outlined two aspects: "First, within the context of formal WTO dispute settlement, what matters is whether the WTO Appellate Body will take into account such other international law one way or another, formally or informally, and why they will do so [...] Second, and critically, new legal realists stress that the implications of such other public international law [...] need to be assessed outside of the adjudicatory context [...] Other public international law is of interest to countries implicated by a WTO dispute, regardless of whether a WTO panel recognizes such other international law as a formal source of WTO law, because it affects the legitimacy of their position in their relations with other countries. Likewise, private stakeholders are interested in such other international law in light of its implications for advancing their priorities both in national and transnational debates".

[6] Basically, since the WTO's creation in 1994, few traditional rules have been agreed upon within the WTO, besides two major exceptions: the 2005 TRIPS amendment and the 2013 Trade Facilitation Agreement.

[7] "Cross border cooperation between public authorities, with or without the participation of private actors and/or international organizations, in a forum other than a traditional international organization (process informality), and/or as between actors other than traditional diplomatic actors (such as regulators or agencies) (actor informality) and/or which does not result in a formal treaty or other traditional source of international law (output informality)". J. PAUWELYN, *Informal International Lawmaking: Framing the Concept and Research Questions*, in *Informal International Lawmaking*, J. PAUWELYN, R. WESSEL, and J. WOUTERS (eds.), Oxford University Press, 2012, p. 22.

[8] For a general overview see, among others: P. WEIL, *Towards Relative Normativity in International Law?*, American Journal of International Law, Vol. 77, issue 3, 1983; C. CHINKIN, *Normative Development in the International Legal System*, in *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System*, D. SHELTON (ed.), Oxford University Press, 2000; J. KLABBERS, *Reflections on Soft International Law in a Privatized World*, Finnish Yearbook of International Law, Vol. 16, 2005; J. D'ASPREMONT, *Softness in International Law: A Self-Serving Quest for New Legal Materials*, European Journal of International Law, Vol. 19, no. 5, 2008.

[9] M. E. FOOTER, *The (Re)turn to Soft law in Reconciling the Antinomies in WTO Law*, Melbourne Journal of International Law, Vol. 11, 2010, pp. 242–243.

Chapter I

The legal nature of international standards under the SPS Agreement

Summary: 1. Introduction. – **2.** Setting the scene: a look back from Punta Del Este. – **2.1.** Negotiators' (different) positions, a request of flexibility?. – **2.2.** The participation of the Codex Alimentarius Commission: the germ of cooperation. – **2.3.** The evolution of the draft texts shaping the harmonization obligations. – **3.** Different tracks for States and distinctive modes of compliance under the SPS Agreement Article 3. – **3.1.** What are international standards under the SPS Agreement?. – **3.2.** Measures conforming to international standards (Article 3 para. 2). – **3.3** Basing measures on international standards (Article 3 para. 1). – **3.4.** Measures deviating from international standards (Article 3 para. 3). – **3.5.** Risk Assessment: the turning point for compliance. – **3.6** Interim conclusions on Article 3: framing its normative value and opening to the cooperative dimension. – **4.** The SPS Committee: the institutionalized dynamism. – **4.1**. The functions: a forum for consultation beyond Dispute Settlement. – **4.2.** The functions (ii): monitoring and shaping standards.

1. Introduction

In Addis Ababa, Ethiopia, the 12 and 13 February 2019 the first Food and Agriculture Organization (FAO), World Health Organization (WHO) and the African Union (AU) International Food Safety Conference[10] took place, aimed to result in a high-level political statement advocating for increased and better coordinated collaboration and support to improve food safety globally. After two months, in Geneva, Switzerland, the WTO International Forum on Food Safety and Trade[11], continuing the same discussions, addressed the trade-related aspects and challenges of food safety, in order to better align and coordinate efforts to strengthen food safety systems across sectors and borders. During the same period, again in Geneva, the SPS Committee was involved in the fifth review of the operation and implementation of the SPS Agreement[12], considering WTO Members proposals on issues such as: discussing the role of the Committee in increasing coordination and harmonization; the development of guidelines for the implementation of Article 13 of the SPS Agreement and the promotion and adoption of science-based procedures like scientific justification for risk assessment.

The three meetings, and the international organization participating, albeit different in terms of mandates, institutional background and purposes, are part of the same broad picture of food safety. In this scenario, some recurrent and shared trends

[10] The Future of Food Safety: Transforming knowledge into action for people, economies and the environment, joint conference co-organized by FAO, WHO, WTO and AU, held in Addis Ababa, 12 and 13 February 2019. Ministers and representatives of national governments, senior policy makers as well as representatives of non-state actor groups were all engaged in urgent reflections on food safety. They aimed to identify key actions and strategies to address current and future global challenges of food safety and strengthen commitment to scale up food safety in the 2030 Agenda for Sustainable Development.

[11] WTO International Forum on Food Safety and Trade, joint conference co-organized by WTO, FAO and WHO, held in Geneva, 23 and 24 April 2019. This event tried to highlight the implications of digital innovation for food safety and trade, the importance of the coordinated advancement of the food safety and the trade facilitation agendas and the fundamental role of Codex in facilitating the harmonization of safety regulatory frameworks as food systems evolve according to rapid technological change.

[12] Committee on Sanitary and Phytosanitary Measures, *Fifth Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures*, *Overview of Papers and Proposals Submitted by Members*, *Note by the Secretariat,* G/SPS/GEN/1625/Rev.2, circulated on 26 April 2019.

emerge. Although different ethos characterizes the activities of the actors involved, political, technical and trade-oriented, coordination and cooperation among them are considered as crucial for an effective response to the challenges of food safety, which is conceived and addressed in the global dimension.

The present research debates over this community, over the actors that are empowered to make or influence law, and is therefore intended to be a dialogue over the sources of law, within the perspective of WTO law. More specifically, it addresses recent developments questioning the source-monopoly of WTO Members, WTO covered agreements and legally binding instruments.

Scholars and practitioners have become accustomed, in relation to the law of the WTO, only in terms of hard rules set by States. As claimed by Pauwelyn[13], the WTO approach to sources of law can be defined as legal positivist, non-teleological, focusing predominantly on WTO covered agreements[14]. Traditionally, the WTO framework has always exemplified, being treaty-based and member driven, two features of hard law centered on States. Moreover, with its quasi-universal membership, and with a Dispute Settlement Mechanism enforcing these obligations – that was "busier than ever"[15] while now in crisis[16] - the hard character of the WTO is even more evident. However, the here examined regulatory architecture will show that the WTO law moved away from its hard-law-only approach and started to regulate trade also in softer forms.

Questioning the source-monopoly of legally binding instruments by looking

[13] This kind of understanding on what can be considered the WTO approach on sources of law is the same adopted, shared and at the basis of this research.

[14] J. PAUWELYN, *Sources of international trade law: Mantras and Controversies at the World Trade Organization*, in *The Oxford Handbook of the Sources of International Law*, J. D'ASPREMONT, S. BESSON, and S. KNUC (eds.), Oxford Handbooks, 2017, pp. 1027–1046. In this regard, also Mavroidis and Palmeter observe that: "[t]he fundamental source of law in the WTO is therefore the texts of the relevant covered agreements themselves. All legal analysis begins there". P. MAVROIDIS and D. PALMETER, *The WTO Legal System: Sources of Law*, American Journal of International Law, Vol. 92, issue 3, 1998, p. 398.

[15] J. PAUWELYN and W. ZHANG, *Busier than ever?: A data-driven assessment and forecast of WTO caseload*, CTEI Working Paper, 2018.

[16] G. SACERDOTI, *The stalemate concerning the Appellate Body of the WTO: Any way out?*, Questions of International Law, Zoom-out no. 63, 2019; J. PAUWELYN, *WTO Dispute Settlement Post 2019: What to Expect?*, Journal of International Economic Law, Vol. 22, issue 3, 2019.

further at something that is created outside the WTO[17], leads us to reflect on whether instruments that were not intended to be legally binding, can nonetheless create law or influence law. Directly or indirectly holding States to a legal instrument they did not consent to as having binding effects challenges the foundational principle that all sources of international law must derive from Sate consent[18]. Where non-Sate actors are (directly or indirectly) empowered to make or influence law, legitimacy questions arise[19].

Among several non-binding instruments, international standards fit perfectly within the definition of informal international lawmaking that it is informal in all three ways: a "[c]ross-border cooperation between public authorities, with or without the participation of private actors and/or international organizations, in a forum other than a traditional international organization (process informality), and/or as between actors other than traditional diplomatic actors (such as regulators or agencies) (actor informality) and/or which does not result in a formal treaty or other traditional source of international law (output informality)"[20].

In an area outside traditional international law, the international standard-setting world, which is dropping individual State consent, a sort of "code of good practice" is emerging. It is trying to impose stricter requirements in terms of actor formality – who is involved and has the capacity in the norm-creating process; process formality – due process procedural requirements (openness, impartiality and transparency); output formality – substantive validity check (effectiveness, relevance

[17] J. PAUWELYN, *Sources of international trade law: Mantras and Controversies at the World Trade Organization*, p. 1033.
The process of standard setting as well as the different formal requirements for the adoption of an international standards, as explained in Chapter I and II of this research, are set outside the WTO framework.
[18] *Ibid*., p. 1038.
[19] *Ibid*., p. 1033.
[20] J. PAUWELYN, *Informal International Lawmaking: Framing the Concept and Research Questions*, p. 22.
The flexible and problem-oriented approach reflected in this definition is suitable for a source of law as international standards in the trade domain being characterized by its technical nature.

and coherence of the norm)[21].

In this broad scenario, the present Chapter examines to what extent international standards are binding according to the normative framework and the institutional architecture of the SPS Agreement and aims to highlight on a much broader basis the relevance of these sources of law in the WTO system. The issues at stake are addressed as follows: first, an overview of the general and historical background behind this scenario. Such frame of reference is specially focused on the *travaux préparatoires*[22] of the Uruguay Round, looking at different State's positions and at the draft versions of the SPS Agreement. Second, an analysis of the content of Article 3, the provision of the SPS Agreement devoted to harmonization, brings out an interpretation that highlights, according to its regulatory structure, the indirect/*de facto* binding authority of standards. This investigation, led even by the procedural angle, makes specific reference to the relevant case law. At the end, a study on the activities of the SPS Committee and on its subsequent practice shows the dynamic and vibrant environment within which international standards are notified, discussed and modified. An institutionalized model of cooperation, provided by SPS Agreement Article 12, through which States are encouraged to adopt these standards.

2. Setting the scene: a look back from Punta Del Este

By looking back on the Uruguay Round negotiations on the SPS Agreement, we can notice that harmonization through international standards was concurrently one of the key and divisive issue among Parties. One early theme of discussion within the SPS negotiating subgroup was the desirability of harmonizing national SPS standards in order to facilitate trade in agricultural products. In this regard, Motaal recounts how negotiating parties initially focused on the use of international standards and reliance

[21] J. PAUWELYN, *Sources of international trade law: Mantras and Controversies at the World Trade Organization*, p. 1039.
[22] This focus is also due given the lack of attention in the literature on that aspect.

on the expertise of international standard-setting bodies, such as Codex, the International Office for Epizootics (OIE) and the International Plant Protection Convention (IPPC), to discipline the heterogeneity produced by multiple differing national standards[23]. Showing how harmonization fits in the picture of negotiations will help us to observe from the very beginning the path along which standards have acquired their current character. The evolution of the meaning, role and effects of international standards passes through the varied proposals by States during the Uruguay Round, crystallized mainly in SPS Agreement Article 3.

During the Uruguay Round negotiations on agriculture, States were very aware of the fact that efforts towards liberalization, and the related progress achieved in the direction of lowering barriers in that sector, could be made ineffective by the increased use of SPS measures for protectionist purposes[24]. SPS regulations, along with the so-called three pillars - domestic support, market access and export subsidies[25] - were slated for reform, as the final obstacles to trade in agriculture.

Both the launching agenda of the negotiations, as reflected in the Punta Del Este Declaration[26], and the final outcome of such dialogues, as stated in the Agreement on Agriculture[27], recognize that the panoply of SPS discipline was inextricably linked

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[23] D. MOTAAL, *The "Multilateral Scientific Consensus" and the World Trade Organization*, Journal of World Trade, Vol. 38, no. 5, 2004, p. 857.

[24] M. TREBILCOCK and J. SOLOWAY, *International trade policy and domestic food safety regulation: the case for substantial deference by the WTO Dispute settlement Body under the SPS Agreement*, in *The Political Economy of International Trade Law*, D. KENNEDY and J. SOUTHWICK (eds.), Cambridge University Press, 2002, p. 537; D. A. MOTAAL, *The "Multilateral Scientific Consensus" and the World Trade Organization*, p. 860.

[25] For a complete overview on the negotiations and on the contents of the Agreement on Agriculture see: J. MCMAHON, *The WTO Agreement on Agriculture: A Commentary*, Oxford Commentaries on GATT/WTO Agreements, 2006.

[26] One of the objectives of the Uruguay Round, is to "minimiz[e] the adverse effect that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements.", Ministerial Declaration on the Uruguay Round Negotiations, Punta del Este in Uruguay, 20 September 1986, MIN.DEC., p. 6.

[27] It has to be recalled that Article 14, by making reference to "Sanitary and Phytosanitary Measures", is redundant in the sense that, considering WTO Agreements as a single legal undertaking, it means that the outcome of the negotiations is a single package that has to be considered as a single treaty, as noted by Marceau and Trachtman. G. MARCEAU and Z. J. 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, Vol. 48, no. 2, 2014, p. 352, footnote 5.

to the purpose of achieving free trade related to food and plant products. However, while the roots for the development of a legal framework protecting public health and safety lies in the domain of agriculture, States realized that all these issues were not negotiable in the "ordinary sense"[28]. This special consideration was thus due to several factors: the technical nature of the matters at stake, the country-based conditions (geographic, climatic and production situations) and the overlapping competence of national authorities in this field of international law[29], in particular in the area of risk assessment and in the definition of best preventive or remedial instruments[30]. The idea of *ad hoc* disciplines for SPS measures flourished in the period when the first signs of the so-called Hormones case[31] came, and in a negotiating context where SPS measures arose problems that are more peculiar than those characterizing other and different technical measures[32].

This framework of rules, albeit distinctive, shares with other disciplines the search for an appropriate balance between free trade and Members regulatory autonomy, a crossroad that lies at the heart of the WTO system[33]. The co-existence of

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[28] Committee on Trade in Agriculture, *Summary of Points Raised at the Meeting of the Committee held on 2 and 3 April 1985, Note by the Secretariat*, AG/W/13, circulated on 4 September 1985, p. 1, para. 2.

[29] *Ibid*.

[30] E. PATTERSON, *International Efforts to Minimize the Adverse Trade Effects of National Sanitary and Phytosanitary Regulations*, Journal of World Trade, Vol. 24, no. 2, 1990, p. 95.

[31] Among the vast literature on this topic see: D. E. MCNIEL, *The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban*, Virginia Journal of International Law, Vol. 39, no. 1, 1998, p.104; D. VOGEL, *Food Safety and International Trade, Trading Up: Consumer and Environmental Regulation in a Global Economy*, Harvard University Press, 1995, p. 155.

[32] D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension*, Wolf Legal Publishers, 2009, p. 483.

[33] This matter has been the subject of controversial debates in the case law dimension in, *inter alia*: Tuna - Dolphin (*United States - Restrictions on Imports of Tuna*, Panel Report DS21/R, 1991); US - Shrimp (*United States - Import Prohibition of Certain Shrimp and Shrimp Products*, Panel Report WT/DS58/R, 1998 and Appellate Body Report WT/DS58, 1998); Korea - Beef (*Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, panel Report WT/DS/161/R, 2001, and Appellate Body Report WT/DS161/AB/R, 2001) and US - Gasoline (*United States - Standards for Reformulated and Conventional Gasoline*, Appellate Body Report WT/DS2 /AB/R, 1996).
For general reflections in the literature see: M. M. DU, *The Rise Of National Regulatory Autonomy In The Gatt/Wto Regime*, Journal of International Economic Law, Vol. 14, issue 3, 2011, pp. 639-675; J. H. JACKSON, *Sovereignty-Modern: A New Approach to an Outdated Concept*, American Journal of International Law, Vol. 97, 2003, p. 782; J. H. JACKSON and D. SAROOSHI, *Sovereignty, the WTO and Changing Fundamentals of International Law*, Oxford University Press, 2007; K. RAUSTIALA, *Rethinking the Sovereignty Debate in International Economic Law*, Journal of International Economic

domestic needs and preferences, as an expression of non-trade values, with the aim of free trade, is made possible by several valves created within the WTO framework, in order to not alter the "balance"[34] of the system. Each of the treaties part of the Marrakesh Agreement defines differently the sphere of this regulatory autonomy, leaving little or greater room for States' right to protect some non-trade values, such as health and safety.

WTO harmonization Agreements[35] - the SPS Agreement, and to some extent the TBT Agreement[36], that promote a "positive model"[37] of integration, with the adoption of international standards - upset the contractual balance provided by the core

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Law, Vol. 6, issue 4, 2003, pp. 846-848; G. VERHOOSEL, *National Treatment and WTO Dispute Settlement: Adjudicating the Boundaries of Regulatory Autonomy*, Hart Publishing, 2002; O. CATTANEO, *Has the WTO Gone Too Far or not Far Enough? Some Reflections on the Concept of Policy Space*, in *Challenges and Prospects for the WTO*, A. MITCHELL (ed.), Cameron May, 2005.
For a comparative understanding see: R. EMILY, *Regulatory Autonomy in the EU and WTO: Defining and Defending Its Limits*, Journal of World Trade, Vol. 44, no. 4, 2010, pp. 877-901.
For an overview on the health and environment dimensions see: J. H. JACKSON, *World Trade Rules and Environmental Policies: Congruence or Conflict?,* Washington and Lee Law Review, Vol. 49, issue 4, 1992; A. O. SYKES, *Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View*, in *Trade and Human Health and Safety*, G. A. BERMANN and P. C. MAVROIDIS (eds.), Cambridge University Press, 2006. For a more recent and balanced review of Article XX case law, see S. CHARNOVITZ, *The WTO's Environmental Progress*, Journal of International Economic Law, Vol. 10, issue 3, 2007, pp. 685-706; F. J. GARCIA, *The Salmon Case: Evolution of Balancing Mechanisms for Non-Trade Values in WTO*, in *Trade and Human Health and Safety*, G. A. BERMANN and P. C. MAVROIDIS (eds.), Cambridge University Press, 2006, pp. 133-152.

[34] In addition to the contractual balance, scholars also refer to the "institutional balance" of the WTO, to be understood as the division of powers between Member States, the Secretariat and the Dispute Settlement Mechanism. In this regard: F. ROESSLER, *The Institutional Balance Between the Judicial and the Political Organs of the WTO,* in *New Directions In International Economic Law: Essays In Honour Of John H. Jackson*, M. BRONKERS and R. QUICK (eds.), 2000, and E. STEIN, *International Integration and Democracy: No Love at First Sight*, American Journal of International Law, Vol. 95, issue 3, 2001. For an overview on both normative and institutional aspects see: G. ADINOLFI, *L'Organizzazione mondiale del commercio. Profili istituzionali e normativi*, Cedam, 2001; P. PICONE and A. LIGUSTRO, *Diritto dell'Organizzazione mondiale del commercio*, Cedam, 2002; G. VENTURINI, *L'Organizzazione Mondiale del Commercio*, Giuffrè, 2015.

[35] D. KALDERIMIS, *Problems of WTO Harmonization and the Virtues of Shields over Swords*, Minnesota Journal of Global Trade, Vol. 13, no. 2*,* 2004, p. 320.

[36] It has to be noticed that these are not the only two Agreements that prescribe positive integration through harmonization. The Agreement on Trade Related Aspects of Intellectual Property Rights, (TRIPS) and the Agreement on Trade-Related Investment Measures (TRIMS) are, among others, two other examples.

[37] F. ORTINO, *Basic Legal Instruments for the Liberalisation of Trade: a Comparative Analysis of EC and WTO Law*, p. 26. On the other hand, the GATT and the GATS are often referred to as negative integration Agreements in that they prohibit certain types of conduct but do not prescribe positive policies for Member States. In this regard E. U. PETERSMANN, *The GATT/WTO Dispute Settlement System: International Law, International Organizations, And Dispute Settlement*, Kluwer Law International, 1997, p. 179.

Agreements, the GATT and the GATS. Indeed, both the Agreements create additional and independent obligations for Members and, in particular, the TBT Agreement "imposes obligations on Members that seem to be different from, and additional to, the obligations imposed on Members under the GATT 1994"[38] and, similarly, "the SPS Agreement [can be conceived] as an agreement which imposes obligations which are different from those imposed by GATT"[39]. The SPS Agreement, by recognizing the right of Members to enact SPS measures and to determine the level of health protection they decide to ensure in their territories[40], while setting certain limits for the exercise of these rights, strikes a balance between different Members' positions and interests. Within this broad scenario, the following paragraph provides a preliminary assessment, bringing to light the different voices between Members on the possible degrees of compliance with international standards, on science as a justificatory tool and on the role of International standards Organization.

2.1 Negotiators' (different) positions, a request of flexibility?

In the negotiations that led to the conclusion of the SPS Agreement[41], different stances of the major parties or groups can be singled out, and each is associated with proposals on the harmonization of SPS measures, and especially on the role of international standards and International standards Organizations. In this frame, the leading role was taken primarily by those countries that account for the largest share

[38] *EC - Measures Affecting Asbestos and Asbestos Containing Products*, Appellate Body Report DS135/AB/R, 2001, para. 80.
[39] *EC - Measures Concerning Meat and Meat Products* (Hormones) (US), Panel Report WT/DS26/R/USA, 1997, para. 8.40 and *EC - Hormones* (Canada), Panel Report WT/DS48/R/CAN, 1997, para. 8.43. Interestingly, the Panel, in para. 8.38 (US) and in para. 8.41 (Canada), among the many provisions of the SPS Agreement that impose substantive obligations which go beyond the GATT (Article XX(b)), refers to Article 3.1.
[40] In the WTO nomenclature that right is conventionally referred to as a right to establish the appropriate level of protection (ALOP). See: L. A. GRUSZCZYNSKI, *Standard of Review of Health and Environmental Regulations by WTO Panels*, in *Research Handbook on Environment, Health and the WTO*, E. G. VAN CALSTER and D. PRÉVOST (eds.), Elgar Publishing, 2013, p. 735.
[41] For a general overview see J. CROOME, *Reshaping the World Trading System: A History of the Uruguay Round*, Kluwer Law International, 1999.

of agricultural trade, namely: the Cairns Group of agriculture exporting countries[42], the United States[43], the European Communities (EC), and an eminent role was also played by the Nordic Group[44]. Moreover, additional relevant proposals on SPS issues - showing different approaches and expected outcomes compared to the abovementioned Members - were made by Japan and developing countries. This group includes Korea, India, Morocco, Nigeria, Brazil and Colombia (acting jointly), Jamaica, Mexico and Peru (acting jointly) and Egypt.

Through an analysis of the proposals contained in those submissions, it can be provided an indication of the areas of agreement and of divergences. The synoptic table of proposals relating to key concepts[45], prepared by the GATT Secretariat in 1990, represents a snapshot of that moment. Its purpose was to focus the Working Group's on Sanitary and Phytosanitary Regulations and Barriers (hereinafter Working Group[46]) attention on some specific issues, in a way that could permit to identify divergences and facilitate the reaching of possible consensus.

The Cairns Group stated, as a general condition, to establish a long-term framework for SPS restrictions that reflects only strict justification of protecting health

[42] At the time of the Uruguay Round negotiations, it was composed of Argentina, Australia, Brazil, Canada, Chile, Colombia, Hungary, Indonesia, Malaysia, New Zealand, the Philippines, Thailand and Uruguay.

[43] The American approach reflects past disputes within the GATT framework and the underlying principle of the food safety system in the United States which is largely based on production and processing methods.

[44] It was composed of Finland, Iceland, Norway and Sweden. These countries made substantial contributions to the adoption of a new Agreement, submitting proposals in different areas. See D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension*, p. 486, footnote 201.

[45] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat, Revision*, MTN.GNG/NG5/WGSP/W/17/Rev.1, circulated on 29 May 1990.

[46] It was chaired by a staff expert from the GATT Secretariat, Gretchen Stanton. Besides a few last-minute changes in 1993, the negotiations of the SPS Agreement were largely concluded by the end of 1990, four years in advance to the rest of the negotiations on agriculture. Several negotiators have attributed such smooth and fast progress of the SPS negotiations in part to the skill of the chairperson in facilitating negotiations and the fact that she was not affiliated with any of the national delegations. Paradoxically, the high level of abstraction and seeming technical obscurity of the issues were additional factors for the rapid conclusion of the negotiation. Some of these obscure aspects are still present, in particular in Articles 3 and 12 of the SPS Agreement, as shown by the analysis provided in this and in the third Chapter. T. BUTHE, *The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization*, Law and Contemporary Problems, Vol. 71, issue 1, 2008, p. 240, note 92.

and safety, and, in particular including: (i) procedures for notification and reverse notification, (ii) a greater recognition of equivalence of treatment if harmonization is not possible and (iii) administrative assistance for developing countries. In accordance with other countries, they supported the harmonization of SPS measures around the standards set by the Codex and, for those not covered by the Codex, around standards set by other relevant International Organizations, that should open for full participation by negotiating Parties[47]. Moreover, in regard to the strength of the harmonization obligations, the Cairns group gave considerable weight to these provisions. Indeed, the proposal set out that, with either the requirement of sound scientific evidence and with the disciplines of GATT Article XX(b), a presumption of consistency for SPS measures based on international standards is provided[48]. In case States adopt more stringent standards, they should bear the burden of proof, and demonstrate that their measures were consistent with sound scientific evidence or the relevant GATT provisions[49]. The last issue, germane to the judicial perspective, suggests for the resolution of SPS disputes, to bring them under, at the time also in the process of being negotiated, a strengthened and enforceable dispute settlement mechanism[50].

The initial proposal of the United States[51], although in some respects akin to the Cairns Group one - like to use internationally agreed standards as a basis for domestic regulations and recognize the principle of equivalence - fixed other main objectives for the negotiations. Notably, to base production and processing methods on equivalent guarantees and to implement procedures for early technical and policy

[47] Negotiating Group on Agriculture, *Sanitary and Phytosanitary Issues: Supplementary Communication from the Cairns Group*, MTN.GNG/NG5/W/164, circulated on 18 April 1990, para. 16. This requirement is still present in the text of the SPS Agreement.
[48] *Ibid*. para. 19. See in this regard the similar structure provided by SPS Agreement Article 3.2, at p. 28.
[49] *Ibid*. para. 20.
[50] *Ibid*. paras. 39-40. Interestingly, on the relationship between the GATT dispute settlement and the Codex (and the other organizations) the Cairns Group communication specifies that "Contracting parties should recognize that, although these organizations may be consulted by GATT dispute settlement panels, the GATT is solely responsible for the conduct of its dispute settlement procedures. Additionally, experts nominated by these organizations would be individuals, known because of their expertise in the relevant field, but would not be representing the organizations".
[51] United States Proposal for Negotiations on Agriculture, Office of the Press Secretary, Executive Office of the President, Washington, 6 July 1987.

consultations on sensitive regulatory issues. Even the United States called for a formal link between the GATT and international standard organizations, and the Codex in particular, and for the abovementioned presumption of compliance with GATT Article XX(b) and with scientific evidence[52]. Furthermore, the American proposal on a mechanism for the resolution of conflicts tried to go beyond the alleged weakness of the Standard Code[53], carving out an important role for the Codex and other international scientific organization[54].

The EC, by aiming to minimize the adverse effects of SPS regulations without jeopardizing the status of national measures, recognized that the strengthening of international harmonization can only be made possible by the action of international organization[55]. Albeit the EC was generally in line with the positions of other

[52] Negotiating Group on Agriculture, *Submission of the United States on Comprehensive Long–Term Agricultural Reform*, MTN.GNG/NG5/W/118, circulated on 25 October 1989, p. 12.

[53] M. E. BREDAHL and K. W. FORSYTH, *Harmonizing Phyto-Sanitary and Sanitary Regulations*, *The World Economy*, Vol. 12, 1989, p. 190. The Standard Code was insufficient for mitigating the uncertainty and complexities of SPS related issues. According to Barton *et al*. it was inadequate for several reasons. The text of the Agreement was ambiguous and not homogenous. The dispute-settlement procedure was incapable of enforcing obligations. Moreover, standards about how products are produced and processed were excluded. Last but not least, no single overarching institution existed at that time, that could authoritatively coordinate and manage safety standards at the international level. A random assortment of international and regional institutions dealt with safety standards in an overlapping and nonsystematic manner. J. BARTON, J. L. GOLDSTEIN, T. E. JOSLING and R. STEINBERG, *The Evolution of the Trade Regime: Politics, Law and Economics of the GATT and WTO*, Princeton University Press, 2006, p. 108 *et seq*.
The TBT Agreement, which entered into force in 1995, is the multilateral successor to the Standards Code, signed by 32 GATT contracting parties at the conclusion of the 1979 Tokyo Round of Trade Negotiations.

[54] "The Codex Alimentarius Commission, the International Office of Epizootics, the International Plant Protection Convention, or other appropriate international scientific organizations shall be asked to provide a list of individuals with technical expertise in various areas. Regarding the consistency of a measure with sound scientific evidence, dispute settlement panels shall give primary consideration to the technical judgment of a technical advisory group composed of individuals selected from the appropriate list, its composition subject to the consent of the interested Contracting Parties.", MTN.GNG/NG5/W/118, p. 13. Moreover, this submission makes reference to the fact that "provisions regarding dispute settlement should be considered in consultation with the Negotiating Group on Dispute Settlement", that, however, in its discussions and proposals only rephrased the work of the Negotiating Group on Agriculture. The United States submitted a proposal that good offices be encouraged, especially of international organizations, and that panels should give primary consideration to the judgment of a technical advisory group, drawn from a list provided by technical international organizations. Negotiating Group on Dispute Settlement, *Note by the Secretariat*, MTN.GNG/NG13/W/37, circulated on 24 January 1990.

[55] Negotiating Group on Agriculture, *Communication from the European Communities. Working Paper. Drafting of an Appropriate Framework of Rules for Sanitary and Phytosanitary Regulations*, MTN.GNG/ NG5/W/56, circulated on 20 April 1988, para. 1. In relation to States' use of standards adopted by international organization, it has been observed by one participant to the negotiation that

developed countries[56], it demonstrated interest in particular areas related to standards and moreover, and more relevant for the purpose of this research, expressed its view on some of the thorniest issues of the negotiations, such as the binding nature of this source of law, and which States bear the burden of proof when higher – than international – standards are applied.

First, the EC recognized that it was necessary, for those countries which have reached a "high health status"[57], be allowed to continue to apply, when appropriate, standards that are more stringent (higher) than international ones[58]. In addition, countries applying stricter standards could be found in violation of GATT provisions if the exporting country could prove that the disputed measures were maintained against sound scientific evidence. This proposal on the allocation of the burden of proof therefore differs from those of the US and the Cairns Group, in that for those countries the onus would be on the importing country[59]. Similarly, the EC idea of a list of relevant international standards be drawn up was subject of criticism[60]. The EC proposals, considering that "standards […] often take the form of recommendations [, conceived them] open to varying degrees of acceptance"[61], as they "were not designed to be legally binding, but as recommendations to be taken into account"[62], ultimately showing "a voluntary character"[63]. The last two aspects addressed by the EC were the harmonization of regional standards[64] considered as a first step towards the

"since the same governments had participated in the establishment of an international standard, the proposed examination of such standards and re-acceptance of some for GATT purposes seemed redundant". Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of the Main Points Raised at the Fifth Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers*, *Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/13, circulated on 19 March 1990, para. 9.

[56] Negotiating Group on Agriculture, *Submission of the European Communities on Sanitary and Phytosanitary Regulations and Measures*, MTN.GNG/NG5/W/146, circulated on 20 December 1989, p. 1

[57] MTN.GNG/NG5/WGSP/W/17/Rev.1, p. 5 and 9.

[58] MTN.GNG/NG5/WGSP/W/17/Rev.1 p. 5 and 9; MTN.GNG/NG5/W/146, pp. 2-3.

[59] MTN.GNG/NG5/W/146, p. 2; MTN.GNG/NG5/WGSP/W/13, para. 9.

[60] MTN.GNG/NG5/W/146, p. 2; MTN.GNG/NG5/WGSP/W/13, para. 9.

[61] MTN.GNG/NG5/W/146, p. 2.

[62] MTN.GNG/NG5/WGSP/W/13, para. 9.

[63] MTN.GNG/NG5/W/146, p. 2.

[64] MTN.GNG/NG5/WGSP/W/13, para. 8.

achievement of international harmonization and to adopt the principle of equivalency on a as wide a basis as possible[65].

The Nordic Group proposal was peculiar compared to those of other developed countries in a specific domain, the personal scope of application of SPS measures. The important question was to which entities do the new (negotiating) rules apply (?) or, in other words, all standards developed by local government bodies, regional bodies and non-governmental bodies are covered by the under-negotiation provisions (?). The proposal started analyzing the deficiencies of the Standard Code in this regard, and noted that it applied directly only to central government bodies. On the other hand, its obligations for local and regional government bodies as well as non-government bodies were of a "best endeavour or second level" nature[66]. Nordic countries suggested to strength these obligations[67]. This commitment was outlined in one of the following notes submitted by the Nordic delegations, where they asked for measures ensuring compliance by regional and non-governmental bodies, and not to require or encourage such bodies to act inconsistently with these provisions[68]. Some countries were concerned that the Nordic text sought too stringent obligations in this regard and could lead to possible constitutional difficulties[69]. Standards set by private bodies were not

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[65] *Ibid*.

[66] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Applicability of the Agreement on Technical Barriers to Trade to Sanitary and Phytosanitary Regulations and Barriers: Note Submitted by the Nordic Delegations*, MTN.GNG/NG5/WGSP/W/5, circulated on 22 May 1989, p. 2.

[67] *Ibid*., paras. 11 and 13.

[68] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Draft Agreement on Sanitary and Phytosanitary Measures: Note by the Nordic Countries*, MTN.GNG/NG5/WGSP/W/21, circulated on 28 May 1990, p. 5.

[69] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of Main Points Raised at the Eighth Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers: Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/24, circulated on 2 July 1990, para. 6. For those countries, the appropriate text in this regard would be the one proposed by the Secretariat: "Contracting parties shall take such reasonable measures as may be available to them to ensure that governmental bodies at all levels, including supra-national governing bodies, national and sub-national governments, comply with the relevant provisions of this agreement. In addition, contracting parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such governmental bodies or non-governmental bodies to act in a manner inconsistent with the provisions of this agreement". Synoptic Table 4, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat. Revision*, MTN.GNG/NG5/WGSP/W/17/Rev.1, circulated on 29 May 1990.

taken into consideration during the discussion on the scope of application of the SPS Agreement[70].

Japan emphasized the importance to recognize that differences in sanitary conditions, for example in geographical conditions and dietary customs, among contracting parties, may necessitate the application of more stringent standards than international standards[71]. In such cases, where differences need to be considered, the Japanese proposal suggested that it would be more appropriate to effectuate harmonization by guidelines rather than standards[72].

The last negotiating position analyzed is that of the Group of developing countries. While this group was not an identifiable group as the Cairns one, it may be said that they frequently spoke with one voice[73]. Compared to the activities and proposals of other States, developing countries participation in the negotiation of the SPS Agreement was rather limited. They asked for harmonization of SPS measures on the basis of standards set by the international standard-setting bodies as well as technical assistance from these bodies and organizations. Their proposals emphasized the importance of transparency as well as the introductions of provisions for special and differential treatment[74]. Almost all Members part of the negotiation were aware of

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[70] The reason was that at the time of negotiation private standards were not as relevant as they are nowadays, and the entire food safety remains the prerogative of public sector. See D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension*, p. 491. For an exhaustive overview of the role of private in the standard-setting see Chapter III of this work.

[71] Negotiating Group on Agriculture, *Supplementary Submission of Japan on Sanitary and Phytosanitary Regulations and Measures*, MTN.GNG/NG5/W/156, circulated on 7 March 1990, para. 1.

[72] Negotiating Group on Agriculture, *Negotiating Group on Agriculture: Submission by Japan*, MTN.GNG/ NG5/W/131, circulated on 6 December 1989, p. 8.

[73] J. M. BREEN, *Agriculture*, in *The GATT Uruguay Round: A Negotiating History (1986–1992)*, T. P. STEWART (ed.), Vol. I: Commentary, Kluwer, 1993, pp. 125-254 and p. 191.

[74] Here are the main proposals: Negotiating Group on Agriculture, *Proposal by Egypt, Jamaica, Mexico and Peru*, MTN.GNG/NG5/W/74, circulated on 13 September 1988; Negotiating Group on Agriculture, *Elements for a Proposal by Developing Countries. Communication from Jamaica*, MTM.GNG/NG5/W/68, circulated on 11 July 1988; Negotiating Group on Agriculture, *Communication from Jamaica*, MTN.GNG/ NG5/W/42, circulated on 4 February 1988, Negotiating Group on Agriculture, *Indian Proposal*, MTN.GNG/NG5/W/84, circulated on 14 November 1988; Negotiating Group on Agriculture, *Communication from Nigeria on Issues before the Negotiating Group*, MTN.GNG/NG5/W/57, circulated on 20 April 1988; Negotiating Group on Agriculture, *Negotiating Group on Agriculture: Statement by the Kingdom of Morocco,* MTN.GNG/NG5/W/121, 2 November 1989.

the difficulties faced by developing countries[75], and different proposal on that were submitted[76].

2.2. The participation of the Codex Alimentarius Commission: the germ of cooperation

Besides States' proposals, also the contributions given by the Codex[77] during the Uruguay Round allows us to better understand which role international standards should have had within the SPS Agreement[78]. Especially, at the time of negotiations, it was really debated the role of the CAC and other "technical organizations"[79] in the suggested dispute settlements procedures. The CAC had been invited as an observer during the meetings, as was the FAO Secretariat, which was already present during the meetings of the Negotiating Group on Agriculture[80]. With the submission of written statements, the CAC made clearer some of the aspects around standards, such as: their necessary international character[81]; how standards have been adopted and accepted[82];

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[75] MTN.GNG/NG5/WGSP/W/13, para. 12.

[76] The most extensive was the one of the Nordic countries and was based on Standards Code rules. Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Technical Assistance to Other Parties and Special and Differential Treatment of Developing Countries, Note by the Nordic Delegations*, MTN.GNG/NG5/WGSP/W/14, circulated on 20 April 1990.

[77] For a general overview on the role and activities of the Codex, provided by itself within the Working Group on Sanitary and Phytosanitary Regulations and Barriers, see Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Background Note On The Codex Alimentarius Commission And The FAO Co-Ordinated Programme of Food Control*, *Paper Submitted by FAO*, MTN.GNG/NG5/WGSP/W/20, circulated on 7 May 1990.

[78] However, an extensive analysis of the institutional character of the CAC and its standards, in particular within the perspective of the outsourcing of standard setting, is addressed in Chapter II of the present research.

[79] MTN.GNG/NG5/WGSP/W/13, para. 6.

[80] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of Main Points Raised at the First Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers: Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/1, circulated on 28 October 1988, paras. 19 and 20.

[81] "[…] in contrast to plant protection, where regional standards appeared most appropriate, food safety standards should be internationally applicable to avoid becoming barriers to trade". Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of the Main Points Raised at the Fourth Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers: Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/8, circulated on December 1989.

[82] "all Codex standards, codes and pesticide residue limits have been adopted by the Commission by

by whom they are developed[83]; their relevance for International agreements, municipal law and in the practice of economic private actors[84] and the degree of acceptance, *i.e.* their binding effects. As regards the latter, the CAC stated that "[a]cceptance by governments of commodity standards, general standards and maximum residue limits can be divided into general categories of (a) full acceptance; (b) acceptance with specified deviations; (c) limited acceptance (*i.e.* non-hindrance of importation of foodstuffs complying with Codex standards or limits) and (d) no action"[85].

The majority of the participants[86] in the Working Group supported a mechanism for submitting SPS conflicts under the GATT Dispute Settlement procedure, with a role for the CAC and other scientific organization as technical advisors[87]. In fact, the CAC emphasized that it had not, or no adequate, its own dispute

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consensus […] A complete working procedure has been designed to ensure that governments have the opportunity to comment and accept standards, codes of hygienic/technological practice and maximum limits for pesticide residues, veterinary drug residues, and specifications of identity and purity for food additives". Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Statement by the Representative of the Codex Alimentarius Commission at the Second Meeting of the Working Group*, MTN.GNG/NG5/WGSP/W/3, circulated on 30 November 1988.

[83] "The programme of work of the Commission depends on expert scientific and technical advice provided by FAO/WHO Expert Committees and by technical and scientific advisors in national delegations to Codex Committees. Essential technical information is also provided by international non-governmental organizations specialized in various fields". *Ibid*.
"The representative of the Codex Alimentarius Commission explained how scientific expert panels were chosen to examine data and give recommendations regarding the handling, use and daily intake of food additives or pesticide residues. These scientific recommendations were then considered by the governmental representatives of the Codex Alimentarius Commission and turned into international recommendations which could be used by governments to protect food safety". MTN.GNG/NG5/WGSP/W/8.

[84] "The Commission has embarked from its inception to secure international agreement on the substance of food standards and then to invite governments to accept them in various specified ways for implementation in national legislation […] Codex commodity standards and maximum residue levels have been accepted by many Codex member countries. In addition, the existence of the various standards, codes of practice and residue levels are invaluable in many different ways to member governments and food producers, processors and marketers. For instance, since they are soundly based on the best available scientific information on food quality and safety and have been thoroughly discussed in Codex Committees and in the Commission, they are used in the establishment of contracts between buyers and sellers, and are often utilized by governments when establishing national food legislation". MTN.GNG/NG5/WGSP/W/3.

[85] *Ibid*.

[86] MTN.GNG/NG5/WGSP/W/13, para. 6.

[87] This view was in contrast with the proposal from Austria, which suggested that the technical aspects should be examined by scientific organizations, and only if the national measure was found not to have a scientific basis, and was not removed in time, a "real" trade dispute should be brought before the GATT mechanism. Negotiating Group on Agriculture, *Submission by Austria*, MTN.GNG/NG5/W/144, circulated on 19 December 1989, p. 7 and 8.

settlement mechanism able to tackle the demand of judging a SPS dispute[88]. It was the communication from the Cairns Group that clearly expressed that international organizations and their scientific experts should embrace supportive role while the final responsibility to solve a dispute lay with the GATT Panel[89]. Some concerns were raised with regard to the fact that a "GATT panel could not judge the scientific value of an SPS measure, but only whether it conformed to the proposed GATT obligations, *i.e.*, did a country act reasonably in its risk assessment, or take reasonable action in the absence of an international standard, or justify its reason for not using an international standard[90]. In other words, a GATT Panel would not determine the validity of international standards, but whether they were being appropriately applied"[91].

2.3. The evolution of the draft texts shaping the harmonization obligations

Amid this chorus of different voices, from Brussels to Washington, from Tokyo to Canberra and from Nordic to developing countries, the achievement of the Working Group[92] represented a bright spot within the overall agriculture negotiation,

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[88] MTN.GNG/NG5/WGSP/W/13, para. 6. Moreover, it was also stressed that "such a procedure could prolong the settlement of disputes, and reduce the effectiveness of these organizations in establishing standards" and that "sanitary and phytosanitary measures were not based only on science, but on a risk assessment which also took account of potential economic damage". *Ibid*. para. 7.

[89] "[A]lthough these organizations may be consulted by GATT dispute settlement panels, the GATT is solely responsible for the conduct of its dispute settlement procedures. Additionally, experts nominated by these organizations would be individuals, known because of their expertise in the relevant field, but would not be representing the organizations". MTN.GNG/NG5/W/164, para. 40.

[90] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of Main Points Raised at the Seventh Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers: Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/22, circulated on 31 May 1990, para. 16.

[91] Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Summary of Main Points Raised at the Third Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers: Note by the Secretariat*, MTN.GNG/NG5/WGSP/W/6, circulated on 17 October 1989, para. 9.

[92] The request to establish a working group to address sanitary and phytosanitary measure came from the United States, *Communication from the United States on a Health and Sanitary Working Group*, MTN.GNG/NG5/77, circulated on 13 September 1988, and, in their vision, the results of this working group should then be incorporated into the overall draft text provided by the agriculture group. See S. ZARRILLI, *WTO Sanitary and Phytosanitary Agreement: Issues for Developing Countries*, *Trade-Related Agenda, Development and Equity (T.R.A.D.E.),* Working Papers, South Centre, 1999, p. 4, footnote 8.

considering that, alone among the other agriculture negotiating groups, negotiators produced a draft text on November 1990. Some of the main points of agreement as well as some of the significant areas subject to dispute in this draft version regarded standards[93]. Standards have been considered as a crucial issue even before that stage, as demonstrated by their status of priority areas during the mid-term review of the Uruguay Round held in Montreal in December 1988[94].

The text of the 1990 draft version[95] makes a valuable contribution to the understanding of the harmonization obligations. In the first part it is spelled out that brackets in the text identify the principal issues where areas of disagreement remained and, when appropriate, alternative phrases have been set. After paragraphs 8 and 9[96], also parts of the provisions devoted to harmonization, paragraph ten, marked within parenthesis, provides for two alternatives in this matter. The first option allows States to opt for national measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards while in the second case, States are not allowed to do that. Moreover, in the case a party decided for a higher level of protection, it shall be determined "avoid[ing] arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised

[93] In the first case the most relevant are the special consideration granted for developing countries for their difficulties in meeting standards and the establishment of an international committee in order to provide for consultation regarding standards. With regard to the second point, whether, and under what conditions, States could impose measures stricter than international standards (the supporter of flexibility in the harmonization provisions were the EC and the US) and whether "other economic considerations and genuine consumer concerns" were factors that should be taken into account in the risk assessment undertaken when using or discussing SPS standards.
See, for a general summary of these point, J. M. BREEN, *Agriculture*, pp. 200-201.

[94] Ministers endorse harmonization of national regulations as a long-term goal and a work programme embodying the following objectives:
"(1) develop harmonization of sanitary and phytosanitary regulations and measures, on the basis of appropriate standards established by relevant international organizations including the Codex Alimentarius Commission […]
(5) improve the effectiveness of the multilateral dispute settlement process within the GATT in order to provide the necessary input of scientific expertise and judgment, relying on relevant international organizations".
Trade Negotiations Committee, *Mid–Term Meeting*, MTN.TNC/11, circulated on 21 April 1989, p. 13.

[95] Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Draft Text on Sanitary and Phytosanitary Measures*, MTN.GNG/NG5/WGSP/7, circulated on 20 November 1990.

[96] They basically replied the text of the current SPS Agreement Article 3 paras. 1 and 2.

restriction on international trade"[97]. The interesting aspect is that, in contrast with the subsequent draft version – in the form of the Dunkel text – and with the final version of the SPS Agreement, the "test" that a party shall pass in order to set a higher level of protection complying with this decision, and thus not basing or conforming to international standards, is not the risk assessment. Indeed, in this event, the party seems to be subject to the same requirements of GATT Article XX[98].

At the end of the 1990, when the Uruguay Round negotiations reached a stalemate, largely based on disagreement on agricultural issues, the GATT Director-General, Arthur Dunkel, issued against this setting, a draft act, now and hereinafter known as the Dunkel Draft[99]. It reflects the content of texts and decisions in area where the negotiators had reached compromises as well as Chairman-driven solutions in area of divergences. The Dunkel Draft closely followed the text produced by the Working Group in November 1990, while generally providing for more stringent national regulations and excluding economic considerations from the SPS domain. In regards with the harmonization provisions, the Dunkel Draft changed significantly compared to the previous draft version in relation to two crucial matters. First, the alternative sentences on the adoption of higher level were removed, providing an answer in the affirmative, secondly, the risk assessment of the appropriate level of sanitary and phytosanitary protection was required[100], under the same terms as the SPS Agreements provides.

It represented the basis for the incoming final text of the SPS Agreement that was approved at the end of the Uruguay Round, and fulfils the general objectives of the Punta del Este Declaration in this area. While the text of the SPS Agreement,

[97] *Ibid*. at para. 10, referring to para. 19.
[98] The textual similarity is evident: "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade", and it is also evident that the structure of the SPS Agreement took inspiration from this Article, thus reflecting a common legal rationale, while expanding the system of rights and obligations on such a basis.
[99] Trade Negotiations Committee, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, MTN.TNC/W/FA, circulated on 20 December 1991.
[100] *Ibid*. at para. 11, referring to paras. from 16 to 23.

Article 3 in particular, will be the object of analysis of the following section, two preliminary remarks should be mentioned, in order to outline some textual differences[101].

Given the concerns[102] raised by the harmonization disciplines that could impose to developed countries to lower their SPS requirements to comply with international standards, in the Preamble, the paragraph stating the desire of Members to further the use of harmonized measures on the basis of international standards was amended by adding the words: "without requiring Members to change their appropriate level of protection of human, animal or plant life or health*"*. In the same direction should be seen the footnote added to clarify the requirement in Article 3.3 of the SPS Agreement of scientific justification for SPS measures more stringent than international standards[103].

To sum up, alone among the various Working Groups negotiating under the auspices of the Negotiating Group on Agriculture, the Working Group on Sanitary and Phytosanitary Regulations and Barriers managed to submit a draft text in November 1990. This achievement was reached in a sensitive scenario where finding a compromise between State's regulatory autonomy in the area of food safety and free trade was undoubtedly hard. Provisions on harmonization specially were a key and divisive issue, one of the reasons why SPS Agreement Article 3 presents margins of interpretation uncertainty.

The text was then incorporated into the Dunkel Draft and, with few changes, eventually became the final text of the SPS Agreement. Since the very beginning it

[101] For a side-by-side comparison of the Dunkel Draft and the final text of the SPS Agreement in the Uruguay Round Final Act see J. M. BREEN, *Agriculture*, pp. 41-45, Annex 2.
[102] The US in particular expressed some critics, based on arguments of consumer and environmental lobbies. See D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension,* p. 504, footnote 306.
[103] It specified that "there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection".

was evident that this treaty represents something "new" for negotiators, given that the issues at stake cannot be addressed in the same way as others subject to different WTO Agreements. The success and results of these negotiations can largely be ascribed to the proactive role taken by the key participants in the negotiations, namely the Nordic Group, the Cairns Group, the EC and the US.

The promotion of harmonizing SPS measures by the use of international standards seemed to be evolving around some points. First, it was subject to the possibility to apply stricter requirements, in the sense that deviation from international standards can occur (only) for higher level of protection that a State deemed to be necessary. Moreover, Members set the framework for a compromise where adherence to standards was not absolute, with vary degrees of acceptance admitted. Standards show a voluntary character and are not legally binding *stricto sensu*. However, besides a nominalistic and formal approach, a proper understanding of international standards effects passes through an analysis that looks at the consequences of adopting (totally or partially) or not these standards. Another aspect of the new disciplines strongly supported by the main actors during the negotiations was the focus on science as a justificatory tool. The specific position, and consequently appropriate *ad hoc* provisions to be set, of developing countries, was another issue were States agreed.

Even the role of standard organizations (CAC in particular) was conceived as crucial both in the activities as standard-setter and in the judicial domain. In the latter, Sates agree that the CAC contribution should be in the sense of an advisor, considering a framework where SPS disputes are set under the Dispute Settlement Mechanism of the WTO.

These negotiations set the framework and are one of the elements on the basis of which determine to what extent standards are binding. The following section will address the content of the SPS provisions, with the additional interpretative tools offered by the relevant case law.

3. Different tracks for States and distinctive modes of compliance under the SPS Article 3

This section presents an interpretation of SPS Agreement Article 3 according to a normative structure that reflects multiple options of compliance. Within this regulatory model, if States decide not to conform to international standards nor even to base their national measures on these standards, they can opt for adopting stricter domestic measures that result in a higher level of protections for their citizens. Nevertheless, WTO Members are encouraged to adopt them even in the third case because of the hard requirements provided by risk assessment under Article 5 and for other practical reasons arising from other procedural obligations under the SPS Agreement. The binding dimension of international standards is therefore theorized in terms of effectiveness, of practical consequences in relation to the time and cost consuming activities required to satisfy the risk assessment test. A conclusion that follows the basic premise in terms of an informal law-making environment that is here adopted. Moreover, the difficulties at stake that dictate the *de facto* compliance with international standards, can also derive from the consideration that the risk assessment embodied/expressed in the content/text of international standards generally reflects the consensus reached on a specific topic in the international scientific community. The interpretation of Article 3 below represents the first, but not exclusively, part of the reasoning that explains the path according to which standards are binding in the abovementioned terms. Therefore, the activities within the SPS Committee represent the dynamic laboratory where the harmonization obligation is shaped.

3.1. What are international standards under the SPS Agreement?

The SPS Agreement is considered as one of the most controversial of the WTO covered Agreements because it oversees the adoption of national measures to protect public health. This issue leads to the core question of how regulatory autonomy of States faces with international standards. The provisions of the SPS Agreement about harmonization, and thus related to standards, remain a grey area of interpretation and are significant in a number of important respects. This work will address primarily the so-called indirect/*de facto* binding force of international standards and the interrelationship between the WTO and International standard-setting Organization, the CAC in particular. Before delving into these two matters, the analysis provided in this Chapter begins by seeking an answer to the question of what international standards in the context of the SPS Agreement are, apart from more in-depth reflections on CAC standards and on private standards, delivered in Chapters II and III.

The relevance and role of international standards[104] can be preliminary assessed by referring to recitals 6 of the SPS Agreement preamble that states:

> "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

[104] The Appellate Body in Canada - Continued Suspension *(Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, Appellate Body Report WT/DS321/AB/R, 2008, para. 532) and in EC – Hormones (*EC - Measures Concerning Meat and Meat Products*, Appellate Body Report WT/DS26/AB/R WT/DS48/AB/R, 1998, para. 165) took note of the prominent role of standards under recital 6 of the preamble in the promotion of harmonization, considered as one of the primary objectives of the SPS Agreement.

requiring Members to change their appropriate level of protection of human, animal or plant life or health" [105].

However, Annex A of the SPS Agreement represents the reference point for an examination of the definition of international standards. After the description of what sanitary and phytosanitary measures are and what harmonization is, paragraph 3 defines International standards, guidelines and recommendations as follows:

"(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covere 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."

These provisions arise a number of questions, the first being the fact that the SPS Agreement does not make any distinctions among standards, guidelines and

[105] As already outlined before, the last phrase was added only at the final stage of the negotiation.

recommendations[106] as to their legal status, legal treatment and effects resulting from that[107]. This homogenous approach, also reflected by fact that the three autonomous legal tools are always mentioned in the entire SPS Agreement in a single reference, has come in for criticism in the literature[108]. Uncertainties and the need for clarifications brought to discussions in the CAC context, during the Twenty-Second Session of the CAC[109], held in Geneva in 23-28 June 1997, on matters relating to the implementation of the SPS and TBT Agreements. It was important to CAC Members to know what effects the legal instruments they set could have under the SPS Agreement framework and requested[110] the CAC Secretariat to write to the Chair of

[106] Although they are clearly quite different international norms and are not intended to have the same status by the international organizations creating them, where possible, in this research it is referred to standards, guidelines, and recommendations taken together as standards, just for the purpose of simplicity, aware of the problematics arising from the homogenous approach adopted in the drafting of these provisions.

[107] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, Oxford University Press, 2010, p. 89.

[108] For reflections on CAC standards in this regard see D. G. VICTOR, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years*, New York University Journal of International Law & Policy, Vol. 32, 2000. Here the author underlines that "the Codex Alimentarius Commission (Codex) adopted not only specific standards (e.g., on food additives) but also more general standards for commodities and advisory guidelines. Does the WTO Agreement apply to all three, even though Codex guidelines were neither designed nor intended to have binding application?", at p. 876.

[109] Here are the most relevant passages:

"[…] The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), on the other hand, made specific reference to Codex texts without providing any clear distinction between standards, guidelines and recommendations. […] The Representative however noted that these issues could formally be clarified through two possible ways: either in the form of decisions by WTO Panels resulting from individual dispute cases or by requesting clarification from the SPS Committee. […] the [CAC] should be able to differentiate between different categories of texts, such as standards, guidelines and recommendations, on the basis of the statutory objectives of Codex […] That Codex Committees review the codes, guidelines and related texts under their responsibility in order to determine to what extent they should be redrafted as standards.

172. The Commission also concurred with the view of the Executive Committee and decided to request the SPS Committee through the Secretariat to clarify how the SPS Committee would differentiate "standards, guidelines and other recommendations" in relation to the implementation of the SPS Agreement by WTO Members.

173. The Representative of the WTO expressed concern that insufficient understanding of the WTO Agreements was apparently hampering the adoption of Codex standards and guidelines at a time when WTO Members, and especially developing countries, had an immediate need for Codex texts to assist them to fulfil their obligations under the WTO. The Representative urged increased involvement of all Commission members in the work of the WTO, in particular, through their participation in the work of the SPS Committee.". Codex Alimentarius Commission, 22nd Session, ALINORM 97/37, 1997, paras. 168-169, 171-173.

[110] Committee on Sanitary and Phytosanitary Measures, *Classification of References to Codex Texts - Request from the Codex Alimentarius Commission*, G/SPS/W/84, circulated on 8 October 1997.

the SPS Committee in order to obtain clarification on how the Committee would differentiate "standards, guidelines and other recommendations" in relation to the text of the SPS Agreement[111]. The issue was discussed in meetings and a response was drafted, later revised[112] and finally formally adopted by the SPS Committee[113]. In this response, the SPS Committee highlighted a series of interesting aspects. As a background, it was outlined that from an institutionally perspective, the "Committee cannot formally interpret the provisions of the SPS Agreement"[114], while it is "required to carry out the functions necessary to implement the Agreement and the furtherance of its objectives and thus may express views, where appropriate, on the meaning of

[111] Other comments were provided to the Chairman of the SPS Committee by the Secretariat of the Codex Alimentarius Commission through the report of the Executive Committee of the Codex Alimentarius Commission, 44th Session, ALINORM 97/4, 1997, paras.15-18.
"15. The Executive Committee was of the opinion that at least as far as Codex was concerned differences were intended in the application of standards and the application of other (Codex) texts. There was some uncertainty as to how these other texts would be handled within the framework of WTO. It proposed that the Commission request the SPS Committee through the Secretariat to clarify how the SPS Committee would differentiate "standards, guidelines and other recommendations" in relation to the implementation of the SPS Agreement by WTO Members.
16. The Executive Committee noted the five recommendations made by the Codex Committee on General Principles as contained in paragraph 8 of the working paper. It proposed that the Commission endorse these recommendations with the following amendment to be made to the third of these
Codex standards or any other texts which establish quality criteria for products additional to essential quality factors should clearly indicate that such criteria are intended for voluntary application by commercial partners, as follows: "This text is intended for voluntary application by commercial partners and not for mandatory application by governments."
17. The Executive Committee also stated that in regard to the elaboration or revision of texts intended to guide internal working arrangements (paragraph 9 of the working paper) these should not be considered as standards, guidelines or recommendations for the purposes of either the SPS or the TBT Agreements.
18. The Executive Committee discussed whether or not texts not intended for application by governments should continue to be considered by Codex but came to no firm conclusion on the matter.".
[112] Committee on Sanitary and Phytosanitary Measures, *Clarification of References to Codex, Texts Draft Response to the Codex Alimentarius Commission, Note by the Chairman*, G/SPS/W/86/Rev.1, circulated on 13 March 1998.
[113] Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting held on 12-13 March 1998*, *Note by the Secretariat*, G/SPS/R/10, circulated on 30 April 1998, para. 50.
[114] G/SPS/W/86/Rev.1, para. 2. The Committee also states that such interpretation "can be done only by the WTO Ministerial Conference or General Council, or indirectly through the dispute settlement process with regard to particular cases."
It can be preliminary observed that the vast majority of the literature on standards regards the few, although relevant, decisions of the Panels and AB, an approach open to criticisms because too narrow and static. The normative and institutional system of standards is therefore dynamic, first of all because this characteristic is necessary in order to be effective and functional system. In this regard, more attentional should be given to the SPS Committee, as some authors do (Scott), and as provided in section 4. This decision, not binding, is a preliminary example to better understand the governance of standards in the SPS Agreement.

particular terms and provisions of the Agreement"[115]. With respect to the core question, the Committee stated that the definition contained in the Annex A paragraph 3 makes no distinction between standards, guidelines and recommendations nor do it any other provisions of the SPS Agreement, where all these terms appear together[116]. This formalistic observation was followed by the acknowledgment that the way in which a Codex text is applied depends on its substantive content rather than the category[117] of that text and that this circumstance has a bearing on how a Member could show that its national measure is based[118] on an international standard, guideline or recommendation under SPS Agreement Article 3. Even if the Committee in this regard gives particular significance or, *rectius*, authority, to the text adopted by the CAC, at the same time it recognizes that the type and content of the texts it develops is an internal decision of the CAC, as to the merits of having a standard, guideline, or recommendation to address each specific food safety issue[119]. Moreover, the SPS Committee noted that there are no legal obligations on Members to apply any of the Codex texts in accordance with the terms of Article 3 of the SPS Agreement.

On these grounds, the Codex Executive Committee noted[120] this response and agreed that the reply of the SPS Committee should be brought to the attention of all CAC Committees[121]and stated that the work of CAC should move forward without concern arising from misunderstandings or misinterpretations as to how CAC

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[115] *Ibid*.
[116] In the drafted version of the note by the Secretariat it was mentioned that "[t]his is in contrast to the WTO Agreement on Technical Barriers to Trade, where "standard" has been explicitly defined, and where there is no reference to "guidelines or "recommendations"". G/SPS/W/86, para. 3.
[117] "For example, a Codex standard, such as an MRL which represented a specific numeric value, may provide a higher degree of precision than much of the content of a guideline or other Codex text. On the other hand, the Committee considered that guidelines and recommendations are intended to allow greater discretion as to the choice of measures which can be regarded as being based on the guideline or recommendation". G/SPS/W/86/Rev.1, para. 5.
[118] While in the drafted version of the note by the Secretariat the reference was to conforms to an international standard, guideline or recommendation in the context of Article 3.2 and deviation from an international standard, guideline or recommendation under Article 3.3, in the final version there is only reference to base on and to a generic Article 3.
[119] From such instance it is possible to figure out the preliminary elements that characterize the institutional interrelationship between the WTO and the CAC.
[120] Codex Executive Committee, 45th Session, ALINORM 99/3, June 1998, para. 44.
[121] An institutional analysis of the CAC system is provided in Chapter II.

standards and related texts might be used[122]. It further agreed that the Committee on General Principles should examine the possibility of developing a set of appropriate preambular statements explaining the intent of different types of Codex texts[123].

In the same context, besides the dispute on the same legal treatment for standards, guidelines and recommendations, it also arose a second question, namely which status might be given to Codex regional standards and related texts. Indeed, it should be noted that the term "standards, guidelines or recommendations" is qualified by the adjective "international" and this would therefore exclude standards set on the regional level. Addressing such question, the SPS Committee observed: "[…] Members noted that regional standards are not included in the definition of international standards provided by Annex A of the SPS Agreement […] [and they] recognize that such scientifically-sound regional standards could become the foundation for the creation and adoption of international standards"[124]. The omission of the requirement of an international nature would have led to the anomalous situation that Members outside the relevant region for which the standard was set would have to scientifically justify their deviation from a standard or guideline neither intended nor appropriate for their adoption[125].

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[122] The possible criticism around a lack, if present, of a unified approach to different types of CAC documents, will be addressed in Chapter II. This reflection leads us to think on the fact that the legitimacy of WTO standards under the SPS Agreement is strictly related to the legitimacy of standards under the CAC and thus how these two international organizations may depend and mutually influence each other's.

[123] However, in view of the reply of the SPS Committee, the Committee on General Principles was of the opinion that the development of a set of preambular statements explaining the intent of the different types of Codex texts was not necessary. Codex Committee on General Principles, 33rd Session, ALINORM 99/33, September 1998, para. 54.

[124] G/SPS/W/86/Rev.1, para. 6. In the drafted version (G/SPS/W/86) the Committee also observed that "[d]espite their relevance for that region, the application of such standards to trade, whether to countries within or outside of the region, could not benefit from any presumption of conformity with the SPS Agreement".

[125] Gruszczynsk notes that the requirement of an international status for standards is desirable in a merely trade-benefit perspective in the sense that it is easier for a coalition of States to favors protectionism by controlling the process of standard-setting placed only at regional level, because it necessitates less participation among Members part of the same market. He also highlights that it is hard to find good reasons for differentiating among regional and international standards in those disputes which involve countries from the same region, even because often regional standards are adopted in a similar procedure to international ones (the adoption process is equally transparent and open to participation). Moreover, they may be best suited to address SPS particularities of a specific region. L.

The third, and most significant[126] observation concerning the question of what international standards are, is the recognition that the SPS Agreement itself does not contain any international standards, nor does it provide for the development of such standards by the WTO framework in general[127]. Neither Article 3 not even any other provision of the SPS Agreement establish harmonized international standards itself but relies on those set by the international organizations listed in Annex A, paragraph 3[128], thus by referring to the work of existing specialized organizations. In a nutshell, in the domain of international SPS standards the WTO is not a regulatory body with norm-setting capacity.

The definition in Annex A indicates that international standards, guidelines and recommendations for the purposes of the SPS Agreement refer to those set by: (i) the CAC[129] in the area of food safety; (ii) the International Office of Epizootics ("OIE")[130] in the area of animal health; (iii) the International Plant Protection Convention ("IPPC") in the area of plant health; and (iv) certain other relevant international organizations for matters not covered by the three mentioned organizations. The CAC, OIE and IPPC are often referred to as the "three sisters" in the WTO jargon. What is useful and necessary to pinpoint at this stage is that each of these standard-setting

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GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 90.

[126] From this kind of regulatory architecture depends the relationship between the WTO and other International Organizations and this gives rise to the phenomenon that can be preliminary defined as the outsourcing of the law-making in the sense of standard setting.

[127] O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, in *WTO: Technical Barriers and SPS Measures*, R. WOLFRUM, P.T. STOLL and A. SEIBERT-FOHR (eds.), Max Planck Commentaries on World Trade Law, Martinus Nijhoff Publishers, 2007, p. 415.

[128] P. L. H. VAN DEN BOSSCHE and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, in *The World Trade Organisation: Legal, Economic and Political Analysis*, P. MACRORY, A. APPLETON and M. PLUMMER (eds.), Springer, 2005, p. 269.

[129] This is the only international organization that is subject to study in this research while the OIE and the IPPC are only addressed to the extent necessary in order to draw up compared analysis useful for a deeper understanding of the CAC.
The Appellate Body in *Canada - Continued Suspension* noted that the relevant international standards, guidelines or recommendations that are referred to in Articles 3.1 and 3.2 are those set by the international organizations listed in Annex A, paragraph 3 of the SPS Agreement, emphasizing the Codex Alimentarius as the relevant standardization body in matters of food safety. *Canada - Continued Suspension of Obligations in The EC – Hormones Dispute*, Appellate Body Report WT/DS321/AB/R, 2008, para. 693.

[130] In May 2003 the Office became the World Organisation for Animal Health but kept its historical acronym OIE.

organizations has its own structure and standard-setting procedure and these are dictated by their own statutes and not by the WTO framework[131].

According to Annex A paragraph 3(d) Members are allowed to make reference to other relevant international standards where the three sisters setters lack coverage. Two elements are required, as a sort of two steps test. Relevant international standardization bodies must be open to membership by all WTO Members and the SPS Committee must identify them as relevant. Given that to date no other international standardizing bodies have sought such recognition, these three standardization bodies have played in practice the role of exclusive[132] "quasi-legislators"[133]. However, in theory, the enumeration of international organizations, and consequently standards, that are relevant under the SPS Agreement is open-ended. The adopted wide and enigmatic formulation[134], rather than establishing a clear approach, raises a number of difficult legal questions[135].

The text of Annex A paragraph 3(d) makes one final point that has to be tackled when addressing the notion of standards under the SPS Agreement which is if the WTO framework set any kind of substantive or procedural requirements for the adoption of standards promulgated by other relevant international organization. It is only provided that the relevant organizations should be "open for membership to all Members"[136]. This, however, says nothing about the actual participation by all

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[131] P. L. H. VAN DEN BOSSCHE and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 269.

[132] Bernstein and Hannah highlight that since there is little regulatory space not covered by one of the three sisters, it is unlikely to have a non-state market driven system under the SPS Agreement and suppose more opportunities for ethical, environmental, or social standards related to food under the TBT Agreement. S. BERNSTEIN and E. HANNAH, N*on-State Global Standard Setting and the WTO: Legitimacy and the Need for Regulatory Space*, Journal of International Economic Law, Vol. 11, issue 3, 2008, p. 594.

[133] G. MARCEAU and J. 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*, p. 838.

[134] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 79.

[135] The most important being if there is room for private standards under the SPS Agreement, addressed in Chapter III.

[136] The role of the SPS Committee in identifying relevant international organization and in the general in the development, adoption and monitoring of standards is addressed in section 4.

Members in norm setting, or about the effectiveness of the participation that does occur. These participatory problems call into question the legitimacy of the use of the standards adopted by standard-setting organizations, not only those admissible under letter d, but even the three sisters.

From the analysis explained above it may be noted that the standard-setting procedure is completely delegated by the WTO to the activities of other International Organizations, in practice, to the three sisters. The SPS Agreement is silent with regard to the requirements in the definition of "standards, guidelines or recommendations" in relations to the procedure by which the relevant legal tools is created, such as requirements regarding the degree of support it should have (*e.g.*, a qualified majority or a consensus in favor), the role of civil society interest groups in standard setting or the extent of participation by developing countries in the setting of the standards.

Nevertheless, this work will try to find if these requirements are set in any other "area" of the WTO framework, and, in case of negative or unsatisfactory results, to provide some *de iure condendo* recommendations in this regard. The critical investigation of the text of the SPS Agreement continues with the analysis of Article 3.2

3.2 Measures conforming to international standards (Article 3 para. 2)

According to the text of Article 3 paragraph 2:

> "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."

Through the reading of this article, two questions come to mind; (i) which is the "conform to" requirement or, in other words, what does it mean that a national measures conforms to an international standard, and (ii) which presumption of

consistency with the SPS Agreement and GATT 1994 is granted by conforming to these standards?

An answer to the first question can be found primarily in the decision of the Appellate Body (AB) in *EC – Hormones* case[137], which made the following distinctions between the three first paragraphs of Article 3:

> "Under Article 3.2 of the *SPS Agreement*, a Member may decide to promulgate an SPS measure that conforms to an international standard. Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard. […]
>
> Under Article 3.1 of the *SPS Agreement*, a Member may choose to establish an SPS measure that is based on the existing relevant international standard, guideline or recommendation. Such a measure may adopt some, not necessarily all, of the elements of the international standard. […]
>
> Under Article 3.3 of the SPS *Agreement*, a Member may decide to set for itself a level of protection different from that implicit in the international standard, and to implement or embody that level of protection in a measure not "based on" the international standard."[138]

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[137] *EC - Measures Concerning Meat and Meat Products*, Appellate Body Report WT/DS26/AB/R WT/DS48/AB/R, 1998.
The literature on this subject is very vast and does not address uniquely the standards issues. See M. D. CARTER, *Selling Science under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy*, Minnesota Journal of International Law, Vol. 6, issue 2, 1997; D. HURST, *Hormones: European Communities – Measures Affecting Meat and Meat Products*, European Journal of International Law, Vol. 9, issue 1, 1998; D. A. WIRTH, *International Decisions. European Communities - Measures Concerning Meat and Meat Products*, American Journal of International Law, Vol. 92, issue 2, 1998; R. QUICK and A. BLÜTHNER, *Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case*, Journal of International Economic Law, Vol. 2, issue 4, 1999.
[138] *Ibid*. paras. 170-172.
The meaning of Article 3 paragraph 2 is even defined in *India - Agricultural Products*, in contrast with paragraph 1, where it is stated that: "A measure that is "based on" a standard may not necessarily 'conform to' that same standard, as some elements of the standard may not be present in the measure at issue. […] Article 3.2 requires that an SPS measure embodies the standard completely to be said to 'conform to' it. Hence, the language in Article 3.1 whereby an SPS measure may be 'based on' an

In this decision the AB reversed the Panel's finding that Article 3 paragraph 2 equates measures based on international standards with measures which conform to such standards. Moreover, it drew a distinction between the terms "based on" and "conform to" and noted certain requirements for a measure to "conform to" an international standard[139]. In particular, the AB after distinguishing between the ordinary meaning of "based on" and "conform to", noted that they were used in different provisions of the SPS Agreement and rejected the view that such different usage was "merely inadvertent"[140]. According to some authors Article 3 paragraph 2 set a high level of compatibility between the national measure and the international standards suggesting that the desired level of protection reflected should be exactly the same[141]. Apart from this substantive aspect, the State's measure should also be

international standard establishes a less rigorous threshold than that contemplated in Article 3.2 ('conform to'). We understand this to mean that failure to meet the 'based on' threshold in Article 3.1 would also result in not meeting the more rigorous 'conform to' threshold in Article 3.2". *India - Measures Concerning the Importation of Certain Agricultural Products*, Panel Report WT/DS430/R, 2014, para. 7.202.
In this case, the Panel outlined that because the challenged measures were not based on the relevant international standard within the meaning of Article 3.1, they also did not conform to that standard and, as a result, could not benefit from the presumption of consistency with other provisions of the SPS Agreement under Article 3.2. Panel report, para. 7.275

[139] "In the first place, the ordinary meaning of "based on" is quite different from the plain or natural import of "conform to". A thing is commonly said to be "based on" another thing when the former "stands" or is "founded" or "built" upon or "is supported by" the latter. In contrast, much more is required before one thing may be regarded as "conform[ing] to" another: the former must "comply with", "yield or show compliance" with the latter. The reference of "conform to" is to "correspondence in form or manner", to "compliance with" or "acquiescence", to "follow[ing] in form or nature". A measure that "conforms to" and incorporates a Codex standard is, of course, "based on" that standard. A measure, however, based on the same standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure." *EC – Hormones* para. 163.

[140] "In the second place, "based on" and "conform to" are used in different articles, as well as in differing paragraphs of the same article. Thus, Article 2.2 uses "based on", while Article 2.4 employs "conform to". Article 3.1 requires the Members to "base" their SPS measures on international standards; however, Article 3.2 speaks of measures which "conform to" international standards. Article 3.3 once again refers to measures "based on" international standards. The implication arises that the choice and use of different words in different places in the SPS Agreement are deliberate, and that the different words are designed to convey different meanings. A treaty interpreter is not entitled to assume that such usage was merely inadvertent on the part of the Members who negotiated and wrote that Agreement. Canada has suggested the use of different terms was "accidental" in this case, but has offered no convincing argument to support its suggestion. We do not believe this suggestion has overturned the inference of deliberate choice.". *Ibid*. para. 164.

[141] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 92.

identical in the structure of the international standard[142]. At the same time, this provision does not predetermine the margin of appreciation in determining the desirable level of protection that is enjoyed by WTO Members[143]. The Hormones case is of a great importance in the "conform to" definition dilemma, as well as permits us to assess the standards issues on a broader view.

On the basis of a wide approach, which is attuned to the political and social context in which the SPS Agreement and the WTO operate, the AB pointed to Article 3 fundamental purpose: to promote the use of international standards while allowing Members to deviate from those standards if such deviations conform with risk assessment under article 5[144]. In sum, while the AB overturned the Panel's view that the SPS Agreement requires strict adherence to international standards, giving Sates considerable latitude in setting SPS levels that were different from international standards, at the same time it anchored this latitude in the requirement of the risk assessment test. The final consequences of this reasoning are better explained in the following step on the presumption of consistency and in the part referring to risk assessment.

The second question leads us to grasp the meaning of Article 3 paragraph 2, that grants a presumption of consistency with the SPS and the GATT 1994 for national measures conforming to international standards. First of all, it has to be recalled that this rule, albeit apparently simple, is not an example of clarity[145], as the entire SPS Article 3. The scope of the presumption under the SPS Agreement and the GATT is ambiguous, allowing for both a narrow and broad approach in interpreting this rule.

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[142] P. L. H. VAN DEN BOSSCHE, and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 276.

[143] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 92.
Moreover, this aspect is influenced also by the content of the particular international standard. For example, as already mentioned, guidelines are normally formulated in a very broad and general language and conformity with them may be achieved in different ways.

[144] D. G. VICTOR, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years*, pp. 900 and 904.

[145] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 92.

According to the first idea, the presumption would not cover all the provisions under both Agreements, leaving the reader in the position to identify specific provisions that could benefit from this presumption[146]. There are several good reasons[147] for a broad reading of the presumption which makes a measure immune under all provisions of the SPS and the GATT 1994 Agreements. These seem to provide a clear and unambiguous rule that is easy to apply and guarantees to maintain the consistency of the results under both the SPS Agreement and GATT 1994. Moreover, this approach does not prevent proof to the contrary, as the presumption is conceptualized as rebuttable[148]. In this regard, still the *EC – Hormones* case is valuable for the understanding of this provision. Here, the AB stated that measures pursuant to Article 3.2 enjoy the benefit of a presumption, albeit a rebuttable one[149]. It also noted that the presumption in Article 3.2 does not mean that Members who decide not to conform their measures with an international standard may be subject to a special burden of proof as penalty[150]. From this reading it follows that if the presumption was considered

[146] For the GATT 1994 Articles I, III, XI and XX have been identified as relevant while for the SPS Agreement this is made difficult because it would bring to paradoxical results not admissible for a proper understanding of the entire Agreement. L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, pp. 93-94.

[147] This is the reading given in the Panel Report, *EC – Hormones (US)*, at para 8.72: "[…] Article 3.2, which introduces a presumption of consistency with both the SPS Agreement and GATT […]". Moreover, this is the most reasonable interpretation considering the entire paragraph, given that a measure which is presumed to be compatible with all the relevant provisions of the SPS Agreement and of GATT 1994 has to be regarded as necessary since the necessity test constitutes one of the requirements under both agreements. Such interpretation is also the widely accepted in the literature: L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, pp. 94-95, 279; J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, Oxford University Press, 2009, p. 258; O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, p. 422. Landwehr also observes that since the SPS and the TBT Agreement are mutually exclusive, the measure at stake cannot be appraised under the TBT Agreement, and thus the presumption applies also for the entire TBT Agreement.

[148] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 258. The author also observed that this is true also for the corresponding provision in the TBT Agreement Article 2.5. At the same time, at p. 258 footnote 58, the author outlines some important differences between TBT Article 2.5 and SPS Article 3.2. The presumption in the TBT domain is constructed in a narrow way both in terms of benefit and on the legal basis required.

[149] "[…] Such a measure enjoys the benefit of a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the SPS Agreement and of the GATT 1994 […]". Appellate Body Report, *EC – Hormones* para. 170. This was confirmed in Appellate Body, *US – Continued Suspension*, WT/DS321/AB/R, para. 532.

[150] "[…] The presumption of consistency with relevant provisions of the SPS Agreement that arises under Article 3.2 in respect of measures that conform to international standards may well be an incentive

irrefutable this would have transformed international standards into binding norms[151], an interpretation that was clearly rejected by the AB. In practice, it is required that the complaining Member demonstrates that the international standards in question (and hence the domestic measure converting it) does not satisfy the demands of the SPS Agreement. However, it seems hard that a Member could successfully challenge the presumption given that generally the standard at stake reflects a consensus shared by the international scientific community[152]. Moreover, to grounds on which the Dispute Settlement Mechanism can evaluate the standards remains a thorny question[153].

The last aspect, which is crucial for a wide and deep understanding of standards role and binding authority within the SPS system, is the relationship between Article 3.2 and Article 5. In a way that has been defined a "plain language" [154], "Article 3 promotes harmonization with international standards, and Article 5 allows countries to escape the straitjacket of international standards, provided that an assessment of risks is the first step in setting such stricter SPS measures"[155]. Put another way, "[…] [a]rticle 3.2 is inapplicable where a Member chooses a level of protection that is higher than would be achieved by a measure based on an international standard. The presumption in Article 3.2 cannot be interpreted to imply that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher

for Members so to conform their SPS measures with such standards. It is clear, however, that a decision of a Member not to conform a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a penalty […]". Appellate Body Report, *EC – Hormones*, para. 102.

[151] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 95.

As pointed out by Quick and Bluthner, this does not mean that international standards become (either directly or indirectly) binding on WTO members as a result of SPS disciplines. The standards are "simply interpretative addenda to the SPS norms, i.e. they provide the Members with an additional 'anticipated scientific justification' like a block exemption, rather than fulfilling the requirements of Article 5 SPS". R. QUICK and A. BLUTHNER, *Has the Appellate Body Erred - An Appraisal and Criticism of the Ruling in the WTO Hormones Case*, p. 613.

[152] O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, p. 422.

[153] See section 8.4.

[154] D. G. VICTOR, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years*, p. 876, footnote 28.

[155] *Ibid*.

level of protection"[156]. This means that where a Member decides to set a level of protection higher than the level provided in an international standard, and thus not "conforming to" it, the State has to pass from the difficult step of risk assessment, as already outlined.

3.3 Basing measures on international standards (Article 3 para. 1)

> "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."

Looking first to Article 3.1, this raises three particular problems: i) when international standards are deemed to exist? ii) Which is the meaning (what are the requirements) of "based on"? iii) what are the legal consequences (the law applicable) under Article 3.1?

The question of the existence of relevant international standards was at issue, once again, in the *EC – Hormones* case. The Panel assessed this matter by looking at the respective scope of the international standards and of the contested municipal measure. In its views, it seems that it was considered enough where the international standard and the national measure cover the same substance, when they are used for the same purpose and applied to the same product category[157]. Interestingly, it also noted that it only needed to determine whether such standards exist rather than considering the level of the standards, the consensus behind them or their timing adoption process[158]. In *Australia – Salmon*, the question of the existence of relevant

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[156] Appellate Body Reports, *Canada – Continued Suspension*, paras. 694.
[157] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 253; Panel Report, *EC – Hormones (Canada)*, para. 8.73.
[158] "Article 3.1 unambiguously prescribes that "... Members shall base their sanitary ... measures on international standards ... *where they exist* ..." (emphasis added). Paragraph 3 of Annex A of the *SPS Agreement* states equally clearly that the international standards mentioned in Article 3:1 are "for food

international standards was also at stake, as the guideline that had been drafted by the OIE did not cover all the twenty-four of the diseases at which the Australian measure was aimed. Here, the Panel held that even if no international standards existed for the entire range of fish diseases at issue, this circumstance did not signify that an international standard applying to only one of the diseases at issue could not be relevant in the case before it[159].

As already outlined previously, the AB addressed the meaning of "based on" in Article 3.1 in *EC – Hormones*[160], making reference to similar expression as "founded" or "built" upon or "is supported by" and defining it mainly on the basis of the differences with the "conform to" requirement. The above observations of the AB on the nature of this relationship were further elaborated in SPS case law, in particular in In *US – Animals*, where the Panel further clarified that a Panel's task under Article 3.1 is to "determine whether the challenged measures are "founded" or "built" upon or "supported by" the relevant standards, guidelines or recommendations [...] such that they serve as a principal constituent or fundamental principle of the [...] measures"[161]. The Panel also stated that "the "based on" does not require the wholesale

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safety, the standards ... *established by the Codex Alimentarius Commission* relating to ... *veterinary drug ... residues* ..." (emphasis added). No other conditions are imposed in the *SPS Agreement* on the relevance of international standards for the purposes of Article 3. Therefore, as a Panel making a finding on whether or not a Member has an obligation to base its sanitary measure on international standards in accordance with Article 3.1, we only need to determine whether such international standards exist. For these purposes, we need not consider (i) whether the standards reflect *levels* of protection or sanitary *measures* or the *type* of sanitary measure they recommend, or (ii) whether these standards have been adopted by consensus or by a wide or narrow majority, or (iii) whether the period during which they have been discussed or the date of their adoption was before or after the entry into force of the *SPS Agreement*.". Panel Reports, *EC – Hormones* (Canada), para. 9.72. and 8.69 (USA).

[159] "[…] we are of the view, however, that the fact that in this case no international guidelines exist for all 24 diseases of concern does not mean that an international guideline which applies to only one of these diseases cannot be relevant (or, according to the language of Article 3.1, does not 'exist') for the measure at issue". *Australia - Measures Affecting the Importation of Salmon*, Report of the Panel WT/DS18/AB/R, 1998, para. 8.46. Prevost observed in this regard that, accorded to these findings, "it appears that a broad and unqualified acceptance of all norms adopted by the "three sisters" for purposes of the Article 3 disciplines is currently the approach followed by panels". P. L. H. VAN DEN BOSSCHE, and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 271.

[160] Besides this issue, the AB was reticent about conferring binding authority on international standards - "which are by the terms of the Codex recommendatory in form and nature" - under Article 3.1, and conceived the goal of harmonization as one to be realized "in the future", and not as a fact "in the here and now". Para. 165.

[161] *United States - Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina*, Panel Report WT/DS447/R, 2015, para. 7.233.

adoption of the international standard, guideline or recommendation into the measure of the importing Member […] [a]s […] this would wipe out any distinction between the scope of coverage of Articles 3.1 and 3.2"[162].

In this perspective, it is reasonable to observe[163] that there are some cases where it will be not possible to base a measure on an international standard without actually conforming to it. Codex Maximum Residue Level(s) may serve as a good example, provided that a numerical value, with its precise formulation, leaves no discretion to WTO Members who may only accept or deviate from it.

The Appellate Body in *EC – Hormones* proceeded to explain the consequences for a Member of choosing the option under Article 3.1. Noting that although a Member that merely bases its measure on an international standard does not benefit from the presumption of consistency set up in Article 3.2, it stated that a State is also "not penalized by exemption of a complaining Member from the normal burden of showing a *prima facie* case of inconsistency with Article 3.1 or any other relevant article of the *SPS Agreement* or of the GATT 1994"[164]. The question which then arises is about the legal consequences of basing a measure on international standards (without, however, conforming with them) in terms of what are the benefits of choosing the option under Article 3.1? It is necessary to start by saying that the case law is silent on this issue and any observations are necessarily speculative. On the basis that the presumption under Article 3.2 is not available here, while some authors have though that there are no advantages to merely basing domestic SPS measures on an international standard[165], others - and it's the interpretation subscribed and proposed in this research - however, believe that a measure which is based on an international standard, should

[162] *Ibid*., para. 7.239.
[163] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 96; O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, p. 420.
[164] *EC – Hormones*, Appellate Body Report, para. 171.
[165] J. PAUWELYN, *The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes*, Journal of International Economic Law, Vol. 2, issue 4, 1999, p. 656; O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, p. 421.

be automatically considered as based on a risk assessment that was used by the relevant international organization in drafting its standard[166]. This is a crucial point, considered that, even among the authors who have a different position on this, they still recognize how it is exceedingly difficult to produce a risk assessment that complies with Article 5[167], as SPS case law has demonstrated in so far[168]. This element is of particular importance to developing countries, because they often lack the resources, expertise and infrastructures to conduct their own risk assessments. This also means that the difference between Article 3.2 and 3.1 lies in the fact that in the first case there is a (rebuttable) presumption of compliance with the entire SPS Agreement and with GATT 1994 while in the second the presumption (again rebuttable) of compliance is only with SPS Article 5 on risk assessment.

Aside from the two possible readings of the legal consequences arising from Article 3.1, there are some advantages, more in practical sense then in the form of a legal presumption[169], by recurring to this provision. Article 5.8[170] provides the right for a WTO Member to request an explanation of the reasons for a particular SPS measure that, even potentially, is constraining for exporter, only in the case such measure is not based on international standards. Thus, *a contrario,* this obligation is

[166] "[I]t seems logical that there should be an advantage over the situation set forth in Article 3.3. It seems that as a measure based on an international standard is automatically based on a risk assessment (namely the risk assessment used by the relevant international organization in drafting its standard), the measure may be assumed to comply with Article 5.1–5.3". P. L. H. VAN DEN BOSSCHE, and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 274.
While it could seem obvious, it is necessary to point out that the measure is presumed to be based on the risk assessment provided by the international standard organization at stake if the part(s) of the standards used "as a basis" include(s) that on the risk assessment procedure.
[167] O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS*, p. 421.
[168] For a complete understanding see the WTO Analytical Index on SPS Agreement Article 5 (Jurisprudence), available at https://www.wto.org/english/res_e/publications_e/ai17_e/sps_art5_jur.pdf.
[169] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, pp. 99-100.
[170] "8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure".

not required with respect to measures based on international standards. The second case regards the notification procedure provided by Annex B[171], paragraph 5 in particular, where it could be argued that basing a measure on an international standard implies that the notification procedure is inapplicable. Both the complainant parting when making a prima facie case of inconsistency[172] and the defendant relying on the scientific data used in the standard-setting process could benefit from these advantages in a fact-finding process.

3.4 Measures deviating from international standards (Article 3 para. 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[[173]]. Notwithstanding the above, all

[171] "5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:
(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

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

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

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

[172] *EC - Hormones*, Appellate Body Report, para. 110; *Japan - Apples*, Panel Report, para 8.41.

[173] "For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines

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 third option provided to Members by Article 3 is to promulgate SPS measures setting a different level of protection than would result from measures "based on" the relevant international standards. This rule recognizes the right of Sates to choose their own level of protection, a fundamental principle in the SPS Agreement. In *EC - Hormones* the AB held that the "right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an 'exception' from a 'general obligation' under Article 3.1"[174]. However, as recognized by the AB, this is not an "absolute or unqualified right. Article 3.3 also makes this clear [...]"[175].

A literal reading of the provision would indicate that two science-related conditions are set in alternative in the SPS Agreement, which introduces a logical disjunction ("or") that envisages two possible separate modes of compliance. However, it is not clear why Article 3.3 provides for two alternative conditions and how exactly they differ, as the language, by the AB own admission, of "Article 3.3 is evidently not a model of clarity in drafting and communication."[176]. This approach to Article 3.3 would conduct to relevant consequences. Given that the first alternative does not explicitly refer to Article 5 of the SPS Agreement, it may be argued that scientific justification is possible without any formal risk assessment. Therefore, a Member will be able to defend domestic SPS measure by simply relying on scientific principles and evidence in accordance with Article 2 or with other SPS Agreement provisions, avoiding in any case the complexity and harshness required by the risk

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or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection."

[174] *EC - Hormones*, Appellate Body Report, para. 172.

[175] *Ibid*. para. 173.

[176] *Ibid*. para. 175.

assessment. The case law[177], however, went in a different direction, both the Panel and the AB agreed that scientific justification has no independent meaning under the SPS Agreement. The Appellate Body held that the distinction between the two situations identified in Article 3.3, is more apparent than real[178]. In fact, both situations require a risk assessment in accordance with Article 5. This conclusion was based on three arguments. First, on a textual basis, the expression "any other provision of this Agreement" includes Article 5. Secondly, the AB observed that the examination and evaluation of available scientific information, as provided by the footnote to Article 3.3 "would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the *SPS Agreement*"[179]. Thirdly, and foremost, the AB looked at the at purpose of Article 3 and the SPS Agreement as a whole[180], and affirmed that "the requirements of a risk assessment under Article 5.1 [...] are essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings"[181].

[177] Besides the Hormone case, there two other relevant cases for this discussion, which basically confirm the same vision on the issue. In the Canada - Continued Suspension, the AB observed that "[…] Where a Member exercises its right to adopt an SPS measure that results in a higher level of protection, that right is qualified in that the SPS measure must comply with the other requirements of the SPS Agreement including the right to perform a risk assessment", para. 532. In Japan - Agricultural Products II, the Appellate Body recalled its findings in EC - Hormones with respect to the relationship between Articles 2.2 and 3.3. and stated that: "[…] In our opinion, there is a "scientific justification" for an SPS measure, within the meaning of Article 3.3, if there is a rational relationship between the SPS measure at issue and the available scientific information.", *Japan - Measures Affecting Agricultural Products*, Appellate Body Report WT/DS76/AB/R, 1999, para. 79.

[178] "We are not unaware that this finding tends to suggest that the distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real. Its involved and layered language actually leaves us with no choice.". *Ibid*. para. 176.

[179] *Ibid*. para. 175.

[180] "[…] In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection." *Ibid*. para. 177.

[181] *Ibid*.

The decision of the AB, by requiring to comply in every situation with the obligations provided under Article 5, seems the most logical answer also in a practical sense. Otherwise, why should a WTO Member perform a risk assessment if it is sufficient to show that a measure is based on scientific evidence? The AB reasoning reflects the central position occupied by the risk assessment obligation in the SPS Agreement legal framework[182].

There is one additional remark on the issue of measures that are less demanding than international standards. According to the first sentence of Article 3.3, deviations are only permitted from relevant international standards where a domestic measure results in a higher level of SPS protection. A merely textual interpretation would thus suggest that WTO Members are precluded from adopting measures which aim at a lower level of protection. However, there seems to be a lack of shared views in the literature as to the permissibility under the SPS Agreement of measures that are less demanding than international standard. This brings to the subsequent doubt about whether the SPS Agreement establishes any minimum harmonization requirement and consequently of health level. From the one side, some authors submit that Article 3 may actually require tightening "national regulations against the countries that fall below the minimum of the international standard"[183]. From the other side, this possibility is refused for multiple reasons[184]. While there are some textual references[185]

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[182] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 101.

[183] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 261, citing R. HOWSE, *A New Device for Creating International Legal Normativity: The WTO Technical Barriers to Trade Agreement and 'International Standards'*, in *Constitutionalism, Multilevel Trade Governance and Social Regulation*, C. JOERGES and E. PETERSMANN (eds.), Studies in International Trade Law, Hart Publishing, 2006.

[184] J. PAUWELYN, *Non-Traditional Patterns of Global Regulation: Is the WTO "Missing the Boat"*, in *Constitutionalism, Multilevel Trade Governance and Social Regulation*, C. JOERGES and E. PETERSMANN (eds.), Studies in International Trade Law, Hart Publishing, 2006; P. L. H. VAN DEN BOSSCHE and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 275; J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 262.

[185] Article 3.1 and first and second recitals of the Preamble. However, there is a textual reference in Article 12.4 – "[the Sate] considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection" – that seems to assume that deviation from international standards is only admissible for stricter, more stringent, rules.

in the SPS Agreement that could lead to the admissibility of measures that are less demanding than international standards, there are some valid and strong reasons against it[186].

First and foremost, this would be contrary to the core idea of the promotion of international free trade, which is the overall objective of the entire WTO system. Moreover, adopting this scheme would imply disequilibrium among the rights and obligations for developed and developing countries. Finally, the perspective of the SPS Agreement that establishes a minimum level of health protection through standards, in this simplistic meaning, would transform those standards into binding norms, even if this was explicitly rejected by the AB.

3.5. Risk Assessment: the turning point for compliance

As pointed out from the very beginning, the SPS Agreement imposes a series of obligations on States that are controversial in that they take the WTO beyond a merely discrimination-based approach to a positive model of trade integration, and place great emphasis upon testing the scientific adequacy of national measures[187]. Article 5 is exemplary in this respect, insisting that national protective measures be based upon a risk assessment. Articles 5.1 to 5.3 of the SPS Agreement elaborate on this issue and builds on the basic obligation contained in Article 2.2. Generally

[186] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 102-104.
Moreover, also the recent practice of the SPS Committee confirms this view: "[…] It should be recalled that the WTO SPS Agreement allows Members to establish sanitary and phytosanitary measures which result in a higher level of protection than would be achieved by measures based on relevant international standards, guidelines and recommendations provided that there is a scientific justification to do so". Committee on Sanitary and Phytosanitary Measures, *SPS Measures and International Standards, Guidelines and Recommendations – Revision*, G/SPS/GEN/1143/Rev.2, circulated on 29 March 2012, para. 6. There are no reference to the admissibility of "lower level of protection" than international standards in the SPS Committee practice.
[187] A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, The European Journal of International Law, Vol. 20, no. 3, 2009, p. 590.

speaking, the purpose of a risk assessment is to serve as a basis for regulatory actions and to provide the necessary information for a rational decision-making[188] .

In the Hormones case risk assessment has been defined has "a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions"[189]. Annex A paragraph 4 of the Agreement provides two substantially different definitions of risk assessment[190], which apply depending on whether "disease- or pest-related risks", or "food/feed-borne risks" are at stake. However, the text of the Article provides little indication of what amounts to an "appropriate" assessment for SPS purposes, beyond articulating the factors and methodologies to be taken into account and requiring that an "evaluation" of risks takes place. The AB examined these definitions in several cases[191], important in assessing what will be required for Members who impose SPS measures not conforming to international standards.

What is relevant here, is that by virtue of Articles 3.2 and 3.1, Article 5 will be rendered largely inapplicable if a harmonization effort under Article 3 results in the adoption of an international standard. At the same time, the relationship between Articles 3 and 5 implies that compliance with Article 3.3 requires compliance with Article 5[192]. The requirements of scientific assessment have been considered as a rigid control system for national measures which is closely limited to adherence clearly and narrowly defined preconditions, which will be met in only a very limited number of cases[193]. The strict view of the requirements for a proper risk assessment taken by the

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[188] P. STOLL and L. STRACK, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 5 SPS*, p. 441.
[189] *EC - Hormones*, Appellate Body Report, para. 187.
[190] "4. Risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs." .
[191] *EC - Hormones*; *Australia - Measures Affecting the Importation of Salmon*; *Japan - Measures Affecting Agricultural Products* and *Australia - Measures Affecting the Importation of Apples.*
[192] P. STOLL and L. STRACK, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 5 SPS*, p. 437.
[193] *Ibid*. p. 466.

Dispute Settlement Bodies[194] is confirmed by the fact that in several occasions the AB takes a more realistic view of the scientific assessment of risks than do the Panels. It tries to shape the obligations under Article 5 given the difficulties inherent in risk assessment by: (i) allowing the probability to be established quantitatively or qualitatively, (ii) not requiring a minimum level of risk to be shown and (iii) finding that the risk to be ascertained is not only that which can be established under controlled conditions in science laboratories, but includes that occurring in the "real world"[195]. Moreover, generally compared to the TBT Agreement, this requirement may constitute a more demanding and rigid threshold than that provided by the necessity test in the TBT Agreement[196].

3.6 Interim conclusions on Article 3: framing its normative value and opening to the cooperative dimension

Article 3 is probably one of the most obscure provisions in the whole SPS Agreement. It does not set any clear normative structure and is open to competing

[194] Another interesting aspect looking at the case law is the relevance of the risk assessment developed by three sisters, which demonstrates again the close relationship of these International Organizations with the WTO. The AB in Australia - Apples noted that Article 5.1 requires Members performing risk assessments to take "into account risk assessment techniques developed by the relevant international organizations". *Australia - Measures Affecting the Importation of Apples from New Zealand*, Appellate Body Report WT/DS367/AB/R, 2010, para. 246. Moreover, they also "[…] observe that the panel in Japan - Apples [Panel Report, Japan - Apples, para. 8.241] found that, while the language in Article 5.1 does not require that a risk assessment be "based on" or "in conformity with" risk assessment techniques of international organizations, it suggests that reference to these risk assessment techniques can provide very useful guidance as to whether the risk assessment at issue constitutes a proper risk assessment within the meaning of Article 5.1". Ibid., para. 246, footnote 377. Here follows the text of the referred Panel Report: "8.241 We recall that Article 5.1 requires the "risk assessment techniques developed by the relevant international organizations" to be "taken into account". We note first that this expression does not impose that a risk assessment under Article 5.1 be "based on" or "in conformity with" such risk assessment techniques. This suggests that such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, per se, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1. Nonetheless, reference to these risk assessment techniques can provide very useful guidance as to whether the risk assessment at issue constitutes a proper risk assessment within the meaning of Article 5.1". *Japan - Measures Affecting the Importation of Apples*, Panel Report WT/DS245/R, 2003, para. 8.241.

[195] P. L. H. VAN DEN BOSSCHE and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 286.

[196] N. WILSON, *Clarifying the Alphabet Soup of the TBT and the SPS in the* WTO, Drake Journal of Agricultural Law, Vol. 8, no. 3, 2003, p. 722.

interpretations. From the analysis carried out this is probably the result of the disagreement that existed among the drafters, in particular due to the fact that one group of countries supported the establishment of strict harmonization disciplines and others sought guarantees for rather unrestrained national regulatory freedom in the area of SPS measures. In this frame, where necessary clarity was not achieved, the approach taken by the AB, in accordance with the principle of *in dubio mitius*, appears to be understandable. The case law holds that Article 3 provides three options that are available to WTO Members and each of these situations brings its own specific legal consequences. Article 3.1 encourages WTO Members to base their measures on international standards, operating as a kind of partial reward, especially in terms of risk assessment. Article 3.2 establishes a rebuttable presumption of consistency with the entire SPS Agreement for those measures that conform to such standards. From the examination of Article 3.3 emerges the role of science, in the form of risk assessment, a crucial (and hard to implement) element in providing consistency in the absence of harmonization.

The relevant standards are "outside" the WTO framework, identified by the SPS Agreement through reference to specific international standard-setting bodies. However, the lack of a rule-making body in the WTO with the task of providing SPS standards creates an institutional gap and opens for criticism in terms of legitimacy. Article 3 attempts to fill this gap by making use of another, universally accepted and thus authoritative provider of uniformity and neutrality, namely science. Science is the rationale of the entire SPS Agreement, and acts as a balancing factor for the institutional and contractual equilibrium. It can be assumed that the consensus that has always been required to WTO Members to impose obligations, has shifted, in the standard international law-making environment, towards a consensus in the scientific community? Where consensus among the scientists appears to exist, as embodied in international standards set by international organizations, Members are (at least) encouraged to use these standards. International standard-setting bodies use recognized risk assessment procedures conducted by scientific committees or expert

groups to draw up standards. In the alternative, where no such standards exist or where Members wish to deviate from these standards, national regulations which differ from harmonized standards follow again the dictates of science as embodied in risk assessment.

Beyond these partial considerations, the analysis of Article 3 is still not finished. The last two paragraphs are respectively dedicated to States cooperation in international standard-setting organizations and to the procedures for monitoring the process of international harmonization by the SPS Committee. These final provisions pave the way for further reflections on the relationship among the WTO framework and the CAC and on the role of the SPS Committee in the WTO governance in general and more specifically in the harmonization process.

According to Article 3.4:

> "4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures."

The questions arising from the reading of this provision are properly addressed in Chapter II, however, generally speaking, it can be outlined that there is no case law on the provision yet and that it would seem too far reaching to consider it as an autonomous legal obligation which requires to join or actively participate in the work of the explicitly mentioned CAC, OIE and IPPC[197].

Pursuant to Art. 3.5:

[197] O. LANDWEHR, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 3 SPS,* p. 425.

"5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations."

Such provision, in accordance with Article, 12 lead this research to what has been called the "the largely invisible infrastructure of the WTO, in the form of its tentacular committee system"[198], in particular the SPS Committee. It is not only involved in the development of a procedure to monitor the process of international harmonization, but also in shaping different elements around standards, as it will be showed in the following section.

4. The SPS Committee: the institutionalized dynamism

The WTO Panels and the AB have been active in giving shape and meaning to the requirements laid down in the SPS Agreement[199]. In this activity they perform the acts as delimiting the area of States' regulatory autonomy in the sensitive area of food safety. Nevertheless, the impacts of these WTO judicial bodies do not exhaust the institutional architecture of the entire SPS Agreement[200].

As in other area of the WTO framework than the SPS one, according to GATT 1994 Article 4 paragraphs 6 and 7, the executive activities take place in the various Councils, Subsidiaries Bodies and Committees. The SPS Agreement institutionalizes

[198] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary,* p. 45.
[199] As already observed, the Hormones case is crucial for a better understanding of the meaning of Article. However, a relevant contribution can be also found in: *Japan - Measures Affecting the Importation of Apples*, Appellate Body Report WT/DS245/AB/R, 2003; *Australia - Measures Affecting the Importation of Salmon*, Appellate Body Report WT/DS18/AB/R, 1998; and *United States - Continued Suspension of Obligations in the EC - Hormones Dispute*, Appellate Body Report WT/DS320/AB/R, 2008.
[200] A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, p. 591.

the SPS Committee as a subsidiary body of the Council for the Trade in Goods, which is competent for the GATT 1994 and for the SPS Agreement.

Article 12[201] establishes the SPS Committee and states a series of functions that should be performed by it. The text of the Agreement is skeletal in its specifications regarding the Committee's institutional profiles and offers little by way of insight into its composition, role, and mode of operation[202]. Also because of this it has been defined as a creature of its own making[203]. Against this background, the Committee has evolved over the years tanks to its own institutional practice, and a study on its activities in relation to international standards cannot be carry out in a static institutional form.

Since the general rule on membership of WTO Organs applies, the Committee composition consists of representatives of all WTO Members[204] and Sates may send delegates of their choice. They generally are officials from their own food safety authorities or veterinary or plant health officials but even diplomats attached to UN or WTO missions or specialists drawn from national ministries in SPS covered fields.

As a consequence of the status of the Committee as a subsidiary organ, observer status is granted to non-Member governments that have observer status in higher WTO bodies, for example in the General Council. Moreover, the SPS Committee grants observer status to certain international intergovernmental organizations with a mandate in the same area[205]. This status is granted on the basis of

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[201] See also Articles 3.5, 5.5 and 10.3 Annex A Article 3(d) which identify further tasks for the Committee.
[202] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 48.
[203] *Ibid*.
[204] According to Rule 7 and 8 of the General Council Rules of Procedure (WT/L/161), each Member shall be represented by an accredited representative and may be accompanied by such alternates and advisers as the representative may require. Furthermore, these rules also provide the Guidelines for Observer Status for Governments in the WTO (Annex 2) and the criteria for the Observer Status for International Intergovernmental Organizations in the WTO (Annex 3). Moreover, it is unknown for States to introduce as part of their delegation also people who are connected to private undertakings. Attendance to the Committee is variable, especially for developing countries.
[205] The nature of the relationship between the SPS Committee and International Organizations has been the subject of lengthy and delicate discussions since the entry into force of the Agreement. International Intergovernmental Organizations having observer status on a regular basis, besides the three sisters, are: the Food and Agriculture Organization (FAO); the World Health Organization (WHO); the International Monetary Fund (IMF); the International Organization for Standardization (ISO); the

functional criteria, namely: "[…] the mandate, scope and area of work covered by the organization. Observer status should be granted to organizations which objectively contributed to the functioning and implementation of the SPS Agreement. Another criteria identified was reciprocity"[206]. The opportunity to obtain the *ad hoc* observer status is granted on a meeting-by-meeting basis. Observers may be invited to speak at meetings and table papers, but do not participate in the decision-making of the Committee. The last institutional aspects concerning the structure of the SPS Committee are those related to the Secretariat, Chair and meetings. It is serviced by the Agriculture and Commodities Division of the WTO Secretariat. The Chairperson, who is appointed on an annual basis, is selected by the Council for Trade in Goods, in consultation with the Committee. The SPS Committee usually holds three meetings per year but may convene informal meetings as appropriate.

4.1. The functions: a forum for consultation beyond Dispute Settlement

Looking at the functions of the SPS Committee, within the terms of Article 12.1, it provides as follows:

> "1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance

International Trade Centre (ITC); the United Nations Conference on Trade and Development (UNCTAD), the World Bank. Moreover, among the International Intergovernmental Organizations having observer status on an *ad hoc* (meeting-by-meeting) basis we can find: the African, Caribbean and Pacific Group of States (ACP Group); the European Free Trade Association (EFTA); the Inter-American Institute for Agricultural Cooperation (IICA); the Organization for Economic Co-operation and Development (OECD); the Regional International Organization for Plant Protection and Animal Health (OIRSA) and the Latin American Economic System (SELA).

[206] Committee on Sanitary and Phytosanitary Measures, *Consideration of Requests for Observer Status, Note by the Secretariat*, G/SPS/W/98, circulated on 19 February 1999; Committee on Sanitary and Phytosanitary Measures, *Criteria for Observer Status*, G/SPS/GEN/229, circulated on 23 February 2001.

of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus."

Paragraph 1 set the overall mandate of the Committee; to provide a regular forum for consultations and further the implementation of the SPS Agreement and in particular the harmonization of SPS measures. The Committee is competent to carry out any action necessary to implement the Agreement and to further its objectives. The task to assist in the implementation of the regulatory approach of the SPS Agreement is focused particularly with respect to harmonization[207], given that Article 12 allocates various functions to the Committee regarding the process of harmonization through international standards. Paragraph 1 also deals with the only rule on the decision-making process regarding the Committee. Pursuant to this provision, it decides by consensus[208]. The exceptional voting procedures provided for under Articles 9 and 19 of the GATT 1994 Agreement do not apply.

The specific tasks of the SPS Committee in the fulfillment of these objectives are elaborated in the other paragraphs of Article 12. The structure of such Article is as follows: Paragraphs 2 and 4 concentrate on the function of the Committee in monitoring the process of international SPS standardization and in rendering the use of the international SPS standards by Members effective and transparent. In this context, these provisions spell out cooperative obligations for Members. In the second part, paragraphs 3, 5 and 6 are concerned with organizing coordination and cooperation between the Committee and other international organizations active in the

[207] The other provisions at stake are: equivalence (Article 4), risk assessment (Article 5) and the notification of SPS measures (Article 7).

[208] Article 9 of the 1994 GATT Agreement provides that the WTO shall continue the practice of decision-making by consensus followed under GATT 1947 and specifies, at footnote 1, that this means that "if no Member, present at the meeting when the decision is taken, formally objects to the proposed decision".
The Committee has also adopted its own working procedures, see in this regard: Committee on Sanitary and Phytosanitary Measures, *Working Procedures of the Committee*, G/SPS/1, circulated on 4 April 1995 and Committee on Sanitary and Phytosanitary Measures, *Rules of Procedure for Meetings of the Committee on Sanitary and Phytosanitary Measures*, G/L/170, circulated on 20 June 1997.

field of SPS protection. Finally, paragraph 7 defines the role for the Committee in the progressive review and implementation of the Agreement.

The general mandate of the Committee is to be a forum for regular consultation on all issues arising under the SPS Agreement. This reflects two curial aspects relevant for harmonization and international standards as well as for the SPS Agreement in general. First, that the SPS Agreement greatly relies on coordination and cooperation between Members[209] and secondly that this provision may go a long way towards helping countries to solve SPS conflicts in a low-cost and less time-consuming manner, without resort to the Dispute Settlement Mechanism[210]. The consultation process is precisely described in the second paragraph of Article 12:

> "2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs."

This provision has to be understood in its broadest sense and covers any form of interaction as such, the consultation among Members may cover any type of issue arising under the Agreement, thus including disputes concerning the interpretation or application of the Agreement[211]. While the mandate of the Committee in this area is broad, it is expected to encourage and facilitate consultations and negotiations between

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[209] V. RÖBEN, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 12 SPS*, p. 528.
[210] P. L. H. VAN DEN BOSSCHE and D. PREVOST, *The Agreement on the Application of Sanitary and Phyto-sanitary Measures*, p. 342.
[211] V. RÖBEN, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 12 SPS*, p. 529.

its Members on specific SPS issues[212]. In practice, the consultation process is mainly performed through organizing a series of meetings, which generally take place at least three times per year[213]. During such meetings, WTO Members have the opportunity to raise and subsequently discuss with other States specific trade concerns relating to the application and maintenance of SPS measures. Discussions on notified changes in SPS legislation take place, with concerns being raised by exporting Members and clarifications given by the Member adopting such measure. At the end of the consultation this could lead to the revision of the notified measure or further bilateral consultations between the Members involved. In the last case, if the concerned Members continue the discussion in the form of bilateral negotiations, they are obliged to inform the SPS Committee of the outcome[214].

As already outlined, the intriguing aspect of the consulting role of the Committee is that within this scenario SPS disputes and trade concern can be solved in alternative, and maybe more fruitful, way than the all-or-nothing (top-down) dispute settlement proceedings[215].

4.2. The functions (ii): monitoring and shaping standards

As part of its consultative forum capacity, the SPS Committee shall encourage the use of international standards, guidelines and recommendations by all Members,

[212] According to the recent Annual Reports on the Activities of the Committee on Sanitary and Phytosanitary Measures, these include, *inter alia*, the following: market access requirement for casein products; ban on the importation of fish, crustaceans and other aquatic animal products; import restrictions on apples and pears and restrictions on poultry meat and poultry meat preparations in 2018, suspension of groundnut seed imports, concerns regarding specific pesticide MRLs adopted by trading partners and about measures on avian influenza and proposal for categorization on compounds as endocrine disruptors in 2017.

[213] The Committee has developed a procedure to encourage and facilitate the resolution of specific sanitary or phytosanitary issues among members in accordance with article 12.2. See Committee on Sanitary and Phytosanitary Measures, *Procedure to encourage and facilitate the resolution of specific sanitary or phytosanitary issues among members in accordance with Article 12.2*, *Decision adopted by the Committee,* G/SPS/61, circulated on 8 September 2014.

[214] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 45.

[215] L. GRUSZCZYNSK, *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*, p. 173.

and sponsor technical consultation and study in this regard. Furthermore, the provision identifies integration, or at least coordination between international and national approaches, as a key instrument for the effective use of international standards by Members.

The following paragraph of Article 12 mandates the Committee to maintain close contact with the most relevant international technical organizations that are active in the area of the SPS Agreement, and in particular with three sisters[216]. It states:

> "3. The Committee 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, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided."

The Committee shall draw on externally available technical expertise both for its function of facilitating consultation and negotiations among Members and for its work in harmonization. In particular, the cooperation efforts see Members encouraged to provide information on their experiences in coordinating their involvement in the work of CAC, IPPC and OIE at the national level. At the same time the relevant international organizations are invited to keep the Committee informed of any work related to the SPS Agreement. The CAC, the IPPC and the OIE regularly provide the SPS Committee with information regarding international standards they have adopted[217].

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[216] Albeit the list is not exhaustive, in practice the Committee makes reference almost exclusive to those three organizations, reinforcing their "quasi-legislators" status.

[217] See, for example: Committee on Sanitary and Phytosanitary Measures, *Submission to the 38th Meeting of the SPS Committee - Information on Activities of the Codex Alimentarius Commission, Submission by the Codex Alimentarius Commission,* G/SPS/GEN/747, circulated on 2 February 2007; Committee on Sanitary and Phytosanitary Measures, *Issues of Interest to the SPS Committee discussed*

As already pointed out in this section on the SPS Committee and in the previous parts devoted to standards under Article 3 and in the analysis of the negotiating practice, a fruitful dialogue among the Committee and the three sister is a crucial aspect for an effective functioning of the harmonization obligation and thus for the adoption of international standards. In this perspective, Article 12 paragraph 4 mandates and empowers the Committee to monitor the process of international harmonization and the use of the resulting international standards by Members. This provision represents a sort of catalyst[218] for the dialogue between the Committee and the three sisters, with the Committee inviting the "relevant international organizations" adopting or revising a standard to provide information. The details of this rule[219] are set as follows:

> "4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor,

by the OIE International Committee at the 74th General Session, Communication from the World Organisation for Animal Health (OIE), G/SPS/GEN/708, circulated on 26 June 2006 and Committee on Sanitary and Phytosanitary Measures, *International Plant Protection Convention (IPPC) Standard-Setting Work Programme (As of Cpm-1, April 2006),* G/SPS/GEN/729, circulated on 11 October 2006. However, an in-depth analysis on the cooperation mechanism and results between the SPS Committee and the CAC is provided in Chapter II.

[218] A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, p. 596.

[219] The adoption of this procedure is also required by Article 3.5.

and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B."

The underlying purpose of such procedure is to identify where there is a major impact on trade as a result from not using international standards and to establish the reasons for the non-use of these standards[220]. In the light of this non-use, the Committee could invite the relevant standard setting bodies to consider reviewing existing standards[221] and it may also be the case that the body in question rejected the need for a specific text[222]. It is also intended to assist in distinguishing where a new standard is needed, or when an existing standard is not appropriate, including because of perceived deficiencies in the appropriate level of protection which it provides[223].

[220] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 66.
[221] See, for example: Committee on Sanitary and Phytosanitary Measures, *Sulphur Dioxide in Cinnamon*, *Letter from the SPS Chairperson and Response from the Codex Alimentarius Commission*, G/SPS/GEN/716, circulate on 25 July 2006. This case saw Sri Lanka calling attention because of the lack of CAC standard for Sulphur dioxide in cinnamon and is illustrative of the Committee role in making recommendations to international standard bodies. Other examples can be found in: Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Eight Annual Report*, G/SPS/42, circulated on 4 August 2006, paras. 4-9; Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Seventh Annual Report*, G/SPS/37, circulated on 19 July 2005, para. 11; Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Third Annual Report*, G/SPS/18, circulated on 19 September 2001, paras. 8 and 10.
[222] This was the case of a negative response from the CAC concerning a certification about the absence of certain pathogens in raw meat products, where it stated that "[t]he Committee on Food Hygiene (CCFH) considered the question of certification of raw meat products regarding the absence of pathogens. The CCFH recognized that it was scientifically impossible to provide such certification, as it concerned only one step of the HACCP system in the framework of risk management, and recommended adherence to good manufacturing practice as specified in the General Principles of Food Hygiene. The CCFH concluded that at this stage there was no need for a specific text". Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Second Annual Report*, G/SPS/16, circulated on 10 October 2000, para. 12.
[223] A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, p. 596.

The Committee started monitoring international standards in 1997 and agreed to implement such procedure on a provisional basis and to review its operation eighteen months after the implementation, with the idea to opt for continuing with it while amending it or developing a new one[224]. The Committee extended the provisional monitoring procedure in 1999, 2001, and 2003, and revised the procedure in October 2004[225]. In 2006, the Committee agreed to extend the provisional procedure indefinitely, and to review its operation as an integral part of the periodic review of the operation and implementation of the Agreement under Article 12.7[226]. The procedure was reviewed as part of the Third Review of the Agreement[227], and again in the context of the Fourth Review[228]. Until now, the Committee has prepared twenty-one annual reports[229] on the monitoring procedure and from this reading some general and precise observations can be drawn. The practice on the monitoring procedure is mainly focused upon substance, in terms of specific trade concerns, investigating on the existence and/or adequacy of a standard[230].

The Committee has been less active and successful and more reticent when it's time to monitor the process of international standards in terms of concerns expressed by Members[231] and legitimacy of the standards themselves. Important examples regard the participation of developing country Members in the relevant standard-setting bodies and the key difficulties developing countries may face in meeting new or

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[224] Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Decision of the Committee*, G/SPS/11, circulated on 22 October 1997.
[225] Committee on Sanitary and Phytosanitary Measures, Revision of the *Procedure to Monitor the Process of International Harmonization*, *Decision of the Committee*, *Revision*, G/SPS/11/Rev.1, circulated on 15 November 2004.
[226] Committee on Sanitary and Phytosanitary Measures, *Decision to Modify and Extend the Provisional Procedure to Monitor the Process of International Harmonization*, G/SPS/40, circulated on 5 July 2006.
[227] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the SPS Agreement*, G/SPS/53, circulated on 3 May 2010.
[228] The draft report of the Fourth Review is contained in: Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the SPS Agreement, Draft Report of the Committee*, G/SPS/W/280/Rev.2, circulated on 6 November 2014.
[229] Those available are here briefly mentioned: G/SPS/13, G/SPS/16, G/SPS/18, G/SPS/21, G/SPS/28, G/SPS/31, G/SPS/37, G/SPS/42, G/SPS/45, G/SPS/49, G/SPS/51, G/SPS/54, G/SPS/56, G/SPS/59, G/SPS/60, G/SPS/GEN/1332, G/SPS/GEN/1411, G/SPS/GEN/1490, G/SPS/GEN/1550 and G/SPS/GEN/1617.
[230] A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, p. 597.
[231] *Ibid*.

modified SPS requirements of their trading partners, and hence in achieving or maintaining access to markets for their products where international standards are at stake. What is emerging is that the SPS Committee – and the entire governance[232] of the SPS Agreement – have decided that a series of thorny issues related to international standards "would require actions outside of the sphere of influence of the SPS Committee, such as actions by the international standard-setting bodies, or by other institutions. The SPS Committee could, however, agree to draw certain issues to the attention of these other bodies, and encourage WTO Members to pursue certain results within the context of Members' involvement in the work of these other bodies"[233].

A number of further concerns has been raised by Members, namely: the increase in the number of SPS measures that were not based on international standards, guidelines and recommendations or that had inadequate scientific justification[234]; the need to support and strengthen confidence in SPS international standard-setting bodies[235], the need for Members' to ensure that non-governmental entities also complied with the Agreement[236] and the Members' tendency to deviate from the use of international standards in the application of measures in international trade[237]. Since now, all these concerns have not brought to an effective reaction in terms of concrete measures adopted by the Committee. It seems that a proper answer should come more from the three sisters than from the WTO itself.

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[232] In particular, a decisive role could be exercised, and to some extent should be exercised, by the AB and by Ministerial Conferences. The reluctance of the AB to impose process conditions on standard setting bodies as a condition for their authority in the SPS Agreement has been expressed by A. LANG and J. SCOTT, *The Hidden World of WTO Governance*, p. 597, footnote 109.

[233] Committee on Sanitary and Phytosanitary Measures, *Report on Proposals for Special and Differential Treatment*, G/SPS/35, circulated on 7 July 2005.

[234] Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization*, *Fourteenth Annual Report*, G/SPS/49, circulated on 31 July 2012, para. 4.

[235] *Ibid*.

[236] *Ibid*. para. 6.

[237] Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Of 14-16 October 2015, Note by the Secretariat*, G/SPS/R/81, circulated on 4 January 2016, para. 11.4.

The last important function[238] that the SPS Committee performs is in relation to norm elaboration. According to paragraph 7:

> "7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation."

The mandate of elaborating the norms laid down in the SPS Agreement addresses two different objectives, one directed to rules and principles for the operation of the Committee and the second involves the elaboration of the open-ended provisions of the SPS Agreement. This is closely tied to the role of the Committee in regularly reviewing the operation and implementation of the Agreement in the light of Member States' experiences. The Committee has established a procedure for such review[239] and conducted its first one in 1998[240]. It concluded the second review of the operation of the SPS Agreement in 2005 and adopted a report on that, including recommendations for future work[241]. The Doha Ministerial Decision on Implementation instructed the SPS Committee to review the operation and

[238] The previous paragraphs of Article 12, number 5 and 6, basically integrate the functions already expressed in the analysis of paragraphs 1-4. Art. 12.5, in line with the general approach of Article 12 to avoid duplication of effort, specifies that the Committee may use the information that Members generate for these organizations for the administration of the Agreement. Moreover, on the basis of the initiative of a Member the Committee, in terms of Article 12.6, it may invite the International Organizations to examine specific matters with regard to a particular standard, guideline or recommendation.

[239] Committee on Sanitary and Phytosanitary Measures, *Procedure to Review the Operation and Implementation of the Agreement*, *Decision of the Committee*, G/SPS/10, circulated on 21 October 1997.

[240] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures*, *Report of the Committee*, G/SPS/12, circulated on 11 March 1999.

[241] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures*, *Report of the Committee*, G/SPS/36, circulated on 11 July 2005.

implementation of the SPS Agreement at least once every four years[242]. This function has been considered as an expression of the dynamic quality of the Committee's work, an element injected into the SPS Agreement and useful for its evolution[243]. Strictly related to this aspect is the issue of the status of the Committee's decisions in terms of nature of the decision, binding force for Members and effects on the SPS system in general. This issue is addressed in Chapter III, by looking at the role and impacts of the Committee in shaping and defining the possibility and legitimacy of private standards under the SPS Agreement.

From this analysis, it is evident that the bulk of the provisions of Article 12 is devoted to defining the role of the Committee with respect to the process of harmonization and the effective use of international standards. In particular, they are devoted to the encouragement of *ad hoc* consultations between Members and the use of international standards (paragraph 2), the monitoring of international harmonization and the use of international standards by Members (paragraphs 4, 5), the initiation of harmonization action by international organizations (paragraph 6) and the definition of the role for the Committee in the progressive review and implementation of the Agreement. Given that the core of the Committee's mandate can be found in Article 12.2 and 12.4, it needs to concentrate on enhancing the quality and practical relevance of international standards and Members' compliance with them[244]. What is also evident is that the Committee supports the relevant "external" harmonization processes already in place – set by other International Organization - rather than engage in harmonization itself, towards its activities that manifest in monitoring, cooperating and coordinating efforts.

However, a look at the activities of the SPS Committee reveals its important role in addressing the so called "externa accountability gap"[245] of Member States in

[242] Ministerial Conference, Fourth Session, Implementation - Related Issues and Concerns, WT/MIN(01)/17, circulated on 20 November 2001, para. 3.4.
[243] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 70.
[244] V. RÖBEN, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 12 SPS*, p. 537.
[245] J. SCOTT, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, p. 43-45.

the area of food safety regulation. This refers to the external impacts deriving from domestic food safety measures creating spillover effects. In this area of regulation, conceivable as a globalized market of agri-food products, characterized by great interdependence among States, there is a disjunction among the regulatory jurisdiction and the regulatory impacts. Moreover, the high degree of political salience and sensitivity that is reflected in State demanded protection of people health makes this gap not an easy one to fill. The possible forms of accountability develop in mechanism that are participatory and cooperative, rather than top-down, and generally operate *ex ante*, at the beginning of the proposal stage[246]. The first form of accountability operates through mutual oversight among the members of the "network governance" as the SPS Agreement can be viewed. In particular, the Committee casts a sort of spotlight on the activities of the three sisters, as it is better observed in the next Chapter. Second, the dynamic quality of the Committee ensures the evolution of the norms of the Agreement, undertaking possible evolution in this sense. Third, given the mandate of the Committee in disseminating information on good practice, regulatory failures and risk, it provides a good benchmark to check the compliance and regulatory capacity of Members.

The vitality of the Committee and its central role as a forum for consultation involved in the governance of food safety is confirmed by its last Annual Report on the Procedure to Monitor the Process of International Harmonization[247]. Among the new issues presented by Members, the proposals related to non-science factors in Codex standards opens a discussion on the status of these standards under the SPS Agreement, on the credibility and reliability of Codex measures and on the implications and influences among the WTO and the Codex. All these issues are addressed in the following Chapter with the primary aim to look at the legitimacy of these standards as a source of WTO law.

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[246] *Ibid*.

[247] Committee on Sanitary and Phytosanitary Measures, *Annual Report on the Procedure to Monitor the Process of International Harmonization, Note by the Secretariat*, G/SPS/GEN/1710, circulated on 28 June 2019.

Chapter II

The outsourcing of standard-setting to the Codex Alimentarius Commission

Summary: 5. Introduction. – **6.** The Codex Alimentarius Commission. – **6.1.** The rise of the Codex - structure and functions. – **6.2.** The Codex: harmonization through standard-setting. – **6.3.** The Codex before 1995: a "Gentlemen's Club". – **6.4.** A new role and status after 1995. – **7.** The WTO shaping the Codex: (i) introducing politics. – (ii) hardening science. – **8.** The WTO-Codex interinstitutional relationship. – **8.1.** Preliminary remarks: different membership and mandate – **8.2.** The judicial dimension: the role of Panels and AB. – **8.3.** Applying non-WTO law: the broad picture of public international law. – **8.4.** Applying and interpreting international standards. – **8.4.1**. An additional option to interpret standards: the role of experts. – **8.4.2.** Internal dispute settlement mechanisms: not in the Codex "garden". – **9.** The delegation of regulatory authority. – **9.1.** The case of Codex: historical and practical reasons. – **9.2.** The politics of delegation: benefits, limits and legitimacy.

5. Introduction

One of the aspects of the international law-making activities has been the incrementation of a specialized approach with area-issue, also referred to as "functional-differentiation"[248]. However, with the increasing interdependencies among different fields, such as health protection and intellectual property rights or trade and societal concerns, the different competences of various International Organizations or institutions started to overlap. These developments of the international scenario led to what has been defined as the fragmentation of international law[249]. An "unorganised system"[250] where actors interact where it's possible to find the "intra-systemic tensions, contradictions and frictions"[251]. Fragmentation in these cases generally refers, first and foremost, to the interpretation of norms[252].

These general issues are at the heart of a research on the status of Codex measures under WTO law. The WTO, Codex, States and national standard-setting bodies all deal with the harmonization of food measures, and this can bring to tensions in terms of conflicts among institution and sources.

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[248] M. KONSKENNIEMI, *Fragmentation of international law: difficulties arising from the diversification and expansion of international law*, in Report of the International Law Commission on its 58th Session, A/CN.4/L.682, p.11.

[249] *Ibid*. Here, at para. 166, with specific reference to the WTO, the relationship of a self-contained (special) regime *vis-à-vis* general international law under normal circumstances, Konskenniemi frame the debate in the following terms: "Nonetheless, academic opinion is divided as to how far this actually goes, with focus especially on the use by WTO organs of law from other special regimes, especially environmental law, or under non-WTO treaties. But whatever view one takes on the *competence* of WTO panels and the Appellate Body, that position is neither identical to nor determinative of the question of whether "WTO law" (or more exactly, "WTO covered agreements") is also *substantively* self-contained".

[250] K. ZEMANEK, *The Legal Foundations of the International System: General Course on Public International Law*, 62 Receuil des Cours: Collected Courses of the Hague Academy of International Law, 1997, p. 266.

[251] G. HAFNER, *Pro and Cons ensuing from Fragmentation of International Law*, Michigan Journal of International Law, Vol. 25, issue 4, 2004, p. 850.

[252] P. M. DUPUY, *The danger of fragmentation or unification of the international legal system and the International Court of Justice*, New York University Journal of International Law and Politics, Vol. 31, 1999, p. 792.

From the analysis provided in the previous Chapter, we know that the authority to develop international food safety standards is explicitly (and totally in practice) delegated to the Codex. Moreover, the WTO system in general - both in terms of the activities of the SPS Committee and of the Ministerial Conferences, and also looking at the decisions of Panels and AB - do not provide any form of control/prescription on the substantive (which seems hard to suppose given the technical nature of the standards stake) or procedural (here seems to be more room for different forms of intervention) aspects of international standards.

That being said, this Chapter addresses the following issues: the structure and functions of the CAC, the nexus between the Codex and the WTO in terms of possible influences and institutional relationship, looking at the different competences (regulatory and judicial) exercised by the two actors. Moreover, it analyzes the process of delegation of standard-setting both in a historical and practical perspective and in an critical dimension. This analysis is drawn in order to define the status of Codex standards under the SPS Agreement and to examine the legitimacy dimension of Codex standards. The implications, influences and interinstitutional relations among the WTO and the Codex regime here described aims at pinpointing any sort of lack, friction or contradiction within the assumed cooperative environment.

6. The Codex Alimentarius Commission

The Codex[253] is an interesting example of a successful cooperation in standard-setting among the two specialized agencies of FAO and WHO. It navigates rocky shoals between international necessity and States preferences in the area of food safety. While it should be generally expected that the power to set binding standards to arise

[253] This work does not specifically address the structure of the Codex, its mandate and the distribution of powers among its organs, the relations with different bodies other than the WTO. For a complete understanding of all these issues, and even for a check of the procedural and substantive legitimacy of Codex standards see M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, T•M•C• Asser Press, 2007.

from the constituent documents[254], in this case this sort of "legislative" power derives from a different instrument[255]. Codex led a dormant existence until the WTO was established and was transformed from an arcane scientific and technical body into an organization where developing *de facto* binding standards is its bread and butter. States do not adhere to norms only because they are considered "hard". Instead, in many circumstances, States do that because it is considered appropriate or an advantage[256]. However, the distinction among soft and hard rules remains crucial in terms of democratic and judicial review and the Codex experience is no exception.

6.1 The rise of the Codex - structure and functions

The roots for the establishment of the Codex can be found after the Second World War, when it was recognized that the international trade of food products could be jeopardized by non-tariff barriers in the form of domestic food regulation[257]. Against this background, the need for cooperation and co-ordination between national authorities and legal systems brought to the creation of several *fora* at regional or international level[258]. When the Codex started its activities, different other initiatives in the domain of food standard setting were already in place, such as those by FAO[259] on fisheries, by the International Dairy Federation on milk, by the United Nations Economic Commission for Europe (UNECE) on fruits and, at regional level, the Latin America Food Code and the Council of the Codex Alimentarius Europaeus[260]. Their

[254] Where is possible to identify the act of delegation from States to the organization. However, in this research, the act of delegation involves an International Organization and an international body, the WTO and Codex.
[255] J. KLABBERS, *Advanced Introduction to The Law of International Organizations*, Edward Elgar, 2015, p. 59.
[256] *Ibid*., p. 66.
[257] A. RANDELL, *International Food Standards: The Work of Codex,* in *International Standards for Food Safety*, N. REES and D. WATSON (eds.), Aspen Publishers, 2000, p. 3.
[258] D. L. LEIVE, *International Regulatory Regimes*, Lexington Books, 1976, p. 377.
[259] Some initiatives in terms of adoption of conventions started under the predecessor of FAO, the International Institute for Agriculture (IIA).
[260] It was created under the auspices of the International Commission on Agricultural Industries and the Permanent Bureau of Analytical Chemistry.

activities were later to be an important catalyst in the development of the Codex, however, the establishment of the Codex Alimentarius Europeaus is where the CAC roots lie[261]. It was a stimulus for a wider participation, requesting that FAO should be in charge for continuing its activities.

This led to the adoption of Resolution 12/61 by the FAO Conference in 1961[262], that, aware of the rapidly growing importance of internationally accepted food standards as a means of protecting consumer and producer in all States, proposed to take into consideration the possibility of a FAO/WHO Food Standards Programme[263]. In a similar way, the Director-General of the WHO put, during the 29th Session, the question of the creation of a Joint WHO/FAQ Food Standards Programme before the Executive Board of WHO[264]. Recognized for their expertise in the area of food, the FAO and the WHO set up Codex in order to develop a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety.

Thus, on the basis of the resolutions of the FAO Conference and that of the Executive Board of WHO, a Joint FAO/WHO Conference on Food Standards was held in Geneva in 1962, from October 1 to 5, to discuss these possibilities. The Conference endorsed the proposals made by the 11th Conference of FAO for a Joint FAO/WHO Programme on Food Standards whose principal organ would be the Joint FAO/WHO Codex Alimentarius Commission. This decision[265] aimed primarily at simplifying and

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[261] Other bodies are considered to form the basis and be influential towards the CAC, namely the Joint FAO/WHO Expert Committee on Food Additivities, the Joint FAO/WHO meeting on pesticide and the Committee of government experts on the code of Principles concerning Milk and Milk Products. See J. P. DOBBERT, *Le Codex Alimentarius vers une nouvelle méthode de réglamentation internationale,* Annuaire Français de Droit Internationale, Vol. 15, 1969, p. 679.

[262] FAO Conference, *Codex Alimentarius*, Resolution 12/61, Report of the 11th Session of the FAO Conference, Rome, 4-24 November 1961.

[263] S. SHUBBER, *The Codex Alimentarius Commission under International Law*, International and Comparative Law Quaterly, Vol. 21, 1972, p. 631.

[264] In this occasion it was adopted a resolution approving the convening of a Joint FAO/WHO committee of government experts in 1962, in order to review the proposed programme of the two Organizations relating to food standards and to draw up recommendations for future activities in this field. Resolution EB29.R23, January 1962, WHO Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board.

[265] Report of the Joint FAO/WHO Food Standards Conference on Food Standards, Geneva 1-5 October 1962, Alinorm 62/8.

coordinating the work on international food standards previously undertaken by different international governmental and non-governmental organizations. The establishment of the Joint FAO/WHO Food Standards Programme, which saw the development of the CAC as a central element, was thus based on two decisions adopted respectively by the FAO[266] and WHO[267]. Both the organizations have set the institutional framework for the execution of the Joint FAO/WHO Food Standards Programme that functions under their authority, and the CAC was appointed as main organ responsible for the implementation of the programme.

Being the CAC a subsidiary body[268] born out of two United Nations specialized agencies means that for the assignment of its competencies, the CAC is dependent on the delegation of powers by the so-called "parent organizations". The explicit powers delegated to CAC are laid down in Articles 1[269] and 7[270] of the Statutes and in Rules

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[266] *Supra* note 262, para. 263.
FAO acted on its constitutional authority to create joint commissions with other Specialized Agencies, in accordance with Article VI, para. 1 of the Constitution of FAO, which provides the possibility to "establish technical and regional standing committees and may appoint committees to study and report on any matter pertaining to the purpose of the Organization". The Constitution was the result of a meeting of plenipotentiaries in Quebec, Canada, at which, on 16 October 1945, the Constitution was signed by thirty-four States and entered into force.

[267] World Health Assembly, Joint FAO/WHO Programme on Food Standards (Codex Alimentarius), Resolution WHA 16.42, Report of the 16th Session of the World Heatlh Assembly, Geneva, 7-23 May 1963.
The WHO has the power under Article 18 (1) - in combination with Article 2 (u) - of its Constitution "to establish such […] institutions as it may consider desirable.". The Constitution was adopted by the International Health Conference held in New Yok from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of sixty-one States.

[268] For a reflection on subsidiary bodies as *de facto* international organization see C. MARTINI, *States' Control over New International Organization*, Global Juris Advances, Vol. 6, 2006, pp. 11-25.

[269] "The Codex Alimentarius Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:
(a) protecting the health of the consumers and ensuring fair practices in the food trade;
(b) promoting coordination of all food standards work undertaken by international governmental and non governmental organizations;
(c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
(d) finalizing standards elaborated under (c) above and publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
(e) amending published standards, as appropriate, in the light of developments.".

[270] "The Commission may establish such other subsidiary bodies as it deems necessary for the accomplishment of its task, subject to the availability of the necessary funds.".

XI and XII paragraph 1 of its Rules of Procedure[271]. Article 1 of the Statutes is devoted to the role of the CAC as a consultative actor for the implementation of the Food Standards Programme while Article 7 of the Statutes and Rule XI of the rules of Procedure gives to the CAC the power to establish subsidiary bodies for the preparation of draft standards. In addition, Rule XII paragraph 1 set that the CAC may establish and amend its own standard setting procedure, procedures that are not subject to the approval of the parent organization.

The main purposes of the Codex are stated in article 1 (a) of the Statutes: "protecting the health of the consumers and ensuring fair practices in the food trade"[272], a dual function which should be reflected in its standard-setting activity. The activities of the Codex are thus constantly designed to balance its public health objectives with the need to promote international trade. This approach is also stated in principle 1 of the General Principles of the Codex Alimentarius, which states that "[…] standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade"[273].

Through the reading of Article 1 of the Statutes in conjunction with the abovementioned Rules of Procedure is possible to pinpoint that the powers of the CAC are not only those expressly stated[274], as also confirmed by the practice of the CAC.

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[271] Generally speaking, the Statutes can be considered the legal basis of the work of the CAC and provides its mandate or terms of reference while the Rules of Procedure set out the formal working procedures of the CAC.

[272] F. VEGGELAND and S. OLE BORGEN, *Negotiating International Food Standards: the World Trade Organization's Impact on the Codex Alimentarius Commission*, Governance: an International Journal of Policy, Administration and Institutions, Vol. 18, no. 4, 2005, p. 676.

[273] World Health Organization and Food and Agricultural Organization of the United Nations, *General Principles of the Codex Alimentarius*, Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section I, 2018, p. 21.

[274] S. SHUBBER, *The Codex Alimentarius Commission under International Law*, p. 634-636. Here the author lists the following powers: formulation of proposals and advice to the Directors-General of FAO and WHO; establishment of subsidiary bodies; preparation of food standards; publication of food standards and co-ordination of work on food standards.

The two powers that are more relevant for this research are those related to the coordination of food standards at the international level and to the standard-setting normative dimension. The promotion of coordinating activities was one of the prime reasons for the adoption of the Joint FAO/WHO Food standards Programme, a competence that includes the adoption of provisions for the functioning of other international organizations within the standard-setting procedure[275]. However, the relationships with other International Organizations are limited because of the status of the CAC as a subsidiary body. Indeed, the CAC does not have the competence to enter into Agreements with other international organization in order to cooperate[276]. On the contrary, the decisions to adopt and publish standards represent an autonomous normative power not submitted to the approval of FAO and WHO[277]. Both of these fundamental functions of the CAC are addressed in more details in the following sections in the specific perspective of the nexus between the CAC and the WTO.

The CAC nature as a subsidiary body of the FAO and WHO jointly has an impact on its institutional structure, which appears to be complex[278]. The CAC itself is the main decision-making organ of the Joint FAO/WHO Food Standards Programme, the plenary body, sessions are held every year and normally lasts about a week and in additional occasions as the need arises[279]. Article 6 of the Statutes requires the CAC to establish an executive organ, the Executive Committee. It primarily exercises its functions between the sessions, making proposals to the CAC with regards with general orientation objectives but also specific problems, and is involved in assistance and implementation activities of the Food Standards Programme. It is

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For a general overview on the doctrine of implied powers of international organizations see J. E. ALVAREZ, *International Organizaions as Law-makers*, Oxford University Press, 2005, pp. 92-95.

[275] World Health Organization and Food and Agricultural Organization of the United Nations, *Guidelines on cooperation between the Codex Alimentarius Commission and international intergovernmental organizations in the elaboration of standards and related texts*, Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section VII, 2018, p. 238- 240.

[276] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 20.

[277] *Ibid*., p. 23

[278] D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension*, p. 328.

[279] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, pp. 28-29.

composed of the Chairperson and three Vice-Chairpersons of the Commission, the Coordinators of the six regional Coordinating Committees and seven additional members elected by the Commission from among its members. In contrast to the requirement to establish the Executive Committee and the possibility to establish subsidiary bodies when deemed necessary, the Codex Statutes do not foresee the option to establish a secretariat. However, Rule III.5 of the Rules of Procedures states that the Directors-General of FAO and WHO are requested to appoint from the staffs of their organizations a Secretary in order to perform all duties that the work of the Commission may require.

6.2 The Codex: harmonization through standard-setting

Standard-setting activities are run mainly by the CAC and are triggered by proposals coming from States or Subsidiary Committees. This means that the CAC has a pivotal role and decides the priority according to which proposals for standards are to be implemented, and which Subsidiary Committees are in charge for the drafting of standards. When a Codex Committee decides to propose the elaboration of a new or revised standard, it should verify whether it fits within the priorities set up by the CAC in the medium-term plan of work before contacting the CAC or the Executive Committee for the approval. Afterward, the elaboration of Codex Standards may follow two types of procedure[280], normal and accelerated, according to the Codex Procedural Manual[281].

[280] In the past, several elaboration procedures existed, on the basis of the type of standard, such as regional standards, MRLs standards and Milk and Milk Products Standards. See C. H. HALEXANDROWICZ, *The Law-Making Functions of the Specialised Agencies of the United Nations*, Angus & Robertson, 1973, pp. 82-84. These procedures were aligned in 1993 and their establishment was mainly due to give special recognition to non-Codex bodies in the early stages of the elaboration procedure.

[281] The establishment of a unique Codex standard setting procedure reflects the strengthening role of the CAC in its role of international coordinator of food standards activities.

The Uniform Procedure (normal) for the Elaboration of Codex Standards and Related Texts[282] consists of eight steps, starting with the decision to elaborate a standard and the appointment of the Subsidiary Committee in charge (step 1). Then, the Secretariat arranges for the preparation of a proposed draft standard, after having heard the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment or the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA), on the basis of the matter at stake (step 2). Such proposed draft standard is then distributed among CAC Members and interested International Organizations (step 3). The comments received are sent by the Secretariat to the Subsidiary Body or other body concerned which has the power to consider these comments and to amend the proposed draft standard (step 4), which is then submitted to the Executive Committee for critical review and to the CAC for the adoption as a draft standards, taking into considerations the comments received (step 5). The draft standard is sent to Members and interested International Organizations for comments (step 6), sent by the Secretariat to the Subsidiary Body or other body concerned, which has the power to consider such comments and amend the draft standard (step 7). The Uniform Procedure terminates with the submission of the standard to the Executive Committee for critical review and to the CAC, together with any written proposals received from Members and interested International Organizations for amendments, followed by the adoption of the final standard (Step 8).

During the first eighteen years of operation of the CAC, the procedure consisted in ten steps, of which the submission to States for acceptance of the standard represented step 9, while the publication of the standard in question was step 10. The acceptance procedure was abolished during the 28th session of the Codex in 2006[283] considering that "[m]any delegations expressed the view that the acceptance procedure

[282] Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section II: Elaboration of Codex Standards and Related Texts, 2018, pp. 33-35.
[283] Codex Alimentarius Commission, 28th Session, ALINORM 05/28/41, July 2005, para. 36

should be abolished as it had not been used by member countries for a long time, its revision had been discussed for several sessions without any conclusion, and it was not relevant any more in the framework of the WTO SPS and TBT Agreements"[284]. The interesting aspect here is that given such abolition, which permitted flexibility in terms of the adoption of the standard at stake[285], the possibilities of deviating from Codex measure are basically examined through the interpretation of the relevant WTO provisions that allow it[286], in terms described in the previous Chapter.

The CAC may initiate an accelerated procedure if there is urgency to adopt a standard, on the basis of a two-third majority vote. It consists of only one round and

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[284] Codex Committee on General Principles, *Report of the 22nd Session of the Codex Committee on General Principles*, 11-15 April 2005, para. 77.

[285] For Codex general standards, they may be accepted by a country in the following ways:
"*(i) Full acceptance*
Full acceptance of a general standard means that the country concerned will ensure, within its territorial jurisdiction, that a product to which the general standard applies will comply with all the relevant requirements of the general standard except as otherwise provided in a Codex commodity standard. It also means that the distribution of any sound products conforming with the standard will not be hindered by any legal or administrative provisions in the country concerned, which relate to the health of the consumer or to other food standard matters and which are covered by the requirements of the general standard.
(ii) Acceptance with specified deviations
Acceptance with specified deviations means that the country concerned gives acceptance, as defined in paragraph 5.A(i), to the general standard with the exception of such deviations as are specified in detail in its declaration of acceptance. The country concerned will further include in its declaration of acceptance a statement of the reasons for these deviations, and also indicate whether it expects to be able to give full acceptance to the general standard and, if so, when.
(iii) Free distribution
A declaration of free distribution means that the country concerned undertakes that products conforming with the relevant requirements of a Codex general standard may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex general standard are concerned",
while a Codex maximum limit for residues of pesticides or veterinary drugs standards may be accepted by a country in accordance with the ways set forth below:
"(i) Full acceptance
Full acceptance of a Codex maximum limit for residues of pesticides or veterinary drugs in food means that the country concerned will ensure, within its territorial jurisdiction, that a food, whether home-produced or imported, to which the Codex maximum limit applies, will comply with that limit. It also means that the distribution of a food conforming with the Codex maximum limit will not be hindered by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum limit.
(ii) Free distribution
A declaration of free distribution means that the country concerned undertakes that products conforming with the Codex maximum limit for residues of pesticides or veterinary drugs in food may be distributed freely within its territorial jurisdiction insofar as matters covered by the Codex maximum limit are concerned."
Codex Alimentarius Commission Procedural Manual, Twelfth Edition, General Principles of the Codex Alimentarius.

[286] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 182.

the CAC adopts the standards in question at step 5. In principle, decisions are adopted by consensus, in particular "[t]he Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed"[287]. The Codex history shows that this has been the case until approximately the 20th Session of the CAC.[288]

However, the core of the standard setting activities is exercised outside the already mentioned Commission, Executive Committee and Secretariat. Indeed, the technical elaboration of standards is done by the Codex committees and ad hoc task forces responsible for the scientific research on specific issues. The competence to establish subsidiary body as those at stake, has been extensively used by the CAC over the years, and their proliferation can be considered as an act giving content, *ratione materiae*, to its mandate[289]. The current list of Codex Committees[290] includes, besides the CAC and the Executive Committee, ten General Subjects Committees[291], five Commodity Committees[292], one had hoc Intergovernmental Task Force[293] and six

[287] Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section I: Basic texts and definitions, p, 18. This is true also for Codex Committees and *Ad Hoc* Intergovernmental Task Forces, as provided by the Guidelines to Chairpersons of Codex Committees and *Ad Hoc* Intergovernmental Task Forces, *ibid*., p. 112.

[288] D. JUKES, *Codex Alimentarius – Current status*, Food science and Technology Today, 1998, p. 10. This issue was relevant in the Hormones case, where the EC argued that the Codex standards in question had not been adopted by consensus as was customary in Codex, and that it had voted against them. Despite their adoption by Codex, therefore, the EC did not view them as "consensual". However, in that occasion the Panel refused to enter into how these standards had been developed, since both parties were members of Codex. Thus, as already observed in the previous Chapter, the WTO does not look at the content or at the procedure of adoption of a sanitary standard, only considering the international standard-setter involved.

[289] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 34.

[290] This refers to those which are still active. It is available at: http://www.fao.org/fao-who-codexalimentarius/committees/en/ visited on September 2019.

[291] Codex Committee on Contaminants in Foods; Codex Committee on Food Additives; Codex Committee on Food Hygiene; Codex Committee on Food Import and Export Inspection and Certification Systems; Codex Committee on Food Labelling; Codex Committee on General Principles; Codex Committee on Methods of Analysis and Sampling; Codex Committee on Nutrition and Foods for Special Dietary Uses; Codex Committee on Pesticide Residues and Codex Committee on Residues of Veterinary Drugs in Foods.

[292] Codex Committee on Cereals, Pulses and Legumes; Codex Committee on Fresh Fruits and Vegetables; Codex Committee on Fats and Oils; Codex Committee on Processed Fruits and Vegetables and Codex Committee on Spices and Culinary Herbs.

[293] Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance.

FAO/WHO Coordinating Committees[294]. Their establishment permitted the CAC to reinforce its role as a promoter in the food standards-setting activities, because of its cooperative action and given the replacement of external bodies with Committees one[295].

Currently the Codex has one hundred and eighty-nine Members made up of 1 one hundred and eighty-eight Member countries and one Member Organization (The European Union)[296]. As a general rule, membership is open to any country that is a member nation or an associate member of at least one among FAO and/or WHO. Only States and regional economic integration organizations can be members of the CAC. In addition, non-member States, international non-governmental organizations[297], and International or Regional Governmental Organizations[298] may be granted observer status to participate in meetings of the CAC and its subsidiary committees[299]. Moreover, in contrast to the OIE and the IPPC, the Codex does not have any form of alternative dispute settlement system that would be available for its members. This aspect was already outlined by the CAC during the Uruguay Round negotiations[300]

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[294] FAO/WHO Coordinating Committee for Africa; FAO/WHO Coordinating Committee for Asia; FAO/WHO Coordinating Committee for Europe; FAO/WHO Coordinating Committee for Latin America and the Caribbean; FAO/WHO Coordinating Committee for North America and South West Pacific and FAO/WHO Coordinating Committee for Near East.

[295] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, pp. 34-35.

[296] At its first session in 1963 they were 30.

[297] According to Article 3 of the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section VII, pp. 241-242.
Among them is it possible to find primary producer organizations (such as the International Peanut Forum), processor organizations (for example the International Dairy Federation and the International Bottled Water Association), standards organizations (for example, the International Organisation for Standardisation) and consumer interest groups (like Consumers International and Greenpeace International).

[298] According to Rule IX para. 5 of the *Rules of Procedure.*
International inter-governmental observers include the WTO, the OECD, ASEAN and the Caribbean Community as well as a number of UN bodies such as UNCTAD, the UNDP and UNEP.

[299] According to Rule IX para. 4 of the *Rules of Procedure*. The role of non-governmental organisations and international governmental organisations in the activities of the CAC is governed by the *Guidelines on Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts* and the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Section VII, pp. 238-242.

[300] See p. 25.

and is particularly relevant as regards the review of Codex standards, as detailed in section 8. This institutional background dictates a series of legal consequences in terms of Codex powers and relationship with the WTO that are addressed in the following sections and aims to highlights the critical aspects related to the legitimacy of its standards.

6.3 The Codex before 1995: a "Gentlemen's Club"

The wording of a representative of the Codex Secretariat during a meeting of the SPS Committee shortly after the entry into force of the SPS Agreement shows clearly the impacts of the process of delegation of regulatory that happened in those years:

> "[…][T]he Codex Alimentarius Commission has made a number of significant changes to its working procedures and the general orientation of its work to meet the post-Uruguay Round situation. The most significant implication for the CAC is that its decisions have a semi-binding effect on governments. This means that the Commission is no longer a 'gentlemen's club' and that negotiations within the CAC are more intense than previously was the case."[301]

The main legal consequences of referring to Codex standards in the text of the SPS Agreement seems to be related to the status of Codex standards, more specifically on their binding effects. However, the report of the SPS Committee provides other inputs in standards-related issues. The question of an innovative approach on risk assessment[302] was raised, the fact that the CAC and Codex Committees should become

[301] Committee on Sanitary and Phytosanitary Measures, *Statement made by the FAO/WHO Codex Alimentarius Commission at the Meeting of 15-16 November 1995*, G/SPS/W/42, circulated on 30 November 1995, p. 1.

[302] "The SPS Agreement calls for food safety standards to be based on risk assessment procedures. This is a relatively new approach to traditional food safety standards-setting procedures, both at national and international level, where risks to the consumer were assumed to be zero. New approaches and new decision-making processes will need to be established by Codex and at the national level.". *Ibid*.

more responsive to current and emerging problems in international trade[303] and the necessity for the CAC to develop a procedure to identify those standards, guidelines and recommendations which have a major trade impact[304]. Simultaneously, within the context of the Joint FAO/WHO Food standards Programme, the report of the twenty-first session of the CAC[305] highlights the implications of the implementation of the Uruguay Round of multilateral trade negotiations, in particular the working arrangements between the Codex Alimentarius Commission and the WTO acceptance of Codex Standards in relation to the SPS and the TBT Agreements[306].

In the pre-1995 context, the notion of Codex as a "gentlemen's club" refers to the following four characteristics: (i) a Codex institutional position and dimension quite far and relatively isolated from international hard law, receiving little attention from the trade law community; (ii) the voluntary nature of Codex activities and status outputs, while not in absolute terms; (iii) agreed-upon legal tool provided, restraining Members from both obstructing the process of new or modified Codex standards; (iv) given the non-binding authority and a lack of a dispute settlement mechanism, no sanctions in situations where Codex standards where not followed were prescribed[307]. Moreover, at that time the number of Codex membership was lower and fewer delegates attended the meetings. This also allowed the Codex to function more as a "club."

The Codex committees were primarily for discourses of a technical nature, a sort of epistemic community. Those attending Codex meetings were mainly food

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[303] *Ibid*., p. 3.
[304] *Ibid*.
[305] Codex Alimentarius Commission, 21st Session, ALINORM 95/37, July 1995, paras. 13-22.
[306] Similarly, Robert Griffin, the coordinator of the IPPC Secretariat in Rome, stated that:
"Until recently, the IPPC led a relatively quiet existence. A multilateral treaty established half a century ago, it was best known for its Phytosanitary Certificate, a standard form used by exporters to guarantee that domestic plants and plant products are free from plant pests specified by the importing country. But following the WTO's Agreements on Agriculture - and other international initiatives, such as the Convention on Biological Diversity - the IPPC finds itself charged with new responsibilities in the spheres of international trade, environmental protection, biotechnology and biosafety.", at http://www.fao.org/ag/magazine/0203sp2.htm.
[307] F. VEGGELAND and S. O. BORGEN, *Negotiating international food standards: the World Trade Organization's impact on the Codex Alimentarius Commission*, Governance: An International Journal of Policy, Administration, and Institutions, Vol. 18, no. 4, 2005, p. 684.

safety experts with a technical and scientific background from national administrations or industries. While the right to vote was given only to governments, the process of standard setting was influenced by other actors, outside the Geneva or Brussels environment. Looking at standards status, it was accepted it was voluntary for States to base their national regulations on Codex standards as Members could ignore standards that they perceived were not in their interest[308]. However, this character was not absolute, also before 1995 the CAC was influential in shaping national food standards practices. Because of this, national interests, including economic ones, have always been played a role in the Codex. Trade considerations and the interests of industries were thus present in the Codex activities even before 1995.

Concerning the process of standards adoption, the parties involved refrained from obstructing discussions around the progress of a new standard Codex, even in the case substantial disagreement emerged. Codex Members could disagree with on content of a standard and have no intention of adhering to it, but nevertheless would abstain from halting the process. Lastly, the SPS Agreement strengthened the authority of Codex standards through the dispute settlement system, introducing new consequences for non-compliance.

6.4 A new role and status after 1995

There is a good number of academic studies that suggest that the entry into force of the SPS Agreement has led to a legalization and politicization of the Codex and its standard-setting procedure[309]. This assumption in the literature is reinforced by

[308] This is confirmed by a comment from a European Commission representative during the changes occurred after 1995:
"In the past, if we disagreed with Codex Standards or Code of Practice, we could ignore it and take our own legislation. Now we can't. If we decide to go beyond the Codex standards . . . we must demonstrate the scientific basis of our measure and how this measure complies with the level of protection fixed by the Codex committee. . . Experience shows that it is very difficult to do that". *Ibid*., p. 683.
[309] E. SPENCER GARRETT, M. L. JAHNCKE and E. A. COLE, *Effects of Codex and GATT*, Food Control, Vol. 9, no. 2-3, Elesevier Science, 1998; T. STEWART and D. JOHANSON, *The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office for Epizootics,* Syracuse Journal of International Law and Commerce, Vol. 26, no. 1, 1998; J. BRAITHWAITE and P.

the evidence of the considerable increase in the number of participating State and non-State actors as well as the sizeable increase in the number of delegates these actors send to the standard-setting Codex committees post-1995[310]. There are various approaches in the literature. Some are more focused on the nexus between institutional design and the evolving structure of regulation[311], while others specifically deal with the governance networks through connected international agencies[312], and other authors, looking at the final consequences of this process, conclude that this kind of institutionalization had increased to cost of non-compliance with Codex standards[313].

Against this background the present Chapter presents an analysis of how the WTO represented a change of the context and resulted in pressures for change that affected the functioning and role of the Codex in the domain of international trade. Consequently, the questions addressed are how the Codex has changed after being

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DRAHOS, *Global Business Regulation*, Cambridge University Press, 2000; M. ECHOLS, *Food Safety and the WTO. The interplay of culture, science and technology*, Kluwer Law International, 2001; R. MUNOZ, *La Communauté entre les mains des norms internationals: les consequences de la decision Sardines au seine de l'OMC*, Revue du Droit Européenne, Vol. 4, 2003; D. G. VICTOR, *WTO Efforts to Manage Differences in National Sanitary and Phytosanitary Policies*, in *Dynamics of Regulatory Change: How Globalization Affects National Regulatory Polic*, D. VOGEL and R. A. KAGAN (eds.), University of California Press, 2004; S. POLI, *The European Community and the Adoption of International Food Standards within the Codex Alimentarius Commission*, European Law Journal, Vol. 10, no. 5, 2004; F. VEGGELAND and S. O. BORGEN, *Negotiating international food standards: the World Trade Organization's impact on the Codex Alimentarius Commission*, Governance: An International Journal of Policy, Administration, and Institutions, Vol. 18, no. 4, 2005 and T. BÜTHE, *The politics of food safety in the age of global trade: the Codex Alimentarius Commission in the SPS Agreement of the WTO*, in *Import safety: regulatory governance in the global economy*, C. COGLIANESE, A. M. FINKEL and D. ZARING (eds.), University of Pennsylvania Press, 2009.

[310] For an updated and comprehensive overview in the literature see S. KLOTZ, *The Nexus between the World Trade Organization and Codex Alimentarius*, working paper presented at the PEIO 2019 poster session, 2018. These data are confirmed and are based on the information provided by reports in different Codex meetings.

[311] K. W. ABBOTT and D. SNIDAL, *The governance triangle: regulatory standards institutions and the shadow of the state*, in *The Politics of Global Regulation*, W. MATTLI and N. WOODS (eds.), Princeton University Press, 2009; P. J. SPIRO, *Nongovernmental Organizations in International Relations (Theory)*, in *Interdisciplinary perspectives on international law and international relations: the state of the art,* J. L. DUNOFF and M. A. POLLACK (eds.), Cambridge University Press, 2013.

[312] L. A. JACKSON and M. JANSEN, *Risk assessment in the international food safety policy arena. Can the multilateral institutions encourage unbiased outcomes?*, *Food Policy*, Elsevier, Vol. 35, no. 6, 2010; M. JANSEN, *Defining the borders of the WTO agenda*, in *The Oxford Handbook on the World Trade Organization*, A. NARLIKAR, M. DAUNTON and R. M. STERN (eds.), Oxford University Press, 2012; M. JANSEN, *Internal measures in the multilateral trading system: where are the borders of the WTO agenda?*, in *Governing the World Trade Organization: past, present and beyond Doha*, T. COTTIER and M. ELSIG (eds.), Cambridge University Press, 2012.

[313] T. BÜTHE, *Institutionalization and Its Consequences*, in *Transnational Legal Orders*, T. C. HALLIDAY and G. SHAFFER (eds.), Cambridge University Press, 2015.

referred to by the WTO as a central reference point for the elaboration of international standards in the area of food safety and how can these changes be explained. More specifically, the analysis tries to investigate whether and, if so, how the international legalization of Codex through the WTO - resulted in a politicization of the standard-setting processes - created a sort of upgrade of Codex standards that changed from being voluntary measures to being *de facto*/indirect legally binding instruments that determine the access to the market.

7. The WTO shaping the Codex: (i) introducing politics

The first part of this research tries to explain how standards have binding effects thanks to the normative and institutional aspects of the SPS Agreement, looking in particular at Articles 3 and 12. Bearing this in mind, this part looks at how the WTO and the Codex interact and how the latter has been influenced in its activities, assuming the legalization of Codex standards after being explicitly referred in the SPS Agreement. After this process, which raised the cost of non-compliance, Codex Members had an increased incentive to actively revise and amend existing standards and shape future standards to be designed according to their needs and interests. Such increased interest among States is reflected both in the discussions within Codex meetings and by the fact that representatives of the WTO Secretariat attend Codex meetings and are actively involved on questions regarding the status of the Codex in relation to the WTO[314].

As the Codex attracted more attention internationally, participation has grown, but besides this "quantitative" aspect, a change happened even on the "qualitative" side. First, the number of actors participating in the Codex committee meetings increases post-1995, most significantly for States and NGOs[315]. Moreover, even the

[314] F. VEGGELAND and S. OLE BORGEN, *Negotiating International Food Standards: the World Trade Organization's Impact on the Codex Alimentarius Commission*, p. 687.
[315] Taking into consideration the period 1963-2015, the average number of participating States is 74 pre-1995 and 144 post-1995. Looking at NGOs presence, prior to 1995, an average of 37 NGOs

number of delegates of the joining actors increased in Codex meetings after 1995[316]. Beyond the numbers, the standard-setting processes of Codex saw big and politically powerful exporters, such as the United States and the European Union, actively involved in order to diffuse their regulatory views and to occupy central positions[317]. This process can also be due to the provisions in the SPS Agreement which require participation and cooperation in standard setting authorities[318]. The influence of the WTO can be found in the fact that States' coalitions that generally characterize Geneva meetings on agriculture seem to be replicated in Codex context, especially on issues perceived to have trade relevance[319]. Within this perspective, countries that are generally open to promote free trade strategies in the WTO try to restrict the scope of applicability of Codex activities, limiting some principles, like precaution, and establishing tight definition of normative concept, like "other legitimate factor". The United States and the Cairns Group are the most prominent supporters of such position. The other group of countries, where the European Union is the most prominent representative, shows more restraint with regard to the liberalization at global level food trade, asking for more autonomy at domestic level, especially for politicized issues. When considering whether or not to accept a proposed Codex text, Member States seem to make an assessment of the expected consequences of certain texts being brought into a WTO dispute.

Another interesting point, as already observed before, regards people who attend Codex meetings. A shift that affirmed the relevance of national delegates from the diplomatic services and ministries of trade and industry over food experts and food

participated in the annual committee meetings of Codex, while post-1995 the number was 76. Some specific committees experienced such results more evidently, like the Codex Committee on Food Hygiene (CCFH), the Codex Committee on Food Labelling (CCFL) and the Codex Committee on General Principles (CCGP). S. KLOTZ, *The Nexus between the World Trade Organization and Codex Alimentarius*, pp. 10-11.

[316] The average number of State delegates increases from 974 pre-1995 to 2449 post-1995. The corresponding average counts NGOs increases from 103 to 366. *Ibid*., p. 13.

[317] *Ibid*., p. 7.

[318] See section 4.

[319] F. VEGGELAND and S. OLE BORGEN, *Negotiating International Food Standards: the World Trade Organization's Impact on the Codex Alimentarius Commission*, p. 689.

agency officials[320]. These findings reveal that the Codex has achieved a more significant role after 1995. Member Sates perceive that their own food safety regulations are more under the microscope in Codex meetings. This also express the trend for States to bring together their work on food safety in the scientific setting of Codex with their work on trade issues in the WTO.

(ii) **hardening science**

Besides the so-called politicization of Codex, the most intriguing but even thorny question is that the fundamental requirement of Codex standards to be "sound science" has been upheld and even reinforced by WTO. Because the existence of the WTO has itself come to shape the structure and work of international standardizing bodies, the debate held in GATT/WTO on the role of science in trade agreements (particularly during the negotiations of the SPS Agreement), also spilled into standard-setting organization. But how has the interaction between the WTO and international standardizing bodies worked in practice then? Do international standardizing bodies function independently of the WTO, or have the rules of the WTO influenced their operation? While WTO Members advocate for a completely separated system among the Codex and the WTO, in practice some influences are evident.

Since the beginning of the 1970s, the WTO system started addressing non-trade barriers to trade and had to develop a more sophisticated set of rules to distinguish legitimate from illegitimate restrictions on the market. This is where rules on science and risk assessment in the area of food safety came into play. Gradually, as the experience of GATT Article XX(b), the Standards Code and the negotiations of the SPS Agreement showed, it became a requirement of WTO rules that countries provide scientific and risk assessment justification for the trade-restrictive product regulations. Placed at the center of these rules was the harmonization provision, *i.e.* the requirement

[320] *Ibid*.

for States to consider, base or comply with international standards. That kind of regulatory architecture changed profoundly the WTO system[321] in that the reference to international standards in the SPS and TBT Agreements has been defined as the "biggest single step in the history of globalization of food standards"[322].

In the SPS Agreement, for the harmonization of food safety regulations, Codex standards appeared as the best candidate to fill this role. This is where the Codex enters the scene as the relevant international standardization body. The paramount for the legitimacy of Codex standards is that they should be based on scientific knowledge.

They became part of a system where the practice of decision-makers examining Members' compliance with WTO rules is characterized by placing science in a privileged position. In most cases WTO decision-makers review national SPS measures operate in a "normative vacuum" where the only criterion available to guide the "balance" struck between competing domestic regulatory policies of Members is that of science[323]. In case of absence of a true normative yardstick for evaluating national decisions, science becomes a default criterion for determining whether measures chosen by States receive international endorsement or not. It can be argued that the irony of constituting science as a default normative yardstick, as an arbiter, is that choices about possible food safety regulatory policies are thereby yielded to a body of knowledge which has (or is not purported to have) any normative content[324].

This requirement was strengthened as a result of the Uruguay Round. As already explained in the previous Chapter, the presumption of consistency provided by SPS Agreement Article 3.2, and 3.1 partially, means that it is the international standards which set the dividing lines to what the WTO accepts as being scientifically justified and what need a further justification. The main threshold for the acceptance

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[321] See p. 15, referring to an institutional and contractual balance altered after the introduction of the TBT and the SPS Agreements.
[322] J. BRAITHWAITE and P. DRAHOS, *Global Business Regulation*, Cambridge University Press, 2000, p. 403.
[323] J. PEEL, *Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?*, Jean Monnet Working Paper *02/04*, NYU School of Law, 2004, p. 95.
[324] *Ibid*., p. 96.

of science under the SPS, as well as the TBT Agreements, is adherence to international standards, which are therefore considered as the principal benchmark against which the WTO would evaluate its Members' scientific regulations[325]. Standards role under the WTO system is to set the dividing line between what the WTO is automatically willing to consider as acceptable in terms of scientific justification, and what it requires discussion and evidence of in order to approve and be consistent with the normative framework[326].

Thus, it was necessary to restate the importance of science in the Codex decision-making process as well as substantiate its principles relating to food safety risk assessment[327]. As required by the text of the SPS Agreement and as confirmed by the case law[328], the risk assessment techniques developed by international organizations are used as a basis or taken into account as an interpretation tool that provide content for the general requirement for the SPS Agreement on risk assessment. This means that Codex rules on risk assessment may restrict the discretion of WTO Members do determine which scientific studies can be used as a justification under Article 5 on risk assessment. Therefore, the Codex entered new terrain also in terms of scientific requirements in 1995 because it was explicitly referred to in the SPS Agreement.

That said, this raises controversial issues as if international standards truly reflect a multilateral scientific consensus, as WTO Members had hoped and planned or if international standards are based only on science. As is clear from the above, therefore, the role of science in international standards has been just as controversial as the role of science in SPS Agreement provisions. The desire of the WTO to use science as a presumed neutral arbiter in a trade dispute has led some to question whether international standards truly represent a consensus in the scientific

[325] D. A. MOTAAL, *The "Multilateral Scientific Consensus" and the World Trade Organization*, p. 856.
[326] *Ibid*., p. 858.
[327] F. VEGGELAND and S. O. BORGEN, *Changing the Codex: The Role of International Institutions*, *Working paper 2002–16*, Norwegian Agricultural Economics Research Institute, 2002, p. 11.
[328] See pp. 53-55.

community, and whether they are indeed purely scientific based. Does the scientific consensus among the Codex "exist" independently of WTO itself and its influences? Looking in parallel how Codex standards for the five disputed hormones were developed on the one hand, and how the 1987 Hormones dispute under GATT, and the subsequent negotiation of the SPS Agreement on the other hand, demonstrates how interconnected the work of multilateral trading system is with that of international standardizing bodies. Between 1987 and 1995, when the SPS Agreement was being negotiated, Codex began to reflect on the role of science and its norms. The way in which the Codex and GATT/WTO timelines have paralleled cannot have been a mere coincidence. Sates have been using one forum to influence the other [329].

The controversy surrounding standards, for some specific issues[330], but even more generally concerns expressed in relation to the Codex - that have become more politicized and that there is greater representation in Codex committees by trade rather than technical specialists, as better explained below - led some countries to call for a more precise definition of the role of science in Codex standard-setting activity, and for Codex to define its principles. Therefore, in 1995, the CAC started to consider working principles concerning the role of science in the decision-making processes and the role of other legitimate factors that might be taken into account[331]. The Statements of Principle concerning the role of science in the Codex decision-making process are now part and annexed to the Codex Alimentarius Commission Procedural Manual and read as follows:

> "1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and

[329] D. A. MOTAAL, *The "Multilateral Scientific Consensus" and the World Trade Organization*, p. 875.
[330] Like the growth promoting hormones used in beef cattle (estradiol 17-beta, progesterone, testosterone, zeranol and trenbolone acetate) and production aids used to increase milk production in cows (recombinant Bovine Somatotropin (rBST or, more simply, BST)).
[331] FAO/WHO, *Report of the twenty-first session of the Joint FAO/WHO Codex Alimentarius Commission*, ALINORM 95/37, 3-8 July 1995, paras. 23-26.

evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex."[332]

While the decision of the Codex above clarified that its work had to be based on sound scientific analysis and evidence, and it is very significant that this principle was included as the very first principle, leeway was made for other legitimate factors.

In 2001[333], Codex Members managed to adopt a decision on the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle[334]:

"• when health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;

[332] World Health Organization and Food and Agricultural Organization of the United Nations, *General Principles of the Codex Alimentarius*, Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Appendix: General decisions, 2018, p. 250.

[333] Previously, in 1999, the following other legitimate factors were identified by the Secretariat: economically sustainable; lack of appropriate methods of analysis; technically achievable and safety factors. Joint FAO/WHO Standards Programme, *Review of the Statements of Principle of the role of Science and the extent to which Other Factors are taken into accou*nt, CX/GP/99/9, 1999.

[334] Codex Alimentarius Commission, Twenty-*fourth Session*, ALINORM 01/41, 2001, p. 89. Now it is part of the Codex Alimentarius Commission Procedural Manual, Twenty-Sixth Edition, Appendix: General decisions, 2018, pp. 250-251.

• other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;

• consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

• it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide;

• only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

• the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

• the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

• the integration of other legitimate factors in risk management should not create unjustified barriers to trade; particular attention should be given to the impact on developing countries of the inclusion of such other factors."

While these criteria still did not define what those other factors were, they established an important basis for how they were to be used[335]. One year later, the FAO/WHO Report on the evaluation of the Codex[336], in defining the criteria concerning the consideration of "other legitimate factors", explicit reference is made to the provisions of the SPS and TBT Agreements while there was still no precise agreement on what constitutes an "other legitimate factor". This kind of development raised awareness among States on the circumstance that all this may conflict with the mandate of the Codex. At a Codex Committee on General Principles meeting in 2001 these tendencies led the representative of the WHO to state that "risk analysis had to be considered as a health issue with trade implications and not as a trade issue with health implications, and that the debate on precaution should be viewed in this light"[337]. This problem has often been presented as international rules and principles are needed to reconcile conflicts, and promote complementarities, between trade and different non-trade concerns[338].

Similar debates took place recently in the context of the SPS Committee, as observed in the final part of the previous Chapter. Notably, the United States expressed its concerns with certain activities of the Codex apparently related to the intersection of Codex standards and the WTO SPS Agreement[339]. This issue was raised at a

[335] What scope is there under a multilateral scientific consensus for other considerations, such as consumer anxieties, to be taken into account by countries? Codex is still debating the role of other legitimate factors in its decision-making, but until that debate is resolved, what must countries do to be allowed to factor those other considerations into their health policies?

[336] FAO and WHO, *Report of the Evaluation of the Codex Alimentarius and other FAO and Who Food Standards Work*, 15 November 2002.

[337] Report of the 16th Session of the Codex Committee on General Principles. Paris, April 23–27 Alinorm. 01/33A, para. 65

[338] For example, in the domain of environmental concerns, it has been observed that Members of the WTO Committee on Trade and Environment tended to focus "primarily on the trade impacts of environmental measures - not on the environmental impacts of trade rules". G. C. SHAFFER, *The World Trade Organization under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environment Matters*, The Harvard Environmental Law Review, Vol. 25, issue 1, p. 23. According to Shaffer this work was characterized by attempts to "GATT the greens" more than to "green the GATT". *Ibid*., p. 80. See also D. C. ESTY, *Greening the GATT - Trade, Environment, and the Future*, Institute for International Economics, 1994.

[339] Committee on Sanitary and Phytosanitary Measures, *The Codex Alimentarius Commission: The Problem of WTO Considerations Influencing Codex Decision-Making, Submission by the United States of America*, G/SPS/GEN/1656, circulated on 16 October 2018.

previous meeting of the SPS Committee, where the Codex Secretariat reported the decision of the Chairperson of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)[340] not to move to the adoption of a standards[341] despite consensus on the science and the safety of this veterinary drug. The CCRVDF Chairperson cited a lack of consensus among Members due to factors that are outside the mandate of Codex. In this regard, the Codex Secretariat representative outlined that the absence of Agreement among some Codex Members may have to do with the status of Codex standards relative to the WTO SPS Agreement. The Codex Secretariat "further suggested that Codex standards being referenced in the SPS Agreement has been negatively influencing discussions in Codex due to some Members' fears that they could be challenged at the WTO with respect to failure to adopt specific Codex standards"[342]. The United States highlighted the two different mandate of the Codex and the WTO[343], addressing the WTO - the proper institutional setting would be probably the SPS Committee - as the appropriate forum for any exploration of the WTO implications of Codex decisions.

Moreover, they also observed that the credibility and reliability of Codex, and its standards, rest on Codex operating within its mandate, based on scientific foundation and procedural requirements[344]. These specifically should be grounded on the criteria established by the Codex Procedural Manual[345]. According to the United States, all this raises concerns related to WTO implications on the decision-making, for example, about whether, or at what levels, to set Maximum Residue Limit standards[346]. The final impact of this implications could be an undermined value of

[340] One of the Codex Committee on General Subjects.
[341] Related to the Maximum Residue Limit for the veterinary drug Zilpaterol.
[342] G/SPS/GEN/1656, para. 2.2.
[343] "[…] Legal interpretation of WTO Agreements falls outside of the mandate of the Codex secretariat […] [,] the unique dual mandate of Codex [is]: to protect the health of consumers and ensure fair practices in the food trade. […] Neither Codex nor the other drafting entities have the authority or the expertise to do a legal analysis of WTO implications.".
Ibid., paras. 3.1, 4.1 and 4.4.
[344] *Ibid*., para. 4.2.
[345] *Ibid*., paras. 4.4 and 5.6.
[346] *Ibid*., para. 5.5.

Codex standards[347] if they are perceived as designed to achieve particular WTO outcomes[348]. In a nutshell, the United States "want to avoid further situations where the WTO 'tail' wags the Codex 'dog'"[349], with a Codex laser-focused on establishing food safety standards, within its mandate[350].

The last Annual Report on the Procedure to Monitor the Process of International Harmonization[351] saw common views on these aspects among WTO Members. The Russian Federation, Argentina, Chile, Costa Rica, Guatemala, Honduras and Paraguay shared the concern raised by the United States. More interesting is the position of the European Union, that stressed that there was no hierarchical order among the SPS Committee and Codex. Moreover, the European Union added that, while the SPS Committee could invite Codex or other international standard-setting bodies to discuss topics of interest to the context of the SPS Committee, in its view, the SPS Committee should not attempt to influence procedures or decision-making processes within Codex[352]. All these discussions pave the way for further reflections on the relationship among the WTO and the Codex.

8. The WTO-Codex interinstitutional relationship

The picture arising from the above tells the reader the context where Codex was established, its mandate and functions, and when – after being referred in the SPS Agreement – and how some of its institutional aspects related to standards changed. As already pinpointed, the 1995 WTO SPS Agreement lifted Codex to a much higher plane in the international political agenda. It is from that date that Codex standards have taken on a new significance. With the establishment of the WTO Agreements,

[347] *Ibid*., para. 5.4.
[348] *Ibid*., para. 5.7.
[349] *Ibid*.
[350] *Ibid*., para. 6.2.
[351] Committee on Sanitary and Phytosanitary Measures, *Annual Report on the Procedure to Monitor the Process of International Harmonization, Note by the Secretariat*, G/SPS/GEN/1710, circulated on 28 June 2019.
[352] *Ibid*., para. 2.15.

trade interests were embedded more strongly in the institutional framework that surrounded the CAC. Thus, is it possible to affirm that the institutional and legal framework of the WTO influenced State behavior in the CAC, although not as originally intended when the SPS Agreement was drafted[353].

The Codex case is an interesting example in the study of international actors, as it shows how it's important to identify changes in the institutional framework that affect the incentives of States. Accordingly, the analysis of the Codex revealed that the WTO framework mattered as a way of constraining the activities and shaping the expectations of States. These possible effects of the link between Codex and the WTO also created incentives for the members to participate actively in Codex deliberations and to contribute more intensely in halting the decision-making process. Similar incentives were also in place before 1995, but as the account of the role of Codex standards in WTO disputes shows, the incentives grew stronger, at the same time as Codex attracted more attention and authority.

After 1995, Codex Members placed more focus on identifying their respective national interests[354] . The overall conclusion is that after 1995, Codex members have changed their behavior because of the increased uncertainty with respect to how decisions in Codex may be binding for them under the WTO Agreements[355]. The link to the WTO changed the rules of the game dramatically. Members realized that not engaging in these decisions could have serious consequences. They could end up spending a lot of time and resources on legitimating deviations from Codex standards[356], as required by risk assessment in particular.

Despite the WTO influences in terms in politicization and hardening of the scientific attitude, the WTO-Codex relationship it's worthy and it's necessary to be seen in an interinstitutional dimension. The previous Chapter already highlighted that

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[353] F. VEGGELAND and S. OLE BORGEN, *Negotiating International Food Standards: the World Trade Organization's Impact on the Codex Alimentarius Commission*, p. 702.
[354] *Ibid*., p. 701.
[355] *Ibid*., p. 703.
[356] *Ibid*., p. 700.

States decide to separate the two functions, the regulatory and the judicial one. Under the SPS Agreement the power to develop international food safety standards is granted to the CAC and, at the same time, the power to interpret those standards is given to the WTO Panels and AB. This institutional differentiation fragments power under the framework of the SPS Agreement so that each actor must rely (at least partially) on the other for its effective operation[357]. The interinstitutional relationship between the WTO and the CAC in the domain of harmonization[358] is characterized by a separation of power where the first is responsible for ensuring the application of standards through the dispute settlement mechanism and the activities of the SPS Committee while the second is in charge for the "legislative acts"[359]. The present section addresses both dimensions, looking at the WTO judicial perspective and at the regulatory authority in the form of the delegation of standard setting to Codex. Besides the respective functions exercised by WTO and Codex in the domain of international food safety standards, it is worthy to preliminary underline two simple differences among them in order to better understand the complex relationship as a whole.

8.1 Preliminary remarks: different membership and mandate

Although most of the WTO Members are even Members of the CAC, and *vice versa*[360], the are some cases where this symmetry is not respected. Codex Members

[357] M. A. LIVERMORE, *Authority and Legitimacy inn Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, p. 790. This statement implies a perspective centered on the WTO and its harmonizing obligation through standards, considering that the Codex operate also independently from the WTO. Moreover, in this article Livermore, in order to address the legitimacy dilemma in Codex standards, argues that the WTO system creates the possibility of an external check on Codex standards in the form of a judicial review by the AB. However, this research shows, in the previous Chapter, that the WTO does not set requirements to be considered an international standard under the purpose of the SPS Agreement. This Chapter confirms that the judicial power is limited and does not provided an incisive model of judicial review.

[358] The SPS Agreement defines harmonization in Annex A (2) as the "establishment, recognition and application of common sanitary and phytosanitary measures by different Members" so that the allocation of powers and competences attributed in this context can be drawn from other references in the WTO system.

[359] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 183.

[360] As already pointed out, the CAC has 189 Members, while the WTO currently counts 164 Members.

that are not WTO Members are not bound by the obligations arising from the SPS Agreement so that Codex standards keep their voluntary status. More complex is the position of those countries that are WTO Members but that have no membership within the CAC. It seems more reasonable that from both practical and theoretical reasons[361] these countries should be bound to use CAC measures event though they have no possibilities to participate and influence the standard-setting activities and their results.

Although this is quite evident, given the different mandate, there are differences related to the objective and content of the obligations resulting from Codex and WTO measures. The object of the obligations dictated by the CAC legal framework are directed to facilitate trade in food products as well as the protection of human health and fair practices in food trade. In the WTO system, Codex standards obligations result limited to the elements that aim at the free circulation of food products. In contrast, the obligation under the SPS Agreement are direct to the prevention of non-trade barriers which may arise by the adoption of national sanitary or phytosanitary measures. Moreover, the common aspect is that neither of the legal frameworks require to use Codex standards as a tool aimed at ensuring a minimum level of protection for citizens and consumers. Having said that, the analysis on the interinstitutional relationship looks first at the judicial dimension, addressing if and in which terms Panels and AB may interpret or review Codex standards, investigating also on other possible solutions (experts consultation and internal dispute mechanism) that may be provided. The last part is devoted to the process of delegating standard-setting to the Codex.

[361] First, it would be too simple for States, in order to avoid the decisions of a Panel or the AB on the basis of a Codex standards, just decide not to be member of the CAC. Second, according to SPS Agreement Article 3.4, WTO Members shall play a full part in the CAC. Thirdly, from the picture outlined in this Chapter on the relationship between CAC and WTO, given the influences and the normative and institutional mechanism which makes standards binding, it seems appropriate that Codex standards effect should be based only on States' membership within the WTO.

8.2 The judicial dimension: the role of Panels and AB

The SPS Agreement was adopted as an integral part of WTO Agreements, so that States can start disputes related to rights and obligations in the SPS domain under the procedure of the dispute settlement mechanism, a system which has been strengthened after 1994[362].

Both Panels and AB can apply and interpret the provisions of the WTO covered Agreements. Sources of law not too long ago one could make waves claiming that WTO rules are, after all, just treaty rules[363]. However, - as this research questions since the very beginning the source-monopoly of WTO Members, WTO covered Agreements and legally binding instruments - in the examination of the merits of the WTO claims[364], the applicable law before Panels and AB ought not be limited to those sources of law.

This matter is part of a broad picture which involves reflections, that are not properly addressed in this work, on the WTO as a self-contained regime[365].

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[362] For a general overview see E. U. PETERSMAN, *The GATT/WTO Dispute Settlement System: International Law, International Organisations and Dispute Settlement*, Kluwer Law International, 1998; M. MATSUSHITA, T. J. SCHOENBAUM, P. C. MAVROIDIS and M. HAHN, *The World Trade Organization: Law, Practice, and Policy*, Oxford International Law Library, 2015, pp. 83-110 and for a specific focus see R. HUDEC, *The New WTO Dispute Settlement Procedure: An Overview of the First Three Years*, Minnesota Journal of Global Trade, Vol. 8, no. 1, 1999.

[363] J. PAUWELYN, *Interplay Between the WTO Treaty and other International Legal Instruments and Tribunals: Evolution After 20 Years of WTO Jurisprudence*, Proceedings of the Québec City Conference on the WTO at 20, C.E. CÔTÉ, V. GUÈVREMONT and R. OUELLET (eds.), Presses de l'Université de Laval, 2018, p. 4.

[364] In different situations where "non-WTO law" (this heterogeneous group of sources of law referred by Panels and Appellate Body in their decisions is addressed in the following section) can constitute an independent defence against claims of violation of WTO law, we are referring to the case where this defence undermines the merits of the WTO complaint and does not undermine the jurisdiction of the WTO Panel/AB. For a brief overview and distinction see J. PAUWELYN, *How to Win a World Trade Organization Dispute Based on Non-World Trade Organization Law? Questions of Jurisdiction and Merits*, Journal of World Trade, Vol. 37, no. 6, 2003, p. 1028.

[365] The literature is particularly wide, see: B. SIMMA, *Self-contained Regimes*, Netherlands Yearbook of International Law, Vol. 16, 1985; J. P. TRACHTMAN, *The Domain of WTO Dispute Settlement Resolution*, Harvard International Law Journal, 1999; L. BARTELS, *Applicable Law in WTO Dispute Settlement Proceedings*, Journal of World Trade, Vol. 35, issue 3, 2001; G. MARCEAU, *Conflicts of Norms and Conflicts of Jurisdictions: The Relationship between the WTO Agreement and MEAS and other Treaties*, Journal of World Trade, Vol. 35, no. 6, 2001; P. PICONE and A. LIGUSTRO, *Diritto dell'Organizzazione mondiale del commercio* , Cedam, 2002; J. PAUWELYN, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law*, Cambridge 2003; B. SIMMA and D. PULKOWSKI, *Of Planets and the Universe: Self-contained Regimes in International Law*,

Traditional international law and non-traditional patterns of global regulation, developed by, or with the input from, State and non-state actor, do offer avenues to take account of both hard law and softer law sources. Albeit with different shades of relevance, even in the case of carefully construed avenues, they raise questions of legitimacy, as standard do. As the case law shows, these incorporation techniques range from provisions of the Vienna Convention on the Law of the Treaties (VCLT) and novel approaches to treaty interpretation to Free Trade Agreements (FTAs) and soft guidelines. Thus, international standards only represent a small fraction of the heterogeneous set of rules referred to by Panels and AB.

8.3. Applying non-WTO law: the broad picture of public international law

As we firstly take into consideration public international law in a broad sense, "[w]ithin the four walls of the WTO building grew a surprisingly rich and vigorous tree of public international law; a tree that few insiders would have predicted when they constructed the WTO edifice in 1994. The tree has deep and long roots that reach way beyond the WTO covered agreements. It is nurtured by customary international law, general principles of law and even non-WTO treaties"[366]. These "fertilizing" tools can be found not just within general international law but also within other, non-WTO treaties and other sub-branches of international law. Such sources have been referred in practice in order to solve issues of treaty interpretation, to fill procedural gaps such

European Journal of International Law, Vol. 17, no. 3, 2006; L. GRADONI, *Regime failure nel diritto internazionale*, Cedam, 2009; I. VAN DAMME, *Jurisdiction, Applicable Law, and Interpretation*, in The Oxford Handbook of International Trade Law, D. BETHLEHEM, I. VAN DAMME, D. MCRAE, and R. NEUFELD (eds.), Oxford University Press, 2009; J. CRAWFORD, *Change Order Change: The Course of International Law, General Course on Public International Law*, Brill, 2014; G. COOK, *A Digest of WTO Jurisprudence on Public International Law Concepts and Principles*, Cambridge University Press, 2015.

[366] J. PAUWELYN, *Interplay Between the WTO Treaty and other International Legal Instruments and Tribunals: Evolution After 20 Years of WTO Jurisprudence*, p. 4.

as burden of proof, standing representation before Panels, the retroactive application of treaties or error in treaty formation[367].

The first example corresponds to the very first report of the AB, the *US – Gasoline* case in 1996[368], where it observed that "that the General Agreement is not to be read in clinical isolation from public international law"[369]. This sort of openness was nevertheless contradicted or, at least, reduced, by a more cautious approach in the *Beef – Hormones* dispute, when it was the case for the EU to invoke the precautionary principle as a general customary rule of international law[370]. Two year after, in the *EC – Poultry* case[371], the AB found that even if a pre-WTO bilateral agreement on oilseeds between the EC and Brazil was not part of WTO covered agreements, it "may serve as a supplementary means of interpretation of [Brazil's agricultural schedule to the WTO treaty] pursuant to Article 32 of the Vienna Convention"[372]. The leading case for several reasons[373], raising questions of legal predictability and state consent, is *US – Shrimp*[374] when the AB, interpreting the words "exhaustible natural resources" under GATT Article XX(g), referred to outside international legal instruments[375] in the

[367] J. PAUWELYN, *How to Win a World Trade Organization Dispute Based on Non-World Trade Organization Law? Questions of Jurisdiction and Merits*, p. 998.
[368] *United States – Standards for Reformulated and Conventional Gasoline*, Appellate Body Report WT/DS2/AB/R, 1996.
[369] *Ibid*., para. 17.
For a general overview see J. PAUWELYN, *The Role of Public International Law in the WTO: How Far Can We Go?*, American Journal Of International Law, Vol. 95, July 2001.
[370] *European Communities – Measures Concerning Meat and Meat Products (Hormones),* Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R, 1996, paras. 123-124.
For a general overview see J. CAMERON and K. GRAY, *Principles of International Law in The WTO Dispute Settlement Body*, International and Comparative Law Quarterly*,* Vol. 50, issue 2, 2001.
[371] *European Communities – Measures Affecting Importation of Certain Poultry Products*, Appellate Body Report WT/DS69/AB/R, 1998.
[372] *Ibid*., para. 84.
[373] First, the variety of sources referred and second the "evolutionary" approach to treaty interpretation adopted by the AB. J. PAUWELYN, *Interplay Between the WTO Treaty and other International Legal Instruments and Tribunals: Evolution After 20 Years of WTO Jurisprudence*, p. 9.
[374] *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Appellate Body Report WT/DS58/AB/R, 2001.
[375] They are: not legally binding instruments as Agenda 21 (the Rio Declaration on Environment and Development, and the Statement of principles for the Sustainable Management of Forests, 1992), instruments not binding on all WTO Members as the 1973 Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) and not binding on all disputing parties in the WTO case before it as the he 1982 UN Convention on the Law of the Sea (UNCLOS) or the 1992 Convention on Biological Diversity (CBD).

process of interpreting the WTO provisions. It stated that WTO treaty must be interpreted "in the light of contemporary concerns of the community of nations about the protection and conservation of the environment"[376].

Interpretation, and the related rules of the VCLT are the center of two decisions. In one case the AB interpreted the term "public body" in the light of customary international rules on State attribution[377], while in another circumstance it accepted that a paragraph of the 2001 Doha Ministerial Declaration constitutes a "subsequent agreement" for the interpretation of the TBT Agreement[378]. In a different occasion, always characterized by making reference to non-WTO treaty provisions, the AB was involved in a dispute where the line between jurisdiction applicable law and treaty interpretation can be blurry[379]. Moreover, also bilateral agreements in the economic domain played a role in the AB jurisprudence. Once, when it considered the provisions of an FTA for the purpose of determining whether a Member has complied with its WTO obligations[380] and in another time the AB was asked if two Members may waive or relinquish their DSU right to a WTO Panel through a bilateral agreement [381].

Lastly, the legal instruments of two important international organizations were at stake. First, the case of the TRIPS Agreement that not only incorporates obligations under World Intellectual Property Organization conventions, it also incorporates

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[376] *Supra* note 374, para. 129. A more open issue remains the possibility to adopt a similar approach in other areas, such as consumer protection, labor standards etc.
[377] *United States – Definitive Anti- Dumping and Countervailing Duties on Certain Products from China*, Appellate Body Report WT/DS379/AB/R, 2011. Here the AB relied on VCLT Article 31.3(c) in order to interpret Article 1 of the Subsidies Agreement referring in particular to Article 5 of the International Law Commission Articles on State Responsibility.
[378] *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, Appellate Body Report WT/DS406/AB/R, 2012. In particular, the AB accepted that paragraph 5.2 in the 2001 Doha Ministerial Declaration constitutes a "subsequent agreement" on the interpretation of Article 2.12 of the TBT Agreement in the sense of Article 31.3(a) of the VCLT.
[379] *Mexico – Tax Measures on Soft Drinks and Other Beverages*, Appellate Body Report WT/DS308/AB/R, 2006.
[380] *Peru – Additional Duty on Imports of Certain Agricultural Products*, Appellate Body Report WT/DS457/AB/R, 2015, para. 5.86.
[381] *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, Appellate Body Report WT/DS27/AB/RW/USA, 2008.

certain exceptions to be found in these conventions[382], and secondly, under the Subsidies Agreement an export credit practice was not considered prohibited because in conformity with the interest rate provisions of the Organisation for Economic Co-operation and Development Arrangement on Guidelines for Officially Supported Export Credit[383] .

Briefly, the approach adopted by the AB tends to accept more easily legal instruments concluded inside rather than outside the WTO as well as procedural deviations over substantive ones. Furthermore, its judicial activity ranges from novel approaches to treaty interpretation to a broader definition of the applicable law before the WTO including explicit references to international standards in the SPS and the TBT Agreements, as here below analyzed. This analysis is fundamental not only in the perspective of addressing the interinstitutional cooperation among the WTO and Codex, but even for deepening the understanding of standards as a source of law.

8.4. Applying and interpreting international standards

Panels and the AB, given the expressed references to the CAC in the SPS Agreement, but Codex standards may also be relevant under the TBT Agreement[384], act as adjudicating bodies over disputes which may arise in relation to the

[382] *United States – Section 110(5) of the US Copyright Act*, Panel Report WT/DS160/R, 2000. In this case it was the Berne Convention for the Protection of Literary and Artistic Works. For a general overview on the WTO – other agreements relationship see M. MATSUSHITA, *Governance of International Trade Under the World Trade Organization Agreements – Relationship Between World Trade Organization Agreements and Other Trade Agreements*, Journal of World Trade, Vol. 38, no. 2, 2004.

[383] *Canada – Export Credits and Loan Guarantees for Regional Aircraft*, Panel Report WT/DS222/R and Corr.1, 2002.

[384] Even the relevant case law under the TBT Agreement is here analyzed to the extent it is useful in a comparative manner and when it offers additional insights to better understand the WTO system in general. Moreover, even in the case law, there are examples of cross references when Panels have to interpret the SPS or the TBT Agreement, see, for example, in India – Agricultural Products: We recall that, in EC – Sardines [para. 242], the Appellate Body, when interpreting the obligation in Article 2.4 of the TBT Agreement to use international standards "as a basis" for technical regulations, considered its approach to the interpretation of the term "based on" in the context of Article 3.1 of the SPS Agreement as relevant for the interpretation of "as a basis" in Article 2.4. We think that the reverse approach is also viable". *India – Measures Concerning the Importation of Certain Agricultural Products*, Panel Report WT/DS430/R, 2014, para. 7.266.

interpretation and application of standards. In this respect, five cases show different insights, the already analyzed *Hormones*, *India – Agricultural Products*, *Russia – Pigs*, *EC – Sardine* and *US – Tuna II*. The first three cases are mainly devoted to specific interpretative issue and are under the SPS Agreement while the last two address the legitimacy aspects of standards and are under the TBT Agreement.

No explicit authority to review the legitimacy of Codex procedures and resulting measures[385] according both to the text of the SPS Agreement and of the Dispute Settlement Understanding is provided. Foreseeably, Panels and the AB in the Hormone case declined to assume such role. In particular, the EC argued on the adoption procedure of Codex standards, considering that the standard at issue received 33 votes in favour, 29 against and 7 abstentions[386]. The EC argument was based on the fact that normally CAC standards are adopted by consensus and rarely by voting procedure as was the case in the MRLs hormones-related standard. However, the Panel, by refusing to verify if the standard had been adopted in accordance to internal Codex rules, saying that "we need not consider […] whether these standards have been adopted by consensus or by a wide or narrow majority"[387], at the end declining all responsibilities to examine the legitimacy of the standard-setting procedure.

In India – Agricultural Products[388], the AB, elaborating on the nature of the obligations contained in SPS Agreement Article 3, offered an overview of that provision, shedding light on how a Panel may go about discerning the meaning of the relevant international standard. In each of the circumstances occurring under the three

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[385] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 185.

[386] After a long and problematic debate, a first attempt to adopt such standards occurred in July 1991 during the 19th Session of the Joint FAO/WHO Codex Alimentarius Commission while they were finally adopted in the 21st Session.

[387] EC – Hormones, para. 8.69.
The Panel also highlighted that "as a panel making a finding on whether or not a Member has an obligation to base its sanitary measure on international standards in accordance with Article 3.1, we only need to determine whether such international standards exist. [Thus] we need not consider (i) whether the standards reflect levels of protection or sanitary measures or the type of sanitary measure they recommend, or […] whether the period during which they have been discussed or the date of their adoption was before or after the entry into force of the SPS Agreement". *Ibid*. Describing the elaboration of Codex standards in para. 215 the Panel made no comment on that.

[388] *India – Measures Concerning the Importation of Certain Agricultural Products*, Appellate Body Report WT/DS430/AB/R, 2015.

first paragraph of Article 3, "a panel must engage in a comparative assessment between the challenged measure and that international standard"[389]. The AB considered international standards as the benchmark to assess compliance under Article 3 and in this process it can "may be guided by any relevant interpretative principles, including relevant customary rules of interpretation of public international law"[390]. This decision also pointed out additional sources that can be used in discerning the meaning of the international standards, as explained in the following section[391].

The following year, the Panel went on with the same reasoning in Russia – Pigs (EU)[392], confirmed to be guided by interpretative principles, including customary rules of interpretation of public international law, when conducting the comparative assessment[393]. However, on the basis of the meaning of "treaty"[394] under the VCLT, the Panel noted that, as opposed to a treaty, "the rules of interpretation in the Vienna Convention would not be directly applicable to the interpretation of the international standards"[395]. Nevertheless, "they may serve as useful guidance in [the Panel] examination of the provisions [of the international standards at issue]"[396].

The case law under the TBT Agreement provides instead critical insights for the scrutiny of Codex standards and for an evolutive approach adopted by the AB in this sense. In EC – Sardine[397], procedural rules on the elaboration and adoption of

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[389] *Ibid*., para. 5.79.
[390] *Ibid*.
[391] For example, Panels may wish to have recourse to the views of the relevant standard-setting body, as referred to in Annex A(3) to the SPS Agreement, through evidence on the Panel record or through direct consultation with that body, or with other experts in the relevant fields, pursuant to Article 11.2 of the SPS Agreement and Article 13 of the DSU.
[392] *Russian Federation – Measures on the Importation of Live Pigs, Pork and Other Pig Products from the European Union,* Panel Report WT/DS475/R, 2016.
[393] *Ibid*., paras. 7.275 and 7.276.
[394] "[A]n international agreement concluded between States in written form and governed by international law". United Nations, *Vienna Convention on the Law of Treaties*, Article 2.1 (a), Treaty Series, 1155, 331, 23 May 1969.
[395] WT/DS475/R, para. 7.278.
[396] *Ibid*.
Even in this case it was made reference to additional sources of interpretation in the form of consultation.
[397] *European Communities – Trade Description of Sardines*, Panel Report WT/DS231/R, 2002.
In this case, Peru challenged an EC Regulation under TBT Agreement Article 2.4, devoted to the labelling and marketing of preserved sardines. The EC Regulation provided that only those products prepared from a specific species of sardine, *Sardina pichardus* (European sardines), could be marketed

Codex standards were again invoked by the EC on the two different grounds. Concretely, the Panel was asked to examine whether Codex Stan 94[398] is a relevant international standard according to the TBT Agreement[399]. In particular, the EC did not preliminary contest the status of the CAC as an international standardizing body for the purposes of the TBT Agreement, while it also observed that only standards of international bodies with international treaty status that respect the same principles of membership and due process that form the basis for WTO membership should be recognized as international standards[400].

Of the two abovementioned grounds[401], the EC relied first on the internal rules of the CAC elaboration procedure, arguing that, in case of violation[402], "Codex Stan 94 would, in this case, be rendered invalid and could not, therefore, be considered a

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and labelled as preserved sardines, while products prepared from other species of sardine, such as *Sardinops sagax* (Peruvian sardines), could not. The case turned on the relevance of a Codex standard (Codex Stan 94) for canned sardines and sardine type products.

[398] The Codex Alimentarius Commission Standard for Canned Sardines and Sardine-Type Products (Codex Stan 94 –1981 Rev.1 – 1995). Article 1 of the standard sates that: this standard applies to canned sardines and sardine-type products packed in water or oil or other suitable packing medium and that it does not apply to speciality products where fish content constitutes less than 50% m/m of the net contents of the can.

[399] Specific reference was made to TBT Agreement 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";
and to Annex 1 (2):
"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.
Explanatory note
The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus".

[400] *Supra* note 151, para. 4.29.

[401] Which are not the only two presented by the EC. See, for a global view: H. HORN and J. WEILER, *European Communities – Trade Description of Sardines: Textualism and its Discontent*, World Trade Review, Vol. 4, issue 1, 2005.

[402] The EC referred that if a substantive amendment had been made at Step 8 of Codex procedure, it would have been necessary to refer the text back to the relevant committee for comments before its adoption.

relevant international standard within the meaning of Article 2.4 of the TBT Agreement"[403]. Nevertheless, the Panel did not address this issue, considering that standards definition under the TBT Agreement neither include procedural requirements nor makes reference to Codex Procedural Manual[404]. The second, and more interesting ground, relied on the principle of consensus contained in the Principles for the Development of International Standards, Guides and Recommendations[405]. EC argued that the Codes measures had not been adopted by consensus, being accepted by only eighteen countries. The Panel rejected such argument as well, stating that "[f]or the purposes of determining whether standards must be based on consensus, the controlling provision is paragraph 2 of Annex 1 of the TBT Agreement and its explanatory note"[406] and that "[t]he Decision to which the European Communities refers is a policy statement of preference and not the

[403] WT/DS231/R, para. 4.34.

[404] On similar grounds, confirming the separation of powers among the WTO and Codex, "Peru disputes the European Communities' argument that Codex Stan 94 is not a relevant international standard because the Codex Alimentarius Commission would have violated its procedural rules according to which substantive changes to proposed standards can only be made under certain circumstances. Peru is of the view that it is for the members of the Codex Alimentarius Commission to examine whether the procedural requirements for the adoption of standards have been observed and, if necessary, to request corrective action in accordance with the rules and procedures of the Commission. Peru claims that the Panel is not competent to make findings on such issues". WT/DS231/R, para. 441.

[405] At the Second Triennial Review of the TBT Agreement, the TBT Committee noted that in order for international standards to make a maximum contribution to the achievement of the trade facilitating objectives of the Agreement, it was important that all Members had the opportunity to participate in the elaboration and adoption of international standards. In order to improve the quality of international standards and to ensure the effective application of the Agreement, the Committee agreed that there was a need to develop principles concerning transparency, openness, impartiality and consensus, relevance and effectiveness, coherence and developing country interests that would clarify and strengthen the concept of international standards under the Agreement and contribute to the advancement of its objectives. In this regard, in November 2000, the Committee adopted a decision containing a set of principles it considered important for international standards development. The full text of the so-called 6 Principles is provided within: Committee on Technical Barriers to Trade, *Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade*, G/TBT/9, Circulated on 20 November 2000, Annex 4 (Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations With Relation to Articles 2, 5 and Annex 3 of the Agreement).

[406] WT/DS231/R, para. 7.89.
The explanatory note for paragraph 2 provides that: "[s]tandards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus".

controlling provision in interpreting the expression "relevant international standard" as set out in Article 2.4 of the TBT Agreement"[407].

The AB agreed on the Panel interpretation and took a hands-off approach when it comes to controlling or double-checking the legitimacy of international standards. It found that "[i]t is not intended to affect, in any way, the internal requirements that international standard-setting bodies may establish for themselves for the adoption of standards within their respective operations"[408]. Strictly speaking, "[t]hat is not for us to decide"[409]. This explicit rejection, which reflects great distance among the WTO and the Codex and a rigid distribution of roles (development and adoption of standards and judicial review), rose a series of criticism[410]. Moreover, as a consequence, this lack of judicial review places more responsibility on the Codex, in order to ensure a proper elaboration and consequently standards legitimacy[411].

Ten years later, the AB on US – Tuna II[412] took a radically different approach, addressing a Mexican challenge against the U.S. concerning the criteria for labeling tuna products as "dolphin-safe" under the requirements of the TBT Agreement. In its 2012 report, the AB has demonstrated its willingness to play a role in respect - to exercise a form of scrutiny - by double-checking the openness, transparency and impartiality of international standards before giving them legal effects under the TBT Agreement.

The AB ultimately denied the label of "international standard" on the basis that the membership of the organization that had enacted the instrument invoked - the Agreement on the International Dolphin Conservation Program (AIDCP) -

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[407] *Ibid*., para. 7.91.
[408] *EC – Trade Description of Sardines*, Appellate Body Report WT/DS231/AB/R, 2002, para. 227.
[409] *Ibid*.
[410] H. HORN and J. WEILER, *European Communities – Trade Description of Sardines: Textualism and its Discontent*, p. 255 and R. MUNOZ, La Communauté entre les mains des norms internationals: les consequences de la decision Sardines au seine de l'OMC, p. 483.
[411] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 188.
[412] *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, Appellate Body Report, WT/DS381/AB/R, 2012.
For a broad overview on the case see G. SHAFFER, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, American Journal of International Law, Vol. 107, issue 1, 2013.

was not "open to the relevant bodies of at least all [WTO] Members"[413]. The AB stated that "an international standardizing body must not privilege any particular interests in the development of international standards"[414] and underscored "the imperative that international standardizing bodies ensure representative participation and transparency in the development of international standards"[415] . To be relevant in the WTO adjudication, international standards must thus meet both source authority[416] and procedural requirements, crucial elements to base the "thick stakeholder consensus" of this soft form of cooperation as standard-setting is, in contrast to treaty-making which is driven by "thin State consent"[417]. Besides the pure judicial perspective, this kind of activity by the AB ensure that standards meet the requirements of predictability[418] and stability that, according to Jackson, a "rule-oriented" regime should have[419]. Moreover, in this sense the AB is part of the gradual transition, from rule-based trade 1.0 - focused on output and effect - to rule-based trade 2.0 - ensuring both output predictability, stability, and neutrality and input legitimacy and coherence[420].

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[413] *Ibid*., para. 399.
In effect, only 13 countries (including the United States and Mexico) had been involved in the creation of the instrument.
[414] WT/DS381/AB/R, para. 384.
[415] *Ibid*., para. 379.
[416] This issue is more troubling and relevant in the framework of the TBT Agreement given that there is no circumscribed and specific reference to some standard-setting bodies as in the SPS Agreement - where the Codex is considered as a "quasi-legislator" in the area of food safety - as even observed by the AB: "[…] contrary to the SPS Agreement, which defines "international standards, guidelines and recommendations" by reference to specific organizations, the TBT Agreement does not contain a list of international standardizing organizations". *Ibid*.
[417] J. PAUWELYN, *Rule-Based Trade 2.0? The Rise of Informal Rules and International Standards and How they May Outcompete WTO Treaties*, Journal of International Economic Law, Vol. 17, issue 4, 2014, p. 740. Here Pauwelyn pinpoints a dichotomy where (thin) State consent is the (only) requirement for traditional international law sources as treaties while the complex of international informal law sources is normatively thicker, requiring consent and legitimacy of the authority and of the "law-making" process. These are the same concepts described in the discussion of informal international law-making at pp. 3-4.
[418] Predictability is not only a relevant requirement that a rule should meets in order to guarantee the proper function of international trade, it is also required in term of due process, as in the Panel report, *Russia – Pigs (EU)*, WT/DS475/R para. 7.265.
[419] J. H. JACKSON, *The Jurisprudence of GATT and the WTO: Insights on Treaty Law and Economic Relations*, Cambridge University Press, 2000, pp. 6-10.
[420] [420] J. PAUWELYN, *Rule-Based Trade 2.0? The Rise of Informal Rules and International Standards and How they May Outcompete WTO Treaties*, p. 740.

Applying the (non-binding) TBT Committee Decision on Principles for the Development of International Standards, the AB carefully scrutinized, *inter alia*, the transparency and openness of the international standard invoked by Mexico. The AB was aware of the fact that, pursuant to Article 3.2[421] of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) "panels and the Appellate Body are to "clarify" the provisions of the covered agreements "in accordance with customary rules of interpretation of public international law""[422]. That being said, within the limits of its powers, the AB "considered [the TBT Committee Decision] as a "subsequent agreement" within the meaning of Article 31(3)(a) of the *Vienna Convention*"[423]. Thus, the AB extensively referred to this Committee Decision to interpret the notion of "international standard" in TBT Agreement Article 2.4[424].

While the TBT Committee Decision merely describes principles that are generally viewed as not legally binding, this did not stop the AB from referring to the Committee Decision as a "subsequent agreement", in line with the Fifth Report on subsequent agreements and subsequent practice in relation to the interpretation of treaties adopted in 2018 in the International Law Commission[425].

In *US – Tuna II* what should be welcomed is not only that the AB is no longer turning a blind eye on what should count as an "international standard", but, and this is especially relevant if looking at the interinstitutional WTO-Codex dimension, even

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[421] "2. The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements".

[422] WT/DS381/AB/R, para. 371.

[423] *Ibid*., para. 372.

[424] In particular the notion of "open" and "recognized activities in standardization".

[425] International Law Commission, Fifth report on subsequent agreements and subsequent practice in relation to the interpretation of treaties, Special Rapporteur George Nolte, A/CN.4/715, ILC Seventieth session, New York, 30 April–1 June 2018 and Geneva, 2 July–10 August 2018, Draft conclusion 10 [9] — Agreement of the parties regarding the interpretation of a treaty, para. 1: "An agreement under article 31, paragraph 3 (a) and (b), requires a common understanding regarding the interpretation of a treaty which the parties are aware of and accept. Though it shall be taken into account, such an agreement need not be legally binding".

the fact that the AB decision represents a sort of point of contact, a bridge, among several aspects[426]. First, it offers a bridge between the "hard" elements of the WTO system - treaty rules and the Dispute Settlement Mechanism - and the informal rules in the form of a Committee decision and standards[427]. Secondly, it represents a unique example of interaction where a judicial body of the WTO, on the basis of a soft law instruments provided by one of its Committees, interpreted and scrutinized, on the basis of principles elaborated by WTO Members, a standard developed and adopted within the CAC.

8.4.1. An additional option to interpret standards: the role of experts

Given the very limited possible use of the VCLT in interpreting international standards expressed by the Panel in Russia – Pigs (EU)[428], and the simultaneous reference to additional sources that can be used in discerning standards meaning, DSU Article 13 and SPS Agreement Article 11.2 could be of help in order to avoid the risk that interpretations of Codex measures may run counter to the meaning, purpose and function of standards within the system of the CAC as intended by its Members[429].

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[426] In any case, the scope of this measure does not change in general terms the already described kind of interinstitutional relationship among WTO and Codex, given that "[t]he purpose of the decision was not to dictate to other international organizations how they should proceed, but rather to encourage the participation of Members in the law-making (standard-setting) bodies to which the TBT seems to have lent certain quasi-legislative authority". G. MARCEAU and Z. J. 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,* p. 389.

[427] J. PAUWELYN, *Rule-Based Trade 2.0? The Rise of Informal Rules and International Standards and How they May Outcompete WTO Treaties*, p. 751.

[428] A similar conclusion can be drawn even on factual and practical grounds considering that standards text, given the technical and often numerical content, do not seem particularly appropriate to be interpreted according to the provision of the VCLT.

[429] Looking at the relationship among the two provisions, Article 1.2 of the DSU states that the provisions of the DSU apply subject to special or additional rules and procedures identified in Appendix 2 thereto. Appendix 2 lists Article 11.2 of the SPS Agreement. Article 1.2 of the DSU further provides: "To the extent that there is a difference between the rules and procedures of this Understanding and the special or additional rules and procedures set forth in Appendix 2, the special or additional rules and procedures in Appendix 2 shall prevail". In the case law, reference to both articles is always made with no distinction, as in EC – Hormones, where the AB stated: "[b]oth Article 11.2 of the SPS Agreement and Article 13.2 of the DSU require Panels to consult with the parties to the dispute during the selection of the experts" (WT/DS26/AB/R para. 148) and in US/Canada – Continued Suspension, when the AB

These articles do not distinguish between the type of consultation with the representatives of the relevant institutions or international organizations and the consultation with scientific experts even though the functions are distinct, a lack of clear mandate which may arise criticisms[430]. On the one hand, the first group provide information that look at the general and institutional background, more related to legal and formal aspects, while on the other hand, the second group is consulted for a specific scientific expertise, more related to substantial issues. Here the analysis is focused on the first type of consultation, which is closer to the WTO/Codex relationship and to possible legitimacy check.

observed that "Panels are understood to have 'significant investigative authority' under Article 13 of the DSU and Article 11.2 of the SPS Agreement and broad discretion in exercising this authority" (WT/DS231/AB/R paras. 437-439).

[430] In particular, scientific experts may be invited to advice on the interpretation of international standards, as occurred in several cases. In *EC – Hormone*, they gave information on aspects related to JEFCA or to the establishment of Codex (WT/DS26/R/USA, para. 7.58 and WT/DS48/R/CAN, para. 8.57). In *Australia – Salmon* two scientific experts were asked to give advices in the interpretation of OIE guidelines (WT/DS18/R, paras. 6.151-6.155.). Moreover, in *Japan – Apples*, scientific experts were asked for their opinion on IPCC Guidelines (WT7DS/245/R, question 33, p. 123).
However, in *India – Agricultural Products*, the AB disagreed that the Panel had exceeded the permissible scope of consultation with the scientific experts under SPS Agreement Article 11.2 and Article 13.2 of the DSU when it posed interpretative, instead of scientific or technical questions. The AB reasoned that these provisions do not limits the scope of a Panel's consultation with experts and international organizations:
"Although Article 11.2 indicates that the reason a panel 'should seek advice from experts' is because the dispute 'involve[es] scientific or technical issues', we consider this to be a reference to the types of issues common to SPS disputes, and not to suggest a limitation as to the scope or nature of questioning that would be permitted in such disputes. Thus, while the language of Article 11.2 indicates that experts should be consulted in disputes involving scientific or technical issues, it does not mandate that the advice sought be confined to such issues. This understanding is also consonant with the scope and nature of questioning permitted under Article 13 of the DSU, which grants panels 'the right to seek information and technical advice from any individual or body which it deems appropriate', to 'seek information from any relevant source', and to 'consult experts to obtain their opinion on certain aspects of the matter'. On the basis of the foregoing, we do not consider that either Article 11.2 of the SPS Agreement or Article 13 of the DSU imposes constraints on a panel's consultation with experts, including with any relevant international organizations, and we see no basis for understanding Article 11.2 of the SPS Agreement to circumscribe the authority or discretion a panel enjoys under Article 13 of the DSU in SPS disputes. For these reasons, we disagree that Article 11.2 of the SPS Agreement limits the permissible scope of a panel's consultations with an international organization in the manner suggested by India. To the contrary, these provisions apply cumulatively and harmoniously in SPS disputes, and reinforce the comprehensive nature of a panel's fact-finding powers. We therefore find that the Panel did not act inconsistently with Article 11.2 of the SPS Agreement or Article 13.2 of the DSU in consulting with the OIE regarding the meaning of the OIE Code".
WT/DS430/AB/R, para. 5.89.

Article 13 of the DSU[431] on the right to seek information provides the possibility of consulting the CAC or its subsidiary bodies with regard to the meaning and validity of its standards. This is a rare example of possible cooperation among international organizations both within the DSU[432] and in the WTO/Codex perspective. While in the first cases[433] relate to this provision the consultation of international organizations was mainly limited to requests of factual information, the Hormones case is interesting in this regard. Among the six experts consulted, one was a representative of the Codex Secretariat, who gave explanations of what JEFCA (FAO-WHO Joint Expert Committee on Food Additive) and Codex are and their increased interest since the Marrakesh Agreement. Moreover, Dr. Alan Randell[434] also gave explanation on ADI (Acceptable Daily Intake) and Maximund Residual Levels (MRLs) concepts and on other scientific aspects[435], useful in assuring that the interpretation of WTO adjudicators is in line with the purpose of Codex measures. In

[431] "1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate. However, before a panel seeks such information or advice from any individual or body within the jurisdiction of a Member it shall inform the authorities of that Member. A Member should respond promptly and fully to any request by a panel for such information as the panel considers necessary and appropriate. Confidential information which is provided shall not be revealed without formal authorization from the individual, body, or authorities of the Member providing the information.
2. Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set forth in Appendix 4".

[432] M. D. MASSON-MATTHEE, *The Codex Alimentarius Commission and Its Standards*, p. 192.

[433] *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, Panel Report WT/DS90/R, 1999, para. 5.12 (in this occasion it was consulted the International Monetary Fund in order to have information on India's monetary reserves and its balance-of-payments situation) and *United States – Section 211 Omnibus Appropiations Act of 1998*, Panel Report WT/DS176/R, 2001, paras. 8.12 and 8.13. (here the Panel consulted WIPO on the Paris Convention for factual grounds). For un updated list of the proceedings in which information was sought from other international intergovernmental organizations, see: WTO Analytical Index, DSU – Article 13/Appendix 4 (Jurisprudence), para. 1.3.1.5.2, available at: https://www.wto.org/english/res_e/publications_e/ai17_e/dsu_app4_jur.pdf

[434] "Mr. Codex", as many delegates like refer to him like this.

[435] *EC - Measures Concerning Meat and Meat Products* (Hormones) (US), Panel Report WT/DS26/R/USA, and *EC - Hormones* (Canada), Panel Report WT/DS48/R/CAN, 1997, Transcript of the Joint Meeting with Experts, annex to the report of the Panel, paras. 26 and 27.

this circumstance it was illustrated that it is a useful instrument that however is not without flaws.

First of all, the possibility to recur to the consultancy of international organization give room for manouvre to Panels and AB, remaining a discretionary power, as confirmed in *EC – Sardines*[436]. Second, the Panel may not delegate legal characterization to experts, as expressed in *Australia – Apples*[437]. However, this does not mean that the role and value of experts should be underestimated. Thus, in *US/Canada – Continued Suspension*, the AB stated that "experts consulted by a panel can have a decisive role in a case, especially when it involves highly complex scientific questions"[438]. In particular, their role can be conceived as acting "[…] as an 'interface'

[436] "We also reject the European Communities' claim regarding the fourth instance of supposed impropriety, which relates to the decision of the Panel not to seek information from the Codex Commission. Article 13.2 of the DSU provides that "[p]anels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter." This provision is clearly phrased in a manner that attributes discretion to panels, and we have interpreted it in this vein. Our statements in EC – Hormones, Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items ("Argentina – Textiles and Apparel"), and US – Shrimp, all support the conclusion that, under Article 13.2 of the DSU, panels enjoy discretion as to whether or not to seek information from external sources. In this case, the Panel evidently concluded that it did not need to request information from the Codex Commission, and conducted itself accordingly. We believe that, in doing so, the Panel acted within the limits of Article 13.2 of the DSU". WT/DS231/AB/R, para. 302. The Panel's authority to seek information in *US/Canada – Continued Suspension* was delineated by the AB, drawing from its conclusion *in Japan – Agricultural Products II*, again a broad way: "Panels are understood to have 'significant investigative authority' under Article 13 of the DSU and Article 11.2 of the SPS Agreement and broad discretion in exercising this authority". WT/DS321/AB/R, para. 439.

[437] The AB clarified that experts may assist a Panel in assessing the level of risk related to an SPS measure and potentially suggest alternative available measures, "[…] but whether or not an alternative measure's level of risk achieves a Member's appropriate level of protection is a question of legal characterization, the answer to which will determine the consistency or inconsistency of a Member's measure with its obligation under Article 5.6. Answering this question is not a task that can be delegated to scientific experts". *Australia – Measures Affecting the Importation of Apples from New Zealand*, Appellate Body Report WT/DS367/AB/R, 2010, para. 384. This view was confirmed by the AB in, *India – Quantitative Restrictions* (WT/DS90/AB/R, para. 149). A panel may not only rely on the opinion provided by an expert but must, instead, make an objective assessment of the matter "by critically assessing the views provided by the expert and considering the other data and opinion before reaching its conclusion".

[438] WT/DS321/AB/R, para. 480. Here it is also highlighted that: "Experts appointed by a panel can significantly influence the decision-making process. If a panel does not ensure that the requirements of independence and impartiality are respected in its consultations with the experts, this can compromise the fairness of the proceedings and the impartiality of the decision-making".

between the scientific evidence and the Panel, so as to allow it to perform its task as the trier of fact"[439].

Moreover, the AB's decision in *India – Agricultural Products* provided a sort of general guidance pertaining to the process of consultation with the experts and the conduct of the expert meeting[440]. A Panel must critically assess the views of that international organization that has been consulted, it was reaffirmed that the Panel must make its own assessment of the meaning of a standard and not simply rely on the views of the standard-setter. One final thorny issue, particular relevant for this work, is the affiliations of experts that may raise doubts as to their independence and impartiality. The AB in *US/Canada – Continued Suspension*, rejected the possibility that scientists[441] could be considered objective when assessing their own work[442]. It considered that the affiliation of the appointed experts with the institution that performed the risk assessment at issue may diminish their independence and impartiality[443]. Thus, according to this orientation, it seems poorly constructed the

[439] *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, Panel Report WT/DS320/R, US – Continued Suspension, para. 6.72; Panel Report WT/DS320/R, Canada – Continued Suspension, para. 6.67.

[440] […] [I]t was incumbent on the Panel to discern the meaning of the OIE Code in order to determine whether India's AI measures satisfy Articles 3.1 and 3.2 of the SPS Agreement. In these circumstances, we do not see that the Panel, in connection with its own assessment of the meaning of the OIE Code, can be faulted for engaging in a consultation with, and according weight to the views of, the very international organization under whose auspices that international standard is developed. We would expect that, in discerning the meaning of an international standard, panels ordinarily would have recourse to the views of the relevant standard-setting body, as referred to in Annex A(3) to the SPS Agreement". WT/DS430/AB/R. para. 5.94.

[441] Drs. Boisseau and Boobis, Chairman and Vice-Chairman, and Joint Rapporteur, in JEFCA, were asked to evaluate the European Communities' risk assessment on the basis of the risk assessment developed by their own institution.

[442] "[…] [O]ur concerns arise from their direct involvement in the risk assessments performed by JECFA for the hormones at issue in this dispute and from the particular role that JECFA's risk assessments, and the Codex standards adopted on the basis of those risk assessments, had in this case". WT/DS321/AB/R para. 479.

[443] "[…] [W]e consider that there was an objective basis to conclude that the institutional affiliation with JECFA of Drs. Boisseau and Boobis, and their participation in JECFA's evaluations of the six hormones at issue, was likely to affect or give rise to justifiable doubts as to their independence or impartiality given that the evaluations conducted by JECFA lie at the heart of the controversy between the parties". *Ibid*., para. 481.

prospective of a greater inclusion of Codex experts under DSU Article 13 or SPS Agreement Article 11.2.

In order to guard against making erroneous judgements on technical and scientific issues, WTO Members not only established some scope for seeking expert advice, in particular from international standardizing bodies. In addition, they also left the door open for countries to use the dispute settlement provisions of other International Organizations. However, as pinpointed from the beginning, this option is not available under the Codex framework.

8.4.2. Internal dispute settlement mechanisms: not in the Codex "garden"

SPS Agreement Article 11, in addition to the provision devoted to the request for advices from experts or International Organizations (para. 2), and to the provision that regards the procedural and substantial link between the SPS Agreement and the general dispute settlement regime (para. 1), at para. 3 makes it clear that disputes regarding SPS-related matters may be properly addressed through resort to other mechanisms for the resolution of disputes. In particular:

> "Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement".

Therefore, while the jurisdiction to hear disputes under the SPS Agreement lies exclusively with the WTO's adjudicatory bodies, the SPS Agreement does not interfere other Members' rights and obligations, derived from other international agreements, including alternative dispute settlement mechanisms. This rule is for example available for a member of a regional organization, such as the North America Free Trade Agreement (NAFTA), where it could choose to take SPS-related matters to that organization's dispute settlement mechanisms instead to WTO Panels or AB.

At the same time, the dispute settlement provisions of the SPS Agreement also allow for disputes to be settled in international standardizing bodies on the basis of their norms.

At the time of the Uruguay Round, lengthy discussions were held on the need to strengthen the dispute settlement mechanisms of international standardizing bodies, such as Codex, the IPPC and the OIE, so that these organizations could partake in the resolution of complex disputes. The weaknesses of the dispute settlement mechanisms of these organizations were highlighted. Bothe the OIE and the IPCC have in place their non-binding mechanisms to resolve disputes between their members or contracting parties. Both of these processes focus on finding technical solutions to sanitary or phytosanitary issues.

In the OIE, its mechanism, the OIE informal procedure for dispute mediation[444], takes the form of a request to the Director-General of the OIE for a mediation by a panel of scientific experts. This procedure, as compared to WTO dispute settlement, is less resource-intensive and allows for face-saving solutions, in parallel with the SPS Committee role within the WTO according to Article 12.2. Moreover, the documentation from this mediation and the experts conducting the mediation are available to WTO Panels and AB should the dispute eventually result in a formal case at the WTO.

The IPPC, similarly to the OIE, offers an alternative dispute settlement mechanism for all matters relating to the interpretation and application of the Convention[445]. The contracting parties concerned are required to engage in consultations to resolve the dispute. The disputes are decided by a committee of experts consisting of five members including two that are proposed by the parties. The report of the committee, which in principle is disclosed only to the parties to the dispute, in some circumstances may be provided to the competent bodies of

[444] Provided in Article 5.3.8 of the Terrestrial Animal Health Code 2019.
[445] International Plant Protection Convention, New Revised Text approved by the FAO Conference at its 29th Session - November 1997, Article XIII.

international organizations responsible for resolving trade dispute. Thus, the results of the process can be expected to have an influence in disputes that may be raised at the WTO level under the SPS Agreement.

A similar mechanism was not part of the CAC at the time of the establishment of the Codex, nor after the Uruguay Round and not even now. While at the beginning of the Codex experience this lack could be justified on the basis of a not adequate structure, after decades different reasons can be found. First, nothing has changed. The Codex is still a subsidiary body of FAO and WHO not particularly structured and financed. Second, sanitary and phytosanitary measures are not based only on science. For example, a risk assessment also takes account of potential economic damages and other legitimate factors may be taken into account in order to take a decision under a standard that may affect human health. Thus, a mere technical body, taking as a model the OIE and IPCC examples, may not address adequately this issue. The third, and more interesting aspect in a WTO-Codex interinstitutional dimension, involves the SPS Committee. A hypothetical Codex internal dispute mechanism would be in competition with the functions exercised by the SPS Committee under Article 12.2, as a facilitator and coordinator among States.

Several different interrelationships at the judicial level among the WTO and the Codex have been explored, trying to underline all possible areas of cooperation. The last section deals with the process of delegation that brought significant regulatory authority to the Codex, highlighting the reasons of this process and the underlying positive and negative elements.

9. The delegation of regulatory authority

The increasing of global trade, boundary-defying pollutants and the spreading of contagious diseases have made the world a much more international place. Today, a host of varied phenomena brings States to participate in a dense network of international cooperation that requires them to grant authority to international actors.

This is where delegation[446] comes into play, as a particular form of institutionalized cooperation, where the authority to develop international standards is explicitly delegated to the Codex.

The SPS Agreement does not refer to a list of international standards as a normative source, instead, it specifically identifies three organizations as sources of international SPS standards for the purposes of the Agreement.

The ambiguities and the complexities of a decision which brings to the already described institutional and normative architecture, lie from negotiators' intention to avoid having the WTO itself get into a discussion of what is deemed to be compatible with scientific consensus but, at the same time, be in a position to address if a scientific justification for a trade measures may or may not be considered protectionist. The case law analyzed in the previous Chapter and the discussions within the SPS Committee demonstrate that the WTO is not immune from these discourses and that provisions on standards had not been totally successful in achieving that intention.

First and foremost, such solution was due to the fact that at the time of the Uruguay Round, States did not want to turn what was to become the most important International Organization in the area of trade into a standard setting institution. Moreover, the WTO would have neither the mandate nor the technical competence to set itself this kind of international norms[447].

[446] For general reflections on this issue see: A. B. CURTIS and J. G. KELLEY, *The Concept of International Delegation*, Law and Contemporary Problems, Vol. 71, no.1, 2008. According to the authors view, among the different types of functions that can be delegated, the Codex exercises, in addition to a regulatory authority, even the agenda-setting authority, which should not be underestimated in terms of effects and relevance. For other references see: D. L. NIELSON and M. J. TIERNEY, *Delegation to International Organizations: Agency Theory and World Bank Environmental Reform*, International Organizations, Vol. 57, no. 2, 2003, D. G. HAWKINS, *Delegation and agency in international organizations*, Cambridge University Press, 2006.

[447] D. A. MOTAAL, *The "Multilateral Scientific Consensus" and the World Trade Organization*, p. 856.

9.1 The case of Codex: historical and practical reasons

Documents and statements from the negotiations do not show in a loud and clear way that references to the CAC were understood at that time as an express act of delegation. However, several factors suggest that this conclusion could be the most credible and coherent within the whole context of the Uruguay Round. First, as observed in the Hormones case, the provisions of the SPS Agreement retrospectively endorse standards already developed by these organizations, even before the entry into force of the SPS Agreement itself. Moreover, any SPS standard adopted by the Codex in the future would be automatically recognized as an international standard for purposes of the SPS Agreement, and no requirements for being considered an international standard for the purpose of the SPS Agreement were provided in the WTO framework. The activities of the Codex are thus not set for a specific timeframe and were not constrained by any straitjackets imposed by WTO legal bodies. The centrality of the CAC and its standards within the negotiating practice of the SPS Committee and in the case law, justify calling it as a "quasi-legislator".

Looking back at the time of the Uruguay Round helps to understand why delegation to Codex, and no other options, represented the more practical and feasible solution, and how it was intended by WTO Members at that time. First of all, there are several reasons, expressed from the outset, which lead to the conclusion that a sort of "internal" solution, in the sense of the WTO itself involved in the standard setting, was not possible. The WTO has no such supranational regulatory authority because of a lack of mandate, *per se* an insuperable obstacle to this hypothesis[448]. Further, it lacks

[448] It could be argued that at the time of negotiations States could have opted for giving mandate to the WTO to set autonomously international standards. However, from a trade perspective, besides practical and technical difficulties, this choice seems less desirable and feasible. The sensitiveness that characterizes the area of agriculture and consumers' health has always represented a block to an incisive intervention of international actors in these domains. Furthermore, a direct implication for a trade organization in the development of SPS standards is open to a wide series of criticism in terms of adequacy, transparency and legitimacy. More in general, even considering areas of regulation under the umbrella of other WTO Agreements, the WTO has no mandate to discipline in detailed provisions different fields of international trade, while provide a general framework to foster free trade.

the technical capacity within its legal bodies and institutions[449], including the existence of a scientific committees devoted to draw up SPS standards[450]. An additional difficulty[451] to be considered involves the fact that decisions within the WTO are almost always taken by its Members by consensus[452].

Having said that, negotiators faced a basic choice among two options. The first one was to draw up a list of specific existing standards[453] that would explicitly be recognized as "international standards" for the purposes of the SPS Agreement, and establish a mechanism for extending or modifying that list in order to update it according to the approval by WTO Members. Additions to that list could not have been developed within the framework of WTO institutions, as just explained, but outsourced to international standard-setting authorities that have the required technical expertise. In any case, this option would not have entailed delegation in the sense of a prospective grant of authority[454].

At different times of the negotiations many States agreed on the fact that, within the Working Group on Sanitary and Phytosanitary Regulations and Barriers, a list of existing and considered unproblematic standards should be negotiated and thus

[449] GATT Secretariat, *Summary of the Main Points Raised at the Fourteenth Meeting of the Negotiating Group on Agriculture*, MTN.GNG/NG5/W/103, circulated on 4 September 1989, p. 4.
[450] A possible ex post endorsement of standards by the WTO SPS Committee was rejected explicitly as overly cumbersome or inefficient, T. BUTHE, *The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization,* p. 249. Moreover, institutional constraints have the effect of making the SPS Committee poorly suited, in practice, for setting harmonizing SPS standards.
[451] The three points are raised by Prevost, D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension*, pp. 323-324.
[452] The same difficulty is evident in the Codex, as similar rules apply. However, the likelihood to find an agreement among States reaching consensus on such decisions between countries with interests as diverse as have the Members of the WTO in the areas of agriculture and health, as stagnation in different Rounds shows, is extremely remote.
[453] In the TRIPs Agreement a similar approach was adopted, with references to specific Agreements as the Paris Convention for the Protection of Industrial Property or Berne Convention for the Protection of Literary and Artistic Works. While in theory negotiators could have opted for a single reference to WIPO, in practice, the normative structure, role and binding authority of a treaty on intellectual property rights and of a Codex standard are not comparable at all. In addition, unlike the TRIPS Agreement, that contains positive obligations for minimum standards of protection, especially in some fields as geographical indications, an agreement harmonizing SPS measures would have to contain not only minimum requirements.
[454] T. BUTHE, *The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization,* p. 233.

recognized as international standards[455]. Nevertheless, negotiators soon realized that the approach would be inefficient and would not appear credible[456]. Given the technical nature, standards would soon become outdated and prompt response to new health concerns would be impossible. They need to be constantly updated and checked. To give any forms of effectiveness to standards as a liberalizing tool, they should reflect both Sate interests, market requirements and scientific innovation.

Delegation did not only seek to efficiency; it was expected to give a clear and impartial baseline against which any given country's regulations could be compared to. The final aim was to make more credible the commitment not to use SPS measures to disguise protectionism and delegation to a single and external authority would strengthen the entire process.

Finally, it could be argued that the desire to shift responsibility played a relevant role. There was an explicit recognition that delegation would permit negotiators to focus on general principles, where agreement would be easier to reach, rather than on a list of specific standards, avoiding possible responsibility for the more politically and economically contentious issues[457]. Considering all the dilemmas inherent to this choice, negotiators opted for delegating to an external authority.

Among the Members promoting harmonization through standards[458], the two major active actors involved in proposing solutions were the EC and the US. The purpose was to select an institution that could authoritatively rule on the level of

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[455] Different positions emerged: GATT Secretariat, *Summary of the Main Points Raised at the Fifth Meeting of the Working Group on Sanitary and Phytosanitary Regulations and Barriers*, MTN.GNG/NG5/WGSP/W/13, circulated on 19 March 1990, p.3; GATT Secretariat, *Synoptic Table of Proposals Relating to Key Concepts*, MTN.GNG/NG5/WGSP/W/17/Rev.1, circulated on 29 May 1990; GATT Secretariat, *Framework Agreement on Agriculture Reform Programme*, MTN.GNG/NG5/W/170, circulated on 11 July 1990; GATT Secretariat, *Draft Text for a Decision by Contracting Parties on Sanitary and Phytosanitary Measures*, MTN.GNG/NG5/WGSP/W/26, circulated on 1 October 1990, p. 16; GATT Secretariat, *Draft Text on Sanitary and Phytosanitary Measures*, MTN.GNG/NG5/WGSP/7, circulated on 20 November 1990, p. 10; GATT Secretariat, *The Working Group on Sanitary and Phytosanitary Regulations and Barriers*, MTN.GNG/NG5/WGSP/6, circulated on 15 October, 1990.

[456] T. BUTHE, *The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization,* p. 249.

[457] *Ibid*.

[458] For an overview on different States positions see pp. 16-23.

acceptable risk in regulating standards and establish a formal linkage between that institution and the WTO.

The CAC[459] was not the only choice, but negotiators rejected the proposed alternatives[460]. For example, the EC idea to link the WTO to the United Nations Economic Commission for Europe (UN/ECE) or the OECD[461], that partially addressed health safety standards, was unpopular[462]. Even ISO was considered as a possible candidate. For decades, these organizations, included Codex, coexisted as voluntary standard-setter and none of them was considered as the focal point in the area of food safety[463].

The reason why Codex got negotiators' favors against ISO is more complex that those related to the rejection of the UN/ECE and OECD. During the Uruguay Round, ISO held the support of the EC, Nordic countries and some members of the Cairns group and of developing countries, enjoying a sort of legitimacy as recognized as a standard setter under the Standards Code. However, ISO representatives did not lobby the negotiators to delegate to their organization[464] and at the same time Codex representatives sought to delegitimate ISO as an alternative contender, arguing on the

[459] At the time of the establishment of the CAC, regulatory cooperation in the area of SPS risks was seen more as a technical, rather than politically charged, exercise. As a result, the rules for standard setting were exile and broad, reflecting the informal, cooperative nature of the standards-setting process.
[460] For different discussions among negotiators see: MTN/GNG/NG5/WGSP/2, MTN/GNG/NG5/WGSP/3 and MTN/GNG/NG5/WGSP/W/22.
[461] MTN/GNG/NG5/W/56, MTN/GNG/NG5/W/103 and MTN/GNG/NG5/W/146.
[462] The other Members of the inner-core groups were largely indifferent vis-à-vis this proposal while developing countries considered those institutions as regional and by consequence illegitimate to cooperate with the WTO. M. KIM, *Disguised Protectionism and Linkages to the GATT/WTO*, World Politics, Vol. 64, no. 3, 2012, p. 464. MTN/GNG/NG5/WGSP/W/130.
[463] T. BÜTHE, *The Politics of Food Safety in the Age of Global Trade: The Codex Alimentarius Commission in the SPS Agreement of the WTO*, in *Import Safety: Regulatory Governance in the Global Economy*, C. COGLIANESE, A. M. FINKEL and D. ZARING (eds.), University of Pennsylvania Press, 2009, p. 99.
[464] MTN/GNG/NG5/WGSP/W/24.

basis that it was a non-governmental organization[465] dominated by private interests[466]. Codex was the ideal choice for the US[467], given that the trade promotion was one of its explicit goals[468]. In addition, the US was already one of the key participants in the CAC, US negotiators had a very good understanding of how Codex worked[469] and Codex restricted access by non-state actors, thereby precluding potential capture by

[465] Besides lobbying activities by the international organizations involved, it is reasonable to affirm that the intergovernmental character was a crucial requirement in order to be appointed as the delegated standards setter by negotiators under the SPS Agreement. Such assumption is reflected in SPS Agreement Annex A(4)d. Given that it is not clear whether the intergovernmental character is one of the preconditions under Annex A(4)d; while the SPS Agreement speaks of international organizations open for membership to all Members, the TBT Agreement refers to international bodies whose membership is open to the relevant bodies of at least all Members. This difference in the language may indicate that the SPS Agreement establishes a higher threshold by actually requiring all relevant organizations to have intergovernmental character.

[466] T. BÜTHE, *The Politics of Food Safety in the Age of Global Trade: The Codex Alimentarius Commission in the SPS Agreement of the WTO*, p. 102.

[467] The US during the SPS negotiations showed an approach predominantly from the perspective of an agricultural exporter, rather than from the perspective of a potential importer with relatively high domestic levels of health and safety regulations.
The US position as a whole can be understood from this statement of 1988:
"Uruguay Round participants could seek agreement that the GATT should formally recognize three scientific international standards-setting bodies, including the Codex Alimentarius Commission for food product […] Procedures and cooperative arrangements could be established to link the standards determined by these bodies with the dispute settlement capabilities within the GATT. Such procedures could include:
- Referring trade issues arising from restrictive health and sanitary laws and regulations to the appropriate international standards body for technical discussion, review of pertinent scientific data, or technical judgment on their scientific rationale.
- Requesting international standards organizations to make determinations regarding equivalency of standards.
- GATT Disciplines: Negotiations could be undertaken to elaborate GATT principles and obligations by clarifying and strengthening the technical requirements governing the imposition of health and sanitary trade restrictions. The following objectives could be pursued:
- Strengthen the GATT to require that measures taken to protect human, animal or plant health or life should be based on sound and verifiable scientific evidence.
- Expand the GATT to recognize the principle of equivalency of standard laws and regulations, and to provide for early compulsory consultations on measures that have a high potential for disrupting trade. Technical consultations could be referred to international standards organizations under proposed procedures to enhance cooperation between the GATT and technical bodies.
- Clarify that the GATT explicitly apply to processes and production methods.
- Establish agreements to: base new technical requirements on existing international standards that were established by deliberation of the scientific issues.
- Adopt international standards and codes of practice, and permit the import and distribution of foreign products conforming to appropriate international standards, to the maximum extent feasible".
Negotiating Group on Agriculture, *A Discussion Paper on Issues related to the Negotiations Submitted by the United States*, MTN.GNG/NG5/W/44, circulated on 22 February 1988, pp. 12-13.

[468] Unlike national health authorities, the CAC has no overarching objective of public health protection. Instead, as already observed, it constantly balances its public health objectives with the need to promote international trade.

[469] T. BÜTHE, *The Politics of Food Safety in the Age of Global Trade: The Codex Alimentarius Commission in the SPS Agreement of the WTO*, p. 102.

antitrade groups[470]. These factors ensured that the linkage would indeed facilitate the reduction of negative externalities on trade from health safety standards. Even FAO played a role, in particular on developing countries, linking Codex to FAO development and technical assistance. Last, Codex itself, unlike other alternative institutions, was enterprising and actively lobbied the negotiating group to win the designation, an initial form of cooperation expressed in the previous Chapter.

The solution chose by negotiators[471] was setting a comprehensive delegation in the sense that the CAC was recognized without reservations as the sources of international SPS standards in the area of food safety, retrospectively and prospectively. It can be defined as "one of the most robust and near-exclusive cases of international delegation of regulatory authority"[472].

9.2. The politics of delegation: benefits, limits and legitimacy

What explains international cooperation in the realm of SPS measures, which took the form of a commitment to harmonize on the basis of "international standards," combined with the legal presumption of compliance with GATT/WTO obligations for health and safety regulations that are based on such standards?

Why did States delegate the standards-setting authority and thus the control over the content of the standards that would be recognized under the SPS Agreement? Why did they not instead draw up a list of standards from among existing ones or institutionalize the negotiation of the content of future SPS standards within the GATT/WTO?

The final decision in favor of delegation was made in the context of a comparison of costs and benefits of delegation to the Codex, OIE, and IPPC with the

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[470] D. W. DREZNER, *All Politics Is Global: Explaining International Regulatory Regimes*, Princeton University Press, 2007, p. 162.

[471] Several authors (Scott, Büthe etc.) suggest that a large part of the negotiations took place over lunches and informal, private meetings among a small core group of negotiators and that the final wording of some SPS Agreement Articles is said to have originated on cocktail napkins.

[472] T. Büthe, *The Politics of Food Safety in the Age of Global Trade: The Codex Alimentarius Commission in the SPS Agreement of the WTO*, p. 103.

costs and benefits of delegating to other possible actors, and the costs and benefits of drawing up a list of specific standards, that is, not delegating. A series of criticism arose, mainly related to the legitimacy dimension of standards. Besides the willingness of GATT/WTO Members,

what happened was that his legalized linkage between the issue-areas significantly altered both institutions.

At the time of the Uruguay Round there were good reason for opting for the delegation of setting standards that still persist. First, it offers the opportunity to continuously benefit from the specialized technical expertise and locks in the policy of deference to international standard, thus conducing to an efficient updating of the set of SPS standards and to a continued effectiveness of the SPS Agreement harmonization provisions. Moreover, delegation to international organizations of technical, scientific experts should enjoy widespread support, because science is usually understood as highly objective and neutral, lending such organizations an inherently high degree of legitimacy.

This expectation was especially true for developing countries, given that they associated international standards with multilateralism, which was generally intended favorably, and with international organizations, which enjoyed a high degree of support and legitimacy as such. In this frame, the three sisters seemed to fit into the newly assigned role. Part of the legitimacy of these organizations seems to have been derived from a perception of these organizations as not being majoritarian, even if their rules clearly permitted this sort of decision making. Such perception was due to the Codex practice in the pre-1994 period. There was a strong emphasis on reaching consensus, even if it came at the expense of the quality or specificity of the standard. Nevertheless, several international standards to which they committed themselves are much more costly and complex to implement or certify than expected, and they are allegedly inappropriate in some contexts. During the negotiations, given a lack of expertise and scarcity of economic resources, developing countries concentrated most

of their energies on getting commitments to the "development agenda" and vague promises of assistance, in Articles 9 and 10 of the SPS Agreement[473].

At the same time, in the realm of SPS measures, States' governments are generally particularly aware of the circumstance that the technical basis that characterize a legal tool may develop into politically sensitive health and safety regulations. Thus, this normative framework used to be predominantly a domestic issue[474]. In this regard, it is possible to wonder if the deemed multilateral scientific consensus within the Codex constitute the only possible account of science in the WTO or can there be other options. What scope does the multilateral scientific consensus leave for sovereign and democratic choices at the national level on the appropriate level of protection? In many occasions during the negotiations, concerns were raised about the objectivity of science, and recognized that science is "not monolithic".

Controversies specifically related to science do not exclude criticisms on the legitimacy of standards based on the observation that technocratic ethos is insufficient in the process of standard setting. This may occur if standards are not conceived as having been politically and socially constructed. Therefore, delegating standards setting to recognized technical experts in a relatively insulated, transnational, authority may seem a positive solution, that creates a sort of blame avoidance or shifting responsibility on trade negotiators (or politicians close to a specific issue). In particular, this happens when a specific standard subsequently turns out to be politically contentious in a dispute or unpopular within a community.

Positive and negative aspects of delegation have to be weighed against what means delegating to the Code in the SPS Agreement, therefore drawing the limits of such mechanism. According to Büthe, the "delegation of regulatory authority from sovereign states to international or global organizations in that the SPS Agreement delegates to these organizations the authority to interpret existing obligations and to

[473] This dimension is addressed in a clear and accurate manner in D. PREVOST, *Balancing trade and health in the SPS Agreement: the development dimension.*
[474] For a general reflection see R. O. KEOHANE and H. V. MILNER, Internationalization and Domestic Politics, Cambridge University Press, 1996.

specify rules for the implementation of those obligations"[475]. Although the author provides several reasons why delegation might seem less radical[476], the initial assumption is soundly mistaken. As described in the first two Chapters, the Codex has neither the power to impact and modify the content of the obligations of the SPS Agreement, in particular of the harmonization provision in Article 3, nor the possibility to give a relevant contribution in the interpretation of standards in a WTO dispute. The Codex provides standards, no other functions are delegated in relation to the WTO. Within the perspective of drawing how delegation was conceived, it can be argued that cooperation among the WTO and international standard-setters is not even "à la carte" but only exists on paper, irrespective of whether it was negotiators' intention, a strategic error or simply the only possibility; standards are WTO's sole interlocutor and standards-setters are silent.

The IPPC is merely an international convention, the IPPC Secretariat is the executive body responsible for the administration of the IPPC, a multilateral treaty. At the same time, at the end of the day the CAC is merely the body established jointly by the FAO and WHO to administer their Food Standards Programme. Looking at its statute, it has neither the mandate nor the appropriate legal tools to be involved in a close cooperation with the WTO. The International Office of Epizootics, now called the World Organisation for Animal Health, is an international intergovernmental organization, thus, the more "structured" and "well designed", of the three

[475] T. BUTHE, *The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization*, *Law and Contemporary Problems*, Vol. 71, issue 1, 2008, p. 225-226.

[476] The first point refers to the fact that it is up to each WTO Member to decide the appropriate level of SPS protection it seeks to establish through regulations. However, the freedom to adopt more stringent standards is subject to more, not fewer constraints, as already expressed in the previous Chapter through the analysis of SPS Agreement Article 3. Second, the author observes that the same States that negotiated the SPS Agreement were also Members and active participants in the CAC. Consequently, there is little difference whether the same participants representing a country negotiate in on forum or another. However, besides the hypothesis where such coincidence is not present, the major criticism derives from the concrete risk, as described in the previous section, to discuss about trade politics in a scientific forum and to speak about ractopamine in Geneva, with reciprocal influences and non-observance of their respective fields of activity. The WTO now deals with issues beyond a discrimination-based approach to international trade and addresses the adequacy of scientific foundations of regulation. Although the possible increased politicization of the standard-setting processes of this organization is regrettable, it is perhaps inevitable. *Ibid*., pp. 228-229.

"International Organizations" referred in the SPS Agreement, for the development of a proper cooperation with the WTO. Unlikely, the OIE has not experienced major involvements in this sense.

This would suggest that the form, the extent and the consistency of cooperation is of secondary importance and that standards developed within the framework of Codex are equally relevant in the context of the SPS Agreement.

The fact that the both the act of delegation and cooperation among the WTO and Codex are limited and that at the same time standards are indirect/*de facto* binding under the SPS Agreement lead to the conclusion that while all this call into question the legitimacy of standards, the institutional and legal margins of manouevre seem quite limited.

From an institutional perspective, when States have pursued the mechanism of multilateral cooperation with a degree of success[477], linkages across issue-areas within the WTO framework have increasingly compromised the traditional institutional separation. This leads to the paradox of efforts to deal with States needs and diversities in the face of greater integration in parallel with an increased institutionalization for governance at the international level[478]. In the area of food and safety these consequences are even more exacerbated.

In terms of legitimacy[479], the different requests for more transparency, participation of developing countries, accountability, democratic participation etc.,

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[477] R. O. KEOHANE and J. S. NYE JR, *Between Centralization and Fragmentation: The Club Model of Multilateral Cooperation and Problems of Democratic Legitimacy*, John F. Kennedy School of Government, Harvard University, Faculty Research Working Papers Series, 2001.

[478] M. KIM, *Disguised Protectionism and Linkages to the GATT/WTO*, p. 468.

[479] Here it is referred in general terms, and in a double perspective. However, this work addresses if Codex standards can be considered legitimate according to the WTO framework, thus, in an institutional and internal perspective. However, most of the criticisms in the literature are related to the external legitimacy of Codex standards as a source of soft law and consider different aspects with different approaches. For example: public participation, democratic accountability and particularly the judicial review are analyzed under the lens of trade law in Livermore (*Authority and Legitimacy inn Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius);* the participation of developing countries and transparency in *Pereira* (R. PEREIRA*, Why Would International Administrative Activity Be Any Less Legitimate? – A Study of the Codex Alimentarius Commission,* German Law Journal*,* Vol. 9, no. 11, 2008) and the internal and external accountability of the Codex in Bevilacqua (D. BEVILACQUA, *La Sicurezza Alimentare negli ordinamenti giuridici ultrastatali*, Saggi di Diritto Amministrativo, Giuffrè editore, 2012) with the methodology of Global

joined the same necessity to introduce formal requirements, mainly as procedural rules, in order to respond to such lack of legitimacy. The "politization" or "legalization" that changed Codex after being referred into the SPS Agreement goes in the same direction of formalizing Codex functions. Against this background, is interesting to notice the conflict between the informal attitude of the Codex in its role of promoting policy convergence and the more formal approach of the Codex involved in the in the standards harmonization process[480]. Besides the institutional nature of the Codex[481], the required formalization of governance authority tends to diminish the ability of intergovernmental networks and informal cooperation to perform their functions[482]. At the time of the Uruguay Round, the decision of WTO Members to delegate a relevant function entails that Codex was considered to have sufficient legitimacy. After more than twenty years, during which the status of Codex and its standards has changed, heightened legitimacy demands in the WTO context will subject standards to greater scrutiny.

The legitimacy of Codex standards is the most relevant flaw for this source of law, a character that was more harmless when their nature was purely voluntary. However, this is not the only challenge for the WTO in the context of food safety and standards. Recent developments in international trade involve the digital transformation of the supply chain, the empowerment of consumers and a particular

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Administrative Law (GAL); a comprehensive research which looks at the institutional, procedural and substantive legitimacy is provided in Masson-Matthee (*The Codex Alimentarius Commission and Its Standards*, Chapter V).

[480] M. A. LIVERMORE, *Authority and Legitimacy inn Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, p. 797.

[481] There is no consensus in the literature concerning the nature of the Codex. For some authors it is a hybrid intergovernmental-private administration (B. Kingsbury, N. KRISCH and R. B. STEWART, *The Emergence of Global Administrative Law, Law and Contemporary Problems*, Vol. 68, issue 15, 2005), while for others is an intergovernmental structure (A. HERWIG, *Transnational Governance Regimes for Foods Derived from Bio-Technology and their Legitimacy*, in *Transnational Governance and Constitutionalism*, C. JOERGES, I. J. SAND and G. TEUBNER (eds.), Hart Publishing, 2004) or essentially a public body (J. PAUWELYN, Non-Traditional Patterns of Global Regulation: Is the WTO 'Missing the Boat'?). In the writer's opinion, in a Codex-WTO perspective, in a static dimension it is a public body with limited institutional structure and powers (being a subsidiary body of FAO and WHO) while, in a dynamic and functional sense, as the most important international standards setter in the domain of food safety, it has both a regulatory and a coordination function.

[482] M. A. LIVERMORE, *Authority and Legitimacy inn Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, p. 797.

attention towards sustainability. Even the Codex is part of this. Codex needs to be informed about the possible need for novel or revised standards to continue harmonized adaptation to change. Codex needs to address emerging and new challenges timely and efficiently, while, at the same time, keeping existing standards up to date.

Aside from facilitating international trade, which is one of the Codex purposes, harmonized food safety regulations have the potential to promote innovation. In the context of rapid change and development in international trade, innovation becomes vital to ensure food safety. In this regard, innovation can be conceived as an innovative technology in food production systems that maximize output while reducing resources and waste or as blockchain and other digital solutions that address evolving consumer concerns in terms of transparency and inclusiveness. Codex should tackle the challenge of embracing new technological developments to avoid regulatory divergence among high-income countries, while ensuring to avoid creating barriers for low-income countries' harmonization of food safety regulations and their participation in international trade.

The normative framework of the SPS Agreement and the Codex Procedural Manual clearly affirms that food safety regulations, including standards, should be firmly based on scientific evaluation. However, nowadays policy makers may take into consideration additional factors, such as the social and environmental impact of a measure. Considering that Codex operates under the auspices of FAO and WHO and within the overall United Nations framework, the contribution of Codex to the 2030 Sustainable Development Agenda needs to be clearly articulated and implemented.

As innovation, consumer concerns and sustainability are generally addressed by private standards, and they are not explicitly referred in the WTO framework, the following Chapter address if they are covered under the SPS Agreement and how reclusive should the WTO be to allow them. Moreover, given the lack of a proper normative framework, some *de lege ferenda* recommendations are provided.

Chapter III

Private sector food-safety standards and the SPS Agreement: challenges and possibilities

Summary: 10. Introduction. – **11.** The SPS Committee practice: beyond the definitional problem. – **12.** The SPS Agreement and private sector standards - which room and which role for private actors. – **12.1.** Scope of application of the SPS Agreement. – **12.2.** Provisions of the SPS Agreement relating to the activities of non-governmental standard-setting organizations – Article 13. – **13.** The case for private standards: limits and challenges.

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10. Introduction

The function to take legal measures in order to ensure appropriate level of safety demanded by citizens has always been referred to domestic and international public authorities[483]. At the same time, private actors such as large food producers and supermarket chains also set their own standards of food safety, which often go beyond the requirements of national legislations or international conventions[484]. Public and private standards are potentially, but even in concrete terms, conflicting models of food safety regulation considering that at the basis there are potentially clashing values and purposes: legitimacy, transparency and democracy on the one hand, effectiveness, dynamism and market needs on the other hand. Public authorities retained functions as depositaries of public interests while private actors, besides the fact that they can ensures a broad and effective participation to stakeholders, must be monitored for accountability and be positively steered toward a general interest.

Private standards in the food sector are typically developed by business actors such as associations of large producers or retailers. There is a wide array of private standards, each with its own scope, advantages and constraints, which makes it difficult to treat these standards as a whole. Besides food safety concerns, they include environmental, ethical and quality requirements. The proliferation of private standards is rooted in several factors such as: the decline of consumer confidence in public SPS regulation; the increased liability of retailers; the growing use of food safety and quality claims for product differentiation and growing consumer demands for food characteristics not typically addressed in regulations, such as organic production or

[483] J. WOUTERS, A. MARX and N. HACHEZ, *In Search of a Balanced Relationship: Public and Private Food Safety Standards and International Law*, Working Paper no. 29, Leuven Center for Global Governance Studies, 2009, p. 3.
[484] A. HERWIG, *The Application of the SPS Agreement to Transnational, Private Food Standards*, European Journal of Risk Regulation, Vol. 7, issue 3, 2016, p. 610.

GMOs-free products[485]. They basically aim at reassuring consumers by setting extra-high safety standards and establishing a competitive advantage for their products.

Looking at the impacts of private standards, despite they have the potential to stimulate improvements as a competitive instrument, they can also be extremely burdensome, in particular for suppliers in less developed countries and in for small-scale producers. While compliance with private sector standards is voluntary, these standards have an important impact on international trade and can be *de facto* mandatory[486]. Thus, the distinction between mandatory SPS requirements laid down in regulations, and voluntary SPS standards demanded by private parties, is losing much of its relevance for economic operators in the food and agricultural industries.

This Chapter provides an overview on private standards under the SPS Agreement[487], an interesting point of view for reflections which are, to some extent,

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[485] R. CLARKE, *Private Food Safety Standards: Their Role in Food Safety Regulation and their Impact*, Paper prepared for presentation and discussion at the 33rd Session of the Codex Alimentarius Commission, FAO, 2010, p. 2.

[486] The WTO Secretariat observed that "[p]rivate standards are not mandatory. Suppliers are not required by law to meet private standards. Compliance with private standards is a choice on the part of the supplier. Where private standards become the industry norm, however, choice is limited. Consolidation in food retailing may be a key factor to consider in this context. Where a small number of food retailers account for a high proportion of food sales, the options for suppliers who do not participate in either an individual or collective retailer standard scheme can be considerably reduced. Furthermore, the retailer scheme may be de facto applied as the industry norm by all actors in the supply chain. Thus the choice of whether or not to comply with a voluntary standard becomes a choice between compliance or exit from the market. In this way, the distinction between private voluntary standards and mandatory "official" or "public" requirements can blur". Committee on Sanitary and Phytosanitary Measures, *Private Standards and the SPS Agreement, Note by the Secretariat*, G/SPS/GEN/746, circulated on 24 January 2007, para. 9.

[487] The literature related to this topic is vast, and not limited to the SPS Agreement or to the food safety domain. For a general perspective see: S. R. GANDHI, *Regulating the use of voluntary environmental standards within the World Trade Organization legal regime: Making a case for developing countries,* Journal of World Trade*,* Vol. 39, issue 5, 2005; R. J. ZELADIS*, When do the activities of private parties trigger WTO rules?, Journal of International Economic Law,* Vol. 10, issue 2, 2007; A. ARCURI, *The TBT Agreement and private standards*, in *Research handbook on the WTO and technical barriers to trade*, T. EPPS and M. J. TREBILCOCK (eds.), Edward Elgar Publishing, 2013; L. CHEA and F. PIÉROLA, *The Question of Private Standards in World Trade Organization Law*, Global Trade and Custom Journal, Vol. 11, issue 9, 2016, T. E KASSAHUN, *Can (and) Should the WTO Tame Private Standards? Antitrust Mechanism as an Alternative Roadmap: Lessons from the WTO Telecommunications Reference Paper*, *in International Economic Law: Contemporary Issues*, G. ADINOLFI, F. BAETENS, J. CAIADO, A. LUPONE and A. G. MICARA (eds.), Springer, 2017; E. VAN DER ZEE, *Disciplining Private Standards Under the SPS and TBT Agreement: A Plea for Market-State Procedural Guidelines*, Journal of World Trade, Vol. 52, issue 3, 2018.
In the food domain see: G. SMITH, *Interaction of Public and Private Standards in the Food Chain*, OECD Food, Agriculture and Fisheries Working Papers, No. 15, OECD Publishing, 2009, T. EPPS, *Demanding perfection: Private food standards and the SPS agreement*, in *International Economic Law*

similar to those related to international standards. First of all, in parallel with the analysis of Article 3 in Chapter I, even in this case the textual reading of the relevant articles addresses obscure provisions. Moreover, it is an interesting frame where the SPS Committee is in charge of determining the admissibility of private standards[488], an aspect that confirms again its relevance and centrality in the governance of food safety under the WTO framework. In addition, it is relevant to see the relationship among the WTO and the Codex, and any other possible areas of cooperation.

Given that this research addresses how the WTO is not "missing the boat" of non-traditional regulatory patterns as international standards, private ones even more represent the gauge according to which is possible to evaluate the WTO responsiveness to market needs and consumers concerns.

Until the 1990s, private standards were typically limited to technical and quality aspects, rather than health and safety ones. The 1990s saw the introduction of private sector food-safety standards both in developing and in certain developed countries, where citizens and consumers concerns with food- safety risks is such that they are willing to pay more for the assurance of very high level of protection, exceeding normal regulatory requirements[489]. While the rhetoric of a WTO only State-centered is characterized by a narrow view of the actors involved in international trade, it is very debated if, and how, the WTO could adapt its State-centered rules for appropriate disciplines in the area of private standards. In Geneva, in officials and delegates thinking, the WTO remains a sort of contract among governments, a legal

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and National Authority, M. KOLSKY LEWIS and S. FRANKEL (eds.), Cambridge University Press, 2009, S. HENSON and J. HUMPHREY, *Codex Alimentarius and private standards*, in *Private food law: Governing food chains through contract law, self-regulation, private standards, audits and certification schemes*, B. M. J. VAN DER MEULEN (ed.), Wageningen Academic Publishers, 2011; M. HUIGE, *Private retail standards and the law of the World Trade Organisation*, in *Private food law: Governing food chains through contract law, self-regulation, private standards, audits and certification* schemes; J. WOUTERS and D. GERAETS, *Private food standards and the World Trade Organization: some legal considerations*, World Trade Review, Vol. 11, issue 3, 2012.

[488] As already observed, according to SPS Agreement Annex A paragraph 3(d), besides matters covered by the three sisters, the SPS Committee is in charge to identify the other relevant international organizations developing international standards.

[489] D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities*, South African Yearbook of International Law, Vol. 33, 2008, p. 3.

framework where it is drawn the line between what is public, and thus covered by the Agreements, and what is private, which is not under the WTO umbrella[490].

Scott refers to the rise of private sector standards as a key element in the "transformation of the governance landscape"[491]. In the SPS Agreement context this means to look at the purpose of Article 13, namely, to take account of the reality of shifts in SPS governance. Requiring Members to take reasonable steps to discipline non-governmental actors should be seen in the context of the broader discussion around the contemporary shifts in the locus of governance, where the area of food safety represents an interesting example. As already observed, the growing importance of non-traditional regulatory patterns, in terms of soft norms developed by non-State actors, if not addressed properly, risks to determine the under-inclusiveness of the WTO itself[492].

This kind of discussion often begins with the necessity to define what can be considered a private standard or a private standard-setter and the WTO is no exception. During the 2005, this issue has been explored within two different contexts, the World Trade Report[493] and a series of meetings of the SPS Committee started in that year. The Report - which emphasizes the centrality of a stable and mutually supportive relationship between standards and international trade rules - addresses this point by pinpointing the distinction among private and public standards:

> "Unfortunately, the line separating these two concepts is not entirely clear and probably depends on the perspective from which the issue is examined. From the point of view of international trade law, "public standards" imply the existence of a domestic or internal law which refers to the standard. Yet, when

[490] P. C. MAVROIDIS and R. WOLFE, *Private Standards and the WTO: Reclusive No More*, EUI Working Paper RSCAS, 2016, p. 1.
[491] J. SCOtt, *The WTO Agreement on Sanitary and Phytosanitary Measures: A commentary*, p. 302.
[492] J. PAUWELYN, *Non-traditional patterns of global regulation: Is the WTO "missing the boat"?*, pp. 19-20.
[493] World Trade Organization, *World Trade Report 2005: Exploring the Links Between Trade, Standards and the WTO*, 2005.

> looking at the institutional environment in which standard-setting takes place […] it appears that many standards which are public by law are based on technical specifications and initiatives by private standard-setting organizations. The question thus arises as to whether such standards should indeed be considered "public" […]. [F]rom the point of view of economic theory, the distinction between public and private standards will depend not so much on whether standards are public law, but rather on whose interests are taken into account when a standard is set and enforced. In the case of public standards, it is assumed that the interests of all actors in an economy are taken into account when the standard is set. This implies that the effect on the profits of all companies and the wellbeing of all consumers have been considered. Externalities like those related to the environment or to public health are also factored into the decision-making of the government. Private standards, on the other hand, are assumed to take account only of the profits of firms. Depending on the situation, individual firms will decide if they are willing to cooperate in standard-setting activities. Private standards may implicitly take consumer interests into account, but only if these interests correspond to their own interests. Standards are also sometimes set by non-governmental organizations (NGOs). From the point of view of international trade law such standards would probably be considered "private standards"."[494]

The here expressed legal perspective, which finds the public nature of standards in accordance with the existence of a law referring to them, seems too rigid and formalistic and not in line with the general approach adopted in the SPS Agreement. Here, harmonization does not consider particularly the domestic dimension of standardization, focusing instead on the activities of external standard-setters at the international level. Moreover, the point of view of economic theory,

[494] Ibid., pp. 32-33. Regarding this distinction see also D. VOGEL, *Private global business regulation*, Annual Review of Political Science, Vol. 11, 2008, p. 265.

which refers to the interests at stake, seems a valid option for standards devoted to environmental or societal concerns while, for safety-related ones, the protection of consumer, albeit for different reasons, is relevant in both public and private dimension.

This said, the most important discussions took place within the context of the SPS Committee where the issue of private standards had been extensively discussed at several meetings since it was first raised by Saint Vincent and the Grenadines in 2005[495].

11. The SPS Committee practice: beyond the definitional problem

As the SPS Agreement was negotiated before private sector standards became widespread in the SPS area, it was not intended to extend its disciple to them. Instead, the SPS Agreement was based on the traditional view where the role of governments in regulating food safety measures was exclusive. Ten years after the entry into force of the SPS Agreement it started being disputed in the SPS Committee the proliferation of private standards, which have been developed by non-governmental entities in order to manage supply chains or attend consumer concerns. Even in this case, the importance of the SPS Committee in the frame of food standards emerged, given its

[495] The position of Saint Vincent and the Grenadines is fully expressed in: Committee on Sanitary and Phytosanitary Measures*, Private Industry Standards: Communication from Saint Vincent and the Grenadines*, G/SPS/GEN/766, circulated on 28 February 2007. The main points were that: "2. It is well established that hundreds of private standards exist and that these standards have an important role to play in ensuring that producers focus on areas such as good agricultural practices and traceability, and have resulted in heightened awareness of environmental concerns. 3. The SPS Agreement recognizes the role of the International Standard Setting Bodies (OIE, Codex Alimentarius and the IPPC) as the only authorities for establishing SPS standards. However, the proliferation of standards developed by private interest groups without any reference to the SPS Agreement or consultation with national authorities is a matter of concern and presents numerous challenges to small vulnerable economies. These standards are perceived as being in conflict with the letter and spirit of the SPS Agreement, veritable barriers to trade (which the very SPS Agreement discourages) and having the potential to cause confusion, inequity and lack of transparency". *Ibid*., paras. 2-3. The proximate reason for complaint by Vincent and the Grenadines was the private standard Eurep/Gap (now GLOBALGAP) which set requirements on pesticides used on bananas destined for sale in the EU market. The ultimate purpose of such complaint was to raise general concern on WTO Members for possible conflicts among private standards and the WTO framework. For an overview on this standard see N. HACHEZ and J. WOUTERS, *A Glimpse at the Democratic Legitimacy of Private Standards: Assessing the Public Accountability of GLOBALG.A.P.*, Journal of International Economic Law, Vol. 14, issue 3, 2011.

nature as a proper environment where is possible to discuss and negotiate SPS related issues.

During the first discussion[496] some of the comments[497] by WTO Members on this issue illustrates the lack of clarity presents concerning the role of the SPS Agreement in addressing it[498]. Another discussion was raised in 2006[499], even in this case, once demanded, the EC simply confirmed the existence of the standards and that they were indeed private ones, but that they neither conflict with EC legislation nor with WTO. The SPS Committee decided in October 2008 to request an *ad hoc* working group to undertake a three-step study, and present a report proposing concrete actions for consideration by the Committee at the end of this process[500]. The established working group handed in 2011 a report on "Possible actions for the SPS Committee regarding SPS-Related Private standards"[501].

At its April 2011 meeting[502], from this report, the SPS Committee endorsed and approved five of the six actions put forward by the *ad hoc* working group, namely: Action 1: The SPS Committee should develop a working definition of SPS-related private standards and limit any discussions to these;

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[496] Committee on Sanitary and Phytosanitary Measures *Summary of the Meeting Held on 29-30 June 2005, Note by the Secretariat, Revision*, G/SPS/R/37/Rev 1, circulated on 18 August 2005, para. 16 ss. It regarded the application of Eurep/Gap (now called GLOBALGAP) standards to bananas by UK supermarkets.

[497] The EC affirmed that Eurep/Gap could not be considered as an EC body and thus its standards could not be seen as EC requirements (*ibid*., para. 18); Peru raised the point of the interpretation of SPS Agreement Article 13 on the meaning of non-governmental entities (*ibid*., para. 19) and Mexico restricted legitimate SPS measures under the WTO only if adopted by governmental authorities (*ibid*., para. 19).

[498] D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities,* p. 16.

[499] Committee on Sanitary and Phytosanitary Measures, *Summary of The Meeting of 24 October 2005, Note by the Secretariat*, G/SPS/R/39, circulated on 21 March 2006. In this case Members concerns were related to TESCO's Nature Choices.

[500] Committee on Sanitary and Phytosanitary Measures, *Private Standards - Identifying Practical Actions for the SPS Committee – Summary of Responses*, *Note by the Secretariat,* G/SPS/W/230, circulated on 28 September 2008, paras. 4-7 and Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Of 8-9 October 2008, Note by the Secretariat*, G/SPS/R/53, circulated on 22 December 2008, paras. 122-137.

[501] Committee on Sanitary and Phytosanitary Measures, *Report of the ad hoc Working Group on Sps-Related Private Standards to the SPS Committee*, G/SPS/W/256, circulated on 3 March 2011.

[502] Committee on Sanitary and Phytosanitary Measures, *Actions regarding SPS-Related Private Standards, Decision of the Committee*, G/SPS/55, circulated on 6 April 2011.

Action 2: The SPS Committee should regularly inform the Codex, OIE and IPPC regarding relevant developments in its consideration of SPS-related private standards, and should invite these organizations to likewise regularly inform the SPS Committee of relevant developments in their respective bodies;

Action 3: The SPS Committee invites the Secretariat to inform the Committee on developments in other WTO *fora* which could be of relevance for its discussions on SPS-related private standards;

Action 4: Members are encouraged to communicate with entities involved in SPS-related private standards in their territories to sensitize them to the issues raised in the SPS Committee and underline the importance of international standards established by the Codex, OIE and IPPC;

Action 5: The SPS Committee should explore the possibility of working with the Codex, OIE and IPPC to support the development and/or dissemination of informative materials underlining the importance of international SPS standards[503].

Despite further revision and discussions, consensus was not reached on Action 6[504]. In addition, six other actions were also identified by the working group on which consensus could not be reached[505]. Since 2011, the Committee's discussions on private standards have focused on the five actions agreed by the Committee and, in particular,

[503] *Ibid*.
[504] "Action 6: Members are encouraged to exchange relevant information regarding SPS-related private standards to enhance understanding and awareness on how these compare or relate to international standards and governmental regulations, without prejudice to the different views of Members regarding the scope of the SPS Agreement". G/SPS/W/256, p. 5.
[505] These are: the SPS Committee should provide a forum for the discussion of specific trade concerns related to SPS-related private standards; the SPS Committee should develop guidelines on the implementation of Article 13 of the SPS Agreement; the SPS Committee should develop guidelines on the implementation of Article 13 of the SPS Agreement; the SPS Committee should develop a Code of Good Practice for the preparation, adoption and application of SPS-related private standards; the SPS Committee should develop guidelines for the governments of WTO Members to liaise with entities involved in SPS-related private standards and the SPS Committee should seek clarification as to whether the SPS Agreement applies to SPS-related private standards. G/SPS/W/256, paras. 28-58. Moreover, in this report it is also provided a series of documents referring to private standards from WTO Members and different institutions and also a series of updates from the Codex, OIE, and IPPC on SPS-related private standards as well as updates on developments in other WTO *fora* regarding private standards.

on Action 1 relating to the development of a working definition of SPS-related private standards. In this regard, in 2012, there was a long debate in the Committee, discussing a working definition on the basis of draft versions prepared by the Secretariat, based on proposals from Members[506]. While divergences between Members did not allow a final conclusion on it and the definitions presented were not approved, two final proposals were presented[507]. These steps reflected once again the fact that there was no consensus among Members, the Committee agreed to move the process forward by forming an electronic working group (e-WG) focused on developing a working definition of an SPS-related private standard with China and New Zealand as "co-stewards"[508]. After several rounds of consultation, the e-WG proposed a compromise working definition in September 2014, stating as follows:

> "An SPS-related private standard is a written requirement or condition, or a set of written requirements or conditions, related to food safety, or animal or plant life or health that may be used in commercial transactions and that is

[506] Committee on Sanitary and Phytosanitary Measures, *Proposed Working Definition on SPS-related Private Standards, Note by the Secretaria*t, G/SPS/W/265/Rev. 2, circulated on 28 September 2012.
[507] "SPS-related private standards are [voluntary, market] requirements which are [developed and/or] applied by [private] [non-governmental] entities in order to protect human, animal or plant life or health."
or
"SPS-related private standards are [voluntary, market] requirements which are [developed and/or] applied by [private] [non-governmental] entities, which may [directly or indirectly] affect international trade, and which relate to one of the following objectives:
(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; and
(d) to prevent or limit other damage [within the territory of the Member] from the entry, establishment or spread of pests."
A non-governmental entity was defined as "any entity that does not possess, exercise, or is not vested with governmental authority. Non-governmental entities are private entities, including private sector bodies, companies, industrial organizations, enterprises and private standard-setting bodies". *Ibid*., para. 5.
[508] Committee on Sanitary and Phytosanitary Measures, *Proposed Working Definition of an SPS-Related Private Standard, Submission by China and New Zealand*, G/SPS/W/272, circulated on 8 October 2013.

applied by a non-governmental entity that is not exercising governmental authority"[509]

There was general agreement among WTO Members on the e-WG proposed text for a working definition, with the exception of the EU and US, concerned about the use of the terms "non-governmental entity" and "requirement"[510]. After these two diverging statements, which generally represent the position of developed countries[511], WTO Members agreed to a time out in their efforts after failing to bridge their impasse on the definitional issue. The last step in the activities within the SPS Committee relevant for the definition of private standards was in July 2017, when WTO Members finally reached a compromise by introducing wording which suggested that they were unable to agree on a working definition of SPS-related private standards[512]. The fact that the SPS Committee agreed to give the co-stewards and the e-WG more time to pursue their efforts in trying to bridge differences and come up with a compromise was essentially yet another way of putting off difficult decisions until a later date.

As the SPS Committee discussed and approved the implementation of other four agreed actions, for the purposes of this research, it is relevant to pinpoint the initiatives of the Committee with the three sisters in terms of information exchange mechanisms and collaboration to develop and disseminate informative materials on the importance of international standards. Moreover, it was also highlighted the role of the Codex with private standard-setting bodies in fostering the development and

[509] Committee on Sanitary and Phytosanitary Measures, *Second Report of the Co-Stewards of the Private Standards E-Working Group on Action 1* (G/SPS/55), *Submission by the Co-Stewards of the E-Working Group*, G/SPS/W/281, circulated on 30 September 2015, para. 15.
[510] Committee on Sanitary and Phytosanitary Measures, *Report of the Co-Stewards of the Private Standards E-Working Group to the March 2015 Meeting of the SPS Committee on Action 1 (G/SPS/55*) Submission by the Co-Stewards of the E-Working Group, G/SPS/W/283, circulated on 17 March 2015.
[511] During the discussion within the SPS Committee, developed countries have held the strong view that private standards fall outside the scope of application of the SPS Agreement, and thus no definition or an innocuous definition that would not be perceived as acceptance that they should come under the aegis of the WTO should be provided.
[512] M. DU, *WTO Regulation of Transnational Private Authority in Global Governance*, International and Comparative Law Quarterly, Vol. 67, issue 4, 2018, p. 871.

implementation of science- based food safety and other standards, whether official or private[513].

The case of private standards is no exception to the general one of international standards in terms of WTO-Codex cooperation, as also in such circumstance it is in practice absent. The issue of private standards had been discussed at the thirty-second[514] and thirty-third[515] session of the CAC and at the 2010/11 sessions of the six FAO/WHO Coordinating Committees. Firstly, the CAC noted that the right forum to address the legal implications of private standards was the WTO SPS Committee where all stakeholders were present[516]. Furthermore, in the following report it was specified that the document at stake did not cover the issue of whether the SPS agreement should apply to private food safety standards, which was a question that would continue to be discussed within the WTO SPS Committee[517]. Until now, discussions are carried in parallel without a proper WTO-Codex dialogue.

Besides this aspect, by facing the challenge of private standards, Codex has to show that it is capable to fulfil its role to set science-based international food standards, otherwise private standards would quickly fill the gap left by Codex. Therefore, it should be taken into account the fact that, according to Article 1(b) of the Statutes of the Codex, among the purposes of the Joint FAO/WHO Food Standards Programme, there is the "promot[ion] [and] coordination of all food standards work undertaken by international governmental and *non governmental organizations*" (emphasis added). The increasing adoption of private standards in global agri-food value chains raises important questions about the role played by Codex, both in general and within the

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[513] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the SPS Agreement, Report Adopted by the Committee on 14 July 2017*, G/SPS/62, circulated on 25 July 2017, pp. 23-25.

[514] Codex Alimentarius Commission, 32nd Session, ALINORM 09/32/REP, 29 June – 4 July 2009, paras. 246-271.

[515] Codex Alimentarius Commission, 33rd Session, ALINORM 10/33/REP, 5-9 July 2010, paras. 218-243.
The main conclusions of the paper were that there was a tendency for individual firm standards to be more stringent than relevant Codex standards without scientific basis, whereas collective food safety standards were largely consistent with Codex.

[516] ALINORM 09/32/REP, para. 268.

[517] ALINORM 10/33/REP, para. 219.

context of the SPS Agreement. However, the threatening of Codex standards status is not obvious. Where private standards exist, they predominantly appear to take Codex standards, as their starting point and set a system of requirements and conformity assessment around them[518].

What is relevant here is to delineate, once again, that the SPS Committee is the battleground for discussions on private standards[519], the fact that it is playing a role in the regulation of private standards as an autonomous actor[520]. The five actions approved in 2011 stress that it is the centre-point, setting the contours of what constitutes an SPS related private standards (Action 1), acting as a meeting point for public bodies (Action 2) as well as other WTO institutions (Action 3), and encouraging the use of private standards (Action 5). Despite a broad scope of action granted to the Committee, results are still lacking, especially for divergencies among developing and developed countries[521]. As the majority of private standards originate from and are applied in developed countries, they do not have much incentive to impose additional disciplines on them[522].

The activities of the SPS Committee do not shed the light on the scope of the obligation of WTO Members in relation to the regulation of private standards, which remains vague and open to divergent interpretations under WTO law. The following sections looks at the relevant provisions in the SPS Agreement, that make some inroads into regulating private standards, and it is followed by some *de iure condendo* considerations.

[518] S. HENSON and J. HUMPHREY, *Codex Alimentarius and private standards*, p. 171.
[519] G. MESSENGER, *The Development of World Trade Organization Law: Examining Change in International Law*, Oxford University Press, 2016, p. 150.
[520] *Ibid*., p. 153.
[521] P. C. MAVROIDIS and R. WOLFE, *Private Standards and the WTO: Reclusive No More*, p. 9.
[522] M. DU, *WTO Regulation of Transnational Private Authority in Global Governance,* p. 872.

12. The SPS Agreement and private sector standards - which room and which role for private actors

The negotiating practice of the SPS Agreement, described in Chapter I, shows that at the time of the Uruguay Round, this treaty seeks to distinguish measures aimed at health protection from those that constitute disguised forms of agricultural protectionism. The distinction between regulatory measures and voluntary private sector SPS standards retains importance when one considers the role of the SPS Agreement in disciplining government, not private, SPS requirements. However, discussions in the SPS Committee tell that private standards are not irrelevant in this context. As expressed by the WTO Secretariat, possible examples include where a government authority develop a public standard on the basis of a private one or when a government permits the entry of imports that are certified to comply with a private standard that incorporates or even exceeds the official SPS requirements[523].

Despite that, in the GATT/WTO jurisprudence it is well established that the actions of private actors may be attributable to a WTO Member given some governmental connections to or endorsement of those actions[524]. In particular, two criteria are decisive in the analysis of attribution, as expressed in *Japan – Semiconductors*[525]. First, whether there are reasonable grounds to believe that sufficient incentives or disincentives by the government exist for the measures to take effect and second, whether the operation of the measures is essentially dependent on

[523] Committee on Sanitary and Phytosanitary Measures, *Private Standards and the SPS Agreement, Note by the Secretariat,* G/SPS/GEN/746, circulated on 24 January 2007, para. 17.
[524] See, *inter alia*: *Japan – Measures Affecting Consumer Photographic Film and Paper*, Panel Report WT/DS44/R, 1998, paras. 10.52 ("As the WTO Agreement is an international agreement, in respect of which only national governments and separate customs territories are directly subject to obligations, it follows by implication that the term measure in Article XXIII:1(b) [of GATT 1994] and Article 26.1 of the DSU, as elsewhere in the WTO Agreement, refers only to policies or actions of governments, not those of private parties") and 10.56 ("[…] [T]he fact that an action is taken by private parties does not rule out the possibility that it may be deemed to be governmental if there is sufficient government involvement with it. It is difficult to establish bright-line rules in this regard, however. Thus, that possibility will need to be examined on a case-by-case basis".) and *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, Appellate Body Report WT/DS244/AB/R, 2004, para. 81.
[525] *Japan – Trade in Semiconductors*, Panel Report L/6309, 1988, para. 109.

government action or intervention. This mechanism mainly aims at preventing a WTO Member from circumventing WTO rules by instructing or allowing private entities to carry out activities that are generally prohibited[526].

According to these terms, the question here addressed is not whether private actors, such as NGOs, supermarkets or retail consortia can be bound, directly or indirectly, to the SPS Agreement. Therefore, the SPS Agreement, like more generally WTO Agreements, binds only WTO Members[527]. Given that, only Members actions or omissions can be challenged in dispute settlement proceedings under the covered Agreements. The question is instead if, and in which cases, a Member can be held responsible for the actions of private parties in its territory. This issue has gained prominence considering that the adoption and implementation of SPS rules is increasingly in the hands of actors other than central government[528].

12.1 Scope of application of the SPS Agreement

Questioning the possible application of private standards under the SPS Agreement means to look into the scope of application of the Agreement itself[529]. Both textual references and the relevant case law generally suggest for a traditional view that considers private standards with no governmental involvement to fall outside the regulatory scope of the SPS Agreement.

Annex A (1)[530] refers to SPS measures as "all relevant laws, decrees, regulations, requirements and procedures", being the "[…] form element […] referred

[526] S. M. VILLALPANDO, *Attribution of Conduct to the State: How the Rules of State Responsibility may Be Applied within the WTO Dispute Settlement System*, Journal of International Economic Law, Volume 5, issue 2, 2002, p. 408.
[527] D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities*, p. 15.
[528] *Ibid*., p. 7.
[529] For a general overview see B. RIGOD, *The Purpose of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)*, The European Journal of International Law, Vol. 24, no. 2, 2013.
[530] "Sanitary or phytosanitary measure - Any measure applied:

in the second paragraph of Annex A (1)" [531]. In *EC – Approval and Marketing of Biotech Products*, the Panel stated that "[…] reference to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form. Rather, we consider that SPS measures may in principle take many different legal forms"[532]. This list, while not exhaustive, makes clear the broad reach pf the Agreement[533], seems to consider only measures with a certain degree of government involvement[534].

(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; 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".

[531] *European Communities — Measures Affecting the Approval and Marketing of Biotech Products (EC –Biotech)*, Panel Report WT/DS291/R, 2006, para. 7.149. In this case, the Panel held that the form of an SPS measure can be "laws, decrees or regulations", *i.e.* governmental acts. Although the following decisions had a different reading of how two of the elements (form and nature) are reflected in the second paragraph of Annex A(1) from that adopted by the Panel in EC –Biotech, this has no impacts with reference to private measures. See Panel Report, Australia – Apples, paras. 7.144-7156, *United States — Certain Measures Affecting Imports of Poultry from China*, Panel Report WT/DS392/R, 2010, paras. 7.97-7.101 and Panel Report, *Russia – Pigs (EU)*, paras. 7.82-7.83.

[532] *EC –Biotech*, para. 7.422. Albeit the Panel opted for a broad interpretation of the notion at stake, at the end the measures considered (two European Directives and one Regulation) met the form element of the definition of the term "SPS measures" as they were governmental measures attributable to a WTO Member.

[533] D. PREVOST, *The role of science in mediating the conflict between free trade and health regulation at the WTO: The EC – Biotech Products dispute,* in *Trade, Health and the Environment - The European Union Put to the Test*, M. VAN ASSELT, M. EVERSON, and E. VOS (eds.), Routledge , 2013, p. 171.

[534] According to Bohanes and Sandford, in the WTO parlance, these terms are always associated with governmental action. J. BOHANES and I. SANDFORD, *The (Untapped) Potential of WTO Rules to Discipline Private Trade-Restrictive Conduct*, Working Paper Presented at the Society of International Economic Law Inaugural Conference, Geneva, 2008, p. 38.

In terms of Article 1.1[535], the SPS disciplines apply to measures which may directly or indirectly affect international trade[536] and its relevance for private standards implies to consider which entities are covered by the SPS Agreement, not specified in such provision.

In addition, the role of the SPS Agreement in relation to private standards should even be considered according to its general objective and purpose. The objective of the SPS Agreement is understood as the preservation of market access commitments, making a balance between the sovereign right of a Sate to protect citizens health and safety and the need to prevent protectionism under the guise of SPS rules. Having said that, the application of the SPS disciplines to private standards would not seem to further this objective as there is no evidence that private standards are motivated by protectionism[537].

Even though the textual reading of Annex A (1) and Article 1.1 suggest for a narrow and traditional interpretation that exclude private standards under the SPS Agreement framework, these provisions do not seem completely dispositive of the question of whether private standards fall within this definition. Therefore, the last, and most relevant, provision in this regard is Article 13.

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[535] Article 1 states:
"1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. 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".

[536] See Panel Reports, *EC – Hormones (Canada)* para. 8.39 and *EC – Hormones (US)* para. 8.36, where the Panel stated that: "According to Article 1.1 of the SPS Agreement, two requirements need to be fulfilled for the SPS Agreement to apply: (i) the measure in dispute is a sanitary or phytosanitary measure; and (ii) the measure in dispute may, directly or indirectly, affect international trade".
See also Panel Reports, *EC –Biotech*, para. 7.2554 and *US – Poultry (China)*, para. 7.82.

[537] M. DU, *WTO Regulation of Transnational Private Authority in Global Governance*, p. 884.

12.2 Provisions of the SPS Agreement relating to the activities of non-governmental standard-setting organizations – Article 13

The application of the disciplines in the SPS Agreement to measures adopted by bodies other than the central government, is addressed in Article 13[538]. This provision states that:

> "Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement".

Article 13[539] provides an explanation on which measures Members have to take in order to ensure compliance with WTO rules in two different scenarios. In the first case, it refers to a federal State or to a substantially decentralized State[540] according to

[538] It echoes TBT Agreement Art. 4.1.
[539] According to Scott, it is one of the most intricate articles in the entire SPS Agreement. J. SCOtt, *The WTO Agreement on Sanitary and Phytosanitary Measures: A commentary*, p. 30.
[540] In *Australia – Salmon (Article 21.5 – Canada)*, it was observed that sanitary measures taken by the government of Tasmania, fell under the responsibility of Australia, according to both general international law and WTO law. The Panel stated that: "[a]rticle 13 of the *SPS Agreement* provides unambiguously that: (1) 'Members are fully responsible under [the SPS] Agreement for the observance of all obligations set forth herein'; and (2) 'Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central

its internal public law while in the second case private (non-governmental) organizations assume a relevant role within the scope of application of the SPS Agreement.

Such key rule of the SPS Agreement raises legal questions, as to whether "non-governmental entities" includes the various private standard-setting bodies and standard-implementing bodies and about the scope of the term "reasonable measures".

First of all, the term "non-governmental entitieS" is not defined in the SPS Agreement[541], and there is also no case law under Article 13 of the SPS Agreement that addresses the question whether this provision brings under its scope private sector. Considering that at the time of negotiation of the SPS Agreement private sector standards were not common, it is more likely that the reference to "non-governmental entities" was intended by negotiators to refer to bodies like national standards bureaus. These kinds of bodies generally operate independently of governments, but their food safety standards are frequently incorporated in national regulation[542]. Thus, the original scope of the third sentence of Article 13 seems to be limited to those bodies that had some link to government regulatory agencies[543]. However, until now, it is still an open question.

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government bodies'. Reading these two obligations together, in light of Article 1.1 of the *SPS Agreement* referred to earlier, we consider that sanitary measures taken by the Government of Tasmania, being an 'other than central government' body as recognized by Australia, are subject to the *SPS Agreement* and fall under the responsibility of Australia as WTO Member when it comes to their observance of SPS obligations". Panel Report *Australia – Salmon (Article 21.5 - Canada)* par 7.13, Panel Report, *Australia – Measures Affecting Importation Of Salmon - Recourse To Article 21.5 By Canada*, WT/DS18/RW of 18 February 200. In a similar way see Panel Report *Brazil – Retreaded Tyres* par 7.406.

[541] However, point 8 of Annex 1 (Terms and their definitions for the purpose of this Agreement) of the TBT Agreement defines "non-governmental body" as follows:
"Body other than a central government body or a local government body, including a non- governmental body which has legal power to enforce a technical regulation". See, in this regard: S. HENSON, *The Role of Public and Private Standards in Regulating International Food Markets*, Journal of International Agricultural Trade and Development, Vol. 4, issue 1, 2008, p. 76.
Considering the last part of this provision and in the light of the context and purpose of the TBT (but also SPS Agreements), "non-governmental entities" are not individual economic operators but rather private entities which have been entrusted by government with the performance of certain tasks or which have otherwise a special status.

[542] D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities*, pp. 19-20.

[543] *Ibid*. p. 20.

These uncertainties are even expressed in a report submitted by the United Kingdom to the SPS Committee in October 2007[544]. Indeed, according to that report[545], it is possible to argued both that only private entities which have been entrusted by government with the performance of certain tasks or which have otherwise a special legal status fall under the definition of "non-governmental entities" under the SPS Agreement and that it can be affirmed the opposite. Recognizing that the application of Article 13 depends very much on the definition of "non-governmental body", and the contribution of the SPS Committee in this sense is still lacking, a definitive response seems far from being achieved.

However, a narrow reading of "non-governmental entities" even dovetails with a systemic interpretation between Annex A (1) and Article 13 of the SPS Agreement[546]. Given that the prerequisite of the application of Article 13 is that the measures at issue are SPS measures as defined in Annex A (1), it is unlikely that Article 13 can be interpreted as applying to measures different from those defined in Annex A (1). This view, against an evolutionary interpretation of Article 13[547], not only echoes the traditional perspective that WTO law does not regulate private market behaviors with no governmental interference but also seems to be congruent with several aspect of the SPS Agreement[548]. First of all, the negotiation history of the SPS Agreement. Second, because of the hypothetical vague discipline for private standards under the SPS Agreement. In particular, the third sentence of Article 13 provides that non-governmental entities "comply with the relevant provisions" of the SPS Agreement. All the major obligations of the SPS Agreement expressly refer to Members, whereas the TBT Agreement has at least the Code of Good Practice, and it is problematic to identify the relevant provisions in this sense.

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[544] Committee on Sanitary and Phytosanitary Measures, *Private Voluntary Standards within the WTO Multilateral Framework*, *Submission by the United Kingdom*, G/SPS/GEN/802, circulated on 9 October 2007.
[545] Written by the consultant Digby Gascoine and by the law firm O'Connor and Company, European Lawyers.
[546] A. ARCURI, *The TBT Agreement and Private Standards*, p. 518.
[547] *Ibid.*
[548] Most of the scholars considered, Arcuri, Epps and Prevost, share this view.

In every case, foe every discussion around private standards under the SPS Agreement, it is necessary to bear in mind the vital role of the SPS Committee and its 5 actions and the textual reference in Annex A paragraph 3 (d) to "other relevant international organizations open for membership to all Members, as identified by the Committee".

The second aspect regards the general responsibility of Members under the WTO framework, and, more specifically, it is necessary to examine the limits of States obligations. SPS Agreement Article 13 is in conformity with general public international law for what concerns the overall responsibility of a State for the compliance of obligations regardless of the domestic organization[549]. Two different kind of obligations are present, a positive and a negative one. In the first case, according to sentence three, it encompasses only those reasonable measures which are available[550]. The following sentence in practice prohibits Members from circumventing the Agreement by relying on private action, requiring Members to abstain from any sort of measures that may encourage the violation of a Member's obligations under the Agreement[551].

13. The case for private standards: limits and challenges

According to the analysis of the activities of the SPS Committee and of the relevant legal framework, it seems more reasonable to consider the current regulatory disciplines of the SPS Agreement as not suitable for application to private sector standards. However, the reality of the fact is that such standards are a significant obstacle to trade in food and agricultural products, and cannot be ignored. While

[549] R. VOLKER, *Agreement on the Application of Sanitary and Phytosanitary Measures, Article 13 SPS*, in *WTO: Technical Barriers and SPS Measures,* R. WOLFRUM, P.T. STOLL and A. SEIBERT-FOHR (eds.), Max Planck Commentaries on World Trade Law, Martinus Nijhoff Publishers, 2007, p. 539.
[550] It encompasses an element of proportionality of the measures employed, measured against the object pursued and the possible negative effects. *Ibid*., p. 542.
Generally speaking, it is an obligation of conduct (best-endeavour) rather than an obligation of result. D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities*, p. 22.
[551] The scope of the obligation is conceived in a very broad way.

private voluntary standards may in many instances provide a stimulus to improved production practices and performance in exporting countries, and potentially give a competitive advantage to complying producers, they may also act as significant barriers to market access for some industries in some countries – especially least developed countries. Moreover, they may also be a proportionately greater disadvantage to smaller-scale producers.

At the same time, interventions in private standards, especially by WTO Members within the SPS Committee, have provided strong evidence demonstrating that private standards are too significant to be left unregulated. For all these reasons, private standards should not be permitted to operate entirely outside the purview of WTO discipline. However, a hypothetical regulatory framework should be established according to the following conditions and limits.

First of all, from a normative perspective, it may be complex to draw a line between private standards that could or not, be subjected to the SPS Agreement. According to the definitions provided in so far within the SPS Committee, the recurrent element seems to be the specific purpose of the standard, namely to protect human life or health, crucial to distinguish these measures from the scope of the TBT Agreement. A thorny issue is related to the fact that output legitimacy would require to pursue public or general interest, not merely self-interest. Private standards, as almost merely market-driven seem far from addressing it. In addition, it is complex to identify other possible crucial requirements for a private standard in order to be eligible for the application of the WTO discipline. In any case, possible answers that try to define the scope of application of the SPS Agreement in relation to private standards should be developed using the available, and effective, environment for multilateral discussion and sharing of experiences that is provided by the forum of the SPS Committee[552].

[552] The existence of an institutional context where such discussions can take place should not be underestimate, as confirmed during one of the first meeting in the SPS Committee: "[…] If the private sector could impose unnecessarily trade restrictive standards, and members had no forum in which to advocate some rationalization of these standards, twenty years of discussions in international fora would

Second, regulatory proposals should leave sufficient transnational regulatory space for private standards without excessive legalization. In this regard the WTO may play a legitimacy-enhancing role for private standards as a governance tool in international trade avoiding an excessive formal and rigid approach. A soft framework that generally characterizes the discipline of food safety under the WTO as described in this research. Thus, WTO rules may be regarded as a meta-regulation for private standard-setting schemes, providing guidelines and lending them legitimacy to realize better regulatory objectives[553]. In those circumstances, the question should be: to what extent can the existing WTO legal framework address the trade-related problems posed by private standards, without losing legitimacy?[554].

The suggestion of a separate Code of Good Practice for the Preparation, Adoption and Application of Standards specifically developed for the SPS Agreement[555], on the basis of that contained in Annex 3 of the TBT Agreement, has some merits[556]. This solution can be achieved whether in the form of guidelines adopted by the SPS Committee in terms of its competence under article 12.1 of the SPS Agreement[557] or in the form of an amendment to the SPS Agreement agreed to by the Ministerial Conference under article X of the WTO Agreement[558].

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have been wasted". Committee on Sanitary and Phytosanitary Measures, *Summary of the SPS Committee Meeting Held on 29–30 June 2005, Note by the Secretariat*, G/SPS/R/37/Rev.1, circulated on 18 August 2005, para. 20.

[553] J. BOMHOFF and A. MEUWESE, *The Mega-regulation of Transnational Private Regulation*, Journal of Law and Society, Vol. 38, issue 1, 2011, p. 159.

[554] A. ARCURI, *The TBT Agreement and Private Standards*, p. 522.

[555] This is one of the actions proposed within the SPS Committee where consensus was not reached among WTO Members.

[556] D. PREVOST, *Private sector food-safety standards and the SPS Agreement: Challenges and possibilities*, p. 28.

[557] As already pointed out, it is important to note that the SPS Committee is not empowered to amend the text of the SPS Agreement or to adopt binding interpretations thereof. Instead, its guidelines are voluntary. Nevertheless, as they embody a "subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions", within the meaning of art 31.3(a) of the VCLT they must be taken into account by WTO Panels and the AB when interpreting the relevant provisions of the SPS Agreement.

[558] This second option is highly unlikely to be achieved. It appears highly unlikely that Article 13 of the SPS Agreement will be amended by WTO Members to make a clear obligation to apply the Agreement to the development and use of private voluntary standards, even if only on a best endeavours basis.

The third point refers to the hypothetical limited role of the Codex, losing its authority of exclusive "quasi-legislators" in favour of concurrent private standard setter bodies. It could be argued that, by designating once and for all a competent body for setting what it is considered to an international standards under the SPS Agreement, the WTO runs the risk of stalling the dynamic process which induces different standard-setting actors to constantly develop and review more effective standards out of a competitive spirit[559]. Therefore, with the designation of Codex as its reference in standardization, the WTO did not succeed in outplaying competing private regulatory schemes but has rather tended to threaten its own relevance in the food safety standards circus. In this respect, the lack of speed and sometimes effectiveness of the standards-setting process within the Codex has long been a cause of concern. However, as the described process of delegation to the Codex explains, among the reasons that brought to this solution there was the fact that its public nature and its expertise in the food safety area ensured the legitimacy of the Codex itself. The activities of private standards setter could bring the risk to undermine the science-based and democratically adopted standards of public international organizations. Moreover, the admissibility of the activities of private standards setter under the SPS Agreement should be achieved even through an effective form of cooperation with the already in place functions of the Codex.

[559] J. WOUTERS, A. MARX and N. HACHEZ, *In Search of a Balanced Relationship: Public and Private Food Safety Standards and International Law*, pp. 12-13.

Conclusion

The SPS Agreement does not contain any international standards, nor does it provide for the development of such standards by the WTO framework in general. Thus, at the time of negotiations there was the necessity to look outside "hard law" sources in terms of covered Agreements. The delegation of regulatory authority comes into play, as a particular form of institutionalized cooperation, where the power to develop international standards is explicitly delegated to the Codex. Cooperation is even vital for the activities of the SPS Committee, a central actor in the governance of food safety. However, in practice, there is a weak cooperation among the WTO, the Codex and the other actors involved. The WTO does not exercise a proper control over Codex standards. At the end of the day, the paramount for the legitimacy of Codex standards remains that they should be based on scientific knowledge. Against this background, a series of different conclusions can be drawn.

Non-tariff barriers, harmonization

As trade obligations gradually moved from the dry and technical field of tariffs to the hardcore political controversies, such as health and environmental standards, the world trade system drew more attention. These pressures on international institutions are, ironically, reflections of their success. The definition and reduction of protectionist non-tariff barriers proved much more difficult than making tariff reductions. With the WTO Agreements in 1994, in particular the SPS and the TBT Agreements, Members shifted from a system in which they were nearly completely free to adopt national regulations that affected trade to one where freedom is constrained. Progressive harmonization agreements shift the institutional *locus* of the WTO from a unipolar concentration on trade values to a multipolar balancing of multiple values. This transformation has not been easy, is still not complete and, if not managed with political sensitivity, it could readily derail.

Sources of law, soft law

From a normative perspective, the function of standards, similarly to other soft law sources, is often to regulate difficult and complex situations. The normative framework and the institutional architecture of the SPS Agreement, with its "positive model" of integration, upset the contractual balance provided by the GATT. The responsiveness of soft law to various antinomies, or paradoxes, in WTO law, makes WTO obligations more manageable. More specifically, soft law can elaborate upon hard rules in order to give meaning to the rule's soft content. Soft law can act as a precursor to the development of other legal norms. This is the case of the activities of the SPS Committee in its norms elaboration and in the development of soft rules by the TBT Committee then annexed in the TBT Agreement.

Soft law in the WTO fulfils all of the functions usually ascribed to it in other areas of general international law, namely flexibility, adaptability, speed and simplicity. Other reasons for soft law in the WTO are that it has proven to be particularly useful where the issue is politically sensitive, where there is broad lack of agreement or coordination among WTO Members, where an issue is highly contestable or where cooperation gives rise to distributive conflicts. The Hormones case is a useful example in this sense. The reference in the SPS Agreement, as well as in the TBT Agreement to some extent, to non-binding or soft law norms, that have been developed by external institutional *fora*, raises the paradox of whether the process of incorporation by reference of a rule or a standard in WTO law has the effect of turning a non-binding norm into a binding one.

Institutional aspects, cooperation and actors involved

Because of the strength of the WTO legal-normative structure, the WTO is often portrayed as a set of rules that prevails over other international frameworks. More voice or input ought finally be given to other International Organizations, even

in the light of the broad field and scope of the trade system that tangentially affects, *inter alia*, the protection of the environment, labor rights and the right to food[560]. WTO cooperation with other International Organizations is part of greater contestation and participation in the world trade system itself. Both in its lawmaking and judicial dimension, the WTO must take account of the activities and rules created elsewhere, in particular those that the disputing parties themselves have consented to.

The need for more cooperation among the WTO and intergovernmental organization is not limited to the Codex case, being one of the priorities of the so called "Sutherland Report". On the eve of the tenth anniversary of the WTO, the Director-General, Supachai Panitchpakdi, asked eminent trade experts to look at the state of the WTO and the challenges it faces in the coming years. The report of the Consultative Board to the Director-General, or the Sutherland Report[561] as it is commonly referred to, aims to reflect about ways to improve the functioning of the organization, while safeguarding its strengths. The report[562] calls for more coherence and coordination with other intergovernmental organizations, where, in Chapter IV, it is discussed the "coherence and coordination with intergovernmental organizations" (paras. 144-175[563]). Here it is described in some details the relationships with organizations which,

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[560] Related to this cross-cutting topic see: G. ADINOLFI, *Alimentazione e commercio internazionale nel rapporto del 2009 del Relatore speciale delle Nazioni Unite sul diritto al cibo*, Diritti umani e diritto internazionale, Fascicolo 1, 2010; G. GRUNI, *The EU, World Trade Law and the Right to Food: Rethinking Free Trade Agreements with Developing Countries*, Studies in International Trade and Investment Law, Hart Publishing, 2018.

[561] *The Future of the WTO - Addressing Institutional Challenges in the New Millennium.* Report by the Consultative Board to the Director-General Supachai Panitchpakdi, Geneva, World Trade Organization, 2004. The Members of the Consultative Board were Peter Sutherland (Chairman), Jadish Bhagwati, Kwesi Botchwey, Niall FitzGerald, Koichi Hamada, John H. Jackson, Celso Lafer and Thieny de Montbrial.

[562] Three times since its founding in 1948, the GATT/WTO has turned to outside experts for help in finding solutions to pressing issues relating to the trading system.

[563] The most relevant paragraphs are the following:
"[…] [L]imit the scope of horizontal cooperation is the need to preserve both the creation and interpretation of WTO rules from undue external interference".
"[…] The WTO legal system is part of the international legal system, but is a *lex specialis*. This *lex specialis*, *qua lex specialis*, cannot be changed from the outside by other international organization that have different membership and different rules for the creations of rules".
Supra note 565, paras. 166 and 168. From these observations it is obvious to notice the limited possibilities of cooperation among the WTO and Codex.

by their very nature, have a connection with the WTO but the report essentially limits such call to the World Bank and the International Monetary Fund, not taking into consideration Codex or other cases. Considering the issues analyzed and the solutions proposed, largely defending the *status quo*, the Sutherland Report seems destined to be regarded by history as a missed opportunity. Indeed, it does not stress sufficiently the independent position of the WTO and therefore is too cautious regarding the cooperation with other institutions. Given the normative and institutional architecture of the WTO, proper and effective possibilities of cooperation seem hard. However, the text of the SPS Agreement, the transnational character of standard setting and the global governance of food safety call for such cooperation. At the same time, even the Codex structure makes it difficult to achieve that result.

Another reflection linked to similar aspects is related to the SPS Committee. From a broader perspective, negotiations stall, highlighting the constraints on the use of WTO institutions for norm elaboration. Moreover, the AB is facing the biggest crisis in its existence. Considering the functions attributed to the SPS Committee, its relevance in the SPS domain is even greater. The participatory and cooperative dimension of the SPS Committee, which ensures forward movement, norms evolution and soft law elaboration of hard law provisions, represents an essential element for the development and evolution of international standards as well as of the SPS Agreement obligations.

Science, legitimacy

The main innovations in the SPS Agreement are science-based obligations with their technocratic view, a normative framework where regulatory choices are guided by rational technical analysis and scientific evidence. Legitimacy challenges emerged as a counterpoint to expertise-based model of governance. Risk assessment, for example, in its crucial role that determines the indirect/*de facto* binding nature of international standards, is neither a science nor a single methodology based on sound science, but rather incorporates policy and value reasonings. Within the SPS

Agreement, the process of interpreting and applying legal concepts is connected to and shaped by the application of procedures and analysis adopted by technical bodies and experts. The lack of a rule-making body in the WTO with the task of providing SPS standards creates an institutional gap and opens for criticism in terms of legitimacy. SPS Agreement Article 3 attempts to fill such gap by making use of another, authoritative provider of uniformity and neutrality, namely science. In conclusion, science acts as a balancing factor for the institutional and contractual equilibrium of the Agreement.

Private standards

There are several doubts related to the application of the SPS Agreement to private safety standards. Several reasons suggest for little regulatory space, considering that it is unlikely to have a non-State regulatory tool under the SPS Agreement. However, if the answer to these doubts is affirmative, what is crucial is to seek a structural cooperation with private bodies and the WTO in order to ensure a form of control through soft instruments, so as not to repeat some of the shortcomings of the WTO-Codex linkage.

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