Agreement on Sanitary and Phytosanitary Standards (The following draws on Mauroidis, House and Bermann, The Law of the WTO, Forthcoming West Publishing)

The SPS Agreement was intended to address measures designed to protect human, animal and plant life and health, and is used primarily as a tool to regulate SPS measures as non-tariff barriers. SPS measures are a highly controversial area of regulation as they concern for the most part the safety of a nation’s food supply and have consequently been the focus of intense NGO lobbying efforts. Central SPS issues such as scientific justification and allowable risk are difficult to arbitrate and lie at the heart of a country’s sovereignty.

The SPS Agreement applies to a defined set of measures, to the exclusion of TBT, namely a wide range of measures that protect human, animal or plant life or health from pests, contaminants, toxins, disease-carrying organisms, etc. GATT rights and obligations concerning such measures (including National Treatment Article III:4) run parallel to the rules in SPS. Thus, the same food safety measure could give rise to a claim that it violates both certain provisions of SPS as well as certain GATT rules. In such a case, a panel would follow the principle of examining the measure first against the more specific norms (here those of SPS) and only then considering the more general provisions of GATT (Bananas, Sardines).

The SPS Agreement gives rise to several types of rights obligations: first of all, the Agreement contains provisions that encourage, without requiring, the use of international standards, including those of the Codex Alimentarius (see below); second, there are provisions that require that SPS measures (unless they conform to international standards) be based on scientific evidence, and an assessment of risk in accord with scientific principles. This is subject to the right of a Member to adopt provisional measures where scientific
evidence is insufficient to conduct a risk assessment \((5.7)\); third, the SPS Agreement contains disciplines to ensure that Members’ SPS measures are not unnecessarily trade-restrictive in relation to the level of risk the Member is prepared to tolerate \((5.6)\), and also to ensure that Members do not address different risks differently so as to engage in arbitrary and protectionist selectivity of which hazards are addressed through stringent regulation and which are not, applying more demanding criteria in areas where the risks arise primarily from imported as opposed to domestic products \((5.5)\); and fourth, the SPS Agreement contains a range of provisions on conformity assessment, the testing and sampling of products at the border, for instance.

\[\text{The role of international standards}\]

Article 3 of the SPS Agreement deals with the relationship between domestic SPS regulations and international standards. There is a general obligation to base domestic SPS measures on international standards. This is subject to a right to deviate from international standards where the result is a higher level of protection. This right to deviate is in turn conditioned on the requirements of scientific risk assessment in the regulatory process detailed in Article 5 of SPS. In the *Hormones* case,\(^{34}\) the Appellate Body (AB) held that the obligation to base measures on international standards was of an aspirational, ‘best efforts’ nature, and did not require that all SPS measures be based on international standards at the time of coming into force of the SPS Agreement.

In addition, measures that ‘conform to’ international standards – which according to the AB in *Hormones* implies a closer fit than ‘based on’ – are presumed to be consistent with the SPS Agreement as a whole as well as justified under Article XX of the GATT.\(^{35}\) Thus, all of the obligations discussed below only relate to situations where measures do not ‘conform to’ international standards.

The term ‘international standards’ is defined in an Annex to the SPS Agreement. In the case of food safety, ‘international’ means primarily the standards of the Codex Alimentarius. Other organizations specifically mentioned as generating ‘international standards’ within the meaning of SPS are International Office of Epizootics and the Secretariat of the International Plant Protection Convention. In addition, where the standards of none of these specifically mentioned bodies are applicable, then those of any other international standardization body, membership of which is open to all WTO Members, will serve as ‘international standards’ for SPS purposes.

\[\text{The requirement of scientific justification}\]

Article 2.2 of the SPS Agreement provides that SPS measures shall not be ‘maintained without sufficient scientific evidence’. In the *Japan – Agricultural Products II* case, the AB held that this requirement is satisfied if there is ‘a rational or objective relationship’ between the SPS measure and the scientific evidence; the existence of such a relationship was to be determined on a case-by-case basis, and would depend on the characteristics of the measure at issue ‘and the quality and quantity of the scientific evidence’ (para. 84). Recently, in the *Japan – Apples* case,\(^{36}\) the AB made it clear that this rational connection test does not, however, require deference by the WTO panel to the authorities of the regulating WTO Member, even where their handling of the scientific evidence is reasonable; instead, it is appropriate for the panel to review de novo the scientific evidence and its relationship to the measure (paras 163–7). This seems unnecessarily intrusive of domestic
regulatory autonomy, and likely to give rise to renewed criticism that WTO tribunals are usurping democratic decision-making at the Member State level. It would have been more appropriate, as Japan was urging, for the panel to consider (much as do domestic courts in the USA and Canada in reviewing decisions of expert regulators) whether the Japanese regulators had acted in a reasonable, objective and unbiased fashion in the manner in which they obtained, weighted and utilized scientific evidence, i.e. a procedural rather than a substantive approach to ‘rational relationship’ that would avoid the panel itself purporting to become an arbiter of scientific method and scientific controversy.

In Japan – Apples, the panel held that Article 2.2 was violated by Japan because its measure was ‘clearly disproportionate to the risk identified on the basis of the scientific evidence available’ (para. 8.198). The notion that a measure cannot be maintained because it is disproportionate to the risk identified reads into the text of Article 2.2 a proportionality requirement that is nowhere to be found there. Article 2.2 deals with the sufficiency of evidence, not whether a risk is sufficient to regulate. The latter determination, as will be discussed below, has been held by the AB to be a matter for each individual WTO Member in setting its appropriate level of protection; it is entirely appropriate for a Member to regulate even to address a risk that is relatively remote, provided its levels of protection are not set in an arbitrary and protectionist manner, as across different kinds of risk. Unfortunately, the AB did not reverse the panel on this point; rather, the AB avoided the issue, by reading the panel’s language of ‘clear disproportion’ as merely expressing the conclusion or result of the panel’s (correct) application of the ‘rational relationship’ test, rather than as suggesting a different or additional test for proportionality (para. 163). Article 5.7 of SPS allows a Member to maintain a provisional SPS measure notwithstanding the requirement of 2.2 (and arguably notwithstanding also the risk assessment obligations in 5.1). In Japan – Agricultural Products II, the AB elucidated the four criteria that must be met in order for a provisional measure to be maintained under 5.7: (1) the measure is imposed in respect of a situation where ‘relevant scientific evidence is insufficient’; (2) the measure is adopted ‘on the basis of available pertinent information’; (3) the Member which adopted the measure ‘seek[s] to obtain the additional information necessary for a more objective assessment of risk’; and (4) the Member which adopted the measure ‘review[s] the ... measure accordingly within a reasonable period of time’. In the Japan – Apples case, the AB held that ‘insufficient’ scientific evidence means insufficient evidence to conduct a risk assessment in accordance with SPS Article 5.1. It is unclear why the AB chose to adopt a different meaning for the sufficiency or insufficiency of scientific evidence in dealing with SPS 5.7 than in the case of SPS 2.2. In the same case, the AB made the rather puzzling statement that ‘the application of 5.7 is triggered not by the existence of scientific uncertainty but rather by the insufficiency of scientific evidence’ (para. 184). It is unclear what the AB thinks is meant by ‘scientific uncertainty’ here.

With respect to the obligation to review a provisional measure within a reasonable period of time, the AB held in Japan – Agricultural Products II that: ‘[W]hat constitutes a “reasonable period of time” has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure.’ The criterion that the provisional measure be adopted on the basis of ‘available pertinent information’ has not yet been considered by the AB.

While the treatment of sufficient scientific evidence in 2.2 and 5.7 seems underevalent to the substantive scientific and policy choices of domestic regulators, it must also be borne in mind that, in Hormones, the AB endorsed the Precautionary Principle — the notion that in
the presence of uncertainty, it is appropriate for a regulator to act before resolving the uncertainty, if delay might result in an irreparable harm to human or animal life or the environment. The AB held that the Precautionary Principle did not have a status in the hierarchy of international legal norms that would result in it trumping the treaty obligations in SPS, but instead it was to be used in interpreting those obligations in which it could be considered to have been reflected. According to the AB:

We agree ... with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle [to the interpretation of SPS]. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining for instance, whether ‘sufficient scientific evidence’ exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.

(para. 124)

Neither Japan – Agricultural Products II nor Japan – Apples were cases where ‘risks of irreversible, e.g. life-terminating, damage to human health’ were at issue; rather, the concern was economic damage. In a different sort of case, where human health and life are at issue, one might expect to see interpretations of SPS 2.2 and 5.7 that are more reflective of the notion of precaution, and accordingly more deferential to the substantive regulatory choices of domestic governments.

Article 5.1 of SPS requires that a Member’s SPS measures (to the extent that they do not ‘conform to’ international standards) must be based on ‘an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations’. Article 5.2, in turn, states the factors that Members ‘shall’ take into account in assessing risk, which are: ‘available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment’. Risk assessment is further defined in SPS Annex A4: ‘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, and feedstuffs.’ Furthermore, Article 5.3 mandates that certain economic factors be considered in risk assessment, including potential damage in terms of loss of production or sales in the case of the spread of a pest.

In Hormones, the AB reversed the panel’s procedural reading that the requirement that measures be based on a risk assessment means that a risk assessment must actually have been taken into account in the regulatory process that gave rise to the measure. Instead, the AB read ‘based upon’ to mean that there is an objective, rational relationship between a risk assessment conforming to the criteria in SPS and the measure adopted, whether or not
the regulating authority knew of or used the assessment in any way, or even whether it existed at the time the measure was adopted. The AB’s interpretation appears at first glance as an unwarranted intrusive reading of 5.1, which would involve the panel in de novo review of substantive scientific justification of a Member’s regulation, as opposed to ensuring that its regulatory process was informed by a risk assessment. At the same time, the SPS Agreement contains no grandfathering provision in respect of measures that existed prior to 1995, and thus the procedural reading of ‘based on’ in 5.1 would have had a dubious retroactive effect: thousands of existing measures would become illegal under SPS because, at the time at which they were adopted, no risk assessment was taken into account, no such requirement having existed, of course, at the time in question.

Having read 5.1 as thus entailing an examination of the substantive basis of a Member’s measures, the AB in Hormones went on, however, to make several interpretations of the requirement in 5.1 that provide a measure of deference to domestic regulators. First of all, the AB held that a risk assessment need not establish a minimum quantitative threshold or level of risk, provided that it goes beyond asserting merely theoretical uncertainty, and entails an actual empirical inquiry into the existence of risk. This holding was marred by its expression in terms of the difference between probability and mere possibility, a misuse of the statistical concepts at issue.

Second, also in Hormones, the AB held that the distinction often used in academic literature between risk assessment and risk management does not preclude, under SPS, a WTO Member taking into account considerations of how different regulatory instruments are likely to address a given risk, and real-world human behaviour in the presence of risk. In the words of the AB: ‘[I]t is essential to bear in mind that the risk that is to be evaluated in a risk assessment ... is not only risk ascertained in a science laboratory operating under strictly controlled conditions, but also risk 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’ (para. 187). There is a strong textual basis for the AB not to have read into SPS the distinction between risk assessment and risk management. Among the mandatory factors to be taken into account in risk assessment according to SPS 5.2 are regulatory tools such as inspection sampling and testing methods as well as ‘quarantine or other treatment’. This makes it clear that the meaning of ‘risk assessment’ in SPS extends to the assessment of risk on alternative scenarios for its containment or management through human behaviour and its regulation. In this respect, SPS would seem to reflect the rethinking by scientists and regulatory economists of the soundness of a sharp distinction between risk assessment and risk management.37

Third, and perhaps most important in addressing current disputes such as that between the USA, Canada and Argentina and the EU over genetically modified organisms (GMOs) where science is recent and contested, the AB held, in Hormones, that in the presence of scientific controversy or disagreement, SPS 5.1 permits a WTO Member to base its measures on minority, as opposed to mainstream, scientific opinion, if it so wishes, provided that the minority view comes from ‘qualified and respected sources’ (para. 194).

The obligation to minimize trade restrictioneness and to avoid arbitrary and protectionist
differences in levels of protection

Article 5.4 of SPS states that ‘Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.’ In Hormones, the panel held that this provision was of a ‘best efforts’ nature,
and thus that a Member has a sovereign right to set its level of protection as high as it wishes, even if the consequence is that only a highly trade-restrictive measure will serve to achieve that level of protection. The panel noted: ‘Guided by the wording of Article 5.4, in particular the words “should” (not “shall”) and “objective,” we consider that this provision of the SPS Agreement does not impose an obligation. However, this objective of minimizing trade effects has nonetheless to be taken into account in the interpretation of other provisions of the SPS Agreement’ (para. 8.166). In the Australia – Salmon case, the AB held that: ‘The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as “the level of protection deemed appropriate by the Member establishing a sanitary ... measure” is a prerogative of the Member and not of the panel or of the Appellate Body ... The “appropriate level of protection” established by a Member and the “SPS measure” have to be clearly distinguished. They are not one and the same thing. The first is an objective, the second is an instrument chosen to attain or implement that objective’ (paras 199–200). Article 5.6 of SPS requires that a Member’s measure be no more trade-restrictive than necessary in order to achieve its appropriate level of protection. In the Australia – Salmon case, the AB set out the interpretive framework for applying SPS 5.6:

The three elements of this test under Article 5.6 are that there is an SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member’s appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the SPS measure contested. These three elements are cumulative in the sense that, to establish inconsistency with Article 5.6, all of them have to be met. If any of these elements are not proven, the measure in dispute would be consistent with Article 5.6. Thus, if there is no alternative measure available, taking into account technical and economic feasibility, or if the alternative measure does not achieve the Member’s appropriate level of sanitary or phytosanitary protection, or if it is not significantly less trade-restrictive, the measure in dispute would be consistent with Article 5.6.

(para. 194)

Article 5.5 of SPS requires consistency in the establishment of levels of protection across different risks; however, differences in levels of protection are only prohibited where these are arbitrary and unjustified and are applied ‘in a manner which would constitute a disguised restriction on international trade’, in other words hidden protectionism. There are many reasons why citizens and governments choose a high level of protection against some risks and not others, even though such distinctions may seem ‘irrational’ to a scientist or regulatory economist. Sunstein and Pildes note:

For laypeople, many contextual features are relevant: (1) the catastrophic nature of the risk; (2) whether the risk is uncontrollable; (3) whether the risk involves some irretrievable or permanent losses; (4) the social conditions under which a particular risk is generated and managed, a point that connects to issues of consent, voluntariness, and democratic control; (5) how equitably distributed the danger is or how concentrated on identifiable, innocent or traditionally disadvantaged victims, which ties to both notions of community and moral ideals; (6) how well understood the risk process in question is, a point that bears on the psychological disturbance produced by different risks; (7) whether the risk would be faced by future generations; (8) how familiar the risk is.38
In the *Hormones* case, the AB showed some appreciation for the complex considerations that enter into decisions concerning the appropriate level of protection that society seeks against particular risks. The United States had argued that the decision of the EU to ban synthetic growth hormones for livestock while doing nothing to counter the (even higher) incidence of such hormones in natural substances such as broccoli constituted an arbitrary and unjustifiable difference in levels of protection. Reversing the panel, which agreed with the USA, the AB explained: ‘we consider there is a fundamental distinction between added hormones (natural or synthetic) and naturally occurring hormones in meat and other foods. In respect of the latter, the European Communities simply takes no regulatory action; to require to prohibit totally the production and consumption of such foods or to limit the residues of naturally occurring hormones in food, entails such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people as to reduce the comparison itself to an absurdity’ (para. 221).

In *Hormones*, the AB did go on to find one difference in the levels of protection to be arbitrary and unjustified – namely certain hormones were banned in beef production but permitted in swine production. However, the AB found that the third prong of the test under 5.5, the requirement that the difference in levels of protection be applied so as to constitute a disguised restriction on trade, was not met. The AB noted that there were reasons for this inconsistency that had nothing to do with trade protection, namely the complex exercise of harmonizing Member State regulation in a federal political structure such as the EC. Rejecting evidence that the EC domestic beef industry had been lobbying for a ban on hormone-fed beef as a protectionist measure, the AB held that there was ample indication that EC-level action was a reaction to genuine public health concerns: ‘The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes clear the depth and extent of the anxieties experiencing within the European Communities concerning the results of the general scientific studies (showing the carcinogenicity of hormones), the dangers of abuse (highlighted by scandals relating to black-marketing and smuggling of prohibited veterinary drugs in the European Communities) of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the meat available in its internal market’ (para. 245).

Here the AB showed sensitivity to the real world of democratic regulation. There is hardly a regulatory measure that some producer pressure group will not lobby for as a matter of protectionist self-interest; to have qualified a measure as an impermissible ‘disguised restriction on international trade’ because some group or other happened to support it for protectionist motives would have sanctioned a massive interference with the capacity to respond to the health and related concerns of the citizenry at large.

In the later *Australia – Salmon* case, the AB developed the notion of ‘warning signals’ that would, cumulatively, lead to the conclusion that an arbitrary and unjustified difference in levels of protection is being applied as a disguised restriction on international trade. These might include extreme differences in the levels (a substance is prohibited while a substance posing comparable risks is left completely unregulated), as well as the failure to conduct a risk assessment as required in SPS 5.1.

**Evidentiary issues**

Under the SPS Agreement, the initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency of proof with a particular provision of the
SPS Agreement on the part of the defending party, or more precisely, of its SPS measure or measure complained about. When the prima facie case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency (Hormones, para. 98)

The issue presented itself once again in the context of the Japan – Agricultural Products II case. This time, however, with a slight ‘twist’ which actually bridges the gap between burden of proof and extent of control by WTO adjudicating bodies, the United States claimed that Japan did not use the least restrictive option to reach its objective. 39 According to the US argument, Japan should have conducted a ‘testing by product’ in order to ensure that its regulatory objective be met. The panel sought advice from experts to see if Japan indeed had not chosen the least restrictive option. It did so, however, not with respect to ‘testing by product’, as the United States had argued, but with respect to ‘sorption levels’ – another method used to reach Japan’s revealed preference, which had not been argued by the United States. Hence, the question arose as to whether the panel had exceeded the limits of its power by seeking expertise to establish that another (potentially less restrictive method, not argued by the complaining party, could have helped Japan reach its objective. The AB dealt with the issue in the following manner: ‘We note that the Panel explicitly stated that the United States, as complaining party, did not specifically argue that the “determination of sorption levels” met any of the three elements under Article 5.6.” And later: ‘Article 13 of the DSU [Dispute Settlement Understanding] allows a panel to seek information from any relevant source and to consult individual experts or expert bodies to obtain their opinion on certain aspects of the matter before it. In our Report ... we noted the “comprehensive nature” of this authority ... to enable a panel to discharge its duty imposed by Article 11 of the DSU’ (para. 127). And then: ‘[W]e note that the present dispute is a dispute under the SPS Agreement. Article 11.2 of the SPS Agreement explicitly instructs panels in disputes under this Agreement involving scientific and technical issues to “seek advice from experts” ’ (para. 128).

Article 13 of the DSU and Article 11.2 of the SPS allow WTO adjudicating bodies to select experts in consultation with the parties to the dispute. In the context of SPS, seeking outside expertise is a routine experience. This is so because of the issues involved: panelists are rarely accustomed to addressing scientific issues.

In the Hormones litigation, the panel first asked the parties to the dispute to name one expert each. It then named two experts (from a list prepared by the Codex Commission and the International Agency for Research on Cancer) and one additional expert in the area of carcinogenic effects of hormones. 41 The European Community appealed the fact that one of the experts was a national of a party or third party and had links with the pharmaceutical industry. The AB, distinguishing the selection of expert witnesses in the context of SPS from expert review groups (Appendix 4 of the DSU), dismissed the EC argument and held that: ‘Once the panel has decided to request the opinion of individual scientific experts, there is no legal obstacle to the panel drawing up, in consultation with the parties to the dispute, ad hoc rules for those particular proceedings.’ 42

In the Australia – Salmon case, the panel chose four experts after consultations with the Office International des Epizooties (OIE). 43 Finally, in the Japan – Agricultural Products II dispute, the panel chose three experts after soliciting suggestions from the Secretariat of the International Plant Protection Convention (IPPC).

Panels, it appears, will – in consultation with the parties to the dispute – seek expertise from outside sources following suggestions by the organizations mentioned in the SPS Agreement (OIE, IPCC, Codex). In the Hormones litigation, the parties to the dispute were given the opportunity to name one expert each.
In these cases, the panels have exhibited some confusion about the appropriate role of scientific expertise. For example, in the *Australia — Salmon* case, panellists asked laboratory scientists questions that related to the costs and benefits of regulatory alternatives, an issue which bears on matters of politics and economics. It should not be presumed that the relevant expertise in SPS cases will always be that of natural scientists: following on the remarks of the AB in the *Hormones* case about the real world in which people live and die, expertise concerning the effectiveness and consequences – social and economic, or even cultural – of particular forms of risk management and regulatory intervention may be appropriate.

*Other provisions*

Article 4.1 of SPS requires that an importing Member recognize the standards of an exporting Member as equivalent, provided that ‘the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection’. Article 4.2 encourages the negotiation of mutual recognition agreements (MRAs). Annex B of SPS contains an extensive list of transparency obligations including notification and publication of SPS measures. Annex C imposes a variety of (mostly due process) obligations with respect to control, inspection and approval procedures.