6

Global Health Standards and Food Security:

Exploring the Double Science Standard of Review under the SPS Agreement after India – Agricultural Products

*Mariela de Amstalden*

Trade and public health are two distinctive, yet highly intertwined concepts that bear increasing relevance for global economic governance. From an international law perspective, public health refers to a state’s right and obligation to ensure the conditions for the population within its territory to be healthy, aiming at the highest possible level of health that is consistent with principles of social justice, with particular emphasis on the fair treatment of the most disadvantaged (Gostin 2008). Arguably, protecting public health is a national regulatory imperative that has been at times limited by some of the obligations imposed on signatory states in international trade agreements. Attempting to reconcile the tension between trade facilitation and national autonomy in protecting public health, the World Trade Organization (WTO) adopted the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) at its inception in 1994. The SPS Agreement promised to make available regulatory space for science-based domestic legislation on public health. However, despite the undeniable extension of sovereignty afforded to the protection of public health under the law of the WTO, participation in the rules-based trading system remains at odds with the pursuit of domestic science-based public health standards. This chapter analyzes the impact of the SPS Agreement on certain domestic legislation in India that seeks to strengthen food safety and security by imposing restrictions on the trade of certain agricultural goods. The relevant global health standard is set out in Sustainable Development Goal (SDG) 2.1, which seeks to “ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round.”[[1]](#footnote-1) While engaging in a legal analysis of the role of science in international economic law, this chapter ultimately asks whether WTO law, and the SPS Agreement in particular, is well-equipped to engage with non-trade concerns in assessing the appropriateness of domestic measures with the potential to display trade-distorting effects.

As noted in Chapter 3, India has been an innovative leader in the developing world in utilizing provisions in international trade law, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), to protect its public health initiatives, especially with regard to pharmaceuticals. I posit here that scientifically unfounded public health measures impose significant non-tariff barriers to trade in cases where they are not based on an international standard. In order to support this point, I will determine whether and to what extent public health measures that are not based on science may potentially constitute disguised non-tariff barriers to trade.[[2]](#footnote-2) I will begin by presenting what I have called the ‘double science standard’ as established under Article 2.2 of the SPS Agreement to identify the legal standard of review that domestic measures must meet in order to comply with trade obligations.[[3]](#footnote-3) This will be followed by a study of the appropriate levels of public health protection and whether and to what extent domestic public health measures may or may not constitute non-tariff barriers to trade. The significance of risk assessments and their symbiotic relationship with scientific principles will be addressed. The chapter concludes with some thoughts on the legal implications of the use of scientific evidence in regulation aimed at protecting public health.

<1>The Double Science Standard of Review under the SPS Agreement

The context for my discussion is a recent WTO dispute over interpretation of the SPS Agreement, namely, *India – Measures Concerning the Importation of Certain Agricultural Products* (*India – Agricultural Products*) (WTO 2015). Brought against India by the United States, the case was eventually appealed to the WTO Appellate Body. In essence, the dispute concerned India’s import prohibition affecting certain agricultural products, such as poultry meats, eggs, and feathers, from countries reporting Notifiable Avian Influenza (NAI) –more commonly known as “bird flu” – to the World Organisation for Animal Health (formerly the Office International des Epizooties [OIE]). According to the United States, these measures were not based on the relevant international standard (the Terrestrial Animal Health Code) or on a scientific risk assessment, and thus unjustifiably encumbered international trade.

This dispute raises many important issues, but the present analysis will focus on the relationship between scientific principles and risk assessment by identifying a legal threshold imposed by Article 2.2 of the SPS Agreement. I will call this legal threshold the “double science standard.”

Figure 6.1

Double science standard as provided for in Article 2.2 of the SPS Agreement

<insert Figure 6.1>

As Figure 6.1 shows, a domestic measure will not be considered a non-tariff barrier if it is demonstrated that three subsequent requirements are fulfilled. First, the respondent party will have to show that the adopted measure is necessary to attain a legitimate aim of protecting human health, such as reducing deaths (A). Second, the measure must be science-based in accordance with the principles set out for risk assessments in Article 5 of the SPS Agreement. Both provisions, Art. 2.2 and Art. 5 of the SPS Agreement have a symbiotic relationship that informs their interpretation. This element constitutes the first science standard. For instance, the adopted regulatory framework has to identify the potential effects on human health and evaluate their likelihood of occurrence (B). And third, the measure must not be maintained without sufficient scientific evidence, which constitutes the second science standard (C). As a result, the double science standard imposed by the SPS Agreement will be met in cases where all three elements are present.

<1>Public Health Protection and the Double Science Standard

The SPS Agreement applies to all sanitary and phytosanitary (SPS) measures that may affect, directly or indirectly, international trade (SPS Agreement, Article 1). The first step in determining whether the SPS Agreement will serve as a backdrop to assessing compliance with international trade obligations is to identify the nature of the domestic measures being challenged. In other words, the scope of application of the SPS Agreement will be established only after a domestic measure is identified as an SPS measure.

<2>Conceptualizing SPS Measures

The SPS Agreement defines SPS measures in its Annex A as any measure applied:

. 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;

. 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;

. 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

. to prevent or limit any other damage within the territory of the Member from entry, establishment or spread of pests. (See also Charnovitz 2007.)

I have argued elsewhere (Maidana-Eletti de Amstalden 2014, 2015) that measures requiring the disclosure of nutritional information on the packaging, such as labelling measures, may not prima faciefall within the ambit of the SPS Agreement. Rather, these type of measures are likely to constitute a technical regulation related to a product, and thus the 1995 Agreement on Technical Barriers to Trade (TBT Agreement) – and its arguably less stringent requirements (Pauwelyn 1999, 644; Downes 2015) – may apply. However, paragraph 2 of Annex A establishes that a domestic measure adopted to protect human health from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs shall be considered an SPS measure, to the exclusion of other WTO agreements. Thus, it is also conceivable that product regulation measures addressing nutritional requirements may fall within the scope of the SPS Agreement in cases where they have been adopted with the aim of protecting human health from risks arising from repeated exposure to elements considered unhealthy in large quantities, such as saturated fats, sugars, or salt. In other words, the legality of measures on the nutritional composition of foodstuffs could become subject to SPS scrutiny to the extent that (1) those risk management measures are adopted with the aim of protecting human health from additives, and (2) saturated fats, sugars, and salt are classified as additives.

<2>Identifying International Health Standards

In establishing the concept of food additive for the purposes of WTO law, the Codex Alimentarius Commission (CAC) standard setting forth the conditions for the use of permitted food additives is relevant. The CAC is the most influential food standard–setting body at the international level.[[4]](#footnote-4) Its main objective is to set international food standards for the protection of public health and the promotion of fair practice in food trade (WHO and FAO 2010, Articles 1[c], [d], and [e]). Unlike more recent WTO instruments, the CAC was established in 1962 by the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Programme as their subsidiary body to respond to the increased trade in food.[[5]](#footnote-5) It elaborates on international standards, codes of practice, guidelines, and related texts addressing food safety and quality with a view to facilitating international trade (CAC 2006). For many decades, the legal relevance of CAC standards was dismissed because of their non-binding nature and merely advisory role.[[6]](#footnote-6) It was only upon the adoption of the WTO agreements that the Codex Alimentarius was upgraded to semi-binding status (Arcuri 2014; Veggeland and Borgen 2005). Articles 3.4 and 12.3 of the SPS Agreement explicitly refer to the adoption of the CAC standards as a way to sustain a presumption of compliance with food safety rules.[[7]](#footnote-7)

The CAC defines additives as “any substance not normally consumed as food by itself and not normally used as an ingredient of the food, whether or not it has nutritional value ... the intentional addition of which ... may be reasonably expected to result in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods.”[[8]](#footnote-8) Paradoxically, the CAC definition further specifies that the term “food additive” does *not* include substances added to food for *improving nutritional qualities.* A WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC – Biotech*) (Peel 2007, 1031), has given some general indication of the manner in which the term “food additive” may be interpreted in accordance with WTO law.[[9]](#footnote-9) This description emphasizes the role of the CAC in providing scientific advice, a matter to which I return below. However, *EC – Biotech,* for all its textually focused reading, does little to clarify the meaning of food additive in the context of measures establishing nutritional composition requirements.

Against this backdrop, saturated fats, sugars, and salt can be considered food additives for the purposes of the SPS Agreement in cases where the following requirements are fulfilled:

1 the substance is not normally consumed as food by itself;

2 the substance is not normally used as an ingredient of the food;

3 intentionally adding the substance results in its incorporation to the foodstuff or otherwise affects the characteristics of such foodstuff; and

4 the substance does not improve the nutritional quality of the foodstuff.

A grammatical interpretation of this threshold – as favoured by the WTO Appellate Body in *Australia – Measures Affecting the Importation of Salmon* (*Australia – Salmon*) (WTO 1998, 1999a) –will undoubtedly lead to an unsatisfactory result, with high evidentiary challenges for both parties to the dispute. First, what constitutes normal consumption in country A is likely to differ from the *normality* standard in country B. This suggests that no clear-cut interpretation is possible and therefore a case-by-case analysis must be conducted. The notion of normality, which by definition excludes perceived risks, is strongly related to the right of Members to adopt an appropriate level of protection (ALOP), as established in Article 5.3 of the SPS Agreement.

<2>The Controversial Nexus between Risk Assessment and Scientific Evidence

In *India – Agricultural Products* (WTO 2015), India contended that eight out of ten challenged measures were based on an international standard. However, the panel still found a violation of Article 3.1 of the SPS Agreement because the challenged measure was not “based on” an international standard, i.e.,it was not based on a risk assessment as established in Article 5, and so it failed to benefit from the rebuttable presumption of compliance as provided for in Article 3.2. The lack of sufficient scientific evidence supporting the implementation of the challenged measure was instrumental in determining its (lack of) legality under the SPS Agreement. In other words, even in cases where a domestic measure is based on an international standard, this fact alone does not release Members from their obligation to conduct a risk assessment. Only in cases where the measure has been found to “conform to” an international standard is the respondent party’s burden of conducting a risk assessment lifted.

The SPS Agreement provides various instruments for determining whether a domestic SPS measure has been adopted as a disguised non-tariff barrier. The umbrella provision establishing the basic obligations for Members adopting SPS measures is found in Article 2.2 of the SPS Agreement, which provides for the double science standard, as elaborated above. This provision imposes a triple threshold to assess the compatibility of domestic measures with the SPS Agreement. Adopted measures (1) shall apply only to the extent necessary to protect human health; (2) are science-based; and (3) are not maintained without sufficient scientific evidence. As the WTO Appellate Body clarified*,* many elements of Article 2.2 are later elaborated in more detail in Article 5 and the interpretation of one should inform the interpretation of the other (WTO 2015, para. 5.12).

<3>First Element of the Double Science Standard: Legitimate Aim

The first element of the double science standard of review demands the execution of a necessity test to assess whether the aim is legitimate, i.e., SPS measures must not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail. The necessity test further requires that SPS measures not be applied in a manner that restricts international trade. In many ways, the novelty of this test is limited, since it reflects the necessity requirement in Article XX(b) of the General Agreement on Tariffs and Trade (GATT) 1994 (GATT 1994). Unlike the general exceptions clause under Article XX of the GATT 1994, however, Article 2.2 of the SPS Agreement will always be applicable, even in cases where other violations of the SPS Agreement could not be established. Article 2.2 also reflects the obligations established in Article III(4) of the GATT 1994, which imposes upon Members the duty to accord nationals of other members any treatment that is not less favourable than that accorded to its own nationals.

In other words, imported goods must be treated no less favourably than like products of national origin. The national treatment prohibition in the GATT 1994 also aims at requiring equality of competitive conditions and protecting expectations of equal competitive relationships.[[10]](#footnote-10) Unlike other instruments, however, the national treatment principle in the SPS Agreement has been interpreted as also prohibiting discrimination between different products (*Australia – Salmon:* WTO1998, para. 252). Thus, a measure will be in violation of WTO obligations where there is evidence that it detrimentally affects competition in a given market.

<3>Second Element of the Double Science Standard: Science-Based Rules

The second element of the double science standard of review requires SPS measures to be based on scientific principles. At its core, the SPS Agreement aims at guaranteeing human, animal, and plant life and health in all Member States (SPS Agreement, Preamble, recital 1), while minimizing the negative trade effect of SPS measures and promoting international trade (*EC – Hormones* 1998, para. 177).[[11]](#footnote-11) As mentioned earlier, although Members retain their right to choose their own adequate level of SPS protection (ALOP),[[12]](#footnote-12) Articles 2 and 5 of the SPS Agreement provide a legal backdrop for assessing whether challenged SPS measures establishing domestic thresholds for the protection of public health are unjustifiably impeding trade. In other words, Members can still determine the level of risk they are willing to accept, for the establishment of an ALOP is both “a privilege and an obligation”(WTO 2015, para. 5.221)in exercising regulatory autonomy.

Article 5.1 establishes that domestic SPS measures must be based on an assessment of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. Risk assessments evaluate the likelihood of entry, establishment, or spread of a pest or disease within the territory of an importing Member and of the associated potential biological and economic consequences (SPS Agreement, Annex A, para. 4). It also refers to 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 animal feed (ibid.). A measure is based on a risk assessment under Article 2.2 of the SPS Agreement in cases where there exists an objective relationship between the former and the latter (*EC – Hormones* 1998, para. 189), that is, the result of the risk assessment is rationally related to the measure.

The WTO Panel found in *Australia – Salmon* that a measure that is not based on a risk assessment (as in Article 5) will suggest that it is not based on scientific principles (as in the second tier of Article 2.2), leading to a violation of both provisions (*Australia – Salmon* 1998, para. 8.52). The WTO Appellate Body upheld this reasoning, stating that a violation of Articles 5.1 and 5.2 will lead to an inconsistency with Article 2.2 of the SPS Agreement *by implication* (WTO1998, para. 138). In other words, there will be a rebuttable presumption of non-compliance with Article 2.2 in cases where a violation of Articles 5.1 and 5.2 of the SPS Agreement is established.

The same legal analysis was put forward once again by the WTO Panel in *India –Agricultural Products:*

‘[W]here an SPS measure is not based on a risk assessment as required by Articles 5.1 and 5.2 of the SPS Agreement, this measure is presumed not to be based on scientific principles and to be maintained without sufficient scientific evidence, in contravention of Article 2.2 of the SPS Agreement. (WTO 2014, para. 7.331, with further references).’

In this case too, the Appellate Body upheld the findings of the Panel (WTO 2015, para 5.15). It also shed light on the manner in which the symbiotic relationship between the basic rights and obligations of Article 2.2 and the more specific requirements of Article 5 of the SPS Agreement should be understood to determine SPS compliance. Furthermore, the Appellate Body clarified that an analysis of whether a violation of Article 5 would lead to a violation of Article 2.2 can be established only on a case-by-case basis (ibid.), and so no clear-cut interpretative guidance is available to date. In other words, could an objective and rational relationship between the SPS measure and the scientific evidence be established with resort to science?

The short answer is yes. The rationality of the relationship will have to be established on a case-by-case basis, taking into account the characteristics of the measure at issue and the quantity and quality of the available scientific evidence that possesses the *“necessary scientific and methodological rigor to be considered reputable science”* (WTO 2015, para 5.28)*.* The risk assessment would further entail an inquiry into evidence adduced by the parties regarding the particular risks that the challenged measure is set to protect against, and to whom the risk is posed (ibid., para 5.27). Hence, the risk assessment will have to (1) identify potential effects on health, and (2) evaluate the likelihood of those potential effects to occur.

<3>Third Element of the Double Science Standard: Scientific Evidence

The third element of the double science standard of review requires that SPS measures are not maintained without sufficient scientific evidence in order to avoid becoming a non-tariff barrier. A careful reading of *India – Agricultural Products* (WTO 2015, para 5.27) suggests that the establishment of a sufficient level of scientific evidence can be pursued by weighing the outcome of the necessity test carried out under the first element of the double science standard of review (A) against the scientific basis as identified in the second element of the same standard (B). The result of this equation will determine whether an SPS measure is being maintained with or without sufficient scientific evidence (C) – that is, there must be a rational relationship between A and B in order to produce C.

Figure 6.2

Scientific evidence under the double science standard of review

<insert Figure 6.2>

Figure 6.2 shows that the double science standard of review will be met in cases where scientific evidence is established after weighing the outcomes from the necessity test and the risk assessment. Equally, a domestic measure will be WTO-compliant in cases where all three elements of the double science standard are cumulatively fulfilled. It is apparent that the SPS threshold is much more stringent than those standards of review established under other WTO agreements.

<1>Implications of the Double Science Standard for Public Health Measures

In the aftermath of *India – Agricultural Products,* the United States requested authorization[[13]](#footnote-13) from the Dispute Settlement Body (DSB) to suspend concessions and other obligations to India in the amount of US$450 million in 2016, to be updated annually.[[14]](#footnote-14) The argument put forward by the United States indicated that the revised Indian measure was still inconsistent with WTO obligations, since it provided for a domestic public health standard that was substantially more restrictive than that suggested by the World Organisation for Animal Health (OIE).

In this chapter, I have focused my analysis on the impact of the SPS Agreement on measures addressing public health. As evidenced in some recent SPS disputes, divergent public health standards of protection arising out of different regulatory approaches among WTO members have the potential to impose important non-tariff barriers to trade. The *India – Agricultural Products* case shows that the use of international standards, such as those adopted by the OIE, as the basis for domestic SPS regulation does not allow Members to deviate from their obligation to conduct a risk assessment. Risk assessments (or lack thereof) will also inform the interpretation of whether a challenged measure can be considered to be based on scientific principles. This line of enquiry suggests that there is a ‘double science standard of review’ under the SPS Agreement. The ‘double science standard of review’ provides that a domestic measure will not be considered a non-tariff barrier to trade if three successive elements are fulfilled (Figure 6.3).

Figure 6.3

The double science standard of review in context

<insert Figure 6.3>

First (A), the respondent party will have to show that the adopted measure is necessary to attain a legitimate aim of protecting human health (i.e., reducing deaths caused by non-communicable diseases) (A). Second, the measure must be science-based in accordance with the principles set out for risk assessments in Article 5 of the SPS Agreement. Both provisions, Art. 2.2 and Art. 5 of the SPS Agreement have a symbiotic relationship that informs their interpretation, i.e.,it will have to identify the potential effects on human health and evaluate whether they are likely to occur (B). Third, the measure must not be maintained without sufficient scientific evidence (C). Thus, it can be presumed that, based on the equation described earlier (A+ B = C), a measure is maintained with sufficient scientific evidence whereas the first and second elements are established. The analysis has shown that a legitimate aim to protect public health alone does not suffice to show compliance with international trade obligations. These domestic measures must be based on sound science, that is, be in accordance with scientific principles of risk assessment, and cannot be maintained without sufficient scientific evidence proving that the measure continues to be necessary to protect public health.

It poses the question, however, of whether, in light of the United Nations Sustainable Development Goals, India is entitled to impose measures that are more trade-restrictive than necessary due to its own societal concerns, particularly with regard to food insecurity and the economic and social inequality within its jurisdiction. Pursuing what one Member State deems as an appropriate level of public health protection entails a certain degree of distribution of a variety of available resources -legislative, financial, social. Arguably, containing a public health risk or protecting food safety and security may take precedence over the free flow of goods in a rules-based trading system. Whether the WTO dispute settlement system is equipped to deal with such legal and policy considerations of the SDG agenda is a topic for another study.

<1>Notes

<insert notes>

1. **Chapter 6: Public Global Health Standards and Food Security in India: The Double Science Standard of Review under the SPS Agreement**

   https://sdgs.un.org/goals/goal2. [↑](#footnote-ref-1)
2. This chapter is partly based on Maidana-Eletti de Amstalden 2015. [↑](#footnote-ref-2)
3. https://www.wto.org/english/tratop\_e/sps\_e/spsagr\_e.htm. [↑](#footnote-ref-3)
4. Other international institutions also devote their work to setting standards in the area of food safety, e.g., the Organisation for Economic Co-operation and Development (OECD). [↑](#footnote-ref-4)
5. As a subsidiary organ, the CAC depends financially and institutionally on the FAO and the WHO, a dependence that impairs its ability to rapidly and effectively adopt standards. [↑](#footnote-ref-5)
6. Prior to the adoption of the SPS Agreement, CAC standards were binding only when voluntarily transposed into national legislation; thus, they remained untouched by national or international political interests. See generally Herdegen 2001; Veggeland and Borgen 2002. [↑](#footnote-ref-6)
7. Article 3.4 of the SPS Agreement reads: “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 ... to promote within these organization(s) the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.”

   Article 12.3 of the SPS Agreement reads: “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 ... with the objective of securing the best available scientific and technical advice for the administration of this Agreement.” [↑](#footnote-ref-7)
8. General Standard for Food Additives, Codex Standard 192-1995, 2, <https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B192-1995%252FCXS\_192e.pdf.> [↑](#footnote-ref-8)
9. WTO 2006, para. 7.301, where the panel referred to the definition provided by the CAC, and in doing so, failed to provide substantive guidance on the matter at hand, largely limiting its interpretation to the ordinary meaning of the terms. [↑](#footnote-ref-9)
10. See, e.g., WTO 1999b, para. 120; WTO 1997, para. 464; WTO 2000, para. 11.182. [↑](#footnote-ref-10)
11. European Communities - EC Measures Concerning Meat and Meat Products (Hormones) -Report of the Appellate Body, 16 January 1998, WT/DS48/AB/R. [↑](#footnote-ref-11)
12. Annex A, para. 5 of the SPS Agreement states that the appropriate level of sanitary or phytosanitary protection is the level of protection deemed appropriate by the Member establishing those sanitary or phytosanitary measures to protect human, animal, or plant life or health within its territory. [↑](#footnote-ref-12)
13. Based on Article 22.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, 1869 UNTS 401 (DSU), which reads: “If no satisfactory compensation has been agreed within 20 days after the date of expiry of the reasonable period of time, any party having invoked the dispute settlement procedures may request authorization from the DSB to suspend the application to the Member concerned of concessions or other obligations under the covered agreements.” [↑](#footnote-ref-13)
14. “Recourse to Article 22.2 of the DSU by the United States,” WT/DS430/16, circulated on July 8, 2016. [↑](#footnote-ref-14)