The Future of SPS Governance: SPS-Plus or SPS-Minus?

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Available at: https://works.bepress.com/markus_wagner/20/
The Future of Sanitary and Phytosanitary Governance: SPS-Plus or SPS-Minus?

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Food safety plays an increasingly important role in today’s interdependent trading relations. The existing multilateral rules embodied in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures are increasingly being supplemented by a series of bilateral and multilateral agreements. Unlike debates surrounding intellectual property rights, the negotiations concerning SPS rules in preferential trade agreements are rarely analysed in a systematic and detailed manner. The article uses the SPS Chapter negotiated for purposes of the Trans-Pacific Partnership Agreement (TPPA) as a model for the future of SPS governance and compares it to the existing disciplines under the SPS Agreement. While the future of the TPPA in its current iteration may be in doubt, the US has clearly posited its SPS Chapter as a blueprint for future SPS governance. While the SPS Chapter contains some procedural advances in SPS governance, its substantive rules – or lack thereof – are not only at odds with the existing SPS regime; they exhibit a flawed understanding of scientific enquiry and how to deal with the uncertainty inherent therein.

1 INTRODUCTION

Within the context of international trade negotiations, issues such as intellectual property rights or investment law often receive considerable attention.1 Reports sometimes highlight particularly egregious health hazards concerning food or feed safety or disputes that involve e.g. hormone-treated beef or genetically modified organisms (GMOs). While food safety is a topic of increasing importance – and contention – on the global, regional and domestic level for developed and developing countries alike,2 it rarely receives systematic and detailed attention in public

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debates. This is understandable given that it is often regarded as a specialized sub-field of international trade law. In the negotiations of the Sanitary and Phytosanitary (SPS) Chapter within the Trans-Pacific Partnership Agreement (TPPA) the issue did not receive much public attention. Given the systemic changes it introduces in comparison to the existing SPS regime, this article aims to fill this void and compares and contrasts the SPS Chapter with the WTO SPS Agreement.

Although not exclusively a provenance of agriculture, SPS measures – i.e. measures dealing with food safety as well as animal and plant health regulations – predominantly concern agricultural products and production methods. This is true for at least two reasons: agriculture supports a significant portion of the economy and, even though the economic importance of agriculture is declining in relation to other sectors of the economy, it occupies an important political space in many societies. This in turn gives agricultural producers significant influence in political decision-making processes.

SPS measures are inherently complex as scientific and institutional matters, in turn raising larger questions concerning international economic governance. The locus of governing SPS measures has so far been the WTO, under the umbrella of which the SPS Committee has provided a forum for discussion, negotiation and dispute settlement. As the WTO’s legislative function has increasingly faded in importance, that focus has shifted towards bilateral agreements as well as more integrated and advanced agreements covering trade and other economic areas. The two most prominent examples are the TPPA and the Trans-Atlantic Trade and Investment Partnership (TTIP).
The article analyses the SPS obligations in the TPPA, posits them as one model for a new generation of SPS governance and compares and contrasts them with the disciplines of the SPS Agreement. These new features include a different understanding of scientific uncertainty and various procedural cooperation and coordination requirements. The article sheds light on the extent to which the SPS Chapter can justifiably be characterized as extending beyond, being congruent with, and falling short of the SPS Agreement.

There is a great deal of uncertainty as to whether the US will ratify the TPPA given the continuing and growing general opposition to deepening trade and investment integration and the position of the US administration under Donald Trump in particular. Regardless of the outcome in this concrete instance, deep trade agreements such as the TPPA or TTIP provide a blueprint for future integration efforts and will likely be used in future negotiations.\(^9\) Given that the US has not only provided the impetus for the TPPA and was its most vocal proponents, but also considered the TPPA to constitute the ‘highest-standard and most progressive trade deal ever negotiated’,\(^10\) its treaty language will either remain largely intact and be reintroduced under a different label\(^11\) or be replicated in future agreements.\(^12\)

2 THE TPP AGREEMENT AND ITS SPS CHAPTER AS A MODEL FOR A NEW INTERNATIONAL ECONOMIC GOVERNANCE?

2.1 THE TPPA’S LEGAL AND GEOPOLITICAL FRAMEWORK

TPPA negotiations between the prospective Member States were concluded in October 2015 after nineteen rounds of negotiations as well as chief negotiators and ministerial meetings over a five year period.\(^13\) The moniker ‘mega-regional’ is unusually apt given the countries involved in the TPPA – Australia, Brunei,
Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. They are not only geographically and culturally diverse, but also differ with respect to their geopolitical, trade and investment interests, government involvement in the domestic economies, as well as their levels of development. The TPP extends to 36% of global Gross Domestic Product (GDP) and 23% of international trade. It would almost nullify tariff barriers among the parties and have a significant impact on non-trade barriers.

Originally conceived of as an agreement among only four countries, the entry into the negotiations of the United States created a new dynamic for the negotiations. But even then it was a proposal for an agreement between the US and eight small and medium-sized economies, some of whom already had existing trade agreements with the US. With the addition of Canada, Mexico and Japan, the TPPA became a more economically meaningful undertaking. The inclusion of Japan in particular was important given the lack of existing agreements with many trading partners and the relatively high barriers to entry for foreign products and services.

In addition to what one has come to expect from trade and investment agreements such as National Treatment and Market Access, Rules of Origin, Trade Remedies, SPS Measures and Technical Barriers to Trade (TBT), Trade in Services, Financial Services, Telecommunications, and Intellectual Property, the TPP’s more than 6,000 pages also include chapters on Investment, E-Commerce, Competition, State-Owned and Small and Medium Enterprises (SMEs), Environment, Regulatory Coherence and Transparency and Anti-Corruption. This is in addition to a dispute settlement mechanism and a large number of annexes, related instruments and bilateral agreements.

The TPPA also – with the exception of the European Union (EU) and potentially the North American Free Trade Agreement (NAFTA) – probes more deeply into the domestic policy and administrative sphere of its parties than most

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18 On SMEs, see Heng Wang, *The Implications of the Trans-Pacific Partnership for SMEs: Opportunities and Challenges*, 6 KLRI J. L. & Legis. 45 (2016).
other treaties. This is best evidenced by the inclusion of the chapter on regulatory coherence.\textsuperscript{19}

On a strategic level, the TPPA incorporates a model of economic integration that is quite different from other – competing – models. It has been described as forming part of the US’s pivot towards Asia. Unlike the current ‘shallow’ undertaking by China, which exhibits a considerably lesser degree of integration,\textsuperscript{20} the TPPA has been described as ‘[preventing] … China from setting less-demanding trade rules that would hinder U.S. interests’.\textsuperscript{21} The US government claims that it does so by ‘setting high-standard trade rules’, ‘providing ambitious liberalization of trade and investment’ and ‘creating a new and compelling model for trade’.\textsuperscript{22} This will undoubtedly have implications for the ongoing negotiations between China and the EU and China and the US. It is hard to imagine – as a strategic matter – that the US or the EU would accept a lower standard than those in existing treaties – provided that the TPPA or the TTIP will actually come to fruition.

2.2 The SPS Chapter

The objectives of the SPS Chapter are the protection of human, animal or plant or life or health in states parties in a transparent manner, to ‘reinforce and build on the SPS Agreement’, increase ‘communication, consultation and cooperation between the Parties’, while preventing that SPS measures ‘create unjustified obstacles to trade’, and to ‘encourage the development and adoption of international standards, guidelines and recommendations’.\textsuperscript{23} While the Chapter is said to be novel,\textsuperscript{24} Article 7.4 affirms the Parties’ ‘rights and obligations under the SPS Agreement’


\textsuperscript{20} Wang, supra n. 9, at 5.

\textsuperscript{21} Otto, supra n. 10; Brock R. Williams et al., \textit{The Trans-Pacific Partnership: Strategic Implications} 9–12 (Congressional Research Service 2016).


\textsuperscript{23} Art. 7.2 TPPA.

and that ‘[nothing] in this Agreement shall limit the rights and obligations that each party has under the SPS Agreement’.  

The parallels between the SPS Agreement and the SPS Chapter start with the definition of what constitutes an SPS measure, adopting the definition of Annex A of the SPS Agreement.  

Similarly, the SPS Chapter contains provisions pertaining to product criteria, processing methods, quarantine measures as well as certification, inspection, testing and sampling requirements. It describes risk analysis, prescribes non-discrimination and having a scientific basis for taking regulatory action. Members also need to act in way that is no more trade restrictive than necessary and carry out their measures in a transparent manner. This is buttressed by a number of rules designed to align administrative processes with one another and to provide an institutionalized framework for cooperation and coordination.

The treatment of agricultural products has been and continues to be an important topic for trade negotiators given the outsize influence farming lobbies hold in virtually all countries. TPPA negotiations have again shown the sensitive nature of this policy area, its susceptibility to governmental regulation (often at the behest of domestic pressure groups) and potential for abuse. While most tariffs on agricultural products would be eliminated, this did not mean that those that pushed the hardest for trade liberalization – major agricultural exporters like Australia, Canada, New Zealand and the United States – did not do their utmost to protect domestic industry sectors that were heavily subsidized and lobbied hard to maintain the support they received.

3 THE SPS CHAPTER: PARALLELS WITH THE SPS AGREEMENT, IMPORTANT SPS-PLUS AND SPS-MINUS ELEMENTS

Some SPS Chapter provisions are genuinely ‘legal instruments that include more detailed or demanding rules than those under the SPS Agreement or that contain additional regulatory or cooperative elements beyond the scope of the SPS Agreement’ and thus fall into the SPS-Plus category. This includes moving from ex post facto administrative action to preventive measures, improved cooperation and coordination, communication concerning the imposition and

25 Art. 7.4 TPPA.
26 Art. 7.1 (1) TPPA.
29 Lin, supra n. 7, at 715 (emphasis in original).
implementation of SPS measures between domestic regulatory agencies and an increased level of transparency for SPS measures. Where genuine improvements over the SPS Agreement occur, they concern largely procedural matters. On the flipside, some of the substantive content of the SPS Chapter are problematic deviations from existing SPS Agreement disciplines and are best characterized as SPS-minus.

Both the SPS Agreement and the SPS Chapter attempt to resolve the tension between trade liberalization on the one hand and securing food safety on the other by facilitating the exchange of goods while providing WTO Members requisite regulatory autonomy. The do so however through different methods and with a different weighing of these competing goals. E.g. the SPS Agreement allows for governments to rely on the precautionary principle in situations in which they lack scientific evidence to conduct a risk assessment, but possess ‘pertinent information’ concerning potential risk. The SPS Agreement therefore entails a spectrum of possibilities for governments when making regulatory decisions: ranging from domestic measures conforming with or being based on international standards, to governments carrying out their own risk assessment or relying on the precautionary principle.

The following analysis is not meant to be comprehensive, but is illustrative of some of the major advances and shortcomings of the SPS Chapter. The division between substantive, procedural and dispute settlement aspects serves explanatory purposes and is not meant to express a stark division between these areas. Indeed, in a number of important ways the substantive and procedural elements are mutually reinforcing.

3.1 Substance

3.1[a] Risk Analysis Under the TPPA: Misunderstanding Scientific Uncertainty, Less Regulatory Autonomy, Potentially More Risk

One of the central elements of evaluating SPS measures is how governments deal with risk. There has been considerable discussion in the SPS Agreement

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and some of the scholarly literature over the distinction between the textually mandated risk assessment and what some consider a separate stage of ‘risk management’. Under the framework put forth by the panel in EC – Hormones, risk assessment is a scientific and empirical inquiry devoid of policy considerations and social value judgments, while risk management consists of a Member having to decide, ‘on the basis of its own value judgments, whether it can accept these risks’. The SPS Chapter extends the framework of risk analysis into three components: risk assessment, risk management; and risk communication. While leaving the notion of risk assessment undefined, it specifies that ‘risk management means the weighing of policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures’ and defines risk communication as the ‘exchange of information and opinions concerning risk and risk-related factors between risk assessors, risk managers, consumers and other interested parties’.

Three things are noteworthy about the risk analysis definition. First, by not defining risk assessment the SPS Chapter adopts the approach of the SPS Agreement contained in Annex A:4 SPS Agreement. On that basis the WTO Appellate Body (AB) defined risk assessment as ‘a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions’. It found that a risk assessment does not require the establishment of ‘a minimum quantifiable magnitude of risk’ and can rely on qualitative approaches; that it was insufficient to rely on ‘theoretical uncertainty’; and that there ‘must be an ascertainable risk’. Second, by positively defining risk management the SPS Chapter directly contravenes the AB’s jurisprudence and cements the artificial differentiation between risk assessment and risk management.

34 EC – Hormones (Panel Report), supra n. 32, paras 8.97 and 8.163 (Canada) and paras 8.94 and 8.160 (US).
35 Art. 7.1 (2) TPPA.
36 Annex A:4 distinguishes between ‘disease- or pest-related risks’ and ‘food/feed-borne’ risks with different thresholds of risk and different levels of scrutiny to be applied. See generally Peter-Tobias Stoll & Lutz Strack, Article 5 SPS, in Max Planck Commentaries on World Trade Law, Volume 3: WTO – Technical Barriers and SPS Measures, paras 12–16 (Rüdiger Wolfrum, Peter-Tobias Stoll & Anja Selbert-Fohr eds, Nijhoff 2007).
38 Ibid., para. 253 (j).
management that has been in operation in the US since the 1980s and has been subject to criticism. The AB rejected this distinction on the basis that it lacked textual basis in the SPS Agreement and that it regarded the panel’s focus on largely quantitative empirical analysis as insufficient to mirror policy making in “human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.” Finally, the inclusion of a third stage – risk communication – appears designed to allow for easier dissemination of information and for exporters and importers to react to a change in the regulatory environment or to individual administrative decisions.

In line with the SPS Agreement, the SPS Chapter mandates that measures undertaken to deal with a risk are ‘not more trade restrictive than required to achieve the sanitary or phytosanitary objective, taking into account technical and economic feasibility’ and that measures do not arbitrarily or unjustifiably discriminate between Parties where identical or similar conditions prevail.

International standards play a crucial role in the SPS Chapter to allow for easier movement of goods. Article 7.9 (2) TPPA requires that domestic measures ‘conform to the relevant international standards, guidelines or recommendations’. The SPS Agreement contains a parallel provision in Article 3.2 SPS Agreement. There, conformity with international standards, guidelines or recommendations means presumptive compliance with the SPS Agreement. However, the SPS Agreement is more permissive in that it also allows WTO Members to ‘base’ their SPS measures on international standards, guidelines or recommendations.

The AB found that while ‘there must be a very strong and very close relationship between two things in order to be able to say that one is “the basis for” the other’, a measure ‘may adopt some, not necessarily all, of the elements of the international standard’. The limitation in the TPPA Chapter to conformity means that the only alternative is for SPS measures to be ‘based on documented and objective

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41 EC – Hormones (Appellate Body Report), supra n. 37, para. 181.

42 Ibid., para. 187.

43 Art. 7.9 (6)(c) TPPA.


45 See EC – Hormones (Appellate Body Report), supra n. 37, paras 163 and 177, respectively. The AB found that ‘base on’ means that a measure “‘stands’ or is “founded” or “built” upon or “is supported by” the standard, guidelines or recommendation and that a measure ‘may adopt some, not necessarily all, of the elements of the international standard’.

scientific evidence that is rationally related to the measures’. At first sight, this language echoes the findings of a number of WTO panel and AB decisions concerning the relationship between a governmental measure and the risk assessment to be carried out.47 However, the design of the SPS Chapter, bearing in mind the analysis above concerning risk analysis, limits the regulatory autonomy of governments considerably. This is especially the case in situations in which a government decides that in order to reach its desired level of protection it cannot be in conformity with an international standard.

The SPS Chapter requires that SPS measures ‘are based on scientific principles’ and that in situations in which Member States decide to ‘not conform to international standards, guidelines or recommendations’, measures ‘are based on documented and objective scientific evidence that is rationally related to the measures’.48 The first requirement is congruent with the SPS Agreement, the latter raises considerable problems. It is arguably designed to curb what some consider ‘abusive SPS measures based on minority science … or exaggerated risk management responses to minimal SPS risks to human, animal, or plant life or health’.49 The combination of these rules uses an unrealistic ideal type of science that leaves out non-scientific factors such as the funding of scientific inquiries and its effect on impartiality that have an influence on scientific inquiries.50

In line with this, minority science may be perfectly acceptable as a basis for governmental action as the AB has explained on a number of occasions.51 One major problem is what constitutes ‘documented and objective scientific evidence’ for purposes of Article 7.9.2 TPPA. Reliance on a small number of peer-reviewed studies appears inadequate, and given the confidentiality of consultations in the Cooperative Technical Consultations (CTC), it remains unclear what evidentiary

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48 Art. 7.9 (1) and (2), respectively.
51 EC – Continued Suspension (Appellate Body Report), supra n. 50, paras 591, 705–712. This is the case as long as a minority view is ‘considered to be legitimate science according to the standards of the relevant scientific community’. See also WT/DS367/AB/R Australia – Measures Affecting the Importation of Apples from New Zealand (Appellate Body Report), 29 Nov. 2010, para. 215; Ronald Labonté, Ashley Schram & Arne Ruckert, The Trans-Pacific Partnership: Is It Everything We Feared for Health?, 5 Intl’ J. Health Pol’y & Mgmt. 487, 490 (2016).
The experience in WTO law may be of particular relevance in this regard: panels and the AB found that ‘reputable science’ exists where scientific opinions possess the ‘necessary scientific and methodological rigour’. While these requirements were elaborated in the context of whether governments are permitted to rely on minority viewpoints, they provide guidance for the interpretation of the term ‘documented and objective scientific evidence’.

In sum, the SPS Chapter has a number of shortcomings: it uses a truncated and inadequate conception of science; its definition of ‘risk analysis’ cements the artificial distinction between risk assessment and risk management, thus leaving out important considerations such as institutional affiliation or a population’s propensity to accept particular risk, and it mandates conformity with international standards, indicating that governments have little regulatory autonomy when taking SPS measures.

3.1[b] Omission I: Lack of the Precautionary Principle

A second problem arises through what the TPPA Chapter omits. The SPS Agreement allows for governments to rely on the precautionary principle in situations in which scientific evidence is lacking. This can be the case when scientific inquiry does not permit for definitive conclusions or if there is disagreement on how to interpret existing information. This requires ex ante (1) ‘insufficient scientific evidence’ and (2) the adoption of measures ‘on the basis of available pertinent information’. Ex post, this necessitates (3) seeking additional scientific information and (4) the review of measures within a ‘reasonable period of time’.

The AB has made clear that Article 5.7 SPS Agreement is a qualified exemption from other provisions of the SPS Agreement, but one that does not justify measures that would otherwise be inconsistent with WTO rules. The very existence of Article 5.7 SPS Agreement has had an impact on the interpretation of other parts of the SPS Agreement: the AB found that lax requirements concerning specificity when conducting risk assessments ‘would render Article 5.7 meaningless’.

52 Even proponents of the TPPA and its SPS Chapter recognize this problem. Hendrix & Kotschwar, supra n. 17, at 58.
53 EC – Continued Suspension (Appellate Body Report), supra n. 50, paras 589–590; Australia – Apples (Appellate Body Report), supra n. 51, para 215.
54 Ibid., para 480 et seq.
settlement organs under Article 28.12 (3) TPPA would therefore be contingent upon a provision that is similar to Article 5.7 SPS Agreement or considerable adaptation of the SPS jurisprudence as a whole by TPPA panels.

The TPPA Chapter does not contain an equivalent provision to Article 5.7 SPS Agreement. This is unsurprising given that the TPPA is modelled on US legislation and that the US has consistently labelled the precautionary principle as an ‘approach’ rather than a legal principle. While Article 7.14 TPPA contains language that is arguably similar to the ex post obligations under Article 5.7 SPS Agreement, it does not mention – and due to the flawed understanding of scientific inquiry described above cannot mention – the important ex ante requirements of ‘insufficient scientific evidence’ and ‘available pertinent information’. It states that the Party adopting an emergency measure must notify the other relevant Parties and take their comments into account; that it must review the scientific basis of its emergency measure within six months and make the results of the review available upon request; and that it must conduct a periodic review of the measure.

The provision’s title – ‘Emergency Measures’ – provides important context for its interpretation and shows that it is designed for situations that require urgency. There is no indication in the text of Article 5.7 SPS Agreement or the relevant jurisprudence of such a requirement. WTO jurisprudence has interpreted the term ‘emergency’ in Article XIX GATT and the Safeguard Agreement in the context of safeguard measures. The context for safeguard measures is different in that such measures are taken where a surge in imports causes, or threatens to cause, serious injury to the domestic industry. The AB report in Argentina – Footwear found that emergency measures may only be taken when the increased imports are ‘recent enough, sudden enough, sharp enough and significant enough … to cause or threaten to cause serious injury’. Translated into the SPS context, this means that emergency measures would cover only a small part of the situations that could conceivably fall under the precautionary principle as currently interpreted. This would leave governments with considerably less regulatory autonomy in situations in which positive scientific evidence to conduct a risk assessment is lacking, but there are strong indications for potential harm. Examples may include the nascent issue of endocrine-disrupting compounds or the initial stages of debate concerning climate change.

58 EC – Hormones (Appellate Body Report), supra n. 37, para. 43.
59 See also Art. 7.9 (3) (c) TPPA, although the provision is not comparable to Art. 5.7 SPS Agreement.
60 Art. 7.14 TPPA.
62 Wagner, supra n. 31, at 749 and 757.
This does not mean that the precautionary principle is without problems. The opponents of the precautionary principle point to the potential for abuse. While there is some cause for concern about protectionist measures, proper dispute settlement processes are one way of alleviating such concerns. The AB has correctly adopted a precaution-based approach in its SPS jurisprudence.63 Allowing governments the possibility to regulate only when a situation turns into an emergency and not allowing them to do so when risks with potentially serious consequences can be identified long before they turn into an emergency - as the SPS Chapter does - is problematic and antithetical to what people expect of governments.64

3.1[c] Omission II: GMOs as Concerns for Human Health or a Question of Market Access?

A second omission is less conceptual, but serves as an example of how the important issue of GMOs has been moved outside of the regulatory framework of the SPS Chapter into Chapter 2 on ‘National Treatment and Access for Market Goods’.65 This is arguably because even the limited opportunities for countries to assert their regulatory autonomy under the TPPA Chapter to conduct a risk assessment for GMO products could have proved a stumbling block for the cross-border trade in such products.

Initially, many saw great potential benefits from GMO products: plants can be designed to better withstand climatic effects such as too much or too little rain or sun, can be made to adapt better to climate change, produce higher yields, increase nutritional value and reduce production costs.66 There are also potential downsides, such as the uncertainty concerning human health due to potential antibiotic resistance and increased usage of herbicides due to cross-breeding of GMO plants and surrounding vegetation. The US has for a considerable period of time argued that challenges to GMO products are not based on scientific evidence, but rather politically motivated. This became clear in the EC – Biotech case.67 Argentina, Canada and the US contested the EU’s implementation of a moratorium on the approval of importing agricultural and

64 EC – Hormones (Appellate Body Report), supra n. 37, para. 187.
65 Art. 2.21 TPPA contains a definition of ‘modern biotechnology’ (not limited to GMO products) and limits its application to agricultural products, while Art. 2.27 TPPA includes lengthy and detailed rules concerning the trade of products of modern biotechnology.
66 There is doubt as to the efficacy of GMO products. See Danny Hakim, Doubts About the Promised Bounty of Genetically Modified Crops, N.Y. Times (30 Oct. 2016).
food imports containing so-called biotech products.\footnote{Ibid., paras 8.13–8.16 and paras 18.17–18.20.} It alleged that the measures of the EU and several EU Member States contravened, inter alia, certain provisions of the SPS Agreement. The panel ultimately found that a general de facto moratorium existed with respect to approving biotech products; these measures led to undue delay and were thus inconsistent with Annex C(1) SPS Agreement.\footnote{Ibid., paras 8.13–8.16.}

This decision, heavily criticized by some,\footnote{Caroline Henckels, GMOs in the WTO: A Critique of the Panel’s Legal Reasoning in EC – Biotech, 7 Melb. J. Int’l L. 278 (2006); Oren Perez, Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel’s Decision, 6 World Trade Rev. 265.} was never appealed. Part of the discussion revolved around the issue of whether GMOs were too novel so that informed decisions concerning the risk such products pose for human or animal health could not be reached. The proponents of GMOs argue that scientific studies do not show actual risk, while the opponents claim that the long-term risks of GMOs have not been properly investigated. Rather than allowing for products containing GMOs to be introduced, this view would require additional testing so as to ascertain whether actual risk exists.\footnote{Angelika Hilbeck et al., No Scientific Consensus on GMO Safety, 27 Envtl. Sci. Eur. 1 (2015); Marek Cuhra, Review of GMO Safety Assessment Studies: Glyphosate Residues in Roundup Ready Crops is an Ignored Issue, 27 Envtl. Sci. Eur. 11 (2015). For conflicting meta-studies, see Sheldon Krimsky, An Illusory Consensus Behind GMO Health Assessment, Sci., Tech. & Hum. Values 1 (2015); Alessandro Nicolia et al., An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research, 34 Critical Revs Biotechnology 77 (2014).} Despite claims to the contrary, there is a robust discussion and thus serious doubt concerning the health implications of food containing GMOs.\footnote{Hendrix & Kotschwar, supra n. 17, at 42 and 58.}

The World Health Organization indicates that the products currently on the market have not shown adverse effects, but also that ‘individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods’\footnote{Hendrix & Kotschwar, supra n. 17, at 42 and 58.}.

The placement of products containing ‘modern biotechnology’ (including GMOs) into the national treatment and market access chapter appears incongruent in light of these ongoing discussions concerning the potential effect of GMO foods on human, animal or plant life or health. Disputes concerning GMO products would have to be brought under Chapter 2, rather than under the more stringent – although by comparison relatively weak – disciplines of the SPS Chapter. Some of the provisions of Article 2.27 TPPA indicate that Parties may not need to change their regulatory framework. Article 2.27 (2) and (3) TPPA do not ‘prevent a Party...
from adopting measures in accordance with its rights and obligations under the WTO Agreement’ and do not ‘require a Party to adopt or modify its laws, regulations and policies for the control of products of modern biotechnology within its territory’. Nevertheless, there are considerable reporting and documentation requirements that apply to this class of products, including information regarding risk assessments conducted, contact information for the applicable entity, and any detection methodologies employed. It therefore stands to reason that the rationale for the inclusion of this provision in Chapter 2 was to soften the resistance to GMO products and to shift the balance of power towards large agricultural commodity exporters. 74

3.1[d] Summary

While parts of the SPS Chapter are congruent with the SPS Agreement, it also contains significant deviations. The three issues discussed in this section are cause for concern, as they have become standard SPS-related matters. They are significant for a variety of reasons, not least of which is how to adequately translate the results of scientific evidence into legal decision-making processes and language. 75 Given the potentially high stakes concerning human health that is at the heart of the SPS disciplines in any trade agreement and given the potential model character of the TPPA for future agreements, this development is a troubling departure from the status quo.

3.2 Administrative Procedure

The majority of the novel content of the SPS Chapter concerns administrative processes for importing or exporting agricultural products. Compared to the SPS Agreement, the SPS Chapter extends these disciplines further, giving private parties a role in the rule-making process and in administrative decisions. Beyond these changes, the procedural rules introduce preventive aspects that are a significant departure from the SPS Agreement.

3.2[a] Prevention as a New Paradigm

Some of the SPS Chapter provisions emulate a trend that has been observed in bilateral agreements, namely ‘shift[ing] from response-oriented border inspection to a more preventive approach’. 76 The underlying idea is to prevent unsafe food or

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75 Wagner, supra n. 63.
76 Lin, supra n. 7, 715.
feed products from entering an importing Party rather than having to react once a harm has already materialized in the importing country. Such measures can take place at the country level, at the producer level, or a combination of both. The SPS Chapter grants each importing Party the right to audit the exporting Party’s authorities and inspection systems on a ‘systems-wide basis’.\textsuperscript{77} This includes audits of the inspection programs of the exporting Party as well as inspections of the facilities. Such audits are to be based on the ‘relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations’.\textsuperscript{78} The SPS Chapter provides that the Parties need to come to an understanding of the auditing process prior to its commencement and gives the audited Party an opportunity to comment on the findings. The auditing Party needs to take these comments into consideration before reaching its conclusion and/or taking any action.\textsuperscript{79} Such conclusions and action need to be supported by ‘objective evidence and data that can be verified’,\textsuperscript{80} with such data being furnished to the audited Party upon request. In this process of reaching a decision or taking action, the provision somewhat cryptically calls for ‘taking into account the auditing Party’s knowledge of, relevant experience with, and confidence in, the audited Party’. This provision appears to give the auditing Party a considerable amount of discretion. Finally, the Parties are to ensure that any confidential information obtained during the audit process not be disclosed.\textsuperscript{81}

These changes are significant for a number of reasons. It allows for a systems-wide audit, thus ascertaining whether the work conducted by domestic agencies itself is sound as opposed to carrying out audits on an individual manufacturing plant basis. This requires trust in domestic inspection schemes and thus at a less granular level compared to inspections at the producer level. Obviating the need for domestic production plants to be audited by multiple foreign agencies will arguably increase efficiency. Whether this results in an equivalent level of food and feed safety will remain to be seen. It is possible that countries with less developed food safety systems will be able to gain a similar level of expertise and capacity as the more developed TPPA Parties. It is also possible that the administrative burden for developing such expertise proves to be too onerous. The future will show whether shifting the burden from the importing to the exporting country will lead to a decrease in exports for developing countries.

\textsuperscript{77} Art. 7.10 (1) and (2) TPPA.
\textsuperscript{78} Art. 7.10 (3) TPPA.
\textsuperscript{79} Art. 7.10 (4)–(5) TPPA.
\textsuperscript{80} Art. 7(6) TPPA.
\textsuperscript{81} Art. 7.10 (8) TPPA.
3.2[b] Cooperation and Coordination Measures

The TPPA Chapter contains a number of administrative measures that are designed to coordinate procedures and thereby facilitate trade between TPPA Members. Many of these measures are a positive step towards greater harmonization among administrative agencies, although it will remain to be seen to what extent the power imbalances between different participating countries will have an effect on the application of these rules.

3.2[b][i] Customs and Trade Facilitation

In order to expedite the customs process for products subject to SPS measures and therefore to avoid delays or spoilage of products, the SPS Chapter contains detailed rules regarding the obligations of TPPA Parties with respect to import checks. In line with the Trade Facilitation Agreement, the procedure must be based on the risks associated with importations; conducted without delay; and allow TPPA Parties to obtain information on the procedures, analytical methods, quality controls, sampling procedures and facilities used. It obliges the importing Party to conduct assessments in facilities that are consistent with international laboratory standards and imposes strict record keeping.

An importing Party is required to notify either the importer or its agent, the exporter, the manufacturer or the exporting Party of cases of import prohibition or restriction. Article 7.11 (7) TPPA mandates that this notification contains the reasons for the measure, its legal basis and the status of the goods in question. This must be done no later than seven days from the decision to prohibit or restrict the import. In order to further expedite the process such notification is to be carried out by electronic means if practicable. All parties have the opportunity to obtain a review of the decision.

Finally, if there are patterns of non-conformity with an SPS measure the importing Party must notify the exporting Party. An exporting Party can request information on goods from its territory that were found not to be in conformity with the importing Party’s SPS measures.

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82 Agreement on Trade Facilitation, WT/L/940, 28 Nov. 2014.
83 Arts 7.11(1), (2) and (4) TPPA.
84 Art. 7.11(6) TPPA.
85 Art. 7.11 (7)–(8) TPPA.
3.2[b][ii] Recognition of Equivalence

A second trade facilitation measure is the recognition of equivalent rules, an important technique to abolish non-discriminatory trade barriers. The technical requirements of different regulatory regimes may have evolved for historical reasons or because of different food safety risks in different parts of the world. One option for such recognition lies in harmonizing the rules among different countries, as exemplified in Article 3 SPS Agreement. The other avenue is through mutual recognition that is often administrative in nature and generally based on consensus.

The SPS Agreement provision on equivalence is sparse, focusing on equivalence of specific products, and is aspirational in nature: WTO Members need to accept other Members’ SPS measures as equivalent only if the exporting Member can objectively demonstrate that its measures achieve the same level of protection as that of the importing Member. A subsequent SPS Committee report laid out the procedure in greater detail.

In line with this report, the SPS Chapter attempts to achieve equivalence, ‘to the extent feasible and appropriate’, either for a group of measures taken by a Member State or ‘on a systems-wide basis’, taking into account relevant guidance by the WTO SPS Committee and international standards, guidelines and recommendations. Exporting Parties can request that importing Parties explain the objective and rationale of their SPS measures, having to identify the risks the SPS measures are designed to address in the process. Any request for equivalence assessment will have to be carried out expeditiously and explain the processes and plans to be employed in the determining whether equivalence status is to be granted. This is the case when a measure of the exporting Party achieves the same level of protection as the importing Party’s measure, or ‘has the same effect in achieving the objective as the importing Party’s measure’. The importing Party is required to implement the measure within a reasonable period of time and can report the outcome to the Committee on SPS Measures. In case a Party does not

87 Art. 4 SPS Agreement.
88 Decision on the Implementation of Art. 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (G/SPS/19/Rev.2, World Trade Organization Committee on Sanitary and Phytosanitary Measure 23 July 2004). This decision was originally taken in order for developing countries to have easier access to the markets of developed countries. Mary E Footer, The (Re)turn to ‘Soft Law’ in Reconciling the Antinomies in WTO Law, 11 Melb. J. Int’l L. 241, 264–265 (2010).
89 Art. 7.8 (1) TPPA.
90 Art. 7.8 (2) TPPA.
91 Art. 7.8 (3)–(4) TPPA.
92 Art. 7.8 (6) (a)–(b) TPPA.
recognize equivalence the importing Party is required to provide its rationale to the exporting Party.\footnote{Art. 7.8 (7)–(9) TPPA.} When making such a determination the importing Party is – different from the SPS Agreement – not only obliged to take into account ‘available knowledge, information and relevant experience’, but also the ‘regulatory competence of the exporting Party’\footnote{Art. 7.8 (5) TPPA.}

While this provision places a considerable burden on importing countries, it by and large replicates existing WTO SPS disciplines. It will remain to be seen whether this provision essentially serves as a rapid harmonization tool on the basis of the ‘regulatory competence’ of the major agricultural exporters among TPPA Parties.

3.2[b][iii]  Improved Coordination Between Domestic Regulatory Agencies

A third element in which the SPS Chapter goes beyond the SPS Agreement is where it aims to improve coordination between domestic regulatory agencies. As further explained below, the CTC contributes to improving the coordination between the relevant domestic bureaucracies. Another is the Committee on SPS Measures, which is designed to consider and coordinate actions on SPS measures among the TPPA Parties themselves and as a stepping stone to the WTO SPS Committee. Institutionalizing the cooperation between the TPPA Parties and holding periodic meetings has at least three benefits. It will arguably lead to closer coordination among the members of the TPPA and lead to more streamlined process between the different bureaucracies; it may aid in avoiding the costly and time-consuming path of formal dispute settlement and it provides a forum for further deepening and broadening of the cooperation among the TPPA Parties.

3.2[b][iv]  Increased Communication

A final element worth noting is the requirement for additional communication for domestic agencies. In addition to carrying out a risk assessment and managing risk, governments are obliged to communicate the results of their efforts in reaching the appropriate level of protection. Article 7.1 (2) TPPA defines risk communication as ‘the exchange of information and opinions concerning risk and risk-related factors between risk assessors, risk managers, consumers and other interested parties’.

Such communication can take place between TPPA Parties, e.g. through the Committee on SPS Measures. Article 7.7 TPPA mandates that in situations in which a Party adopts a measure that affects products from a particular region in an
exporting Party, it is obliged to notify the exporting Party in writing. Similar requirements are contained in Article 7.8 TPPA concerning Equivalence. Given that audits under the TPPA take place on a systems-wide basis, Article 7.11 (9) TPPA requires that the importing Party notify the exporting Party in situations of ‘significant, sustained or recurring pattern of non-conformity with a sanitary or phytosanitary measure’. Similar notification requirements exist with respect to emergency measures under Article 7.14 TPPA.

A second line of communication is between the importing Party and private parties. This is the case in situations in which a shipment is being inspected. Given that a large number of SPS concerns are raised with respect to perishable items, Article 7.11 (6) TPPA attempts to provide importers or exporters a chance to remedy the concerns of administrative agencies rather than having to face the possibility of having their products discarded. As pointed out above, the importing Party has to communicate that a shipment has been inspected and restrictions have been imposed, as well as the rationale and legal basis for its action. This imposes considerable obligations on the importing Party with respect to its administrative processes and the human resources required. The efficacy of this rule will have to be assessed in the future, but it at least has the potential to remedy the problem of food waste as a result of border measures.

Finally, the TPPA mandates communication to a more general audience. In reality, communication of this kind will likely be limited to experts and industry groups.

3.2[c] Transparency and Public Engagement in the Rule-Making Process

Parties are obliged to document the risk analysis process and provide information to other TPPA Parties. Article 7.9 (4) TPPA imports something akin to the so-called notice and comment procedure from US administrative law into the TPPA.

The idea behind the notice and comment procedure is to allow for the inclusion of stakeholders and the broadening of the public understanding. The process is designed to provide the interested public with the initial analysis of the administrative agency, the ability to influence governmental rule-making, and an increase in the transparency of the rule-making process.

The TPPA ‘translates’ these requirements such that Parties are required to ‘[provide] interested persons … an opportunity to comment, in a manner to be

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95 Art. 7.11 (7) TPPA.
96 See also Art. 9 Agreement on Trade Facilitation, WT/L/940, 28 Nov. 2014.
determined by that Party'. This obligation is reiterated in the provision on transparency, which explains ‘the value of sharing information about SPS measures on an ongoing basis’. Going beyond other parts of the TPPA, the SPS Chapter mandates the publication of written comments or a summary of the written comments from the public with respect to proposed SPS measures when publishing an SPS measure.

Whether the ‘alignment’ of other countries’ safety and regulatory systems with that of the US is an unmitigated good is open to question. Transplanting domestic administrative rules from one jurisdiction to another entails a range of difficulties. The US experience with administrative rule-making – especially as it concerns the ability of some participants in the process to have an outsized influence on the rule-making process – may also be a cautious tale.

Other areas in which transparency is mandated concern the publication of new or altered rules (including an explanation of the rationale for alteration), risks arising within a Member’s territory and new scientific insights that may alter the regulatory framework.

3.2[d] Committee on Sanitary and Phytosanitary Measures

Composed of government representatives, the objectives of the Committee on SPS Measures are to enhance the Chapter’s implementation and to be a forum for consideration of, as well as communication and cooperation on, SPS matters of mutual interest. The most interesting aspect of this committee could be the formulation of common positions before the WTO SPS Committee as well as meetings held under the auspices of the Codex Alimentarius Commission, the World Organization for Animal Health and the International Plant Protection Convention. Given the already strong position of industry groups in these forums, fears of weakening the role of the

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98 Art. 7.9 (4) TPPA.
99 Art. 7.13 (4) TPPA.
100 Art. 7.13 (1) TPPA.
101 Art. 7.13 (5) TPPA.
102 See the contributions in Daniel P. Carpenter & David A. Moss, Preventing Regulatory Capture: Special Interest Influence and How to Limit It (Cambridge University Press 2014).
103 Arts 7.8–7.11 TPPA.
104 Art. 7.2 TPPA.
105 Art. 7.5 (3)(g) TPPA.
WTO SPS Committee are not unfounded. Depending on the degree of agreement among the TPPA Parties, this committee could lay the groundwork for a powerful common voice in standard-setting efforts in other fora, especially in light of the substantive differences between the SPS Chapter and the SPS Agreement analysed above and further discussed below.

3.3 Dispute settlement: a three step process

SPS measures are subject to the dispute settlement process laid out in Chapter 28 TPPA. Dispute settlement under the SPS Chapter is a three-step process: the first step consists of a domestic administrative process, if available; the second is geared towards finding a diplomatic solution; this is followed by a more formal dispute settlement process should the former approaches not resolve the conflict. At any time however, if a party determines that the 'continued use of the administrative procedures or bilateral or other mechanisms would not resolve the matter', it can resort to so-called CTC.

3.3[a] Cooperative Technical Consultations

Resort to the CTC is contingent on the requesting party or parties to make a written request to the primary representative of the responding party, identifying the reason for the request, and setting out the applicable SPS Chapter provisions. The following provisions contain detailed rules concerning the timeline for an initial response and an initial meeting, with the prospect of resolving the disputes within 180 days of the request. By default, all communication between relevant trade and regulatory agencies is to be kept confidential unless the parties agree otherwise or other obligations mandate greater transparency. Such a greater degree of transparency at this stage would be desirable as some disputes over SPS measures – ostensibly based on scientific evidence – may be resolved at this stage and it would be important to understand the reasoning for any form of dispute resolution.

108 Art. 7.17 (1) TPPA.
109 Arts. 7.17 (2)–(4) TPPA. Meetings can take place in person or by electronic means.
110 Arts 7.17 (5)–(6) TPPA.
Formal Dispute Settlement

Only upon exhausting the consultative procedure before the CTC can a Party resort to the formal dispute settlement process under Chapter 28 TPPA. TPPA panels will have to consider the interpretation by WTO panels and the AB when considering provisions that have been incorporated into the TPPA. The SPS Chapter is replete with references to the SPS Agreement. Article 7.4 TPPA states that the parties’ ‘rights and obligations under the SPS Agreement’ are affirmed and that ‘nothing in this Agreement shall limit the rights and obligations that each Party has under the SPS Agreement’. This can potentially lead to problems in situations in which an agreement’s approach is different from that already in existence within the WTO. The AB has interpreted the SPS Agreement in light of the balance the agreement strikes between the need for universal rules and a government’s regulatory autonomy, which e.g. includes the ability to rely on the precautionary principle. The lack of such an option must have an impact not only on how a panel interprets the language of the SPS Chapter, but also how it translates the relevant WTO jurisprudence. A similar concern arises in determining which factors are to be taken into consideration when making a risk assessment. The AB has made clear that Article 5.2 SPS Agreement is an open-ended list, an approach that is in contradistinction to the SPS Chapter.

The SPS Chapter itself contains a provision pertaining to dispute settlement regarding the use of experts (Article 7.18 TPPA). The ability of a panel to avail itself of technical expertise either at the request of the parties or on its own initiative is appropriate given the often intricate difficulties WTO dispute settlement panels have faced when interpreting scientific evidence. In this context, the AB has rightly pointed out the proper division of labour between the experts and WTO panels: the latter are tasked to make legal decisions on the basis of information received from the former, but are not in a position to decide what the ‘best science’ consists of.

Given the potential for conflicting jurisprudence and the increasing significance of human health in international trade, the dispute settlement chapter’s provision for greater transparency in dispute settlement is to be welcomed. This includes the ability of the public to access the parties’ submissions, the openness of the proceedings to the

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112 See Art. 28.12 TPPA.
113 See generally EC – Hormones (Appellate Body Report), supra n. 37. See also Wagner, supra n. 63, at 194 et seq.
115 Wagner, supra n. 63, at 160 et seq.
public unless the parties agree otherwise and the publication of the majority of the decisions. The dispute settlement chapter also permits the submission of \textit{amicus curiae} briefs, although it will have to be seen to what extent adjudicators will make use of such submissions.

4 CONCLUSION

The SPS Chapter of the TPPA contains a number of novel and innovative features. As outlined above, some of the procedural provisions genuinely fall into the ‘SPS-Plus category’. This is true – and for as long as it is approached in good faith – with respect to greater coordination among administrative agencies, increased transparency in rule-making and decision-making, and the recognition of equivalence. On the other hand, the conception of science, the manner in which the SPS Chapter deals with scientific uncertainty and the lack of the precautionary principle is a genuine weakness of the SPS Chapter. Moreover, given the different substantive rules, it is not implausible that governments wishing to bring a case may choose the forum that they think may best fit their needs. This is not a new phenomenon, but could in the long term have an impact on the jurisprudence under the SPS Agreement.

Although the US entered the TPPA negotiations late, it did so – with the backing and under pressure of industry groups – with the idea of crafting new rules. Once standards are set on the (mega)regional level and used as a template for further preferential agreements, the stage is set for multilateralizing them at the WTO level with the help of the new partners. Those that favour a different regulatory approach – most notably the EU – may find that their own policies are influenced by such developments or that their opposition to this new type of SPS governance could become considerably more challenging.

\footnotesize{\begin{itemize}
  \item 117 Art. 28.13 (d)(i) and Art. 28.13 (b) TPPA.
\end{itemize}}
This would constitute less of a problem if the new rules reflected how scientific inquiries actually worked. As it stands, the SPS Chapter is regressive and reminiscent of a throwback to the early days of the panel jurisprudence under the SPS Agreement. That approach was characterized by a deterministic view of science that envisaged a high degree of certainty in the outcomes of scientific inquiry. This is evident in the language of the TPPA Chapter, which not only cements the artificial barrier between risk assessment and risk management, but also requires ‘documented and objective evidence’. Where such objective – and presumably quantitative – documented evidence exists, this is not a cause for concern. But in the large majority of cases that will be contentious, whether litigated or not, this is unlikely to be the case. Rather, results of scientific inquiry will contain a significant degree of uncertainty, with respectable scientists holding different opinions over the risks inherent in particular products or production methods. In sum, the SPS Chapter not only shows a troubling lack of differentiation compared to the WTO jurisprudence. It also regresses – both textually and by its telos – into a time and understanding of science that many thought was overcome.
