CHAPTER 7

THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

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TABLE OF CONTENTS

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I. Introduction

A. International Trade and SPS Measures

1. An Uneasy Relationship

The protection of human, plant and animal life and health is clearly a duty of all governments within their sovereign sphere. For this purpose, governments have in place regulatory measures aimed at the protection of health[1] in their territories against risks contained in food and agricultural products. These health measures can focus on human or animal life or health (sanitary measures) or on plant life or health (phytosanitary measures). Together, they are termed sanitary and phytosanitary ("SPS") measures and can take many forms. One can think of examples such as regulations setting maximum residue levels for toxins or contaminants,[2] approval procedures for additives, quarantine requirements to minimize the spread of pests and diseases, labeling requirements to notify consumers of potentially-harmful foodstuffs (such as allergen-containing products), regulations governing the process or production method whereby the product is made, inspection or certification requirements or outright bans on potentially hazardous products.[3] These are all SPS measures.

In recent years we have witnessed a proliferation of SPS measures. This can be attributed to three main factors. First, there is an increase in the number and variety of potential risks contained in food and agricultural products due to both increasing use of new technologies in agriculture and food processing (such as pesticides, additives and genetic modification) and the growth in imports from developing countries whose domestic food-safety infrastructures are often inadequate. Second, regulators have to respond to rising consumer expectations and demands with regard to food safety in developed countries, resulting from increased affluence and consumer awareness of food-related risks. Third, regulators are confronted with pressure from the agriculture and food industry lobbies in the face of increased competition due to agricultural trade liberalization. As a result, more and more SPS regulations are adopted and market access for food and agricultural products is greatly reduced.[4]

[1] For purposes of this chapter, unless otherwise specified, a reference to "health" or "public health" should be taken to mean human, animal or plant life or health. Similarly, "health measures" refer to measures for the protection of human, animal or plant life or health.

[2] The EC's maximum residue levels for aflotoxins are an example of such an SPS measure.

[3] For example, many countries banned beef imports from the EC in response to the outbreak of foot-and-mouth disease in 2001.

[4] Several studies have been conducted into the trade impact of SPS measures and technical barriers to trade more generally. Some have focused on the impact on developing country exports. Although quantification of the effect of these measures has proved difficult due to the complexity of the impact of standards on supply and demand, it is widely acknowledged that SPS measures can have significant negative effects on trade flows. *See* for example Tsunehiro Otsuki *et al.*, *Measuring the Effect of Food Safety Standards on African Exports to Europe*, in THE ECONOMICS OF QUARANTINE AND THE SPS AGREEMENT (Kim Anderson, *et al.,* eds. 2001); Tsunehiro Otsuki *et al., Saving Two in a Billion: A Case Study to Quantify the Trade Effect of European Food Safety Standards on African Exports,* Working Paper, Development Research Group, World Bank (2001); Spencer Henson and Rupert Loader, *Barriers to Agricultural Exports from Developing Countries: The Role of Sanitary and Phytosanitary Requirements,* 29 WORLD DEVELOPMENT 85 (2001); T. Ademola Oyejide *et al.*, *Quantifying the Trade Impact of Sanitary and Phytosanitary Standards: What Is Known and Issues of Importance for Sub-Saharan Africa*, Paper presented at the WORKSHOP ON QUANTIFYING THE TRADE EFFECT OF STANDARDS AND REGULATORY BARRIERS: IS IT POSSIBLE?, April 27, 2000; John S. Wilson *et al.*, AGRICULTURE IN THE WTO—THE ROLE OF PRODUCT ATTRIBUTES IN THE AGRICULTURAL NEGOTIATIONS Commissioned Paper number 17, April, The International Agricultural Trade Research Consortium (2001).

SPS measures can have an important impact on international trade. Currently there is a large volume of trade in food and agricultural products.[5] Not only are consumer tastes, especially in developed countries, increasingly international so that demand for foreign food products is growing, but there has also been a growth in the number of countries, especially developing countries, that participate in food and agricultural trade.[6] When one bears in mind the vast array of differing SPS standards that exist in different countries, reflecting their national priorities, stage of economic development and consumer preferences, it becomes clear that the possibilities exporters have of exploiting economies of scale on the international market are significantly reduced. The high cost of meeting the plethora of health standards means that exporters are forced to charge higher prices for their products on the export market or are even completely excluded from this market.

Many SPS measures are based on legitimate health concerns but others are based on more questionable motives. Clearly governments, under the influence of domestic industry pressure groups, may misuse SPS measures as disguised trade barriers for protectionist purposes. It is for this reason that all free trade regimes, including the WTO, contain rules to mediate the conflict between the competing goals of trade liberalization (and thus economic growth) and the protection of human, animal and plant health from risks contained in food and agricultural products.

2. The Importance of Rules

(a) For Developed Countries. Traditionally, developed countries have primarily been food importers. Increasing affluence gives rise to increased consumer demand, not only in terms of quantity of food but also with regard to variety. Developed country consumers also expect their governments to ensure high food quality and safety standards. For this reason, developed country regulators impose a large number of SPS measures. It is important for these regulators that international trade agreements recognize their right to impose SPS measures and lay down clear rules regarding any limitations to this right. This avoids the situation under the relevant GATT rules where it was left to dispute-settlement panels to flesh out the rather rudimentary provisions of the Article XX(b) exception for health measures, reading into it increasingly complex requirements that GATT contracting parties had to comply with in order to defend a measure from challenge.

Developed countries are also exporters of food and agricultural products. For this reason, producers in developed countries benefit from disciplines on the ability of importing countries to impose SPS measures in a way that restricts market access for their products. Clear rules provide security for producers and encourage them to invest in producing goods for export. There is an increased use of sophisticated technologies in the agricultural and food industries of some developed countries, which entail huge investment. Some of these technologies have been the subject of much controversy and have led to consumer health concerns. Examples such as the use of hormones in cattle feed to enhance growth, the administration of the hormone bovine somatropin ("BST") to increase

[5] The share of trade in agricultural products in world trade in goods amounted to 10.5 percent in 1998 (larger than sectors such as iron and steel, automobiles, textiles and clothing, chemicals). In that year, food products made up eighty percent of total agricultural trade. WTO Secretariat, THE AGREEMENT ON AGRICULTURE, July 1999.

[6] W.C.K. Hammer, *Food Trade and Implementation of the SPS and TBT Agreements: Current Status of Food Trade, Including Food Quality and Safety Problems*, Paper presented at the CONFERENCE ON INTERNATIONAL FOOD TRADE BEYOND 2000: SCIENCE-BASED DECISIONS, HARMONIZATION, EQUIVALENCE AND MUTUAL RECOGNITION, Melbourne, Australia, October 11–15, 1999, at 1.

milk production in dairy cows, and the genetic modification of crops to make them resistant to pests and herbicides come to mind. Regulations restricting market access have proliferated as a result of consumer concerns and public opinion regarding such new technologies. Developed countries employing such new technologies have an interest in ensuring that rules exist prohibiting the rejection of their products on the import market on the basis of ungrounded public fears and ensuring that scientific evidence of risk underlies regulatory decisions.

In many cases, agricultural producers in developed countries have become accustomed to generous government support.[7] Attempts to liberalize the agricultural sector at the national level, even though they make economic sense for the country concerned, are made difficult by the strength of the agricultural lobby.[8] Now, with increasing reduction of traditional market barriers in the agricultural sector due to WTO disciplines, as achieved by the Agreement on Agriculture and ongoing negotiations for the further liberalization of trade in agricultural products,[9] regulators in developed countries are subject to increasing pressure from the agricultural lobby to restrict market access by other means. Typically, technical standards and health regulations are measures open to abuse for protectionist purposes. The creation of international rules imposing disciplines on non-tariff barriers to trade enables governments to reject calls for protectionism with the convenient excuse that their hands are tied by the rules they have negotiated at the international level. Open markets in the agricultural sector are often to the economic advantage of developed countries as this provides them with access to cheaper agricultural imports, which are beneficial to expanding processed-food industries in these countries.

(b) For Developing Countries. Agriculture is a sector of primary importance for trade in most developing countries. It comprises a much larger share of economic output in developing countries than in developed countries,[10] and accounts for a large part of developing countries' exports and foreign exchange earnings.[11] In addition, several developing countries rely on exports of only a few agricultural products. These countries are thus extremely vulnerable to trade barriers in this sector. A reduction in market access for agricultural products from developing countries has far-reaching effects not only on

[7] Total support for agriculture in OECD countries was estimated to be U.S.$327 billion in 2000. Organization for Economic Cooperation and Development, AGRICULTURAL POLICIES IN OECD COUNTRIES—MONITORING AND EVALUATION (2001), *quoted in* World Trade Organization, ANNUAL REPORT 2002, 36 (2002).

[8] The difficulty of liberalization of the agricultural sector has been ascribed to the distribution of the costs and benefits of agricultural subsidies. The costs are borne by a diffuse group of consumers and taxpayers who are unlikely to organize to lobby for policy reform. On the other hand, the benefits go to an identifiable, already highly organized group of farming interests, who are experienced in exerting political pressure to secure protection and support from their governments. Furthermore, concerns regarding excessive dependency on food imports to meet domestic food requirements as well as concerns over the impact of reduced agricultural activity on the environment and the survival of rural communities, have strengthened the opposition to liberalization of the agricultural sector.

[9] Now taking place in the context of the Doha Development Round, launched in Doha on November 14, 2001.

[10] In 1997, agriculture accounted for three percent of the GDP of developed countries, but 26 percent of GDP for developing countries and fifty percent of the GDP of least-developed countries. Food and Agriculture Organization, *Issues at Stake Relating to Agricultural Development, Trade and Food Security*, FAO Symposium on AGRICULTURE, TRADE AND FOOD SECURITY: ISSUES AND OPTIONS IN THE FORTHCOMING WTO NEGOTIATIONS FROM THE PERSPECTIVE OF DEVELOPING COUNTRIES, September 23–24, 1999, at 12–15.

[11] In developing countries, agricultural exports account for on average 27 percent of total merchandise exports whereas in developed countries this share is only four percent. Thomas C. Beierle, FROM URUGUAY TO DOHA: AGRICULTURAL TRADE NEGOTIATIONS AT THE WORLD TRADE ORGANIZATION 4, Resources for the Future (2002).

export revenues, which are crucial for the development needs of these countries, but also on income and rural employment in these countries.[12]

With the increasing liberalization of the agricultural sector by means of disciplines on traditional trade barriers (such as quotas) under WTO rules, the focus has started to shift to non-tariff barriers, such as SPS regulations and standards, as obstacles to market access. As is to be expected, there is a large difference in consumer expectations in developed and developing countries regarding food safety and vast differences in the standard of the food-safety and animal and plant health systems in place to ensure that food and agricultural products meet the standards set in a particular country. As a result, developing countries increasingly face the rejection of their food and agricultural exports, causing great financial losses. It is therefore crucial for developing countries to ensure that effective disciplines are in place to deal with non-tariff barriers in the form of SPS measures, in order to prevent their misuse for protectionist purposes in lieu of traditional market barriers. In addition, it is important for developing countries that the rules in place take account of their financial and human resource constraints in meeting those SPS standards that are legitimate.

With the creation of a rules-based system for international trade, the WTO has strengthened the position of developing countries in the international arena *vis-à-vis* their trading partners. Now developing countries can challenge the trade-restrictive measures of other Members in accordance with WTO rules, by means of the WTO dispute settlement system.[13] The creation of clear and enforceable disciplines, in an international agreement, that enhance trade opportunities in an area of crucial interest to developing countries, namely the food and agricultural sector, provides tools for developing countries to use in securing market access for their export products.

B. Rules on SPS Measures before the SPS Agreement

1. GATT 1947, Articles III, XI and XX(b), and the Tokyo Round Standards Code

The trade disciplines in GATT 1947 covered the use of non-tariff measures, including SPS regulations, as trade barriers, and tried to limit the possibilities for their misuse for protectionist purposes. The disciplines of GATT 1947, now incorporated by reference into GATT 1994, contained provisions that were (and still are) applicable to health regulations and standards, to the extent that they discriminate against imports. The most important provisions in this regard are Articles III, XI and XX(b) of the GATT.

Article III contains what is commonly known as the National Treatment provision, which prohibits discriminatory tax and regulatory treatment of imported products from WTO Members once they have crossed the border. Under Article III:4, Members agree to provide imported products treatment "no less favorable" than that granted to "like" domestic products by means of all laws, regulations and requirements affecting their

[12] While in developed countries only nine percent of the population is employed in the agricultural sector, in developing countries this is more than fifty percent. *Id.*

[13] The WTO dispute settlement system is discussed in Chapters 25 *et seq* of this book, so it will not be described here. It should, however, be remembered that the dispute settlement system includes a consultation phase during which a mutually acceptable solution to a trade dispute (in accordance with WTO rules) can be agreed upon without recourse to the panel procedure. Thus, even if developing countries lack the resources to make use of the full dispute settlement procedure of the WTO, they still benefit from the rules of the SPS Agreement according to which they can raise challenges to trade-restrictive SPS measures in consultations with their trading partners. In Part III D, below, we briefly discuss a few specific issues of WTO dispute settlement that have arisen in the context of disputes on SPS measures.

sale, purchase, distribution, transportation or use. Thus any health regulation, such as a maximum residue level for pesticides, must be applied equally to imports and "like" domestic products. Article XI, on the other hand, focuses on border measures and prohibits quantitative restrictions, such as bans or other restrictions, on imports from Members, except in very limited cases. Import bans that are imposed on products for health reasons would be prohibited by this provision unless covered by an exception to the general rules.

It is clear that in some cases regulations that discriminate against imports or set quantitative restrictions on imported products are a justifiable exercise of the sovereign duty of a government to protect certain societal values in its territory. For this reason, the GATT provides, in Article XX, for certain qualified exceptions to its rules for measures aimed at particular policy objectives. One of these exceptions, contained in Article XX(b), is that for measures *necessary* to protect the life or health of humans, animals and plants. Such measures are allowed, provided that they are not applied in a manner constituting arbitrary or unjustified discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, in terms of the *chapeau* of Article XX.

The early negotiating rounds under the auspices of the GATT focused on tariff negotiations, and were quite successful in reducing tariff levels. As a result, the relative importance of standards and regulations as trade barriers increased. At the same time, growing consumer awareness of health and environmental issues was leading to a proliferation of regulations and standards in these areas, particularly in developed countries. Thus, in the Tokyo Round of trade negotiations,[14] there was a shift in focus towards tackling this form of trade barrier and four codes on non-tariff barriers were adopted. One of these was the Agreement on Technical Barriers to Trade, commonly known as the "Standards Code". The Standards Code did not focus specifically on regulations for the protection of human, plant or animal life or health, but was aimed broadly at all technical regulations and standards, as is the Uruguay Round Agreement on Technical Barriers to Trade ("TBT Agreement"). The Standards Code was not binding on all GATT Contracting Parties but only on those 32 Contracting Parties that were signatories to it.[15]

The Standards Code reiterated the GATT obligation of "national treatment" for like imported products. However, unlike the GATT, it applied also to non-discriminatory measures, laying down disciplines for the setting and application of standards and regulations even where they applied to domestic and imported products alike. Under the Standards Code, signatories agreed to adopt only standards and regulations that were necessary to achieve a legitimate aim, such as the protection of public health, and not to apply these measures in a manner that would constitute a disguised restriction on trade or create unnecessary obstacles to trade. More importantly, the Code required signatories to apply relevant international standards where they existed, unless these were deemed inadequate to meet the intended goal, thus introducing the first reference to harmonized standards into the international trade regime. In addition (and perhaps the main achievement of the Code) it introduced transparency requirements for the adoption of regulations and standards that were not "substantially the same" as international standards.

[14] These negotiations lasted from 1973–1979.

[15] Under the GATT regime it was possible for GATT contracting parties to choose whether or not to become signatories to the agreements which were negotiated to supplement the basic GATT disciplines. In the Uruguay Round, in contrast, all WTO Members undertook to be bound to all the multilateral agreements as part of a "single undertaking".

The Standards Code included a dispute-settlement mechanism that established the possibility for review by a panel or a technical group of experts of regulations or standards that could have "the effect of creating unnecessary obstacles to international trade". Thus, a Member could challenge the regulations or standards of another Member on the grounds that they violated a provision of the Standards Code. Despite the fact that no dispute-settlement proceeding was ever conducted under the Code, it did assist in the resolution of a few trade disputes involving industrial standards.[16]

2. Insufficiency of the GATT 1947 Rules and the Standards Code

The rules of GATT 1947 were insufficient in several respects to address the problem of the increasing use of SPS measures to restrict trade in agricultural and food products. First, GATT disciplines on national regulations focus on prohibiting discrimination against imported products. Thus, the rules do not catch non-discriminatory SPS measures that have trade restrictive effects. Most SPS measures apply not only to imports but also to domestic products. For this reason, they often escaped GATT disciplines. Second, the exception provided in Article XX(b) to the usual GATT rules for measures necessary to protect human, animal or plant life or health does not contain detailed rules disciplining the use of such measures. For example, no risk assessment is required as a basis for a health measure, nor are Members required to publish their proposed health measures in advance. Lastly, there is no recognition in the GATT of the *right* of governments to enact regulations for the protection of human, animal and plant life or health in their territories. Instead, health measures are seen as an *exception* to the usual GATT disciplines and thus the government imposing the measure bears the burden of proving that it falls within the scope of the exception provided in Article XX(b).

The Standards Code also had certain inherent shortcomings that limited its effectiveness in disciplining the use of regulations for the protection of human, animal and plant life and health as barriers to trade. First, it was only binding on its 32 signatories, thus excluding the majority of GATT Contracting Parties from its rules. Second, it did not directly apply to non-product-related processes and production methods ("NPR-PPMs").[17] Thus, regulations on how a specific product was produced fell outside its scope and were dealt with in terms of the usual GATT disciplines. Third, the dispute settlement mechanism created in the Standards Code, like that in GATT 1947, required consensus among WTO Members for the establishment of a panel or technical expert group to review a complaint. It was thus possible for a Member whose regulation was being challenged to block the establishment of a panel or review group. Further, even if review of the measure were not blocked, the findings of the relevant panel or review group had to be adopted by consensus of the signatories to the Standards Code in the Committee on

[16] Vogel discusses a few cases where agreement was reached in bilateral consultations following a challenge on the basis of the Standards Code. David Vogel, *Ships Passing in the Night: GMOs and the Politics of Risk Regulation in Europe and the United States*, Paper prepared for the CONFERENCE ON REGULATORY ISSUES OF GENETICALLY MODIFIED ORGANISMS, Maastricht, June 24–25, 2002, at 152–153.

[17] The definition in the Standards Code of a measure that would fall under its disciplines was "(a) specification contained in a document which lays down the characteristics of a product such as levels of quality, performance, safety or dimensions". This implicitly excludes process and production standards to the extent that they are not reflected in the product characteristics themselves. However, under Article 14 of the Standards Code, a signatory could challenge a PPM measure under the Code where it considered that the requirements had been drafted in the form of regulations on PPMs in order to avoid the Standards Code disciplines.

Technical Barriers to Trade in order to become binding. This created a second possibility for a signatory to block the dispute settlement process. Finally, no enforcement mechanism existed to ensure compliance with adopted dispute settlement reports, and thus compliance depended on the good faith of the Members and the shaming effect of the ruling.

In the 1980s, a dispute arose between the United States and the European Communities ("EC"), concerning an EC ban on the use of hormones for growth-promotion purposes in livestock farming, and an import prohibition on hormone-treated meat.[18] Despite attempts to address this dispute in informal discussions and later in dispute settlement proceedings under the Tokyo Round Standards Code, the conflict remained unresolved.[19] This ongoing dispute served to highlight the insufficiency of the existing rules with respect to the use of measures for the protection of human, animal or plant life or health in ways that restrict international trade. This resulted in an increased awareness of the need for new rules.[20]

C. Uruguay Round Negotiations on the SPS Agreement

1. Negotiating History

One important aim of the Uruguay Round negotiations was the liberalization of the agricultural sector. This sector had remained subject to much protection, despite the existing GATT rules. Thus, agricultural liberalization was one of the main driving forces behind the launching of the Uruguay Round of trade negotiations in September 1986. The agenda for these negotiations was set out in the Punta Del Este Declaration.[21] The Declaration called for the liberalization of trade in agricultural products and for bringing "... all measures affecting import access ... under strengthened and more operationally active GATT rules and disciplines" by, *inter alia*, "minimizing the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements."[22]

During the Uruguay Round negotiations on agricultural trade liberalization and on what would eventually become the Agreement on Agriculture, negotiators were very aware of the possibility that progress towards lowering trade barriers in the agricultural sector could be made ineffective by the increased use of SPS measures for protectionist purposes. Thus special disciplines for SPS measures were seen as crucial and inherently linked to the attempts to liberalize the agricultural sector.

[18] Council Directive of December 31, 1985, *Prohibiting the Use in Livestock Farming of Certain Substances having a Hormonal Action*, 1985 O.J. (L.382) 228. For details of the various EC Directives and proposals on this issue as well as this history of this dispute, *see* Dale E. McNiel, *The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban,* 39 VIRGINIA JOURNAL OF INTERNATIONAL LAW 89, 99–107 (1998).

[19] In 1987, after unsuccessful consultations on this dispute between the United States and the EC, the United States requested that the matter be referred to a technical expert group. The EC blocked the establishment of this expert group.

[20] Patterson discusses possible reasons why, before the Uruguay Round, disciplines for SPS measures were not negotiated despite the fact that the abuse of SPS measures for protectionist purposes was not new. Briefly, these are the importance attached to national sovereignty in health matters and the fact that agreement on uniform rules is made difficult by the fact that national health priorities differ widely. *See* Eliza Patterson, *International Efforts to Minimize the Adverse Trade Effects of National Sanitary and Phytosanitary Regulations*, 24 JOURNAL OF WORLD TRADE 91, 95–96 (1990).

[21] *Ministerial Declaration on the Uruguay Round: Declaration of September 20, 1986,* ("*Punta Del Este Declaration*") GATT B.I.S.D. 33S/19 (1987).

[22] *Punta Del Este Declaration, supra* note 21, at 20.

Originally, the idea was to strengthen the rules in the Standards Code with respect to SPS measures. However, as negotiations progressed, the issue of SPS measures was seen as meriting special attention, apart from the larger genus of technical standards.[23] This led to the creation of a separate Working Group on Sanitary and Phytosanitary Regulations and Barriers in 1989, under the Negotiating Group on Agriculture. As a result, two separate agreements on technical barriers to trade emerged from in the Uruguay Round: first, the Agreement on Technical Barriers to Trade ("TBT Agreement")[24] applicable to technical regulations, standards and conformity assessment procedures other than sanitary or phytosanitary measures; and second, the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement").[25]

2. Position of the Major Trading Nations

In the negotiations that led to the conclusion of the SPS Agreement, the leading role was taken primarily by those countries that account for the largest share of agricultural trade, namely the Cairns Group[26] of agriculture exporting countries, the United States and the EC.[27]

By the mid-term review of the Uruguay Round negotiations in December 1988, five priorities had been agreed upon for SPS disciplines, namely (1) international harmonization of SPS measures around standards set by international organizations; (2) the establishment of an effective notification procedure for SPS measures; (3) improvements to the multilateral dispute settlement system; (4) the possibility of obtaining scientific input and expertise, relying on the international organizations; and (5) an effective mechanism for bilateral settlement of disputes.[28] After the creation of the Working Group on Sanitary and Phytosanitary Regulations and Barriers in 1989, negotiations proceeded on this basis.

Written proposals were submitted to the Working Group. In these proposals, the United States, the EC and the Cairns Group all supported harmonization of SPS measures around the standards set by the Codex Alimentarius Commission, the International Plant

[23] Reasons that have been suggested for this view are the close link between agriculture and SPS standards, the importance of the beef hormone dispute, and the fact that SPS measures were thought to raise problems different from those linked to other technical standards, for example the greater importance of scientific risk assessment, the greater divergence in national approaches to standard setting and the crucial role of national regulatory authorities in deciding on the need for regulation and the measures to be taken. *See* David A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines,* 27 CORNELL INTERNATIONAL LAW JOURNAL 817, 824 (1994).

[24] Agreement on Technical Barriers to Trade, Annex 1A to the Marrakesh Agreement, reprinted in GATT SECRETARIAT, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 6–18 (1994). This Agreement elaborates on and replaces the Tokyo Round Standards Code of 1980. The TBT Agreement goes further than the Standards Code in that it applies to both mandatory technical regulations and optional standards, and extends not only to products but also to related processes and production methods. The TBT Agreement is discussed in Chapter 8 of this book.

[25] Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A to the Marrakesh Agreement, reprinted in THE RESULTS OF THE URUGUAY ROUND, *supra* note 24, at 69–84. The scope of the SPS Agreement and its relationship to the TBT Agreement are discussed *infra* Part II(A).

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

[27] Significant input was also provided by Japan and the Nordic group of countries. Israel, Korea, Austria, Morocco, Brazil and Colombia made proposals on SPS issues within their proposals for the agriculture negotiations in general.

[28] Simonetta Zarrilli and Irene Musselli, THE SPS AGREEMENT AND THE DEVELOPING COUNTRIES, World Bank (2002).

Protection Convention and the International Office of Epizootics or, for matters not covered by these organizations, around standards set by other relevant international organizations open for full participation by WTO Members. However, the proposals initially differed with respect to the strength of the harmonization provision. The United States and the Cairns Group envisaged a presumption of consistency with either the requirement of sound scientific evidence[29] or with the disciplines of Article XX(b)[30] of the GATT for SPS measures based on international standards, requiring Members that impose more stringent standards to prove that their measure was consistent with sound scientific evidence or the relevant GATT provisions. By contrast, the EC saw the international standards as constituting only a "principal source of scientific or technical advice when considering the sanitary and phytosanitary aspects of international trade" and emphasized the need "to provide for countries that have reached a high health status to be able to continue to apply standards more stringent than the international standards, where appropriate".[31] A convergence in positions resulted when, during the negotiations, the EC was faced with restrictions on its wine exports to the United States due to the presence of the pesticide procymidone, while Codex was in the process of adopting a maximum residue level for this pesticide. The EC then realized the potential benefits of harmonized standards and strengthened its support for a stricter harmonization provision.

There was general consensus on the inclusion of a non-discrimination principle and a requirement that the measure not constitute a disguised restriction on trade. In addition, the importance of ensuring transparency by means of notification procedures was agreed upon. The EC and the Cairns Group also indicated the need for technical assistance and special and differential treatment with regard to developing countries, with the Cairns proposal going further in calling for phased introduction of new SPS measures, longer time frames for compliance by developing countries, assistance for dispute settlement, and compensation where SPS measures more stringent than necessary are applied to developing country products.

The Working Group drew up a draft text of the SPS Agreement in October 1990. In the last months of 1990, however, the Uruguay Round negotiations faltered and the Brussels Meeting at which the Round should have been completed ended in deadlock. The deadlock was largely due to disagreement on issues relating to the liberalization of agricultural trade. To break the deadlock, in December 1991 the then Director-General of the GATT tabled what is now known as the "Dunkel Draft", embodying an overall compromise position. With respect to the SPS Agreement the Dunkel Draft closely followed the text of the 1990 draft prepared by the Working Group on Sanitary and

[29] Negotiating Group on Agriculture, *Submission of the United States on Comprehensive Long-Term Agricultural Reform,* MTN.GNG/NG5/W/118 *referred to in* Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat. Revision,* MTN.GNG/NG5/WGSP/W/17/Rev.1, May 29, 1990 at Table 3.

[30] Negotiating Group on Agriculture, *Sanitary and Phytosanitary Issues—Supplementary Communication for the Cairns Group,* MTN.GNG/NG5/W/164 *referred to in* Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat. Revision,* MTN.GNG/NG5/WGSP/W/17/Rev.1, May 29, 1990 at Table 3.

[31] Negotiating Group on Agriculture, *Submission of the European Communities on Sanitary and Phytosanitary Regulations and Measures*, MTN/GNG/NG5/W/146 *referred to in* Negotiating Group on Agriculture, Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat. Revision,* MTN.GNG/NG5/WGSP/W/17/Rev.1, May 29, 1990 at Table 3.

Phytosanitary Regulations and Barriers and this formed the basis for the final text of the SPS Agreement.[32]

3. Role of Developing Countries

Apart from those developing countries that were members of the Cairns group at the time of the Uruguay Round negotiations,[33] developing country participation in the negotiation of the SPS Agreement was very limited. Some developing country Cairns Group members, such as Argentina and Chile, made statements and actively participated in the discussions in the meetings of the Working Group. However, only Brazil and Colombia, acting jointly, and Morocco (not a Cairns Group member) submitted written negotiating proposals in this area, as part of their broader submissions for the agriculture negotiations. These developing countries emphasized the importance of harmonization of SPS measures on the basis of standards set by the international standard-setting organizations, as well as technical assistance and special and differential treatment for developing countries. In addition, it was proposed by Brazil and Colombia that when, without sound scientific evidence, Members apply stricter SPS measures to developing country products than to products from other countries, resulting in a reduction of the market share of developing countries or their exclusion from the relevant market, it should be possible to claim equitable compensation in dispute settlement.[34]

The lack of broader participation from developing countries in the negotiations leading to the drafting of the SPS Agreement can be attributed to their limited resources and the resulting wish to focus on those aspects of the negotiations that they perceived as being of most direct relevance to them (such as the agriculture and textiles negotiations). The technical nature of negotiations regarding disciplines on sanitary and phytosanitary measures may have further discouraged their participation, due to their lack of technical expertise in this area.

D. Overview of the Main Features of the 1994 SPS Agreement

The SPS Agreement tries to balance the right of Member governments to enact measures for the protection of human, animal and plant life or health in their territories against risks contained in imported products, with the goal of liberalizing trade in agricultural and food products. It thus aims to reconcile free trade with the legitimate concerns of governments for the life and health of humans, animals and plants. It does this by recognizing the right

[32] Some significant differences between the Dunkel Draft and the final version of the SPS Agreement were: (1) the addition of a footnote clarifying what the "scientific justification" required when an SPS measure deviates from an international standard is composed of; (2) the change in the initial requirement of Article 5.6 that SPS measures be least restrictive to trade, to indicate that they must be no more trade restrictive that required to achieve their appropriate level of sanitary or phytosanitary protection; (3) the indication in Article 5.3 that the requirement that economic factors be taken into account in a risk assessment does not apply to human health risks; and (4) the extension of the transitional period for implementation of the SPS Agreement from two years to five years, for least-developed country Members. THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986–1994), VOL. IV: THE END GAME 44–45 (Terence P. Stewart ed. 1999).

[33] *See supra* note 26.

[34] Negotiating Group on Agriculture, *Meeting of 27–28 November 1989—Proposal on Special, Differential and More Favourable Treatment for Developing Countries—Communication from Brazil and Colombia,* MTN.GNG/NG5/W/132 *referred to in* Negotiating Group on Agriculture Working Group on Sanitary and Phytosanitary Regulations and Barriers, *Synoptic Table of Proposals Relating to Key Concepts: Note by the Secretariat. Revision,* MTN.GNG/NG5/WGSP/W/17/Rev.1, May 29, 1990 at Table 6.

of Members to enact SPS measures[35] and to determine the level of health protection they want to ensure in their territories,[36] while setting certain limits for the exercise of these rights.

The SPS Agreement lays down specific rules and disciplines applicable to SPS measures. Going further than a mere elaboration and clarification of Article XX(b) of GATT 1994,[37] the SPS Agreement establishes a new, comprehensive set of norms for the adoption, maintenance and enforcement of SPS measures. Unlike the new TBT Agreement, the SPS Agreement emphasizes the role of scientific justification for the validity of national health measures.

The SPS Agreement introduces scientific disciplines for SPS measures. It requires that Members base their SPS measures on science, in the form of a risk assessment.[38] Certain requirements are set for risk assessments. Further, it encourages, without obliging, Members to harmonize their SPS measures around international standards, where these exist.[39] The SPS Agreement makes specific reference to three international standard-setting organizations in the area of SPS standards. Members are obliged to participate fully, within the limits of their resources, in international standard setting in these organizations. If Members wish to adopt SPS measures that are not based on international standards, they must provide scientific justification for these deviating measures. Where scientific evidence is insufficient, Members are allowed to take provisional measures, subject to certain requirements.[40]

In addition to the scientific disciplines on SPS measures, the SPS Agreement incorporates and elaborates GATT disciplines relevant to measures for the protection of human, animal or plant life or health. For example, SPS measures must be necessary to protect human, animal or plant life or health.[41] Members may not adopt measures that are more trade restrictive than required to achieve their chosen level of protection and must take into account the aim of minimizing negative trade effects when choosing their appropriate level of protection.[42] The SPS Agreement prohibits SPS measures that discriminate between Members or between a Member's own territory and that of other Members or are applied so as to constitute a disguised restriction on trade.[43] Members may not make arbitrary or unjustifiable distinctions in the levels of protection they deem appropriate in different but comparable situations.[44]

[35] Contained in Article 2.1of the SPS Agreement and discussed *infra* Part II(B)(1).
[36] *See infra* Part II(F)(1).
[37] Previously Article XX(b) of GATT 1947.
[38] The scientific disciplines are contained in Articles 2.2 and 5 of the SPS Agreement and are discussed *infra* Parts II(B)(2)(b) and II(D) respectively.
[39] The rules in respect of harmonization are contained in Article 3 of the SPS Agreement and are discussed *infra* Part II(C).
[40] Rules on provisional measures are contained in Article 5.7 of the SPS Agreement and discussed *infra* Part II(E).
[41] The "necessary" test is found in Article 2.2 of the SPS Agreement and discussed *infra* Part II(B)(2)(a). It reflects the "necessary" requirement of Article XX(b) of the GATT.
[42] The least-trade-restrictive requirement is found in Article 5.6 and (in non-mandatory form) in Article 5.4 of the SPS Agreement, discussed *infra* Parts II(F)(3) and II(F)(2) respectively, and reflects one element of the "necessary" test in Article XX(b) of the GATT.
[43] This non-discrimination provision is found in Article 2.3 of the SPS Agreement, discussed *infra* Part II(B)(2)(c). It encompasses the national treatment obligation of Article III of the GATT as well as the most favored nation treatment obligation of Article I of the GATT. It also reflects the requirements of the *chapeau* of Article XX of the GATT but is broader in scope.
[44] The goal of consistency in levels of protection is contained in Article 5.5 of the SPS Agreement, discussed *infra* Part II.(F)(2). It is a concrete application of the prohibition on arbitrary or unjustifiable discrimination or disguised restrictions on trade embodied in the *chapeau* to Article XX of the GATT.

The SPS Agreement also creates novel disciplines, specifically designed to minimize the trade-restrictive effect of legitimate SPS measures. It obliges Members to accept different SPS measures as equivalent to their own where they have been shown to achieve the same level of protection,[45] and to adapt their measures to take account of differences such as pest- and disease free status (and low pest and disease prevalence) in different countries and regions.[46]

Further, the SPS Agreement sets out procedural rules to ensure that the adoption and application of legitimate SPS measures do not unnecessarily limit trade. It requires that new or amended SPS measures be notified in advance to other Members and that a reasonable period of time be provided for Members to adapt to the new measures.[47] It also obliges Members to restrict administrative procedures for control, inspection and approval to ensure that they are no more burdensome, lengthy or costly than is reasonable and necessary.[48] An SPS Committee is established to oversee the operation and implementation of the SPS Agreement[49] and special rules are established to deal with scientific expertise in dispute settlement.[50]

Finally, particular rules are in place to address the special position of developing countries. These rules are aimed at the provision of technical assistance to developing country Members[51] as well as special and differential treatment of developing countries.[52]

II. Substantive Provisions of the SPS Agreement as Applied and Interpreted in Case Law

A. Scope of Application of the SPS Agreement (Article 1.1 and Annex A, paragraph 1)

Before examining the substantive disciplines of the SPS Agreement, it is necessary to determine what falls within its scope. Article 1.1 sets out the scope of application of this Agreement. It provides that the SPS Agreement applies to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade."

Thus, as set out by the Panel in *EC—Hormones*, there are two requirements for the SPS Agreement to apply:

> According to Article 1.1 of the SPS Agreement, two requirements need to be fulfilled for the SPS Agreement to apply: (i) the measure in dispute is a sanitary or phytosanitary measure; and (ii) the measure in dispute may, directly or indirectly, affect international trade.[53]

[45] The disciplines on recognition of equivalence are found in Article 4 of the SPS Agreement, discussed *infra* Part II(G)1.
[46] Rules on adaptation to regional conditions are found in Article 6 of the SPS Agreement, discussed *infra* Part II(G)2.
[47] The transparency obligations are contained in Article 7 and Annex B of the SPS Agreement, discussed *infra* Part III(A).
[48] The rules on control, inspection and approval procedures are found in Article 8 and Annex C of the SPS Agreement, discussed *infra* Part III(B).
[49] The provisions relating to the SPS Committee are found in Article 12 of the SPS Agreement, discussed *infra* Part III(C).
[50] Special rules with regard to dispute settlement under the SPS Agreement are found in Article 11 of the SPS Agreement, discussed *infra* Part III(D).
[51] Rules regarding technical assistance for developing countries are found in Article 9 of the SPS Agreement, discussed *infra* Part IV(A).
[52] Provisions relating to special and differential treatment are found in Article 10 of the SPS Agreement, discussed *infra* Part IV(B)(1).
[53] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, WT/DS48/R/CAN (1997), ¶ 8.39 (footnotes omitted); Report of the WTO Panel, *EC—Measures*

The first step is therefore to determine whether the measure is an SPS measure, after which the effect on international trade needs to be examined.

1. Definition of an SPS Measure (Annex A, paragraph 1)

Not all measures imposed for the protection of health are SPS measures for purposes of the SPS Agreement. The term SPS measure is defined in Annex A of the SPS Agreement, which provides in relevant part that an SPS measure is:

> . . . any measure applied: (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

It is clear from this definition that whether a measure falls under the SPS Agreement depends on its purpose or goal. Broadly speaking, the definition covers measures aimed at protecting humans and animals from food-borne health risks and protecting humans, animals and plants from risks from pests or diseases. Measures addressing other health risks relevant for international trade (such as a ban on toys made from toxic plastics or on products containing asbestos) and measures not directly aimed at health protection, but rather at consumer information or ethical concerns (such as requirements for labeling of biologically-grown vegetables or free-range eggs) do not fall under this definition. Such measures would thus not be subject to the disciplines of the SPS Agreement and would have to be analyzed under the relevant provisions of GATT 1994 and the TBT Agreement.[54]

While the characterization of a measure as an SPS measure depends on the purpose or goal of this measure, we are of the opinion that it is not the purpose or goal that a Member ascribes to the measure that is the determining factor.[55] If that were the case, a Member could avoid the application of the Agreement by denying that the purpose of its measure is one of those falling within the Annex A definition. We believe that to establish whether

Concerning Meat and Meat Products (Hormones), Complaint by the United States, WT/DS26/R/USA (1997), ¶ 8.36. It should be noted that in this dispute, the complaints by the United States and Canada regarding the EC ban on hormone-treated beef were dealt with separately by two Panels. However, since the two Panels had the same composition and heard and decided the two complaints together, we will refer to the Panels as "the Panel" (singular). The Panel did, however, circulate two separate reports, which were largely identical. Thus, where reference is made to this dispute, the relevant paragraphs of each of the two reports will be mentioned.

[54] In a recent case the Appellate Body found that a French ban on asbestos products from Canada could be challenged under the TBT Agreement and GATT 1994. *See* Report of the Appellate Body, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (2001), ¶ 75.

[55] *See also* McNiel, *supra* note 18, at 112.

a measure is an SPS measure one has to determine objectively the regulatory goal of the measure (for example by examining the formulation of the measure, its structure or design, and its effect), rather than trying to determine the subjective intent of the Member imposing the measure.

Health protection may be only *one of several* goals or objectives pursued by a measure. How does this affect the characterization of a measure as an SPS measure?[56] Could the Member imposing a measure argue that the other goals or objectives predominate and that the measure is thus not an SPS measure? Would the mere existence of one of the health objectives listed in paragraph 1 of Annex A be sufficient to characterize the measure as an SPS measure? This question has not received any attention in the case law so far. In all four cases to date, the Member defending its measure actually claimed that its purpose was the protection of health.[57]

Once it is established that a measure falls within one of the definitions in Annex A, paragraph 1, it is also important to determine precisely which definition applies since this affects the kind of risk assessment required to support the measure.[58] The risk assessment required differs depending on whether the measure is classified as a measure against food-borne risks (definition in paragraph 1(b)) or as a measure against risks from pests or diseases (definitions in paragraphs 1(a), 1(c) and 1(d)).

In *Australia—Salmon*, the Panel examined whether an Australian ban on imports of fresh, chilled or frozen salmon to prevent the importation of exotic diseases was a "sanitary measure" within the meaning of Annex A, paragraph 1(a) or (b), and stated as follows:

> In the circumstances at hand, we consider that the definition of a "sanitary measure" in paragraph 1(a) encompasses the coverage sought by Australia under the definition in paragraph 1(b). The definition in paragraph 1(a) deals with risks arising from "the entry, establishment or spread of pests, diseases ... or disease-causing organisms" in general. In the context of disease-causing organisms, the definition in paragraph 1(b) is limited in the sense that it only addresses risks arising from "disease-causing organisms in foods, beverages or feedstuffs" (hereafter also referred to as food-borne risks). We are of the view that, even though both definitions of a "sanitary measure" invoked by Australia might be applicable to the measure in dispute, the *objectives for which that measure is being applied* are more appropriately covered by the definition in paragraph 1(a). These objectives have been clearly expressed by Australia on several occasions.[59] (Emphasis added)

It appears in this case that the Panel first objectively determined which of the provisions of Annex A applies, before affirming its conclusion by reference to the fact that Australia had expressed this objective.

Significantly, the definition in Annex A specifies that the measures must aim to protect human, animal or plant life or health "within the territory of the Member." Thus measures

[56] *See also* Joost Pauwelyn, *The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes: EC—Hormones, Australia—Salmon and Japan-Varietals,* 2 JOURNAL OF INTERNATIONAL ECONOMIC LAW 641, 643 (1999).

[57] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.22; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.25; Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon,* WT/DS18/R (1998), ¶ 8.32; Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products,* WT/DS76/R (1998), ¶ 8.12. Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples*, WT/DS245/R (2003), ¶ 4.33. The Panel decisions in each of these cases was appealed. *See* notes 70, 97, 112, and 141 for citations to the Appellate Body Reports. The Appellate Body finding in the cases are discussed extensively in this chapter.

[58] This issue will be discussed *infra* Part II(D)(1).

[59] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.34.

aiming at the extra-territorial application of domestic health standards are excluded from the application of the SPS Agreement. This issue relates to the treatment of measures with respect to processes and production methods ("PPMs") under the SPS Agreement. Although the definition of SPS measures in Annex A of the SPS Agreement expressly includes PPMs, this is qualified by the requirement that SPS measures aim to protect health "within the territory of the Member". Thus, while, for example, rules relating to hygiene in foreign packaging or processing plants or abattoirs would fall within the definition of SPS measures as they aim to prevent health risks in the importing Member, rules on, for example, foreign forestry practices aimed at protecting plant health in the exporting Member would not be considered SPS measures for purposes of the SPS Agreement. Such extra-territorial PPMs would fall under the rules of the GATT[60] or possibly the TBT Agreement.[61]

The definition in Annex A, paragraph 1, goes on to state that SPS measures "include all relevant laws, decrees, regulations, requirements and procedures . . ." and gives a broad, illustrative, non-exhaustive list of such measures ranging from end-product criteria and quarantine requirements to certification and sampling procedures. The SPS Agreement therefore provides broad coverage of legal measures and is clearly intended to cover all measures aimed at one of the above-mentioned purposes, whether by means of legislation, administrative regulation or procedural rules. Thus, if the measure at issue is aimed at one of the goals mentioned in points (a) to (d) of the definition, it is an SPS measure for the purposes of the SPS Agreement, regardless of the specific form it takes.

The scope of application of the SPS Agreement is not limited to discriminatory measures. WTO Members negotiating the SPS Agreement realized that a test based on discrimination does not adequately distinguish between legitimate SPS measures and those used for protectionist purposes.[62] It is possible for a measure which neither discriminates de facto nor de jure between domestic products and imports to have a negative impact on international trade, and thereby serve to protect domestic industry from foreign competition. For example, a low maximum residue level for the presence of a specific chemical used in pesticides, applicable to both domestic and imported fruit, may have the effect of excluding fruit exports from many countries from the domestic market. The SPS Agreement is thus also applicable to non-discriminatory SPS measures that affect international trade. The application of the Agreement therefore extends beyond the scope of GATT 1994, which is limited to discriminatory measures. An SPS measure is subject to the disciplines of the SPS Agreement even if it is neither directly nor indirectly discriminatory and is thus GATT-consistent.

2. Direct or Indirect Effect on International Trade (Article 1.1)

The second requirement set forth in Article 1.1 for the application of the SPS Agreement is that it must be shown that the relevant measure may directly or indirectly affect international trade. It would appear that this is not an empirical standard, necessitating proof

[60] There has been extensive discussion in the literature regarding whether, under GATT law, Members are allowed to distinguish between products in their regulations on the basis of PPMs. The debate focuses on whether products made using different PPMs are to be considered "like products" for purposes of the non-discrimination rules of the GATT. If so, the question remains open whether the exceptions in Article XX of the GATT could in limited cases justify extra-territorial measures dealing with PPM issues.

[61] There is some debate regarding whether PPMs that do not affect the characteristics of the product fall under the definition of a "technical regulation" for purposes of the TBT Agreement. Since the TBT Agreement is dealt with in Chapter 8 of this book, this issue will not be addressed here.

[62] David R. Hurst, *Hormones: European Communities—Measures Affecting Meat and Meat Products,* 9 European Journal of International Law 182, 182 (1998).

that the measure has led to a reduction in trade flows, but rather a theoretical standard, met by showing that the measure applies to imports and can therefore be presumed to have a negative impact on trade.[63] In *EC -Hormones* the Panel agreed with both parties that this requirement had been met and stated that "it cannot be contested that an import ban affects international trade."[64] This requirement should be easy to fulfill, and has yet to be discussed in any SPS case.

3. Other Issues relating to the Scope of Application

(a) Applicability to Bodies Other than Central Government Bodies (Article 13). The applicability of the disciplines in the SPS Agreement to bodies other than the central government is addressed in Article 13 of the SPS Agreement. This provision states:

> Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

The compliance Panel in *Australia—Salmon* in this regard found, with respect to the applicability of the SPS Agreement to a measure taken by a state government (Tasmania), as follows:

> Article 13 of the SPS Agreement provides unambiguously that: (1) "Members are fully responsible under [the SPS] Agreement for the observance of all obligations set forth herein"; and (2) "Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies". Reading these two obligations together, in light of Article 1.1 of the SPS Agreement referred to earlier, we consider that sanitary measures taken by the Government of Tasmania, being an "other than central government" body as recognized by Australia, are subject to the SPS Agreement and fall under the responsibility of Australia as WTO Member when it comes to their observance of SPS obligations.[65]

Thus the rules contained in the SPS Agreement will not only have an impact on the central government bodies of a Member, but indirectly also on other bodies under its responsibility charged with duties in the area of sanitary and phytosanitary protection. It is the task of the Member to ensure that these bodies comply with the disciplines of the SPS Agreement.

(b) No Requirement of Prior Proof of GATT Violation. Before the coming into force of the SPS Agreement, Members were only required to justify their health measures under

[63] McNiel, *supra* note 18, at 113.
[64] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.23; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.26.
[65] Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon, Recourse to Article 21.5 by Canada*, WT/DS18/RW (2000), ¶ 7.13.

Article XX(b) of the GATT once a violation of GATT disciplines had been shown. This is a logical consequence of the rule/exception relationship between Articles III and XI on the one hand and Article XX on the other. The Panel in *EC—Hormones* was faced with the question whether a prior violation of the GATT 1994 must be shown before the SPS Agreement is applicable to a dispute. The EC argued that since the Preamble of the SPS Agreement explicitly states as one of its aims the elaboration of rules for the application of the provisions of the GATT 1994 relating to SPS measures, particularly Article XX(b), the SPS Agreement is not an independent agreement but only an interpretation of Article XX(b). It would thus only apply in cases where Articles I, III or XI of the GATT 1994 had been violated and recourse could be had to the Article XX(b) exception.[66] The Panel rejected this argument, finding that the SPS Agreement is an independent agreement, imposing substantive obligations that go beyond those of the GATT.[67] After referring to the two requirements of Article 1.1, it held:

> . . . There are no additional requirements. The SPS Agreement contains, in particular, no explicit requirement of a prior violation of a provision of GATT which would govern the applicability of the SPS Agreement, as asserted by the European Communities.[68]

Thus, prior proof of a violation of the GATT is not a precondition for the applicability of the SPS Agreement.[69] This finding is clearly correct, since the scope of the SPS Agreement is broader than that of the GATT. As noted above, an SPS measure that is non-discriminatory and thus in compliance with GATT rules could still fall foul of the disciplines of the SPS Agreement, for example by not being based on a risk assessment. While, as has been stated above, the negotiations on the SPS Agreement started out, *inter alia,* as an attempt to clarify Article XX(b) of the GATT, it is clear that the result went far beyond this. The SPS Agreement now lays down a comprehensive set of rights and obligations, independent of those contained in GATT 1994 and covers all SPS measures that could have an impact on international trade, not only those that are discriminatory in nature or effect. Therefore it is clear that a violation of the GATT cannot be a prerequisite for the applicability of the SPS Agreement.

(c) Temporal Scope of Application. The temporal scope of application of the SPS Agreement also deserves attention here. In EC— *Hormones* the EC argued that, as its measure

[66] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 4.4; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 4.3.

[67] The Panel based its finding on the following grounds: (1) under the plain language of Article1.1 which governs the applicability of the SPS Agreement, the only requirements are that the relevant measure be an SPS measure as defined in Annex A and that it affect international trade. No prior violation of GATT is required. (2) The SPS Agreement does not only elaborate on GATT provisions but establishes its own substantive obligations in order to further, *inter alia*, the harmonization of SPS measures. (3) Under Article 2.4 of the SPS Agreement, measures that conform to the SPS Agreement are deemed to comply with GATT provisions, in particular Article XX(b). (4) Article 3.2 of the SPS Agreement states that measures conforming to international standards are presumed consistent with GATT 1994. These presumptions imply that the SPS Agreement contains at least as many and probably more obligations than Article XX(b) of the GATT 1994.

[68] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.39 (footnotes omitted); Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.36.

[69] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.42–8.44 (footnotes omitted); Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.39–8.41.

predated the entry into force of the SPS Agreement on January 1, 1995, the SPS Agreement was not applicable to it. The Appellate Body agreed with the Panel's finding that the SPS Agreement nevertheless governed the dispute. The Appellate Body held as follows:

> If the negotiators had wanted to exempt the very large group of SPS measures in existence on 1 January 1995 from the disciplines of provisions as important as Articles 5.1 and 5.5, it appears reasonable to us to expect that they would have said so explicitly. Articles 5.1 and 5.5 do not distinguish between SPS measures adopted before 1 January 1995 and measures adopted since; the relevant implication is that they are intended to be applicable to both.[70]

The Panel had based its conclusion on Article 28 of the Vienna Convention on the Law of Treaties[71] which provides that—as a rule—a treaty cannot apply to acts, facts or situations ceasing to exist before the treaty came into force. As the EC measure continued to exist after the entry into force of the SPS Agreement and since there were no provisions in the SPS Agreement itself limiting its temporal application, the Agreement was held to apply to the measure in question.[72] The Appellate Body also pointed to Article XVI:4 of the Marrakesh Agreement which obliges Members to ensure the conformity of their laws, regulations and procedures with their obligations under the annexed Agreements.[73] It is thus apparent that Members have to review their existing SPS measures in the light of the new disciplines of the SPS Agreement, in particular those relating to the scientific basis for SPS measures.

Recognizing the difficulties that this could cause for Members, particularly in the light of the requirement contained in the SPS Agreement that measures be based on risk assessments, the Appellate Body pointed to the qualification to this obligation in Article 5.1, which provides for a degree of flexibility by requiring only a risk assessment "as appropriate to the circumstances."[74]

From the above discussion it is apparent that the SPS Agreement has a very broad scope of application. The disciplines it establishes will have a far-reaching impact on national measures for the protection of health falling within the definition of SPS measures.

4. Relationship with other WTO Agreements

Where a measure for the protection of health is at issue, it could fall under any of the following three WTO agreements, namely the SPS Agreement, the TBT Agreement or GATT 1994, depending on the nature and content or objective of the measure. While both the SPS Agreement and the TBT Agreement circumscribe the measures to which they apply,[75] GATT 1994 rules[76] generally apply to discriminatory measures applicable

[70] Report of the Appellate Body, *EC—Measures Concerning Meat* and *Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, ¶ 128.

[71] Concluded in Vienna on May 23, 1969, 8 I.L.M. 679 (1969).

[72] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.25; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.25.

[73] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 128.

[74] *Id.* ¶ 129.

[75] The SPS Agreement applies to SPS measures as defined in Annex A thereto and the TBT Agreement applies to technical regulations, standards and conformity assessment procedures, as defined in Annex 1 thereto, except where these are covered by the SPS Agreement.

[76] Most relevant for our purposes are Articles III:4, XI and XX(b) of GATT 1994, the provisions of which are described briefly *supra* Part I(B)(1).

to trade in goods.[77] Thus, the treatment of measures for the protection of health under WTO law is determined by the relevant provisions of these three agreements within their respective spheres of application. The relationship between these agreements will therefore be addressed. In addition, the relationship between the SPS Agreement and the Agreement on Agriculture also deserves attention here due to the close link between the aims of these agreements.

(a) The TBT Agreement. As discussed above, during the Uruguay Round negotiations it was agreed that separate disciplines were necessary for SPS measures aside from those applicable to technical standards generally.[78] This led to the drafting of two separate agreements on technical barriers: the SPS Agreement and the TBT Agreement.

The importance of establishing which of these two agreements applies when dealing with a technical regulation or standard for the protection of health comes from the fact that the two agreements apply different disciplines to measures falling within their respective ambits. The rules in the TBT Agreement are less strict; they are primarily aimed at ensuring that technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to trade, while recognizing the right of governments to pursue legitimate objectives by means of such measures. In brief, the TBT Agreement prohibits discrimination in the preparation, adoption and application of technical regulations, standards and conformity assessment procedures, establishes a Code of Good Practice for standardizing bodies, mandates the use of the least-trade-restrictive measure available, obliges transparency in the regulatory process and encourages the adoption of international standards. However, unlike the SPS Agreement, it sets no scientific requirements for the adoption of measures and it allows deviation from international standards where necessary to fulfill a legitimate objective, without requiring scientific justification for the deviation.

It is clear, therefore, that it would be to the advantage of a complaining Member to challenge a measure under the SPS Agreement rather than the TBT Agreement. However, this choice is not left to the complaining Member. Instead, the TBT Agreement provides in Article 1.5:

> The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Thus, once a measure falls within the definition of an SPS measure in Annex A of the SPS Agreement, it falls under the disciplines of the SPS Agreement to the exclusion of the TBT Agreement.

(b) GATT 1994 (Article 2.4). The insufficiency of Article XX(b) of GATT 1947 to deal with the complexities of SPS regulations was one of the factors that led Members to negotiate the SPS Agreement in the Uruguay Round, as set out above. Members sought to flesh out Article XX(b), thereby establishing limits on the use of health measures in ways that could adversely affect international trade. However, the resultant SPS Agreement goes further than a mere elaboration of Article XX(b). Instead, it establishes a new, comprehensive set of norms for the adoption and maintenance of SPS measures.

[77] The scope of application of GATT 1994 is thus at once narrower (including only discriminatory measures) and broader (including all such measures, not only SPS measures) than that of the SPS Agreement.
[78] For a more detailed discussion of the negotiating history, *see supra* Part I(C).

The Panel in *EC—Hormones* held the following on the relationship between the SPS Agreement and Article XX(b) of GATT 1994:

> . . . we find the EC claim that the SPS Agreement does not impose "substantive" obligations additional to those already contained in Article XX(b) of GATT not to be persuasive. It is clear that some provisions of the SPS Agreement elaborate on provisions already contained in GATT, in particular Article XX(b). The final preambular paragraph of the SPS Agreement provides, indeed, that the Members desired "to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Examples of such rules are, arguably, some of the obligations contained in Article 2 of the SPS Agreement. However, on this basis alone we cannot conclude that the SPS Agreement only applies, as Article XX(b) of GATT does, if, and only if, a prior violation of a GATT provision has been established. Many provisions of the SPS Agreement impose "substantive" obligations which go significantly beyond and are additional to the requirements for invocation of Article XX(b). These obligations are, *inter alia,* imposed to "further the use of harmonized sanitary and phytosanitary measures between Members"[79] and to "improve the human health, animal health and phytosanitary situation in all Members".[80] They are not imposed, as is the case of the obligations imposed by Article XX(b) of GATT, to justify a violation of another GATT obligation (such as a violation of the non-discrimination obligations of Articles I or III).[81]

The SPS Agreement, however, does not expressly supplant the relevant provisions of GATT 1947 (now incorporated by reference in GATT 1994) applicable to health measures. Nor is it subordinate to the GATT. Instead, the two agreements now operate as complements to each other and to the TBT Agreement.[82]

Where the measure at issue is an SPS measure as defined in Annex A of the SPS Agreement, it may fall within the scope of application of the SPS Agreement and, to the extent that it is also discriminatory, within that of GATT 1994. Therefore, both these agreements would, in principle, apply to such a measure. The relationship between GATT 1994 and the other multilateral agreements on trade in goods, including the SPS Agreement, in case of conflict is defined in the General Interpretative Note to Annex 1A of the WTO Agreement, which provides:

> In the event of conflict between a provision of the GATT 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the WTO (referred to in the Agreements in Annex 1A as the "WTO Agreement"), the provision of the other agreement shall prevail to the extent of the conflict.

Therefore, in the case of a conflict between the applicable GATT rules and the SPS Agreement, the latter prevails. The SPS Agreement could be seen as a kind of *lex specialis* specifying rules applicable to SPS measures, aside from the more generally applicable rules of the GATT 1994.

However, the possibility for conflict between GATT rules and the disciplines of the SPS Agreement is slim, as the SPS Agreement incorporates the relevant GATT disciplines. This fact is reflected in Article 2.4 of the SPS Agreement, which, unlike the case with

[79] Preambular ¶ 6 of the SPS Agreement [Footnote in original].
[80] Preambular ¶ 2 of the SPS Agreement [Footnote in original].
[81] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.38, and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.41.
[82] A detailed discussion on the relationship between the GATT, the SPS Agreement and the TBT Agreement can be found in Gabrielle Marceau and Joel P.Trachtman, *The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade: A Map of the World Trade Organization Law of Domestic Regulation* 36 JOURNAL OF WORLD TRADE 811 (2002).

the other Annex 1A agreements, contains a presumption of consistency with GATT 1994 for measures conforming to its provisions. Article 2.4 of the SPS Agreement provides:

> Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

We consider that one can infer from the presumption of consistency in Article 2.4 that the provisions of Article XX(b) of the GATT 1994 and all other relevant provisions of that Agreement could be regarded as being subsumed into the SPS Agreement, to the extent that they would apply to discriminatory SPS measures.

When an SPS measure is at issue, it is therefore logical to examine this measure under the SPS Agreement first.[83] This argument is borne out by the finding of the Panel in *EC—Hormones* which, when it addressed the question of which of the two agreements to examine first, held:

> The SPS Agreement specifically addresses the type of measure in dispute. If we were to examine GATT first, we would in any event need to revert to the SPS Agreement: if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement. For these reasons, and in order to conduct our consideration of this dispute in the most efficient manner, we shall first examine the claims raised under the SPS Agreement.[84]

Also, in *Australia—Salmon*, the Panel first examined the SPS Agreement, holding:

> Canada recognizes that the SPS Agreement provides for obligations additional to those contained in GATT 1994, but, nevertheless, first addresses its claim under Article XI of GATT 1994. Australia invokes Article 2.4 of the SPS Agreement, which presumes GATT consistency for measures found to be in conformity with the SPS Agreement, to first address the SPS Agreement. We note, moreover, that (1) the SPS Agreement specifically addresses the type of measure in dispute, and (2) we will in any case need to examine the SPS Agreement, whether or not we find a GATT violation (since GATT consistency is nowhere presumed to constitute consistency with the SPS Agreement). In order to conduct our consideration of this dispute in the most efficient manner, we shall, therefore, first address the claims made by Canada under the SPS Agreement before addressing those put forward under GATT 1994.[85]

While the presumption of GATT-consistency of measures found to be in compliance with the SPS Agreement could in theory perhaps be rebutted, in which case the provisions of

[83] In favor of this position, *see* Reinhard Quick and Andreas Blüthner, *Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case,* 2 JOURNAL OF INTERNATIONAL ECONOMIC LAW 603 (1999). *See also contra,* Pierre Pescatore, *The Reconciliation of Interests and the Revision of Dispute Resolution Procedures in the Framework of the WTO*, paper presented at the expert meeting FREE WORLD TRADE AND THE EUROPEAN UNION Academy of European Law, Trier, June 11–12, 1998, at 23 (summarized in Quick and Blüthner, at 627), where it is argued that the SPS Agreement is subordinate to GATT principles and therefore the first question in a dispute should always be whether there is a violation of GATT rules which can give rise to the application of Article XX(b) and consequently to SPS rules.

[84] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.42; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.45.

[85] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.39.

the GATT 1994 would subsequently need to be examined,[86] it is difficult to think of any examples where this would be the case.[87] In our opinion, the relevant GATT rules are best seen as having been subsumed into the disciplines of SPS Agreement, and this leads us to the conclusion that the presumption of GATT-consistency contained in Article 2.4 should be regarded as irrebuttable.

(c) The Agreement on Agriculture. It was clear to the negotiators of the Agreement on Agriculture that special disciplines for SPS measures were crucial and inherently linked to the attempts to liberalize trade in agricultural products. This link is made explicit in Article 14 of the Agreement on Agriculture, which states that "Members agree to give effect to the Agreement on the Application of Sanitary and Phytosanitary Measures."

This provision is, legally speaking, redundant, since all WTO Members are bound to give effect to *all* multilateral WTO agreements including the SPS Agreement. However, this provision does serve to emphasize the negotiators' acknowledgement of the importance of the disciplines in the SPS Agreement in securing the gains for agricultural trade liberalization achieved in the Agreement on Agriculture.

The SPS Agreement and the Agreement on Agriculture are complementary in nature. Both have the common aim of enhancing market access in the agricultural sector by creating disciplines on trade-restrictive measures. However, the SPS Agreement covers measures affecting not only agricultural but also food products. In addition, while the Agreement on Agriculture addresses the traditional trade barriers in the agricultural sector, the SPS Agreement was negotiated to deal with trade barriers that were not covered by the disciplines of the Agreement on Agriculture, namely sanitary and phytosanitary measures. Thus, together these two agreements represent an important step forward in securing market access for food and agricultural products.

B. Basic Rights and Obligations (Article 2)

1. Right to Take SPS Measures (Article 2.1)

Article 2 of the SPS Agreement sets out the basic rights and obligations under the Agreement. They are further elaborated in subsequent articles. This article reflects the underlying aim of the SPS Agreement of balancing the legitimate right of sovereign governments to take health protection measures, with the goal of promoting free trade and preventing protectionism. Article 2, under the heading *Basic Rights and Obligations* provides in relevant part as follows:

[86] *See* Quick and Blüthner, *supra* note 83, at 628.

[87] Quick and Blüthner argue that an interpretation of those SPS rules which are similar to GATT disciplines (such as those in Articles 2.3 and 5.5 of the SPS Agreement), in a way that diverges from that given to the relevant GATT provision (Article XX), would make it possible for a challenging Member who loses the case under the SPS Agreement, to "easily" rebut the presumption of compatibility and pursue its challenge under the GATT. This result would go against the aim of the SPS Agreement to clarify and give further meaning to the relevant GATT provisions (while going further than GATT). Thus they argue that the panels and Appellate Body should interpret these SPS rules in the light of existing GATT jurisprudence to avoid this possibility. *Id.* At 630–632. On the other hand, Goh and Ziegler claim that where an SPS measure is at issue, the SPS Agreement should apply exclusively, making recourse to the GATT impossible. Gavin Goh and Andreas R. Ziegler, *A Real World Where People Live and Work and Die: Australian SPS Measures after the WTO Appellate Body's Decision in the Hormones Case,* 35 JOURNAL OF WORLD TRADE 271 (1998). This would imply that the presumption of compatibility with the relevant GATT provisions is irrebuttable.

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

Significantly, paragraph 1 of Article 2 explicitly recognizes the *right* of Members to take SPS measures necessary for the protection of human, plant or animal life or health provided that they conform to the provisions of the SPS Agreement. This is an important provision as it represents a movement away from the situation under GATT 1994 where discriminatory health measures are, in principle, prohibited unless they can be justified under the exception provided in Article XX(b). Thus, under the GATT rules, the burden of proof rests on the Member imposing the SPS measure to prove that it meets the requirements of Article XX(b) and the *chapeau* of Article XX. On the contrary, Article 2.1 of the SPS Agreement makes clear that SPS measures are, in principle, allowed and it is therefore for the complaining Member to prove that the measure is not consistent with the provisions of the SPS Agreement.

However, the right of Members to impose SPS measures is not unlimited but subject to the disciplines set out in the rest of the SPS Agreement. These disciplines can usefully be divided into two categories: first, the new scientific disciplines on the use of SPS measures, introduced by the SPS Agreement, and, second, the familiar GATT trade disciplines, which are reiterated in the SPS Agreement.[88] These disciplines are first reflected in paragraphs 2 and 3 of Article 2 and are further elaborated in later provisions.

2. Limits to the Right to Apply SPS Measures (Articles 2.2 and 2.3)

Article 2.2 lays down three requirements for SPS measures: they must be (a) applied only to the extent necessary to protect human, animal or plant life or health; (b) based on scientific principles; and (c) not maintained without sufficient scientific evidence, except as provided for in Article 5.7. Article 2.3 contains the familiar GATT prohibitions on arbitrary or unjustifiable discrimination and disguised restrictions on trade.

(a) Applied Only To the Extent Necessary to Protect Human, Animal or Plant Life or Health (Article 2.2). The obligation on Members, contained in the first part of Article 2.2, to ensure that SPS measures are applied "only to the extent necessary to protect human, animal or plant life or health" reflects the well-known discipline contained in Article XX(b) of GATT 1994 justifying measures with health-policy objectives. This requirement of Article 2.2 has not yet been subject to dispute settlement. However, cases decided under Article XX(b) of GATT 1994 can usefully be examined to determine how this discipline is likely to be interpreted by panels and the Appellate Body in future cases

[88] The prohibition on arbitrary or unjustifiable discrimination and disguised restrictions on trade is contained in the *chapeau* of Article XX of GATT 1994 and the necessary test in paragraph (b) of that article.

under the SPS Agreement.[89] In particular, those aspects of the "necessary" test under Article XX(b) of the GATT that are not already reflected in later provisions of the SPS Agreement,[90] would probably be addressed under Article 2.2. It should, however, be borne in mind that while GATT Article XX(b) represents an exception to the normal disciplines, and thus the burden of proof to show that its requirements are met rests on the Member imposing the health measure, under the SPS Agreement this rule-exception relationship is not present and it is for the complaining Member to prove that this obligation has not been fulfilled.

(b) Based on Scientific Principles and Not Maintained Without Sufficient Scientific Evidence (Article 2.2). Article 2.2 of the SPS Agreement also requires that SPS measures be based on scientific principles and not be maintained without sufficient scientific evidence. The importance of these basic scientific disciplines, which are further elaborated in Article 5.1 and which mediate between the goals of national health protection and the liberalization of trade, was made explicit in *EC—Hormones*, where the Appellate Body stated:

> The requirements of a risk assessment under Article 5.1, as well as of "sufficient scientific evidence" under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings.[91]

Article 2.2 raises the question of the meaning of "scientific principles" and "scientific evidence", as well as what will be regarded as sufficient, both in terms of the quantity of evidence required and its quality or scientific validity.[92]

Although this issue was raised in *EC—Hormones*, the Panel found violations of Articles 3 and 5 and thus did not consider it necessary to decide whether Article 2 was also violated (*see* note 53, *supra*). The Appellate Body agreed with this application of judicial economy, but stated that it would have been more logical for the Panel to start

[89] The likelihood that a similar interpretation will be followed can be inferred from the presumption in Article 2.4 SPS that measures conforming to the SPS Agreement are in accordance with GATT obligations, in particular Article XX(b), discussed *supra* Part II(A)(4)(b). See in this regard the argument of Quick and Blüthner, set out *supra* note 87.

[90] The Panel in *U.S.—Gasoline* identified two requirements for the test of Article XX(b) of the GATT to be met, namely that the policy aimed at by the measure falls within the ambit of policies designed to protect human, animal or plant life or health, and that the measure imposed be necessary to achieve this objective. Report of the WTO Panel, *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/R (1996) ¶ 6.20. The first part of this test is already covered by the definition of SPS measures in the SPS Agreement. Measures not falling within the policy objective of this definition will not be covered by the SPS Agreement. It is the second element of the test that is more interesting here, namely the "necessity" test. To the extent that it has been interpreted in Article XX case law to require the least-trade restrictive measure reasonably available that achieves a Member's appropriate level of protection, it is already embodied in Article 5.6 of the SPS Agreement. Report of the GATT Panel, *Restrictions on Importation of and Internal Taxes on Cigarettes*, BISD, 37th Supp. 200 (1991), ¶ 75. However, the Article XX(b) case law also establishes an element of weighing and balancing of factors, including the contribution made by the measure to the aim it pursues, the importance of the common interests of values protected by the measure and the trade restrictive effect of the measure. Report of the Appellate Body, *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R (2000), ¶¶ 162–164; Report of the Appellate Body, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products,* supra note 54, ¶ 172. We argue that this element will be of importance in the interpretation of the first requirement of Article 2.2 of the SPS Agreement.

[91] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 177.

[92] McNiel, *supra* note 18, at 117.

by focusing on Article 2, which sets out the basic rights and duties, before considering Article 5 (*see* note 70, *supra*).

In *Japan—Apples*,[93] the Panel, for the first time, examined the meaning of the words "scientific evidence" in Article 2.2. It held that in order to be "scientific" the evidence must be gathered through scientific methods.[94] It also established that both direct and indirect evidence can be scientific, although the probative value ascribed to each would differ.[95] According to the Panel, "evidence" excludes insufficiently substantiated information and non-demonstrated hypotheses.[96]

In *Japan—Agricultural Products,* the Panel and the Appellate Body were once again faced with the issue of the meaning of "sufficient scientific evidence" in Article 2.2, and they established a very vague test for sufficiency. The Appellate Body stated:

> The ordinary meaning of "sufficient" is "of a quantity, extent, or scope adequate to a certain purpose or object". From this, we can conclude that "sufficiency" is a relational concept. "Sufficiency" requires the existence of a sufficient or adequate relationship between two elements, *in casu,* between the SPS measure and the scientific evidence.
>
> The context of the word "sufficient" or, more generally, the phrase "maintained without sufficient scientific evidence" in Article 2.2, includes Article 5.1 as well as Articles 3.3 and 5.7 of the SPS Agreement.[97]

In examining this context of the term "sufficient", the Appellate Body first agreed with the Panel that the Appellate Body's finding in *EC—Hormones* regarding Article 5.1 provides guidance for the interpretation of Article 2.2.[98] In *EC—Hormones* it had held that the requirement in Article 5.1 that a measure be "based on" a risk assessment, read together with Article 2.2, means that there must be a rational relationship between the measure and the risk assessment. Second, the Appellate Body looked at Article 3.3 which allows Members to introduce or maintain measures resulting in a higher level of protection than those based on the relevant international standard, *inter alia* if there is sufficient scientific justification. The Appellate Body held that there is sufficient scientific justification if there is a rational relationship between the measure and the available scientific information.[99] Third, the Appellate Body turned to Article 5.7, which allows Members to adopt provisional measures in case of insufficient scientific evidence. It held that this is a qualified exemption from Article 2.2 and that a too-broad interpretation of Article 2.2 would render it meaningless.[100]

The Appellate Body then concluded:

> . . . we agree with the Panel that the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence. Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.[101]

[93] *Supra*, note 57.
[94] *Id.* ¶ 8.92.
[95] *Id.*, ¶¶ 8.91 and 8.98–8.99.
[96] *Id.*, ¶ 8.93.
[97] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, WT/DS76/AB/R (1999), ¶¶ 73–74.
[98] *Id.* ¶ 76.
[99] *Id.* ¶ 79.
[100] *Id.* ¶ 80.
[101] *Id.* ¶ 84.

The Appellate Body then proceeded to agree with the Panel that Japan's SPS measure, the varietal testing requirement,[102] was maintained without sufficient scientific evidence for four of the eight products at issue.[103]

In *Japan—Apples*, the meaning of the word "sufficient" in Article 2.2 was again at issue. The Panel followed the interpretation of the Appellate Body in *Japan—Agricultural Products,* namely that sufficiency is a relational concept and thus that there must be a sufficient or adequate relationship between the SPS measure and the scientific evidence. The Panel took this to mean an objective or rational relationship.[104] It then stated that although the term "sufficient" is clearly to be considered in relation to the phytosanitary measure itself, "scientific evidence relates to a risk and is supposed to confirm the existence of a given risk."[105] It thus linked the concept of sufficiency in Article 2.2 to the extent to which the scientific evidence indicates the existence of a risk.

After examining the evidence submitted to it, the Panel held that a *negligible*[106] risk of transmission of fire blight through apple fruit was shown and there was no sufficient scientific evidence that apple fruit was likely to serve as a pathway for the entry, establishment or spread of fire blight in Japan.[107] In order to come to this conclusion, the Panel disassembled the sequence of events on the transmission pathway for fire blight, in order to identify the risk, and then compared the risk so identified with the measure at issue.[108] As a result, the Panel held that Japan's measure, which consisted of a range of cumulative requirements that had to be met for importation to be allowed,[109] was

[102] The varietal testing requirement refers to Japan's requirement that different varieties of eight agricultural products, which are potential hosts of codling moth, be tested before importation to ensure the efficacy of the quarantine treatment.

[103] The Panel's decision was based on a factual finding of an absence of a causal link between varietal differences and test differences with respect to the relationship between the fumigant concentration and the time period of fumigation (CxT value) and the dose required to kill 50 percent of codling moths (LD50 value). The experts advising the panel were of the view that the differences in CxT and LD50 values could have been caused by a number of factors not related to varietal differences (*e.g.*, leakage in the fumigation chamber, sorption by the packaging material and experimental errors). The Appellate Body understood this finding to indicate the absence of a rational relationship between the varietal testing requirement and the scientific evidence.

[104] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶¶ 8.101–8.103.

[105] *Id.*, ¶ 8.104.

[106] One of the experts consulted by the Panel, Dr Hayward, indicated that the standard scientific definition of "negligible" was a likelihood of between zero and one in one million.

[107] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶¶ 8.169 and 8.176.

[108] The Panel based this finding on its conclusions on the basis of the evidence available to it with regard to mature symptomless apples and other apples. With regard to mature, symptomless apples, it found that infection with fire blight had not been established; that populations of endophytic bacteria have not been found and epiphytic bacteria are very rare; and that the risk of completion of the transmission pathway is negligible. With regard to apples other than mature, symptomless fruit, it held that infected apples are capable of harbouring populations of bacteria which could survive through the various stages of commercial handling, storage and transportation; that risks of errors of handling or illegal actions could legitimately be taken into account, although the experts considered these risks small or debatable; but that completion of the last stage of the transmission pathway (the transmission of the bacteria to the host plant) was not shown to be likely. This was because only a reduced number of bacteria would survive commercial storage, handling and transportation and the existence of a vector (such as rain splash or bees), which could transmit the bacteria from the imported apples to the host apple plant in Japan, had not been established. Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶¶ 8.136, 8.139, 8.153, 8.157, 8.161, 8.168.

[109] These conditions are: that the apples are produced in designated fire blight-free orchards; that the orchard is free of fire blight-infected plants and other host plants of fire blight; that the orchard is surrounded by

"clearly disproportionate" to the negligible risk identified.[110] The Panel thus introduced a *proportionality test* into the "rational relationship" requirement in Article 2.2.[111]

On appeal, the Appellate Body accepted as appropriate the methodology of the Panel of disassembling the sequence of events and comparing the risk to the measure, in its Article 2.2 analysis, but noted that this does not exhaust the range of possible methodologies and that the circumstances of each case will determine the appropriateness of a given methodology.[112] The Appellate Body also did not take issue with the Panel's view that "clear disproportion" between the risk and the measure implies that a "rational or objective" relationship does not exist.[113] It rejected Japan's contention that the Panel should have accorded Japan a "certain degree of discretion" in the way in which it chose, weighed and evaluated the scientific evidence, finding that deference by panels to the findings of national authorities would not be compatible with the standard of review[114] applicable to panels.[115]

The "rational relationship-test" developed in the case law does not lay down clear guidelines on what will be regarded as "sufficient scientific evidence", beyond establishing a proportionality requirement. By leaving wide discretion to panels to make *ad hoc* decisions based on their evaluation of the circumstances of the case, it explicitly gives panels the mandate to evaluate the quality or weight of the scientific evidence presented. Are panels, which are primarily composed of trade experts, qualified for this task?[116] It has been argued that a panel should limit its enquiry to the question whether there is scientific consensus or scientific uncertainty regarding the issue at hand. Scientific uncertainty is most often the case and is evinced by the presence of a good faith difference of opinion among scientists. In such cases, a panel should determine which of the alternative accounts are found plausible by scientists and which are not. If there is any reputable scientific support for the Member's measure, it should be held to be based on "sufficient scientific evidence".[117]

Article 2.2 embodies the core SPS obligation establishing the role of science as a crucial part of the disciplines in respect of SPS measures. This provision sets science as

a 500-meter buffer zone; that the orchard and buffer zone are inspected at least three times per year; that the harvested apples, harvesting containers and interior of the packing facility be disinfected; that apples destined for Japan be kept separate from other apples after harvesting; that US officials certify that the apples are not infested or infected with fire blight and were disinfected; and that Japanese officials confirm the certification and carry out inspections themselves.

[110] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶¶ 8.181 and 8.198.

[111] The Panel proceeded to examine two elements of Japan's measure, namely the buffer-zone requirement and the requirement of inspections three times yearly, as instances of elements most obviously maintained without sufficient scientific evidence either as such or when applied cumulatively with other elements. *Id.*, ¶¶ 8.182–8.197.

[112] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples*, WT/DS245/AB/R (2003), ¶ 164.

[113] *Id.*, ¶ 163.

[114] It is well-established case law that the standard of review to be applied by panels is that of an "objective assessment" of the matter, which implies neither total deference by panels to national authorities' determinations, nor *de novo* review. The issue of the appropriate standard of review is discussed *infra* Part III(D)(1)(c).

[115] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 165.

[116] The issue of the composition of the Panels is discussed further *infra* Part III(D)(1).

[117] Vern R. Walker, *Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute,* 31 CORNELL INTERNATIONAL LAW JOURNAL 251, 280 (1998).

the touchstone against which SPS measures are judged for validity. However, today the notion of "universal science" as neutral, objective and valid for all is widely rejected. The same factual situation can lead to different, equally valid, scientific conclusions.[118] This situation is commonly referred to as the problem of "dueling science." Regulation thus involves a choice between various scientifically plausible alternatives. It therefore becomes necessary to ask: *whose* science must measures be tested against? In judging the validity of an SPS measure against the scientific criteria of Article 2.2, must a panel defer to the scientific approach of the government imposing the measure, or can it substitute its own judgment for that of the government?

The U.S. Administration's Statement of Administrative Action that accompanied the bill to implement the Uruguay Round Agreements into U.S. law claimed that the requirement of "sufficient scientific evidence" does not authorize a panel to substitute its judgment for that of the government imposing the measure. It stated that by requiring only "sufficient scientific evidence," rather than a weighing of the preponderance of the evidence, this provision recognizes the existence of scientific uncertainty and the fact that decisions are based on choices between differing scientific views.[119] This approach would leave the evaluation and choice between the different scientific views in the hands of the government imposing the measure, and would require panels and the Appellate Body to defer to these decisions. This interpretation of Article 2.2 by the U.S. Administration is, of course, not an authoritative statement of the way in which this provision must be understood and applied. In fact, as will be seen in the following discussion, the positions taken by panels and the Appellate Body to date regarding scientific evidence do not indicate such complete deference. While the Appellate Body has shown greater deference to national choices than panels, recognizing the right of regulatory health authorities to rely on minority opinions and to act with caution in life-threatening situations, it reserves for panels the ability to rule on the quality and weight of the scientific evidence. Members imposing SPS measures must be able to offer evidence that would be acceptable to prominent scientists and that indicates a risk proportional to the measure imposed.[120]

In *EC—Hormones*, the issue of competing scientific opinions did not arise as there was unusually broad consensus among scientists that the use of hormones for growth-promotion purposes, in accordance with good veterinary practice, is safe. A single scientist, Dr. Lucier, was of the opinion that using oestrogen for growth promotion could raise the risk of breast cancer by up to one in one million. His opinion was deemed, by the Panel and Appellate Body, to be of insufficient weight to overturn the contrary results of the other studies referred to by the EC (which confirmed the safety of the hormones at issue, when used in accordance with good agricultural practice), in

[118] *See* Wirth, *supra* note 23 at 842. Wirth notes that "there is unlikely to be a single, unique way to analyze even the purely scientific significance of much empirical data. . . And even if we could somehow get a group of scientists to endorse a consensus position, it would be, in the first place, only tentative and subject to revision with the arrival of new discoveries; and in the second place, it may be entirely wrong. In science, the majority does not rule, as the history of science amply demonstrates".

[119] Statement of Administrative Action ("SAA"), H.R. Doc. 103–316, at 746, *quoted in* McNiel, *supra* note 18, at 118.

[120] McNiel, *supra* note 18, at 118. *See* Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 194, where the Appellate Body held (for purposes of Article 5.1) that a risk assessment may embody a minority opinion, provided it comes from a "qualified and respected source". As Article 5.1 is a specific application of Article 2.2, this finding is also relevant to the interpretation of "sufficient scientific evidence" in the latter article (held in the Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products, supra* note 97, ¶ 77).

particular because this opinion was not based on studies, carried out by him or under his supervision, specifically focused on hormone residues in meat from cattle on which such hormones were used for growth-promotion purposes. This does not necessarily imply, however, that if his opinion had been so based, it could have overturned the majority opinion. Whether there is "sufficient scientific evidence" will be determined on a case-by-case basis, depending on the circumstances of the case, including not only the specificity of the studies conducted but also the quantity and quality of scientific evidence.[121] In addition, the seriousness, i.e. the life-threatening nature, of the risks involved may affect the determination whether there is "sufficient scientific evidence" within the meaning of Article 2.2. It may be expected that the more serious the risks, the easier it will be to have "sufficient scientific evidence".[122]

(i) Relevance of the Precautionary Principle for Article 2.2

Another important issue raised in *Japan—Agricultural Products* was that of the applicability of what is known as the precautionary principle, to the interpretation of Article 2.2.[123]

The precautionary principle has gained wide acceptance on the international level,[124] particularly in the field of environmental protection, in response to the increasing realization of scientific uncertainty. According to the precautionary principle, in cases where there are threats of serious or irreversible harm, lack of full scientific certainty should not be used as a reason for postponing measures to prevent such harm.[125] In *Japan—Agricultural Products*, Japan contended that since it had established that certain products were potential hosts of codling moth (a pest of great significance for Japan), it was entitled to adopt a precautionary attitude and require testing of each variety of imported product, rather than accept the results for one variety. Thus, it argued that Article 2.2's requirement of "sufficient scientific evidence" must be interpreted in the light of the precautionary principle.

This claim was rejected by the Appellate Body,[126] which referred back to its decision on the use of the precautionary principle to soften the application of SPS disciplines in *EC—Hormones*.[127] In the latter case, the Appellate Body considered (in the context of its review

[121] *See* Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products, supra* note 97, ¶ 84.
[122] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 124.
[123] For further discussion of the role of the precautionary principle in the SPS Agreement, *see* Wirth, *supra* note 23, at 838–840.
[124] The precautionary principle is recognized in the following international instruments amongst others: the Treaty establishing the European Community, as amended by the Treaty on the European Union, in Article 174 (with regard to environmental protection), 31 I.L.M. 247 (1992); the United Nations Framework Convention on Climate Change, in Article 3.3, 31 I.L.M. 849 (1992); Agenda 21 of the United Nations Conference on the Environment and Development U.N. Doc.A/CONF.151/26, (1992); the Rio Declaration on Environment and Development, United Nations Conference on the Environment and Development, in Principle 15, U.N. Doc. A/CONF.151/5/Rev.1 31 I.L.M. 876 (1992); and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, in Articles 10.6 and 11.8, 39 I.L.M. 1027 (2000). For an interesting discussion on whether the precautionary principle has emerged as a norm of customary international law, *see* Owen McIntyre and Thomas Mosedale, *The Precautionary Principle as a Norm of Customary International Law* 9 JOURNAL OF ENVIRONMENTAL LAW 221 (1997).
[125] This definition was adapted from the one appearing in Principle 15 of the Rio Declaration, *supra* note 124.
[126] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products, supra* note 97, ¶ 81.
[127] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 125.

of the Panel's findings on Articles 5.1 and 5.2) that it would be "unnecessary and probably imprudent" for it to decide whether the precautionary principle now forms part of general customary international law (as opposed to customary international environmental law, where it has gained wide acceptance).[128] However, it held that even if this were the case, the specific rule for cases of scientific uncertainty in Article 5.7 of the SPS Agreement overrides any such general principle.[129] Thus, according to the Appellate Body, the precautionary principle cannot be used to justify an otherwise inconsistent measure except to the extent provided for in Article 5.7.[130] The Appellate Body did, however, recognize that:

> . . . 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.[131]

It is as yet unclear what effect this directive to panels will have in practice on the interpretation of Article 2.2.[132] In our opinion, however, this directive will, for extreme cases of risks to human life or health, lower the threshold for finding "sufficient scientific evidence" within the meaning of Article 2.2. The Appellate Body's finding on the precautionary principle in *EC—Hormones* applies not only to the interpretation of Article 5.1,[133] but also to all science-based rules in the SPS Agreement (as evidenced by the reference thereto in *Japan—Agricultural Products* with respect to Article 2.2). Thus, under the current case law, the precautionary principle cannot be used as an interpretative principle with regard to the scientific disciplines of the SPS Agreement. Instead, all situations of insufficient scientific evidence must be dealt with by means of provisional measures under Article 5.7.[134]

[128] *Id.*, ¶ 123. Pauwelyn has criticized this ruling on the grounds that the Appellate Body was obliged to make a finding regarding whether the precautionary principle is part of customary international law or not, since if it is and if it were shown to have emerged later in time than the SPS Agreement and be in conflict with it, it would prevail over the treaty rule, in the absence of an intention to continue applying the SPS Agreement as *lex specialis*. *See* JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW—THE EXAMPLE OF THE WORLD TRADE ORGANIZATION: INTERNAL HIERARCHY AND HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW 312, Doctoral Thesis, Faculty of Law, University of Neuchâtel (2001).

[129] This ruling presupposes a hierarchy or norms in international law where treaty rules have priority over custom. This idea has been criticized. *See* PAUWELYN, *supra* note 128, at 60–61, where the wide support for the idea that there is no inherent hierarchy or norms is discussed.

[130] The question whether Article 5.7 SPS deals adequately with the issue of lack of certainty in science will be discussed *infra* Part II(E).

[131] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 124.

[132] The Appellate Body in *Japan—Agricultural Products, supra* note 100, and in *Japan—Apples, supra* note, did not address the effect of this directive for the interpretation of Article 2.2, probably because what was at stake in those cases was a threat to plant health rather than human health whereas the directive is limited to cases of irreversible risks to human health.

[133] *See* discussion of Article 5.1 *infra* Part II(D).

[134] Article 5.7 of the SPS Agreement will be discussed *infra* Part II(E), where the question whether it sufficiently incorporates the precautionary principle with respect to the different aspects of risk analysis will be raised. It should be noted that under the points for negotiation raised in the failed Seattle Ministerial Conference was the need to strengthen the precautionary principle in the SPS Agreement, as Article 5.7 is not perceived as going far enough in recognizing it.

This conclusion is supported by the Appellate Body's finding with regard to the relationship between Article 2.2 and Article 5.7, where it stated:

> . . . it is clear that Article 5.7 of the *SPS Agreement,* to which Article 2.2 explicitly refers, is part of the context of the latter provision and should be considered in the interpretation of the obligation not to maintain an SPS measure without sufficient scientific evidence. Article 5.7 allows Members to adopt provisional SPS measures "[i]n cases where relevant scientific evidence is insufficient" and certain other requirements are fulfilled.[135] Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless.[136]

Thus it would appear that the Appellate Body would prefer to limit the scope for deviation from the scientific disciplines of Article 2.2 to the "qualified exemption" provided for by Article 5.7. Increased flexibility in the interpretation of Article 2.2 by application of the precautionary principle is thus rejected by the Appellate Body on the grounds that it would make Article 5.7 "meaningless".

(ii) Relationship between Article 2.2 and Articles 5.1 and 5.2

The question of the relationship between Article 2.2 and other, more specific, provisions needs to be addressed. Does Article 2.2 impose independent obligations on Members, or are its general disciplines subsumed by the specific rules contained in the later provisions of Articles 5.1 and 5.2? This question arose in *EC—Hormones,* where the Panel, after finding violations of Articles 3.1, 5.1 and 5.5, applied, as already discussed above, the principle of judicial economy to refrain from ruling on the Article 2.2 challenge. The Appellate Body confirmed the Panel's application of judicial economy. It agreed that Article 5.1 can be seen as "a specific application of the basic obligations contained in Article 2.2",[137] and thus once a violation of Article 5.1 is established, it is unnecessary to determine whether Article 2.2 has also been violated. However, the Appellate Body expressed its surprise that the Panel had not followed the more "logically attractive" route of starting with an analysis of the basic obligations contained in Article 2.[138] The Appellate Body did not elaborate further on the relationship between Articles 2 and 5, aside from expressing the view that Articles 2.2 and 2.3 inform Articles 5.1 and 5.5 respectively and these articles must thus be read together.[139]

In *Australia—Salmon* the Appellate Body again had the opportunity to address this relationship, and it clarified that Article 2.2 is more general than Articles 3 or 5.1–2. It thus agreed with the Panel that, while a violation of the specific rules regarding risk assessment contained in Articles 5.1 and 5.2 necessarily implies a violation of the more general requirements of "sufficient scientific evidence" and a basis in "scientific principles" embodied in Article 2.2,[140] due to the more general nature of Article 2.2

[135] The Appellate Body here cited ¶ 89 of the same report, where it set out the four requirements of Article 5.7.
[136] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 80.
[137] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 180.
[138] *Id.* ¶ 250.
[139] *Id.* ¶¶ 180, 212 and 250. The Appellate Body held that further analysis of the relationship between these articles "should await another case."
[140] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon, supra* note 57, ¶ 8.52.

not all violations of Article 2.2 are subsumed into Articles 5.1 and 5.2.[141] In *Japan—Agricultural Products*[142] the Appellate Body rejected as textually unfounded Japan's proposition that Article 2.2 should only be directly applied in cases where scientific evidence is patently insufficient and that the case at issue should be dealt with under Article 5.1 instead. The Appellate Body emphasized that the finding in *EC—Hormones* that Article 5.1 is a specific application of the basic obligation contained in Article 2.2, does not justify limiting the scope of Article 2.2 in favor of Article 5.1. It thus appears that the Appellate Body is at pains to make clear that Article 2.2 sets disciplines which are broader than those contained in the more specific provisions of Article 5 and lays down independent obligations against which measures can be directly challenged, without recourse to Article 5.

(c) No Arbitrary or Unjustifiable Discrimination or Disguised Restriction on International Trade (Article 2.3). Article 2.3 imposes a general prohibition on SPS measures which arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members, and on the application thereof so as to constitute a disguised restriction on international trade. Article 2.3 thus clearly embodies certain familiar GATT trade disciplines. In this regard, the Appellate Body in *Australia—Salmon* held:

> This provision takes up obligations similar to those arising under Article I:1 and Article III:4 of the GATT 1994 and incorporates part of the "chapeau" to Article XX, of the GATT 1994. Its fundamental importance in the context of the *SPS Agreement* is reflected in the first paragraph of the preamble of the *SPS Agreement*.[143]

It is necessary to examine how a violation of Article 2.3 can be established. This issue was raised before the *Australia—Salmon* compliance Panel. In that case, Canada claimed that Article 2.3, first sentence, was violated since Australia imposed import requirements for salmonids from Canada but had no control measures in place regarding the internal movement of dead Australian fish. It alleged that this constituted discrimination between Canada and Australia. The compliance Panel identified the requirements for proof of a violation of Article 2.3 as follows:

> . . . three elements, cumulative in nature, are required for a violation of this provision:
>
> (1) the measure discriminates between the territories of Members other than the Member imposing the measure, or between the territory of the Member imposing the measure and that of another Member;
> (2) the discrimination is arbitrary or unjustifiable; and
> (3) identical or similar conditions prevail in the territory of the Members compared.
>
> In respect of the first element we only note the following. Given: (1) the Panel and Appellate Body finding[144] in the original dispute that discrimination contrary to Article 5.5 by implication entails discrimination contrary to Article 2.3, first sentence; and (2) that under Article 5.5 different situations including *different* products can be

[141] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon,* WT/DS18/AB/R, ¶ 137.
[142] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 82.
[143] Report of the Appellate Body, *Australia—Measures Affecting Importation of Salmon*, *supra* note 141, ¶ 251.
[144] Panel report, *op. cit.*, ¶¶ 8.109 and 8.160 and Appellate Body report, *op. cit.*, ¶¶ 178 and 252. [Footnote in original.]

> compared,[145] we are of the view that—contrary to what Australia argues—discrimination in the sense of Article 2.3, first sentence, may also include discrimination between *different* products, e.g. not only discrimination between Canadian salmon and New Zealand salmon, or Canadian salmon and Australian salmon; but also discrimination between Canadian salmon and Australian fish including non-salmonids, as referred to by Canada in this case.[146]

Therefore, Article 2.3 prohibits not only discrimination between similar products but also between different products (in this case salmonids from Canada and other dead fish from Australia). This represents a significant deviation from the position under GATT 1994, which only prohibits discrimination between "like"[147] or "directly competitive or substitutable"[148] products. The aim of this broader prohibition on discrimination is to take into account the fact that different products can pose the same or similar health risks (one could think here of the possibility that different fruits may be vectors for the same pest, or that various animals can be carriers of foot and mouth disease). The breadth of the prohibition is tempered by the second and third requirements of Article 2.3, namely that the discrimination must be arbitrary or unjustifiable and identical or similar conditions must prevail in the territories of the Members subject to different treatment. With regard to the third requirement, the compliance Panel held:

> . . . we also harbor doubts as to whether "identical or similar conditions" in the sense of the third element of Article 2.3, first sentence, prevail in the territories of both Canada and Australia in respect of the situations compared. We note, for example, the substantial difference in disease status between Canada and Australia.
>
> We thus find that Australia has not acted inconsistently with Article 2.3, first sentence.[149]

As has been stated above, Article 2 lays down core disciplines, which are further specified in later articles. In this way, the prohibition contained in Article 2.3 is reflected again in Article 5.5, which proscribes arbitrary or unjustifiable distinctions in the levels of protection that a Member deems appropriate. The relationship between these two articles therefore deserves attention here. In *EC—Hormones,* when dealing with Article 5.5, the Appellate Body stated the following regarding Article 2.3:

> It is well to bear in mind that, after all, the difference in levels of protection that is characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the *SPS Agreement*.[150]

In *Australia—Salmon*, the issue of the relationship between Articles 2.3 and 5.5 was raised before the Appellate Body by Canada, which argued that the Panel had erred in only applying Article 2.3 through Article 5.5 and not independently. The Appellate Body found

[145] As long as they have a risk of entry, establishment or spread of the same or a similar disease, *or* a risk of the same or similar associated potential biological and economic in common, *different* products can be compared under Article 5.5. *See supra* ¶ 7.89. [Footnote in original]
[146] Report of the WTO Compliance Panel, *Australia—Measures Affecting Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.111–7.112.
[147] Article I:1 (most favored nation treatment) and Article III:2 and 4 (national treatment).
[148] Add Note to Article III:2 (in respect of taxes).
[149] Report of the WTO Compliance Panel, *Australia—Measures Affecting Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.113–7.114 (in relevant part).
[150] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 240.

that the Panel had not intended to deny that Article 2.3 contains an obligation independent of Article 5.5[151] but had merely refrained from addressing Article 2.3 separately on grounds of judicial economy. Further discussing the relationship between Articles 2.3 and 5.5, the Appellate Body in *Australia—Salmon* held:

> We recall that the third—and decisive—element of Article 5.5, discussed above, requires a finding that the SPS measure which embodies arbitrary or unjustifiable distinctions in levels of protection results in "discrimination or a disguised restriction on international trade". Therefore, a finding of violation of Article 5.5 will necessarily imply a violation of Article 2.3, first sentence, or Article 2.3, second sentence. Discrimination "between Members, including their own territory and that of others Members" within the meaning of Article 2.3, first sentence, can be established by following the complex and indirect route worked out and elaborated by Article 5.5.[152] However, it is clear that this route is not the only route leading to a finding that an SPS measure constitutes arbitrary or unjustifiable discrimination according to Article 2.3, first sentence. Arbitrary or unjustifiable discrimination in the sense of Article 2.3, first sentence, can be found to exist without any examination under Article 5.5.[153]

It is therefore clear that Article 2.3 contains disciplines broader than those embodied in Article 5.5 and thus a violation thereof may be found independently of a violation of Article 5.5.

C. Harmonization (Article 3)

Pursuant to the preamble of the SPS Agreement, one of the primary objectives of the SPS Agreement is:

> . . . to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, . . . without requiring Members to change their appropriate level of protection of human, animal or plant life or health. . . .[154]

The use of internationally harmonized SPS measures would obviously promote trade and eliminate trade restrictions. Yet the SPS Agreement does not oblige Members to use harmonized SPS measures. It rather encourages the use of such harmonized measures and, at the same time, acknowledges the sovereign right of each Member to determine its own appropriate level of protection of human, animal and plant life and health.

[151] Report of the Appellate Body, *Australia—Measures Affecting Importation of Salmon*, *supra* note 141, ¶ 248. The Appellate Body here quoted the Panel's finding that "given the more general character of Article 2.3, not all violations of Article 2.3 are covered by Article 5.5." Report of the WTO Panel, *Australia—Measures Affecting Importation of Salmon*, *supra* note 57, ¶ 8.109.

[152] (Footnote in original) In *European Communities—Hormones* we characterized Article 5.5 as "marking out and elaborating a *particular* route leading to the same destination set out in Article 2.3" (emphasis added). Adopted February 13, 1998, WT/DS26/AB/R, WT/DS48/AB/R, ¶ 212.

[153] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 252.

[154] This aim is expressed in the sixth paragraph in the Preamble. It is notable that the preamble makes no mention of scientific disciplines on remaining (not harmonized) SPS measures. *See* David G. Victor, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years,* 32 JOURNAL OF INTERNATIONAL LAW AND POLITICS 868, 884 (2000), where the author claims that harmonization is the principal objective of the SPS Agreement. However, after analyzing the interpretation of Article 3 by panels and the Appellate Body, Victor comes to the conclusion that the SPS Agreement will not lead to harmonization of SPS measures and appropriate levels of protection set by Members, but will rather lead to harmonization of national SPS procedures, such as requiring risk assessments. *Id*. at 936.

In *EC—Hormones*, the Appellate Body elucidated the aim of Article 3 as follows:

> In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection.[155]

Article 3 of the SPS Agreement, entitled "Harmonization", sets out how this aim is to be achieved. Article 3 provides:

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[156] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.
5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

[155] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 177.

[156] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection. [Footnote in original].

The rules contained in Article 3 and their interpretation by the Appellate Body deserve particular attention here, as they provide a good illustration of the use of science in conjunction with the promotion of harmonization in the policing of national health regulations in the SPS Agreement. Briefly, Article 3.1 expresses the aim of harmonizing SPS measures on as wide a basis as possible, and states the obligation of Members to "base" their SPS measures on international standards, guidelines or recommendations, where they exist, except as provided for in Article 3.3. Article 3.2 creates a presumption of consistency with GATT 1994 and the SPS Agreement for measures that "conform to" international standards. Article 3.3 recognizes the right of Members to use SPS measures which result in a higher level of protection than would be achieved by measures "based on" the relevant international standards and sets certain requirements for this.

The Appellate Body in *EC—Hormones* identified the various options open for Members under these provisions. It rejected the Panel's approach of seeing Articles 3.1 and 3.2 as the general rule and Article 3.3 as the exception.[157] Instead, it identified *three autonomous options* available to Members under these provisions. The Appellate Body first noted:

> It appears to us that the Panel has misconceived the relationship between Articles 3.1, 3.2 and 3.3, a relationship discussed below,[158] which is qualitatively different from the relationship between, for instance, Articles I or III and Article XX, of the GATT 1994. Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on an international standard. . . . [159]

It subsequently held:

> Under Article 3.2 of the *SPS Agreement*, a Member may decide to promulgate an SPS measure that conforms to an international standard. Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard. Such a measure enjoys the benefit of a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the *SPS Agreement* and of the GATT 1994.
>
> Under Article 3.1 of the *SPS Agreement*, a Member may choose to establish an SPS measure that is based on the existing relevant international standard, guideline or recommendation. Such a measure may adopt some, not necessarily all, of the elements of the international standard. The Member imposing this measure does not benefit from the presumption of consistency set up in Article 3.2; . . .
>
> Under Article 3.3 of the *SPS Agreement*, a Member may decide to set for itself a level of protection different from that implicit in the international standard, and to implement or embody that level of protection in a measure not "based on" the international standard. The Member's appropriate level of protection may be higher than that implied in the international standard. The right of a Member to determine its own appropriate level of sanitary protection is an important right.[160]

Each of the three options identified by the Appellate Body will now be examined in detail.

[157] *Id.* ¶ 168.
[158] (Footnote in original) ¶¶ 169–172 of this Report.
[159] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 104.
[160] *Id.* ¶¶ 170–172.

1. SPS Measures Based on International Standards (Article 3.1)

(a) International Standards (Annex A, paragraph 3). It is necessary to begin with an examination of what the term "international standards, guidelines or recommendations" specifically refers to in Article 3. The WTO is not a regulatory body with norm-setting capacity. Thus, it does not establish the harmonized international standards itself, but relies on those set by the international organizations listed in Annex A, paragraph 3. Members are obliged under Article 3.4 to participate in the work of these organizations, to the extent that their resources permit, and to promote development and periodic review of SPS standards. Article 3.5 mandates the SPS Committee to establish a procedure to monitor the process of international harmonization in co-ordination with the relevant international organizations.[161]

Paragraph 3 of Annex A of the SPS Agreement defines the term "standards, guidelines or recommendations" broadly, with reference to the three main international standard setting organizations in the area of health. The definition indicates that international standards, guidelines and recommendations for purposes of the SPS Agreement refer to those set by: (1) the Codex Alimentarius Commission ("CAC") in the area of food safety; (2) the International Office of Epizootics ("OIE") in the area of animal health; (3) the International Plant Protection Convention ("IPPC") in the area of plant health; and (4) certain other relevant international organizations for matters not covered by the three mentioned organizations. The CAC, OIE and IPPC are often referred to as "the three sisters" in WTO jargon. Each of these standard-setting organizations has its own structure and standard-setting procedure. These are dictated by its own statutes and not by the WTO. In general, the activities of these organizations may be characterized as taking risk management decisions (such as laying down guidelines or setting standards, which embody a certain level of protection) on the basis of scientific information from risk assessments. However, the way in which they do this varies considerably.

There are no requirements in the definition of "standards, guidelines or recommendations" in the SPS Agreement relating to the procedure by which the relevant norm was created, such as requirements regarding the degree of support the norm should have (*e.g.*, a qualified majority or a consensus in favor), the role of civil society interest groups in standard setting or the extent of participation by developing countries in the setting of the norm. It is only provided that the relevant organizations should be "open for Membership to all Members." The latter requirement, however, says nothing about the actual participation by all Members in norm setting, or about the effectiveness of the participation that does occur.[162]

Further, no distinction is made in the SPS Agreement between standards, guidelines and recommendations although they are clearly quite different international norms and are not intended to have the same status by the international organizations creating them.

[161] Article 12 of the SPS Agreement reiterates this obligation, stating that the SPS Committee must develop a procedure to monitor the process of international harmonization. *See infra* Part III(C)(2)(b). A provisional procedure was adopted on October 22, 1997(*see* G/SPS/11) and thereafter extended. Six Annual Reports have been prepared by the SPS Committee on the basis of this procedure. *See* G/SPS/13, G/SPS/16, G/SPS/18, G/SPS/21, G/SPS/28 and G/SPS/31.

[162] The problematic nature of developing country participation in international standard setting is discussed *infra* Part IV(B)(1). In addition, concerns have been raised with regard to the weak role of civil society NGOs as opposed to industry interest groups in the standard-setting process, both as observers and as members of national delegations, in certain standard-setting bodies. See, for example, Natalie Avery *et al*, CRACKING THE CODEX. AN ANALYSIS OF WHO SETS WORLD FOOD STANDARDS, National Food Alliance, (1993). These participatory problems call into question the legitimacy of the use of the standards adopted by these standard-setting organisations as benchmarks by the SPS Agreement.

This issue has been raised in the context of the Codex Alimentarius Commission. On September 29, 1997, a question was sent by the CAC to the SPS Committee regarding whether the obligations in Article 3 of the SPS Agreement applied equally and without distinction to standards, guidelines and recommendations set by the CAC. This was important to CAC Members in order to know what effect the norms they set would have on their obligations under the SPS Agreement.[163] This issue was discussed in the SPS Committee meetings[164] and a response was drafted and later revised.[165] In this response, the SPS Committee[166] stated that the SPS Agreement makes no distinction between the three types of norms, namely standards, guidelines and recommendations, in the Annex A definition or later provisions and that they would thus be equally applicable to the disciplines set by Article 3 of the SPS Agreement. However, the Committee noted that the substantive content of a Codex text might have an impact on how a Member could show that its measure was based thereon—for example a standard such as a "maximum residue level"[167] provides a high degree of numerical precision whereas a guideline or recommendation may allow greater discretion as to the choice of measures which can be regarded as based thereon.[168] It is thus the content rather than the category of the Codex text that affects its application. The SPS Committee also emphasized the fact that there is no legal obligation on Members under the SPS Agreement to apply any Codex texts.

The Codex Executive Committee noted this response[169] and agreed that it should be brought to the attention of all Codex Committees. It further agreed that the Codex Committee on General Principles should examine the possibility of developing a set of appropriate preambular statements explaining the intent of different types of Codex texts. However, the Committee on General Principles decided that, in view of the response of the SPS Committee, there was no need to develop such a set of preambular statements.[170]

In *EC—Hormones* the issue arose whether either the type of international measure at issue, the date of its adoption or the standard-setting procedure used were relevant to the application of the disciplines in Article 3 of the SPS Agreement. In this context, with respect to the international standards referred to in Article 3.1, the Panel noted that:

> Article 3.1 unambiguously prescribes that "... Members shall base their sanitary ... measures on international standards ... *where they exist* ..." (emphasis added). Paragraph 3 of Annex A of the SPS Agreement states equally clearly that the international standards

[163] Victor notes that Codex codes of conduct and guidelines are intended to augment the application of core Codex standards rather than to act as main standards themselves and are often adopted by the CAC where agreement cannot be reached on a commodity or residue standard. *See* Victor, *supra* note 154, at 886. It would thus be inappropriate to give these looser norms the same status as applies to commodity and residue standards under the SPS Agreement although this seems to be the intention of the Annex A definition. It should be pointed out that, contrary to the view of Victor, this does not give guidelines "potentially binding application" since no international norms are made binding by the disciplines of the SPS Agreement. This point is discussed *infra* Part II(C)(1).

[164] SPS Committee meetings of October 1997 and March 1998.

[165] *See* G/SPS/W/86 and G/SPS/W/86/Rev.1.

[166] The SPS Committee began by noting that it is not competent to formally interpret the provisions of the SPS Agreement. Thus, this opinion is not binding.

[167] A maximum residue level sets a numerical limit for the amount of residue of a potentially harmful substance (for example of a pesticide) that is permissible.

[168] This draft response was formally adopted by the SPS Committee in its meeting of March 12–13, 1998 (G/SPS/R/10, ¶ 50).

[169] Codex Executive Committee, *Report of the Forty-Fifth Session of the Executive Committee of the Codex Alimentarius Commission*, ALINORM 99/3, June 3-5, 1998, ¶ 44.

[170] Codex Committee on General Principles, *Report of the Thirteenth Session of the Codex Committee on General Principles*, ALINORM 99/33. September 7–11, 1998, ¶ 54.

mentioned in Article 3:1 are "for food safety, the standards . . . *established by the Codex Alimentarius Commission* relating to . . . *veterinary drug* . . . *residues* . . . " (emphasis added). No other conditions are imposed in the SPS Agreement on the relevance of international standards for the purposes of Article 3. Therefore, as a panel making a finding on whether or not a Member has an obligation to base its sanitary measure on international standards in accordance with Article 3.1, we only need to determine whether such international standards exist. For these purposes, we need not consider (i) whether the standards reflect *levels* of protection or sanitary *measures* or the *type* of sanitary measure they recommend, or (ii) whether these standards have been adopted by consensus or by a wide or narrow majority, or (iii) whether the period during which they have been discussed or the date of their adoption was before or after the entry into force of the SPS Agreement.[171]

This issue was not raised on appeal.

In *Australia—Salmon*, the question of the existence of relevant international standards was once again at issue, as the guideline that had been drafted by the OIE did not cover all 24 of the diseases at which the Australian measure was aimed. The Panel found that:

> . . . Paragraph 3(b) of Annex A to the SPS Agreement indicates that the international standards, guidelines or recommendations referred to in Article 3 *for animal health* (the concern at issue in this dispute) are those developed under the auspices of the International Office of Epizooties ("OIE"). Both parties agree that the International Aquatic Animal Health Code adopted by the OIE in 1995 ("OIE Code") provides international guidelines on a disease-by-disease basis. However, they also agree that as of today no relevant OIE guideline exists which deals with salmon on a product specific basis. Moreover, both parties also agree that OIE guidelines do not exist for all of the 24 diseases of concern to Australia. Therefore, even if we were to examine first, if and how many relevant international guidelines exist and second address the question of whether Australia deviates from these guidelines, we would thereafter still need to examine either (1) in the event Australia does deviate from any such guidelines contrary to Article 3, whether the measure in dispute could not be based on Australia's concern for any of the other diseases for which no international guideline exists (*in casu*, under Articles 2 and 5); or (2) in the event Australia's measure is based on and/or conforms to any such guidelines, whether that part of the measure for which no guidelines exist, is consistent with the provisions of the SPS Agreement other than Article 3 (*in casu*, Articles 2 and 5). In this respect, we are of the view, however, that the fact that in this case no international guidelines exist for *all* 24 diseases of concern does not mean that an international guideline which applies to only *one* of these diseases cannot be relevant (or, according to the language of Article 3.1, does not 'exist') for the measure at issue.[172]

Further, the Panel found that "the SPS Agreement (paragraph 3(b) of Annex A) explicitly directs us to the OIE and the standards, guidelines and recommendations it develops. . . The fact that the OIE Code is subject to revision or the way it has been adopted in our view does not change its validity for our purposes".[173] There was no appeal on this point in this dispute. From these findings it appears that a broad and unqualified acceptance of all norms adopted by the "three sisters" for purposes of the Article 3 disciplines is currently the approach followed by panels.

It should be noted, however, that the term "standards, guidelines or recommendations" is qualified by the adjective "international". This would therefore exclude standards set on the regional level, intended to address specifically regional health concerns. An example

[171] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.72, Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, *supra* note 53, ¶ 8.69.
[172] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.46.
[173] *Id.* ¶ 7.11.

would be the standards set by the regional offices of the International Plant Protection Convention, or those adopted by the Codex Alimentarius Commission on a proposal by one of the regional committees for purposes of that region only (such as the Codex guidelines for street vending of foods, explicitly intended to apply to African countries only). The omission of the requirement of an international nature would have led to the anomalous situation that Members outside the relevant region for which the standard was set would have to scientifically justify their deviation from a standard or guideline neither intended nor appropriate for their adoption. This was confirmed by the SPS Committee.[174] The Committee further stated that even if based on scientific evidence, regional standards are intended to apply only within a specific geographic region. However, it recognized that scientifically sound regional standards could form a foundation for the creation and adoption of international standards.[175]

(b) The "Based On" Requirement. Article 3.1 embodies the obligation to "base" national SPS measures on international standards, guidelines and recommendations. The meaning of "based on" in Article 3.1 was addressed in *EC—Hormones*. The Panel had held that Article 3.1 does not define "based on" but that Article 3.2 equates measures "based on" international standards with those which "conform to" these standards.[176] They had also held that to be "based on" an international standard, the measure must achieve the same level of sanitary protection as that standard, a conclusion implied by Article 3.3.[177] The Appellate Body rejected this reasoning, finding that the plain meaning of the terms "based on" and "conform to" differ.[178] It held:

> In the first place, the ordinary meaning of "based on" is quite different from the plain or natural import of "conform to". A thing is commonly said to be "based on" another thing when the former "stands" or is "founded" or "built" upon or "is supported by" the latter. In contrast, much more is required before one thing may be regarded as "conform[ing] to" another: the former must "comply with", "yield or show compliance" with the latter. The reference of "conform to" is to "correspondence in form or manner", to "compliance with" or "acquiescence", to "follow[ing] in form or nature". A measure that "conforms to" and incorporates a Codex standard is, of course, "based on" that standard. A measure, however, based on the same standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure.
>
> In the second place, "based on" and "conform to" are used in different articles, as well as in differing paragraphs of the same article. Thus, Article 2.2 uses "based on", while Article 2.4 employs "conform to". Article 3.1 requires the Members to "base" their SPS measures

[174] This was in its response to a question of the CAC, regarding the status of Codex regional standards and related texts. *See supra* note 165.

[175] Committee on Sanitary and Phytosanitary Measures, *Clarification of References to Codex Texts: Draft Response to the Codex Alimentarius Commission, Note by the Chairman. Revision,* G/SPS/W/86/Rev.1, March 13, 1998, adopted in the decision contained in the report of the SPS Committee meeting of March 12–13, 1998. Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 12–13 March, 1998,* G/SPS/R/10, April 30, 1998, ¶ 50. It should be noted, however, that the CAC is moving away from the adoption of regional standards as much as possible.

[176] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.72, and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.75.

[177] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.73 and *EC—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, *supra* note 53, ¶ 8.76.

[178] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones*, *supra* note 70, ¶ 163–166.

> on international standards; however, Article 3.2 speaks of measures which "conform to" international standards. Article 3.3 once again refers to measures "based on" international standards. The implication arises that the choice and use of different words in different places in the *SPS Agreement* are deliberate, and that the different words are designed to convey different meanings. A treaty interpreter is not entitled to assume that such usage was merely inadvertent on the part of the Members who negotiated and wrote that Agreement. Canada has suggested the use of different terms was "accidental" in this case, but has offered no convincing argument to support its suggestion. We do not believe this suggestion has overturned the inference of deliberate choice.[179]

The Appellate Body also pointed out that the Panel's interpretation was contrary to the object of Article 3, which sets the harmonization around international standards as a goal to be achieved in the future, not as a current obligation on Members.[180] In this regard, it stated:

> . . . the object and purpose of Article 3 run counter to the Panel's interpretation. That purpose, Article 3.1 states, is "[t]o harmonize [SPS] measures on as wide a basis as possible . . . ". The preamble of the *SPS Agreement* also records that the Members "[d]esir[e] to *further the use of harmonized [SPS] measures between Members* on the basis of international standards, guidelines and recommendations developed by the relevant international organizations . . . ". (emphasis added) Article 12.1 created a Committee on Sanitary and Phytosanitary Measures and gave it the task, *inter alia*, of "furtherance of its objectives, in particular with respect to harmonization" and (in Article 12.2) to "encourage the use of international standards, guidelines and recommendations by all Members". It is clear to us that harmonization of SPS measures of Members on the basis of international standards is projected in the Agreement, as a *goal*, yet to be realized *in the future*. To read Article 3.1 as requiring Members to harmonize their SPS measures *by conforming those measures with international standards*, guidelines and recommendations, *in the here and now*, is, in effect, to vest such international standards, guidelines and recommendations (which are by the terms of the Codex *recommendatory* in form and nature) with *obligatory* force and effect. The Panel's interpretation of Article 3.1 would, in other words, transform those standards, guidelines and recommendations into binding *norms*. But, as already noted, the *SPS Agreement* itself sets out no indication of any intent on the part of the Members to do so. We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation by mandating *conformity* or *compliance with* such standards, guidelines and recommendations. To sustain such an assumption and to warrant such a far-reaching interpretation, treaty language far more specific and compelling than that found in Article 3 of the *SPS Agreement* would be necessary.[181]

The Appellate Body thus made it clear that "based on" in Article 3.1 could not be understood to mean "conform to". The Appellate Body also emphasized that the voluntary standards set by the relevant international organizations did not become mandatory through the operation of the SPS Agreement.[182]

The Appellate Body proceeded to explain the consequences for a Member of choosing the option under Article 3.1. Noting that although a Member that merely bases its

[179] *Id*. ¶¶ 163–164.
[180] *Id*. ¶ 165.
[181] *Id*.
[182] Before the panels, the EC had argued that CAC members were used to adopting voluntary standards and were not aware that the standards for hormones in beef would in effect become mandatory through the operation of the SPS Agreement. Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.68; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.71.

measure on an international standard does not benefit from the presumption of consistency contained in Article 3.2, it stated that a Member is also "not penalized by exemption of a complaining Member from the normal burden of showing a *prima facie* case of inconsistency with Article 3.1 or any other relevant article of the *SPS Agreement* or of the GATT 1994."[183]

The question which then arises is what the benefits of choosing the option under Article 3.1 are. As noted by the Appellate Body, a Member that merely bases its SPS measures on international standards, without conforming to them, does not enjoy a presumption of compliance of its measures with the SPS Agreement and GATT 1994. Still, it seems logical that there should be an advantage over the situation set forth in Article 3.3. It seems that as a measure based on an international standard is automatically based on a risk assessment (namely the risk assessment used by the relevant international organization in drafting its standard), the measure may be assumed to comply with Article 5.1–5.3. Thus, an evaluation of whether the strict requirements for a risk assessment are met is rendered unnecessary. This is of particular importance to developing countries, which often lack the resources and infrastructure to conduct their own risk assessments.

Despite the more lenient interpretation of the requirements of Article 3.1 given by the Appellate Body in *EC—Hormones*, the EC ban was obviously not "based on" the existing Codex standards and did not adopt any elements thereof. The Appellate Body thus continued by analyzing the measure under the requirements of Article 3.3 for measures that are not based on international standards.[184]

The Appellate Body also refrained from deciding on the correctness of the rest of the Panel's analysis on the meaning of "based on", including the finding that "for a sanitary measure to be *based on* an international standard . . . , that *measure* needs to reflect the same level of sanitary protection as the *standard.*"[185] The Appellate Body stated:

> It appears to us that the Panel reads much more into Article 3.3 than can be reasonably supported by the actual text of Article 3.3. Moreover, the Panel's entire analysis rests on its flawed premise that 'based on', as used in Articles 3.1 and 3.3, means the same thing as "conform to" as used in Article 3.2. As already noted, we are compelled to reject this premise as an error in law. The correctness of the rest of the Panel's intricate interpretation and examination of the consequences of the Panel's litmus test, however, have to be left for another day and another case.[186]

Although the question was thus left open by the Appellate Body, it would appear that the Panel was correct in informing the term "based on" in Article 3.1 with reference to the use of the same term in Article 3.3.[187] Thus, we argue that in order to be regarded as "based on" an international standard, the SPS measure must not only adopt at least some of the elements of the international standard but also result in *the same level of protection*.

[183] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 171.
[184] *Id*. ¶¶ 176–177.
[185] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.76; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.73.
[186] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 168.
[187] It does not seem that the Appellate Body's general comment that the Panel reads more into Article 3.3 than is supported by the text would contradict this conclusion, since this reading of the meaning of "based on" is firmly grounded in the text of Article 3.1 and 3.3. In any case, the Appellate Body decided to leave the examination of the correctness of the Panel's interpretation for another day.

If it is not "based on" the international standard, it must then meet the requirements of Article 3.3.

(c) Nature of the Obligation under Article 3.1. One could ask whether Article 3.1 obliges Members to maintain at least the minimum level of health protection that is reflected in relevant international standards, while allowing higher, but not lower, levels of protection. This would seem to be the case from an examination of the words of the relevant provisions, since a Member is obliged to adopt measures that are "based on" international standards, that is, achieving the same level of protection, unless the provisions of Article 3.3 are complied with. The latter article allows SPS measures resulting in a *higher* level of protection under certain conditions. Nowhere are measures aimed at a lower level of protection mentioned.

It has been argued that a measure should not be analyzed under Article 3.3 simply because the Member imposing it claims that the measure achieves a higher level of protection than the international standard, but that it should first be determined whether the measure actually does so.[188] However, it seems unlikely that a positive obligation of a certain minimum level of health protection was intended or would be accepted by WTO Members. The international standards are used as a ceiling that Members cannot exceed without complying with the additional science disciplines of Article 3.3, rather than as a floor that all Members must reach. No provisions specifically deal with the possibility of challenging measures that fall below the relevant international standards.[189] This can be explained by the fact that the role of the WTO is regarded as limited to disciplines relating to trade barriers and thus does not extend to the promotion of health objectives. There are other international organizations that have mandates in the area of promotion of public health, such as the World Health Organization. Further, it is hard to imagine one Member challenging another within a trade forum for having too low a level of health protection for its own citizens, a situation which could have no negative trade implications for other Members.[190]

2. SPS Measures which Conform to International Standards (Article 3.2)

(a) The "Conform To" Requirement. The second option a Member has is to promulgate an SPS measure that conforms to the relevant international standard, guideline or recommendation. What is required for a measure to "conform to" an international standard

[188] McNiel, *supra* note 18, at 126.

[189] A Member could arguably base a challenge on Article 3.1, claiming that the lax measure is not "based on" an international standard and cannot be justified by Article 3.3 as the latter only refers to stricter measures. However, the obligation to base a measure on international standards cannot be read to require that a Member adopt at least the level of protection embodied in the international standard. This would go against the aim and purpose of the SPS Agreement, which is to promote free trade rather than to ensure a minimum level of health protection.

[190] *See contra* Victor, *supra* note 154, at 884, who argues that the requirements of Article 5 apply whether a Member's standards are stricter or looser than international standards. He states that for manufactured food products, lax standards could have the effect of benefiting local producers who do not have to comply with expensive stricter standards. The SPS Agreement could be used to force a higher level of health protection in these countries. He does acknowledge that such challenges would be rare due to the difficulty of proving a trade effect from weak SPS measures. The correctness of this argument can be questioned, however, since producers in countries with strict SPS standards can, and often do, export food and agricultural products of lesser quality to countries with lower standards. They are thus not bound by high local standards for their exports. Therefore it is doubtful that lax standards could constitute a trade barrier. More compelling, however, is the legal argument that the provisions of Article 3.3 refer only to a "higher level of sanitary or phytosanitary protection".

was addressed by the Appellate Body in *EC—Hormones*, where it stated:

> Under Article 3.2 of the *SPS Agreement*, a Member may decide to promulgate an SPS measure that conforms to an international standard. Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard.[191]

The measure must thus completely embody the international standard. This would seem to mean that they must be identical in both structure and desired level of protection.

(b) Presumption of Consistency. The SPS Agreement promotes measures conforming to international standards by granting them a presumption of consistency with the SPS Agreement and GATT 1994. This presumption was held to be rebuttable in *EC—Hormones*.[192] The Appellate Body in this case also addressed the implications of the presumption of consistency, stating as follows:

> The presumption of consistency with relevant provisions of the *SPS Agreement* that arises under Article 3.2 in respect of measures that conform to international standards may well be an *incentive* for Members so to conform their SPS measures with such standards. It is clear, however, that a decision of a Member not to conform a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a *penalty*.[193]

It has been argued that the fact that a measure, which is in accordance with international standards, enjoys a presumption of validity, increases the importance of standard setting on international level.[194] This is because international standards have hereby become the benchmarks against which national SPS measures are judged.

3. SPS Measures Resulting in a Higher Level of Protection (Article 3.3)

(a) Higher Level of Protection. The third option open to Members is to promulgate SPS measures providing a higher level of protection than would result from measures "based on" the relevant international standards. This provision recognizes the right of Members to choose their own level of protection, an important principle in the SPS Agreement. The Appellate Body held in *EC—Hormones* that the "right of a Member to establish its own level of sanitary protection under Article 3.3 of the *SPS Agreement* is an autonomous right and *not* an 'exception' from a 'general obligation' under Article 3.1".[195]

However, as recognized by the Appellate Body, this is not an "absolute or unqualified right". Two science-related conditions are set in the alternative. Either there must be a

[191] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 170.

[192] *Id*. The implications of this presumption for the burden of proof are discussed further *infra* Part III(D)(1)(a).

[193] *Id*. ¶ 102.

[194] As pointed out by Quick and Blüthner, *supra* note 83, at 613, this does not mean that international standards become (either directly or indirectly) binding on WTO members as a result of SPS disciplines. The standards only give content to the provisions of the SPS Agreement. It is the latter provisions that have binding force. However, the effect of the SPS provisions on harmonization is to encourage the adoption of international harmonized standards and thus they do increase the status and relevance of these standards for WTO Members.

[195] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 172.

scientific justification for the measures,[196] or they must be the result of the higher level of protection chosen by the Member in accordance with Article 5.1–5.8. It is not quite clear why Article 3.3 provides for two alternative conditions or how exactly they differ. What is clear, however, is that in both cases the measures must be consistent with all other provisions of the SPS Agreement.[197]

In *EC—Hormones,* the EC argued that since there was a "scientific justification" for its measure, it need not be in accordance with the provisions of Article 5.1–5.8, which are required only for the second situation. It thus claimed that no risk assessment was required as a basis for its ban on hormone-treated beef, despite the fact that it deviated from Codex standards. The Appellate Body held that the distinction between the two situations identified in Article 3.3, is more apparent than real.[198] In fact, both situations require a risk assessment in accordance with Article 5. The Appellate Body in *EC—Hormones* stated:

> Article 3.3 is evidently not a model of clarity in drafting and communication. The use of the disjunctive "or" does indicate that two situations are intended to be covered. These are the introduction or maintenance of SPS measures that result in a higher level of protection:
>
> (a) "if there is a scientific justification"; or
> (b) "as a consequence of the level of . . . protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5".
>
> It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that "all measures which result in a [higher] level of . . . protection", that is to say, measures falling within situation (a) as well as those falling within situation (b), be "not inconsistent with any other provision of [the SPS] Agreement". "Any other provision of this Agreement" textually includes Article 5. Secondly, the footnote to Article 3.3, while attached to the end of the first sentence, defines "scientific justification" as an "examination and evaluation of available scientific information in conformity with relevant provisions of this Agreement . . . ". This examination and evaluation would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the *SPS Agreement*.
>
> On balance, we agree with the Panel's finding that although the European Communities has established for itself a level of protection higher, or more exacting, than the level of protection implied in the relevant Codex standards, guidelines or recommendations, the European Communities was bound to comply with the requirements established in Article 5.1. We are not unaware that this finding tends to suggest that the distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real. Its involved and layered language actually leaves us with no choice.[199]

Thus this ruling should be understood as requiring that a Member claiming scientific justification for its deviation from international standards, must base such a claim on a valid risk assessment, in the same way as a Member that justifies its deviation from the international standard on the grounds that it has chosen a different level of protection

[196] A footnote to Article 3.3 clarifies the term "scientific justification" (quoted *supra* at note 155). This footnote was not present in the Dunkel Draft but was added to the final text of the SPS Agreement due to controversy regarding the meaning of the "scientific justification" requirement for deviation from international standards. Wirth, *supra* note 23, at 827.
[197] *See* last sentence of Article 3.3.
[198] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 175.
[199] *Id.*, ¶¶ 173–175.

than that achieved by the international standard.[200] The Appellate Body went on to indicate its "... belief that compliance with Article 5.1 was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection"[201] and pointed out that the scientific requirements of Articles 2.2 and 5.1 are crucial in maintaining the delicate balance between the competing goals of trade liberalization and health protection.[202] Thus, the Appellate Body sees science as the scale on which these interests are balanced.

In *Japan—Agricultural Products*, the Appellate Body again faced the question of what a Member needs to show when it claims there is "scientific justification" for a deviating measure. It held:

> In our opinion, there is a "scientific justification" for an SPS measure, within the meaning of Article 3.3, if there is a rational relationship between the SPS measure at issue and the available scientific information.[203]

This finding seems to stop short of actually requiring a risk assessment in the case of reliance on a "scientific justification". However, in order to prove that the measure is based upon "available scientific information," it seems unavoidable that a Member will have to show a risk assessment.

It has been argued that the reason behind distinguishing between the two different situations mentioned in Article 3.3 is to emphasize the difference in the scope of review in each case.[204] The first situation deals with the Member's judgment, on the basis of scientific information, that the international standards are inadequate to meet its level of protection. This could, for example, be the case where, due to local peculiarities, the international standard is ineffective in securing the desired level of health protection.[205] The second situation deals with the choice of a different level of protection by a Member, which is a policy choice. One could thus speak of a scientific justification and a policy justification.[206] Scientific justifications could be more rigorously reviewed than policy justifications and thus harmonization of the former more vigorously promoted than the latter.[207]

What is clear from an examination of this harmonization provision in the SPS Agreement is the role of science, in the form of scientific justification or risk assessment, in providing norms or rules in the absence of harmonization. Free trade necessitates harmonized health standards in order to do away with the barriers created by disparate requirements in various countries. However, the lack of a rule-making body in the

[200] McNiel, *supra* note 18, at 126.
[201] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 177.
[202] *Id.*
[203] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 79.
[204] Walker, *supra* note 108, at 275–276.
[205] *See* Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.84. Here the Panel stated that both Canada and the EC interpreted the first situation as existing where the relevant international standard is outdated, inadequate, faulty or obsolete from a scientific perspective, for example where it in fact does not provide the level of protection it was intended to provide.
[206] *See contra* Wirth, *supra* note 23, at 827, where he argues that the footnote explaining the term "scientific justification" might be taken to mean that there are scientific constraints on the choice of the appropriate level of protection. However, it seems that the scientific analysis mandated by that footnote is directed at the question of whether the international standards are effective in achieving the Member's chosen level of protection, rather than at the choice of an appropriate level of protection.
[207] Walker, *supra* note 108, at 276.

WTO to take on the task of providing generally applicable health standards creates an institutional gap.[208] Article 3 attempts to fill this gap by making use of another, universally accepted and thus authoritative provider of uniform standards, namely science. Where a large degree of scientific consensus appears to exist, as embodied in standards set by international organizations,[209] Members are encouraged to use these standards. International standard-setting bodies use recognized risk assessment procedures conducted by scientific committees or expert groups to draw up standards. In the alternative, where no such standards exist or where Members wish to deviate from these standards, "scientific justification will operate to generate norms and rules".[210] The reason for this approach is the fact that science is seen to be a universal body of knowledge, based on physical experience and neutral and thus valid for all. Therefore, requiring that national regulations which differ from harmonized standards follow the dictates of science as embodied in risk assessment, should result in greater uniformity of health measures by promoting gradual regulatory convergence across national borders.

While this would be the case if science were really universal and absolute, the lack of consensus that exists among scientists as to the true state of scientific knowledge makes it of limited effect in achieving greater uniformity in national health measures.

D. Risk Assessment (Article 5.1–5.3)

Members are obliged, under Article 5.1 of the SPS Agreement, to base their SPS measures on a risk assessment. Articles 5.2 and 5.3 list factors that Members must take into account in the assessment of risks. Paragraphs 1 to 3 of Article 5 state:

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

[208] This is unlike the situation that exists in the EU where negative integration (lowering of trade barriers) is accompanied by positive integration (setting of general norms or rules). This is possible due to the norm-setting capacity of the EU institutions, which can operate on a supranational level, a characteristic that is absent in the WTO.

[209] The Secretariat of the Codex Alimentarius Commission released a paper on the role of science in the Codex decision-making process. *See* Codex Alimentarius Doc. CX/GP 94/4.

[210] Jeffrey Atik, Symposium -*Institutions for International Economic Integration: Science and International Regulatory Convergence,* 17 JOURNAL OF INTERNATIONAL LAW AND BUSINESS 736, 739 (1997).

Before proceeding to an analysis of what the obligation to base an SPS measure on a risk assessment entails, it is first necessary to determine what is meant by a "risk assessment" for purposes of Article 5.

1. Concept of "Risk Assessment" (Annex A, paragraph 4)

Paragraph 4 of Annex A to the SPS Agreement defines two types of risk assessment. The *first* type is 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". The *second* type is the "evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

The Appellate Body examined these definitions in four cases.[211] The interpretation of these definitions is important in assessing what will be required of Members who impose SPS measures not conforming to international standards. The cases dealing with these definitions will be addressed in the order in which they were decided, as later cases referred back to the findings in earlier cases.

In *EC—Hormones*,[212] the second type of risk assessment was at issue. The Panel had held that there were two steps to this kind of risk assessment, namely that it should:

(i) *identify* the *adverse effects* on human health (if any) arising (in that case) from the presence of the hormones at issue when used as growth promoters *in meat or meat products*, and
(ii) if any such adverse effects exist, *evaluate* the *potential* or probability of occurrence of these effects.[213]

The Appellate Body did not take issue with the two-step test, but regarded the Panel's use of "probability" as an alternative for "potential" as cause for concern as the word implies a higher degree of potentiality and seems to introduce a quantitative element.[214] The Appellate Body addressed the appeal of the EC on the point that the Panel was "in effect requiring a Member carrying out a risk assessment to quantify the potential for adverse effects on human health",[215] and found:

> It is not clear in what sense the Panel uses the term "scientifically identified risk". The Panel also frequently uses the term "identifiable risk"[216], and does not define this term either. The Panel might arguably have used the terms "scientifically identified risk" and "identifiable risk" simply to refer to an ascertainable risk: if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists? In one part of its Reports, the Panel

[211] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70; Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 132; Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97; and Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112.

[212] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 182.

[213] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.101; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.98.

[214] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 184–186.

[215] *Id.*, ¶ 185.

[216] U.S. Panel Report, ¶¶ 8.124, 8.134, 8.136, 8.151, 8.153, 8.161, 8.162; Canada Panel Report, ¶¶ 8.127, 8.137, 8.139, 8.154, 8.156, 8.164, 8.165. [Footnote in original].

opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects.[217] We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed. In another part of its Reports, however, the Panel appeared to be using the term "scientifically identified risk" to prescribe implicitly that a certain *magnitude* or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with Article 5.1.[218] To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the *SPS Agreement*.[219]

Thus it is clear that in the view of the Appellate Body, theoretical uncertainty is not the kind of risk to be assessed under Article 5.1. Such uncertainty always exists since it is not possible for science to ever completely rule out the possibility of risk.[220] Instead, there must be proof of an actual risk, not just uncertainty about whether a risk exists or not. However, no quantitative requirement that a certain magnitude of risk be shown is contained in the second definition. A panel may only determine whether the measure is sufficiently supported or reasonably warranted by the risk assessment and not whether a threshold level of risk has been shown.[221] Further, the Appellate Body stated that the risk assessment may go beyond the controlled conditions in a scientific laboratory, and take account of the actual potential for adverse effects in the real world.[222]

In *Australia—Salmon*,[223] the first type of risk assessment was relevant as the concern did not relate to food safety but rather to fish diseases that could be introduced through the importation of adult, wild, ocean-caught Pacific salmon from Canada. Referring to the definition in Annex A, the Panel clarified the risks that must be evaluated in this type of risk assessment:

(1) the risk of entry, establishment or spread of a disease and
(2) the risk of the associated potential biological and economic consequences.[224]

The Appellate Body in this case agreed with the Panel which had set out a three-pronged test that must be met by a risk assessment of the type described in the first definition of risk assessment in Annex A.[225] In terms of this test, the risk assessment must:

(1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;

[217] U.S. Panel Report, ¶¶ 8.152–8.153; Canada Panel Report, ¶¶ 8.155–8.156. [Footnote in original].
[218] U.S. Panel Report, footnote 331; Canada Panel Report, footnote 437. [Footnote in original].
[219] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 186.
[220] *See contra* Walker, *supra* note 117, at 305. He states that: "On the continuum between a merely speculative risk and a conclusively demonstrated one lies a vast stretch of undemonstrated, unquantified, but scientifically plausible risks. Within that zone, the risk of harm is real so long as safety is unproven."
[221] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 186.
[222] *Id.*, ¶ 187.
[223] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 120.
[224] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.72.
[225] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 121.

(2) *evaluate the likelihood* of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
(3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*.[226]

Australia had contended that its 1996 Final Report constituted a risk assessment in terms of Article 5.1. The Panel examined the Australian risk assessment and found that it met the first requirement of the test as it identified up to twenty diseases whose establishment or spread Australia was trying to prevent. Second, the Panel found that Australia had evaluated *some* elements of possibility and probability regarding the likelihood of entry or spread of these diseases. Third, the Panel held that Australia had considered a range of risk reduction factors to mitigate these risks. It accordingly assumed that the three-pronged test was met by Australia's risk assessment. This finding was overturned by the Appellate Body due to Australia's failure to meet the second and third requirements. The Appellate Body addressed each of the three requirements in turn.

With regard to the first requirement, the Appellate Body in *Australia—Salmon* agreed that Australia had identified the relevant diseases and that this requirement was thus met.[227] With regard to the second and third requirements, the Appellate Body examined the meaning of the term "evaluation of the likelihood". The Appellate Body pointed to the different language used in the first and second definitions of risk assessment in Annex A.[228] While the second calls for an evaluation of the "potential" for adverse effects, the first requires the evaluation of the "likelihood" of entry, establishment or spread of pests or diseases and their associated biological or economic consequences. The Appellate Body held that, contrary to the EC's assertion, these substantial differences in the two kinds of risk assessment should not be diminished.[229] Further, it stated:

> We note that the first definition in paragraph 4 of Annex A speaks about the evaluation of "likelihood". In our report in *European Communities—Hormones,* we referred to the dictionary meaning of "probability" as "degrees of likelihood" and "a thing that is judged likely to be true", for the purpose of distinguishing the terms "potential" and "probability".[230] For the present purpose, we refer in the same manner to the ordinary meaning of "likelihood", and we consider that it has the same meaning as "probability". On this basis, as well as on the basis of the definition of "risk" and "risk assessment" developed by the Office international des épizooties ('OIE') and the OIE *Guidelines for Risk Assessment,* we maintain that for a risk assessment to fall within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A, it is not sufficient that a risk assessment conclude that there is a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the

[226] *Id*. It should also be noted that in *Japan—Agricultural Products* the Appellate Body once again endorsed this three-pronged test and found that a risk assessment, on which Japan argued it had based its measure, did not refer to any SPS measure which could be taken to reduce the risk, and thus did not comply with the third requirement. Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 100, ¶ 113. This test was also used by the compliance Panel in *Australia—Salmon.* Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶ 7.41. In *Japan—Apples* the Appellate Body again used this test to evaluate Japan's risk assessment. Report of the Appellate Body, *supra* note 112, ¶ 196.
[227] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 126.
[228] *Id.* ¶ 123.
[229] *Id.* n.69. The EC was a third party participant in this dispute.
[230] Adopted February 13, 1998, WT/DS26/AB/R, WT/DS48/AB/R, ¶ 184. [Footnote in original].

> "likelihood", i.e., the "probability", of entry, establishment or spread of diseases and associated biological and economic consequences as well as the "likelihood", i.e., "probability", of entry, establishment or spread of diseases *according to the SPS measures which might be applied*.[231]

It seems likely that the different terminology in the two definitions of risk assessment was intended to set less stringent requirements in cases where human health is more likely to be at risk, namely where food safety is at issue, than in cases where the risk relates to pests or diseases, which are more likely to affect plants or animals.[232]

The Appellate Body went on to find that the second and third requirements of this definition of risk assessment were not met by just *some* evaluation of likelihood.[233] In this regard, it held:

> We note that, although the Panel stated that the definition of a risk assessment for this type of measure requires an "evaluation of the likelihood", for the purpose of satisfying the second and third requirements,[234] it subsequently was hesitant in applying these requirements, by stating or suggesting in paragraphs 8.80, 8.83, 8.89 and 8.91, that *some* evaluation of the likelihood or probability would suffice. We consider this hesitation unfortunate. We do not agree with the Panel that a risk assessment of this type needs only *some* evaluation of the likelihood or probability. The definition of this type of risk assessment in paragraph 4 of Annex A refers to "the evaluation of the likelihood" and not to *some* evaluation of the likelihood. We agree, however, with the Panel's statements in paragraph 8.80 that the *SPS Agreement* does not require that the evaluation of the likelihood needs to be done quantitatively. The likelihood may be expressed either quantitatively or qualitatively. Furthermore, we recall, as does the Panel,[235] that we stated in *European Communities—Hormones* that there is no requirement for a risk assessment to establish a certain magnitude or threshold level of degree of risk.[236]

In coming to the conclusion that Australia's 1996 Final Report did not meet the requirement of an "evaluation of likelihood" of the entry, establishment or spread of the relevant diseases and of their associated potential biological and economic consequences, the Appellate Body relied on findings of the Panel based on statements of the experts

[231] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 123.

[232] Contrary to the EC's contention, it is not the case that both definitions apply equally to human life or health and plant and animal life or health. In fact the second definition omits plants. While the second definition refers to animal health as well as human, clearly the human health consideration was paramount in the setting of a more lenient criterion to satisfy the obligation to conduct a risk assessment in this definition. The first definition, referring to the entry, establishment or spread of pests or diseases is obviously most likely to affect animals and plants, and a stricter requirement was set. While not explicitly stated, it seems that risks to human health were not envisaged as likely to fall within the first definition. It would, in any case, appear unlikely that pests or diseases that can be spread by cross-border movement of goods that are not food or beverages (or they would fall under the second definition) could be transferred to humans. It should, however, be noted that the definition of SPS measures in Annex A expressly includes, in paragraph 1(c), measures to protect *human* health from risks from pests or diseases carried by animals or plants or products thereof. Thus the possibility of risks to humans falling under the first definition of risk assessment cannot be excluded. In such a case, the wisdom of interpreting the first definition to lay down a stricter requirement can be questioned.

[233] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 124.

[234] Panel Report, ¶ 8.72. [Footnote in original].

[235] Panel Report, ¶ 8.80. [Footnote in original].

[236] Adopted February 13, 1998, WT/DS26/AB/R, WT/DS48/AB/R, ¶ 186. [Footnote in original].
The case cited is: Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, supra note 141, ¶ 124.

advising the Panel.[237] These experts expressed the view that the 1996 Final Report lent more weight to unknown and uncertain elements of the assessment and looked at the *possibilit*y of adverse effects occurring rather than assessing the *probability* thereof.[238] The Appellate Body pointed out that the existence of unknown or uncertain elements does not justify a departure from the requirements for a risk assessment.[239]

While in *EC—Hormones* the Appellate Body had expressed concern that the Panel's use of the term "probability" might introduce a quantitative element into the second definition, in *Australia—Salmon*[240] it found that likelihood or probability in the first definition could be expressed quantitatively or qualitatively. However, Australia's evaluation of the probability as "low" or "small" was not deemed sufficient.[241] It is not clear what kind of qualitative determination of probability would satisfy this requirement.

Further, the Appellate Body in *Australia—Salmon* confirmed the finding in *EC—Hormones* that the risk assessment need not establish a certain magnitude or threshold level of risk. Thus, even a very small, demonstrated probability of risk is sufficient. The Appellate Body[242] distinguished between the evaluation of risk, which must show an ascertainable risk, not just a theoretical uncertainty, and the determination of an appropriate level of protection, which may be premised on a zero-risk level. It is thus possible for a Member (once an actual risk, however small, has been proven to have a *certain quantitative or qualitative probability*) to choose a zero-risk level of protection and institute SPS measures to achieve this level.[243] The usefulness of the determination of probability is thus doubtful, since no matter how small the probability of the risk, the state's chosen level of protection cannot be challenged on grounds of proportionality.[244] The more stringent criterion ("probability" as opposed to "potential") thus only serves to make it harder to satisfy the risk assessment requirement without serving any real purpose with regard to disciplining the resulting SPS measure.

With respect to the third element of this definition of a risk assessment, namely the evaluation of likelihood "according to the SPS measures which might be applied", the Appellate Body in *Australia—Salmon* agreed with the Panel that this term refers to those measures that reduce the risks of concern.[245] In *Australia—Salmon (21.5)*, the compliance Panel further clarified what is required under this element. It rejected the contention that, in order for the third element of the definition to be met, the SPS measure applied must

[237] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 129.

[238] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon, supra* note 57, ¶ 8.83.

[239] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 130.

[240] *Id.* ¶ 124.

[241] It should be noted that the OIE, which is recognized in the SPS Agreement as the relevant standard-setting organization in the area of animal health, defines a qualitative risk assessment as "[a]n assessment where the conclusions on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible". *See* OIE, *Diagnostic Manual for Aquatic Animal Diseases*, 3rd edition (2000), Article 1.4.1.3.

[242] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon, supra* note 141, ¶ 125 (quoted *infra* Part II(F)(1)).

[243] This point is discussed further *infra* Part II(F)(1).

[244] This can be compared to the situation under EC law, where the exception for health measures, which requires that the measure be "necessary" to protect human life or health, has been interpreted by the ECJ to include the requirement that the measure be proportional to the aim it seeks to achieve.

[245] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon, supra* note 57, ¶ 132.

be shown to be linked with the risk assessment. It stated as follows:

> Canada's claim . . . raises the question of whether the definition of risk assessment *as such*, requiring Members to assess risk "according to the [sanitary] measures which might be applied", can be construed so as to include the obligation to make the link between the assessment, the measures *finally selected* and the necessity to use these measures in order to achieve the ALOP.[246] We find it difficult to read such a requirement into paragraph 4 of Annex A.
>
> In our view, the rights and obligations in respect of these linkages are set out *not* in the definition of risk assessment itself—which logically *precedes* the selection of measures—but, *inter alia*, in the obligation to *base* sanitary measures *on* a risk assessment in Article 5.1 and to ensure that sanitary measures are not more trade-restrictive than required to achieve the ALOP in the sense of Article 5.6. To examine these questions of relationship between the risk assessment, the measures selected and the ALOP under the definition of risk assessment—as Canada . . . seem[s] to do—would, in our view, run the risk of adding to or diminishing the more specific rights and obligations of Members set out in other SPS obligations, contrary to Article 19.2 of the DSU.
>
> . . . In any event, we prefer to address this question of relationship between the measures selected and the risk assessment under the obligation to *base* measures *on* a risk assessment pursuant to Article 5.1 rather than under the very definition of risk assessment referred to in the same provision.[247]

Thus, the third element of the three-pronged test, requiring the evaluation of the likelihood of entry, establishment or spread of the relevant diseases *according to the SPS measure that might be applied* does not necessitate a determination of the link between the measure applied and the risk assessment itself. Instead, it only requires that the risk be determined according to the different options available to mitigate the risk.

In *Japan—Apples*, the Panel found that Japan had not evaluated the risk according to the SPS measures which might be applied, as its risk assessment examined only the SPS measure it had imposed to address the risk of fire blight. The Panel held that "consideration should be given not just to those specific measures which are currently in application, but at least to a potential range of relevant measures."[248]

On appeal, the Appellate Body found:

> We agree with the Panel that this phrase "refers to the measures *which might* be applied, not merely to the measures which *are being* applied." The phrase "which might be applied" is used in the conditional tense. In this sense, "might" means: "were or would be or have been able to, were or would be or have been allowed to, were or would perhaps". We understand this phrase to imply that a risk assessment should not be limited to an examination of the measure already in place or favoured by the importing Member. In other words, the evaluation contemplated in paragraph 4 of Annex A to the *SPS Agreement* should not be distorted by preconceived views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*.[249]

Risk assessments must therefore evince an evaluation of a range of possible SPS measures which could be applied to address the risk at issue, and their relative effectiveness,

[246] "ALOP" is an abbreviation for Appropriate Level of Protection. [Note added by the authors].
[247] Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.68–7.70.
[248] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 8.285.
[249] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 208 (footnotes omitted).

not merely address the measure actually applied. Otherwise they could be regarded as prejudging their own outcome[250] by showing that the measure actually applied is appropriate and effective, without regard for possible alternatives.

From the above discussion of its interpretation of the requirements for the two types of risk assessment, it is apparent that the Appellate Body takes a more realistic view of the scientific assessment of risks than do the Panels. It would appear that the Appellate Body is trying to make provision for the difficulties inherent in risk assessment by: (1) allowing the probability to be established quantitatively or qualitatively, (2) not requiring a minimum level of risk to be shown, and (3) finding that the risk to be ascertained is not only that which can be established under controlled conditions in science laboratories, but includes that occurring in the "real world".

Aside from the findings regarding the specific requirements of each of the two definitions, the decisions in these cases also address common issues relating to risk assessment in general. It is useful to identify certain common elements.

(a) Specificity. One of the issues common to both types of risk assessment is the *requirement of specificity* in the analysis of risk. On this issue, the Appellate Body in *EC—Hormones* stated:

> . . . [the studies submitted by the respondent] constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake—the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes—as is required by paragraph 4 of Annex A of the *SPS Agreement*. Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand.[251]

Further, the Appellate Body in *EC—Hormones* agreed with the Panel that a risk assessment must be comprehensive, i.e. it must cover each of the substances at issue. Thus, the Appellate Body upheld the Panel's finding that "there was no risk assessment with regard to MGA",[252] one of the six growth hormones at issue, stating that "[i]n other words, there was an almost complete absence of evidence on MGA in the Panel proceedings."[253] On this point, the Panel explained that, "one of the basic principles of a risk assessment appears to be that it needs to be carried out for each individual substance."[254]

When dealing with the second element of its three-pronged test, the Panel in *Australia—Salmon* emphasized the need for specificity in a risk assessment, finding:

> . . . given the definition of risk assessment applicable in this case (the "evaluation of the likelihood of entry, establishment or spread of a . . . *disease*", in the singular form), a risk assessment for the measure at issue in this dispute at least has to *identify* risk on a disease specific basis, i.e., it has to identify the risk for any given disease of concern separately, not simply address the overall risk related to the combination of all diseases of concern. . . . The experts advising the Panel on this issue confirmed this. In the *EC—Hormones* case

[250] This comment was made by one of the experts advising the Panel in *Japan—Apples*. Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 6.177.
[251] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 200.
[252] *Id*. ¶ 201.
[253] *Id*.
[254] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.255; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.258.

> as well, both the panels and the Appellate Body required some degree of specificity for a risk assessment—or a study or report allegedly part thereof—to be in accordance with the requirements imposed in Article 5.1.[255]

Although the Appellate Body agreed with the Panel that Australia had identified the risk on a disease-specific basis in its risk assessment, it held that Australia had not assessed or evaluated this risk and had thus not complied with the requirements of a risk assessment. On the relevance of studies on one product category for a risk assessment in respect of another product category, the Panel in *Australia—Salmon* addressed Australia's submission that to the extent that a disease agent was common to wild Pacific and other Canadian salmon products, its risk assessment (contained in the 1996 Final Report) with regard to the former product was equally valid for the latter. The Panel noted:

> (. . .) [W]e do not consider—nor has Australia claimed—that the 1996 Final Report (which is explicitly limited to adult, wild, ocean-caught Pacific salmon) constitutes a risk assessment, in the sense of Article 5.1, for the other categories of salmon products covered by the measure in dispute. We do, however, agree with Australia that some of the evidence, assessments and conclusions contained in the 1996 Final Report might be relevant for the risk assessment to be carried out (or relied upon) for the other categories of salmon products and that, therefore, a completely new risk assessment for these other categories of salmon products might not be necessary.[256]

The issue of specificity was again addressed in *Japan—Apples*, where the Panel examined Japan's risk assessment which evaluated the risk of entry, establishment and spread of fire blight through a collection of possible hosts, including apples. The Panel found that as Japan's risk assessment did not evaluate the risks in relation to apple fruit separately from those posed by other hosts, whereas scientific evidence showed that the risks vary significantly depending on the vector (host plant) involved, it did not meet the requirement of specificity.[257] On appeal, Japan argued that the methodology of a risk assessment is not regulated by the SPS Agreement and a Member may thus decide for itself whether to analyse the risk on the basis of a particular pest or disease, or on the basis of a particular commodity.[258] The Appellate Body upheld the Panel's finding, holding that it did not limit a Member's choice of risk assessment methodology. Members are free to organise their risk assessments along the lines of pests or diseases, or of the commodity imported, provided that a likelihood of entry, establishment or spread of the disease is attributed to *each agent specifically*.[259] The Appellate Body emphasised that, as held in *EC—Hormones*, the risk to be specified in a risk assessment is the harm concerned *as well as* the precise agent that may cause the harm.[260]

Therefore, a rather high degree of specificity is required in a risk assessment. It has to focus and address the particular kind of risk at stake from the product at issue, not just generally establish that the substance may be harmful. It must assess the risk for each type of disease or harmful substance at issue separately it must also specify due risk from the specific agent at issue. Although a completely new risk assessment is not

[255] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.74.
[256] *Id.* ¶ 8.58.
[257] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶¶ 8.268–271.
[258] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 204.
[259] *Id*.
[260] *Id.*, ¶ 202.

necessary for each product category, a risk assessment for one product cannot be regarded as constituting a risk assessment for related product categories.[261]

(b) "As Appropriate to the Circumstances" (Article 5.1). The requirement of Article 5.1 that SPS measures be based on a risk assessment is qualified by the phrase "as appropriate to the circumstances." It is therefore necessary to examine what this qualification entails to determine whether circumstances such as scientific uncertainty, the fact that the measure predates the coming into force of the SPS Agreement, or the lack of economic resources or scientific capabilities of a Member might mitigate the strict requirements relating to risk assessments. When addressing the applicability of the SPS Agreement to those measures adopted before the entry into force of the WTO Agreement, the Appellate Body in *EC—Hormones* noted the following:

> We are aware that the applicability, as from 1 January 1995, of the requirement that an SPS measure be based on a risk assessment to the many SPS measures already in existence on that date, may impose burdens on Members. It is pertinent here to note that Article 5.1 stipulates that SPS measures must be based on a risk assessment, *as appropriate to the circumstances*, and this makes clear that the Members have a certain degree of flexibility in meeting the requirements of Article 5.1.[262]

However, what this flexibility would entail in practice is not clear, as the Appellate Body did not seem to relax any of the normal disciplines in its ensuing assessment of whether the EC had met the requirements for a risk assessment in this case. In respect of Australia's claim that its risk assessment for one product category was equally valid with respect to other product categories to which the same disease agent was common, the Panel in *Australia—Salmon* referred back to the above-mentioned finding of the Appellate Body in *EC—Hormones* and noted:

> As to the product coverage of Article 5.1, the reference contained in Article 5.1 to base sanitary measures on an assessment "as appropriate to the circumstances" cannot, in our view, annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute (irrespective of the products that measure may cover) on a risk assessment. We consider that the reference "as appropriate to the circumstances" relates, rather, to the way in which such risk assessment has to be carried out.[263] Only Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment.[264]

Turning to an examination of Australia's 1996 Final Report, to determine if it constituted a risk assessment in respect of adult, wild, ocean-caught salmon, the Panel further stated:

> Following Article 5.1, a risk assessment needs to be "appropriate to the circumstances". Answering a Panel question in this respect, Canada is of the view that the circumstances thus referred to are the source of the risk (e.g., an animal pathogen or a chemical contaminant) and the subject of the risk (i.e., whether it is to human, animal or plant life or health). For Australia, the phrase "as appropriate to the circumstances" confers a right and obligation on WTO Members to assess the risk, on a case by case basis, in terms of product, origin and destination, including, in particular, country specific situations. We

[261] The Panel's finding of the absence of a risk assessment with regard to the other product categories ("other Canadian salmon") covered by the measure was not appealed.
[262] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 129.
[263] *See further* in ¶ 8.70. [Footnote in original].
[264] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.57.

> agree that both interpretations may be covered by the term "as appropriate to the circumstances". In our view, also the OIE risk assessment techniques as well as the scientific opinions we gathered, may shed light on what is a risk assessment "appropriate to the circumstances".[265]

The Panel, however, did not proceed to evaluate whether Australia's 1996 Final Report met the requirements of a risk assessment, but merely assumed it did so[266] and went on to determine whether the measure was "based on" the Final Report. The Appellate Body in this case did not find it appropriate to base its examination of Article 5.1 on this assumption of the Panel, and thus examined itself the question whether Australia's 1996 Final Report was a risk assessment within the meaning of Article 5.1. In its finding that the second requirement of a risk assessment (the evaluation of the likelihood of the risk) was not met, it stated as follows:

> . . . the existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3, read together with paragraph 4 of Annex A, for a risk assessment. We recall that Article 5.2 requires that "in the assessment of risk, Members shall take into account available scientific evidence". We further recall that Article 2, entitled "Basic Rights and Obligations", requires in paragraph 2 that "Members shall ensure that any sanitary . . . measure . . . is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.[267]

Although the Appellate Body was not specifically addressing the question of the meaning of the phrase "as appropriate to the circumstances", it did not seem to allow the existence of scientific uncertainty to mitigate the requirements for a risk assessment in Article 5.1.

In *Japan—Apples*, the Panel examined what is meant by a risk assessment "as appropriate to the circumstances". It held that this factor, together with the consideration of the risk assessment techniques developed by the relevant international organizations,[268] pervades the entire risk assessment as defined in Annex A and is therefore relevant to the evaluation of the risk assessment as a whole. It therefore addressed this first, before looking at other requirements for a risk assessment.[269] The Panel first found, rather obviously, that as Japan's measure was a phytosanitary measure, it must focus on risks related to plant life and health.[270] It then noted that the term "as appropriate to the circumstances" has been interpreted, in *Australia—Salmon*, to provide some flexibility for risk assessments, on a case-by-case basis, including consideration of country-specific situations. It therefore found that Japan's fire blight-free status and its climatic conditions, which were favorable to the spread of fire blight, were relevant "circumstances" to be taken into account in Japan's risk assessment, and noted that they related to some of the factors required to be considered under Article 5.2.[271]

From the above discussion it appears that the qualifying phrase "as appropriate to the circumstances" has been interpreted by panels to indicate that the *manner* of conducting a risk assessment may differ, depending on the source of the risk (e.g. chemical or pathogen), subject of the risk (human, plant or animal), product involved, and country-specific situations regarding the country of origin or destination of the product. What the

[265] *Id.* ¶ 8.71.
[266] *Id*. ¶ 8.83 and 8.92.
[267] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 130.
[268] This factor is discussed *infra* Part II(D)1(c).
[269] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 8.237.
[270] *Id.*, ¶ 8.238.
[271] *Id.*, ¶ 8.240 and note 372. Article 5.2 is discussed *infra* Part II(D)2.

appropriate manner of conducting a risk assessment is in a specific case is determined with reference to the opinions of scientific experts, and risk assessment techniques established by international standard-setting organizations in the area at issue.

(c) "Taking into Account Risk Assessment Techniques Developed by the Relevant International Organizations."(Article 5.1). Article 5.1 further requires that a risk assessment take into account the risk assessment techniques which are developed by the relevant international organizations. It can be assumed that these organizations are those referred to in the definition of "international standards, guidelines and recommendations" in Annex A, paragraph 3, namely primarily the CAC, OIE and IPPC, since these are the most relevant for SPS matters. In *Australia—Salmon*, as noted above, the Panel took account of the risk assessment techniques developed by the OIE as part of its consideration of what is covered by the term "as appropriate to the circumstances".[272] In *Japan—Apples*, however, the Panel examined this issue separately, as one of the two factors which pervade the evaluation of a risk assessment. After noting that Article 5.1 merely requires that these risk assessment techniques be "taken into account", rather than that a risk assessment be "based on" or "in conformity with" them, the Panel found that:

> . . . such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, *per se*, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1. Nonetheless, reference to these risk assessment techniques can provide very useful guidance as to whether the risk assessment at issue constitutes a proper risk assessment within the meaning of Article 5.1.[273]

It is thus clear that the risk assessment techniques developed by the relevant international organizations, while useful, are not determinative to the determination whether a risk assessment complies with Article 5.1.

(d) Borrowed Risk Assessments. On the question whether the risk assessment relied upon must be conducted by the Member itself, the Appellate Body in *EC—Hormones* pointed out that the SPS Agreement is not prescriptive as to *who* carries out the risk assessment. It stated that:

> Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment . . . The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization.[274]

Thus it is sufficient if the measure is *based on* a risk assessment, whatever its origin. This is particularly significant for developing countries, which often lack the financial and technical capacity to carry out their own risk assessments. They may thus rely on those risk assessments conducted in the relevant standard-setting organizations or in other countries, to the extent that they are applicable to their own situations.

[272] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon, supra* note 57, ¶ 8.71.

[273] *Id*. ¶ 8.241. In this context, the Panel examined two relevant standards set by the International Plant Protection Convention, ISPM 2 on Guidelines for Pest Risk Analysis, and ISPM 11 on Pest Risk Analysis for Quarantine Pests. The parties agreed that both instruments build upon the same framework, thus the Panel focused on the key issue of whether Japan's risk assessment sufficiently identified and assessed the possible pathways for the introduction and spread of fire blight through apple fruit and the likelihood for their being realised, as required by both instruments. *Id.,* ¶ 8.244.

[274] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 190. This finding was recalled by the Appellate Body in *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, n. 68.

(e) Risk Assessment as Distinct from Risk Management. To further elucidate what a risk assessment entails, it is useful to distinguish it from risk management. There is a commonly-drawn distinction in risk analysis methodology between *risk assessment* (the science-based process of determining the existence of a risk and the likelihood of it occurring according to the SPS measures which could be applied), and *risk management* (a policy-based choice of the level of protection deemed appropriate by a state, taking into account various societal value judgments such as the citizens' tolerance of risk, economic considerations, *etc.* and the choice of measure to achieve this level of protection).[275] While a Member's risk assessment must be founded on scientific analysis, scope is left for risk management decisions in the setting of an appropriate level of protection and the choice of a measure to achieve this level of protection. This distinction was recognized by the Panel in *EC—Hormones*.[276] However, it used this distinction to exclude from the scope of a risk assessment certain non-scientific reports as well as opinions of the European Parliament and the Economic and Social Committee, which evaluated reports submitted to them, and the question of risks associated with the problem of control of the use of hormones. It viewed these issues as having to do with social-value judgments and thus as not scientifically based and belonging under "risk management" rather than "risk assessment". The Appellate Body rejected the Panel's distinction, stating that the SPS Agreement nowhere refers to the term "risk management" but only to "risk assessment".[277] Thus the Panel's use of the distinction to limit the scope of what falls under risk assessment was held to have no basis in the text. The Appellate Body held:

> . . . The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a "scientific" examination of data and factual studies; it is not, in the view of the Panel, a "policy" exercise involving social value judgments made by political bodies.[278] The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment".[279] We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used.[280]

[275] For a more detailed analysis of this distinction, *see* Walker, *supra* note 117, at 256–277. In addition, risk communication forms part of the risk analysis process. It is defined as follows in Article 1.3.2.7 of the OIE *International Animal Health Code*: "Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout." (Emphasis in original). This aspect of risk analysis is party covered by the rules on transparency in the SPS Agreement, dealt with in Part III(A) below.

[276] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.98; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.95.

[277] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 181.

[278] U.S. Panel Report, ¶ 8.94; and Canada Panel Report, ¶ 8.97.[Footnote in original].

[279] U.S. Panel Report, ¶ 8.95; and Canada Panel Report, ¶ 8.98. [Footnote in original].

[280] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 181.

While it is true that the term "risk management" is not explicitly mentioned in the SPS Agreement, the Agreement deals in different ways with the Members' obligation to base their SPS measures on a risk assessment and their right to establish their own level of protection and choose a measure to achieve this level of protection. The former is subject to strict scientific criteria, whereas the latter choices are not reviewable, provided they takes into account the aim of reducing negative trade effects when determining the appropriate level of protection,[281] and avoid arbitrary or unjustifiable distinctions in the levels of protection established in different situations, and ensure that the measure taken is the least restrictive.[282] The criteria against which the choice of the level of protection is evaluated do not have a scientific basis. This recognizes the sovereign right of Members to make their own policy choices in the area of public health, taking into account various non-scientific considerations. The choice is ultimately one based on societal value judgments. The latter area of decision-making is commonly known as risk management.

It would perhaps have made more sense for the Appellate Body to take issue only with the Panel's classification of the risks associated with control as non-scientific and thus belonging under risk management and not under risk assessment, rather than objecting to the Panel's distinction between risk management and risk assessment. Such an approach would be in line with the Appellate Body's view, expressed in *EC—Hormones*, that a risk assessment deals with real-world risks and not just risks ascertainable by means of laboratory experiments.[283]

2. Factors Taken into Account (Article 5.2 and 5.3)

Although the SPS Agreement does not specify a methodology to be used in making a risk assessment,[284] it does list in Article 5.2 and 5.3 the scientific (in a broad sense) and economic factors that Members must take into account.

First, Article 5.2 provides that Members must take certain objectively ascertainable factors into account when assessing risks. These 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. As stated above, the Panel in *EC—Hormones* held that the risks relating to detection and control of failure to observe good veterinary practice should be excluded from risk assessment *a priori* because they are non-scientific and thus do not fall within the scope of Article 5.2's provision on "relevant inspection sampling and testing methods", but rather are taken into account in risk management. The Appellate Body rejected this finding, holding that the scope of Article 5.2 allowed consideration of these risks. The Appellate Body noted:

> The listing in Article 5.2 begins with "available scientific evidence"; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is "a *scientific* process aimed

[281] Article 5.4 SPS.

[282] Article 5.5 SPS and Article 5.6 SPS.

[283] As will be discussed below, the Appellate Body did overrule the Panel's decision that risks from failure to observe good veterinary practice and problems relating to detection and control of such failure must be rejected *a priori* because they are unscientific and thus do not belong under risk assessment. The Appellate Body found that the Panel had misinterpreted the scope of Article 5.2 and that these considerations did, in fact, belong thereunder. Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 187.

[284] However, Members are required, in Article 5.1, to take account of the risk assessment techniques developed by the relevant international organizations.

> at establishing the *scientific* basis for the sanitary measure a Member intends to take".[285] To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable. However, to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some of the kinds of factors listed in Article 5.2 such as "relevant processes and production methods" and "relevant inspection, sampling and testing methods" are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable 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.[286]

The Appellate Body further stated:

> It should be recalled that Article 5.2 states that in the assessment of risks, Members shall take into account, in addition to "available scientific evidence", "relevant processes and production methods; [and] relevant inspection, sampling and testing methods". We note also that Article 8 requires Members to "observe the provisions of Annex C in the operation of control, inspection and approval procedures . . . ". The footnote in Annex C states that "control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification". We consider that this language is amply sufficient to authorize the taking into account of risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice.[287]

The Appellate Body qualified its finding, however, as follows:

> [T]he *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2.[288]

Thus, the Appellate Body has clarified that the SPS Agreement requires an assessment of the potential for adverse effects on human, animal or plant life or health from contaminants or toxins in food, or pests or diseases, regardless of their origin. Whether a specific risk must be examined should be determined on a case-by-case basis but no risk should be excluded *a priori*.

[285] U.S. Panel Report, ¶ 8.107; Canada Panel Report, ¶ 8.110. [Footnote in original].
[286] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 187.
[287] *Id.* ¶ 205.
[288] *Id.* ¶ 206.

Article 5.3 sets out certain economic factors to be taken into account in assessing risks to animal or plant life or health and in determining which SPS measure should be applied. These economic factors listed in Article 5.3 are "the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks." This list of factors implies a recognition of the fact that risk assessments are not purely science-based but involve economic considerations as well. It is significant that in the assessment of human health risks these economic factors are not required to be taken into account.[289] Thus, governments are not required to weigh economic factors against the protection of human health.

3. The "Based on" Requirement (Article 5.1)

Article 5.1, quoted above, sets out the requirement that SPS measures be "based on" an assessment of the risks to human, animal or plant life or health, as appropriate to the circumstances and taking into account risk assessment techniques developed by the relevant international organizations.

The meaning of "based on" in Article 5.1 was discussed in *EC—Hormones*.[290] In this case, the Panel read a procedural requirement into the term, obliging Members to take a risk assessment into account when enacting or maintaining SPS measures.[291] It looked to preambles of EC Directives for evidence that this was in fact done.[292] The Appellate Body rejected this subjective requirement as having no basis in the text. It found:

> The term "based on", when applied as a "minimum procedural requirement" by the Panel, may be seen to refer to a human action, such as particular human individuals "taking into account" a document described as a risk assessment. Thus, "take into account" is apparently used by the Panel to refer to some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals. We believe that "based on" is appropriately taken to refer to a certain *objective relationship* between two elements, that is to say, to an *objective situation* that persists and is observable between an SPS measure and a risk assessment. Such a reference is certainly embraced in the ordinary meaning of the words "based on" and, when considered in context and in the light of the object and purpose of Article 5.1 of the *SPS Agreement*, may be seen to be more appropriate than "taking into account". We do not share the Panel's interpretative construction and believe it is unnecessary and an error of law as well.[293]

[289] As mentioned previously, this exclusion of human health risks from Article 5.3 in the final text of the SPS Agreement was not present in the Dunkel Draft. *See supra* note 32.

[290] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶¶ 188-209.

[291] Thus, the panel found that the EC could not rely on new scientific evidence regarding the risks posed by hormone-treated beef, published in journals in 1995 and 1996, since it could not have been considered by the EC at the time of imposing the import ban. Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.113; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.116.

[292] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.116–8.119; and Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.114.

[293] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 189.

The Panel also found that Article 5.1 contained a substantive requirement, namely that the scientific conclusions reached in the risk assessment and those implicit in the SPS measure should *conform*.[294] The Appellate Body agreed with the relevance of the relationship between the two sets of conclusions, but emphasized that this is only one of the relevant factors. It held:

> The relationship between those two sets of conclusions is certainly relevant; they cannot, however, be assigned relevance to the exclusion of everything else. We believe that Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the *SPS Agreement*, requires that the results of the risk assessment must sufficiently warrant—that is to say, reasonably support—the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment.[295]

The Appellate Body further clarified what the requirement of "based on" entails in cases of divergent scientific views as follows:

> We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. . . . In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects.[296]

This conclusion has been criticized for leaving intact the issue of dueling science and opening the door for the use of "hired scientists" in future dispute settlement cases.[297] However, it should be recognized that this is the only realistic approach that could be taken in the light of a lack of consensus that frequently exists within the scientific community. For this reason, the Appellate Body has recognized that Members may in some cases base their SPS measures on minority scientific views, if they come from qualified and respected sources. Whether such measures will be regarded as "based on" a risk assessment will depend on the circumstances of each case.

The Appellate Body's ruling in *EC—Hormones* on the "based on" requirement leaves, considerable scope for discussion as to what kind of relationship would be considered "rational". Would a measure based on a single divergent scientific opinion be considered rationally related to the risk assessment?

[294] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.120. Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.119.
[295] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 193.
[296] *Id.* ¶¶ 193–194.
[297] McNiel, *supra* note 18, at 134.

It does not necessarily follow that if the EC in the *EC—Hormones* dispute had found a single scientist willing to report that human consumption of beef treated with hormones for growth-promotion purposes poses a real risk of cancer, this would meet the requirement of Article 5.1. Such a result would seem to frustrate the SPS Agreement's goal of using science to create clear rules and disciplines.[298] It would also encourage the "purchasing" of scientific opinions by national governments. Instead, it appears the ruling of the Appellate Body, that the determination of whether a rational relationship exists between an SPS measure and a divergent scientific view will be done on a case-by-case basis taking into account all relevant considerations. Where serious and imminent threats to public safety are at issue, it will be easier for measures based on minority scientific opinions to fulfill the criterion of having a "rational relationship" to a risk assessment and thus be based thereon for purposes of Article 5.1.

It is also important to determine *when* the risk assessment needs to have been made in order for a measure to be "based" thereon. Obviously there are a multitude of SPS measures that were in existence long before the coming into force of the SPS Agreement. It is possible that many of these were not based on a risk assessment, particularly in Members whose resources are too scarce to permit them to undertake thorough risk assessments before enacting SPS measures. As discussed above, the SPS Agreement applies also to those measures predating its coming into force, provided the measures are still in existence.[299] The question arises whether Article 5.1 may be an exception to this rule.

With respect to the risk assessment requirement for SPS measures enacted *before* the entry into force of the SPS Agreement, the Panel in *EC—Hormones* noted:

> [Article 5.1] does not prevent that with respect to a sanitary measure enacted *before* the entry into force of the SPS Agreement, the risk assessment is carried out or invoked *after* the entry into force of that Agreement (and thus *after* the enactment of the sanitary measure in question). However, the fact that a sanitary measure may be enacted *before* the entry into force of the SPS Agreement does not mean that, once the SPS Agreement entered into force, there is no obligation for the Member in question to base that measure on a risk assessment.[300]

The Appellate Body in that case confirmed this finding.[301]

The same approach was followed by the Panel in *Australia—Salmon*, which stated:

> Article 5.1 does not qualify—either in terms of application in time or product coverage—the substantive obligation imposed on all WTO Members to base their sanitary measures on a risk assessment.[302]

Therefore, it is clear that the requirement in Article 5.1 that SPS measures be based on a risk assessment also applies to SPS measures in existence before the coming into force of the SPS Agreement. However, it is not necessary for the risk assessment to precede the enactment of the SPS measure in order for the latter to be regarded as "based on" a risk

[298] *Id.* at 93.
[299] *See supra* Part II(A)(3)(c).
[300] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.102 [footnote omitted]; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.99.
[301] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 129.
[302] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.56.

assessment. This added flexibility is only applicable to measures predating the coming into force of the SPS Agreement in order to lessen the burdensome consequences of the fact that the SPS Agreement also applies to measures already in existence.[303]

Before the compliance Panel in *Australia—Salmon*, Canada claimed that the new Australian measures could not be said to be based on a risk assessment, because the publication of the new measures, on July 19, 1999, preceded the publication in its final form of Australia's new risk assessment, contained in the 1999 Import Risk Analyses ("IRA"), on November 12, 1999. The Panel rejected this argument as follows:

> We note that the final form of the 1999 IRA, though only edited and published in book form on 12 November 1999, is still dated July 1999 and that . . . the amendments made in the final 1999 IRA "do not alter the substance or the conclusions of the report as announced on 19 July".
>
> On these grounds, we find that the fact that the 1999 IRA was only published in final form subsequent to the date the new sanitary measures were taken, does not, in this case, preclude the measures from being *based on* the 1999 IRA. All substantive elements of the risk assessment we looked at earlier were already included in the draft 1999 IRA of July 1999, i.e. *before* the new measures were taken.[304]

From these findings of the compliance Panel in *Australia—Salmon*, it appears that for measures postdating the SPS Agreement at least the substantive elements of the risk assessment must already have been in existence at the time of adoption of the measure. The fact that the risk assessment was *published* only after the measure was adopted is of no relevance to the question whether the measure can be regarded as "based on" the risk assessment.

E. Provisional Application of SPS Measures (Article 5.7)

1. Relationship between Article 5.7 and the Precautionary Principle

It is generally accepted that there are situations where governments need to take measures to prevent risks to health even when sufficient scientific evidence confirming the risk is lacking.[305] Thus, governments may act with precaution in order to protect against risks without waiting for the conclusive results of scientific analyses. This is in line with the old adage "better safe than sorry", and is particularly important where risks to health are concerned. Citizens prefer their governments to err on the side of caution when faced with decisions on the protection of health where complete information is lacking. This is commonly referred to as acting in accordance with the precautionary principle.[306]

It is necessary to examine the extent to which the precautionary principle is taken into account in the SPS Agreement. Article 5.7 of the SPS Agreement allows for provisional measures to be taken by Members when there is insufficient scientific evidence, under certain conditions, and thus could be said to reflect a particular formulation of the

[303] *See supra* Part II(A)(3)(c) regarding the temporal scope of application of the SPS Agreement.

[304] Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.76–7.77.

[305] For an interesting discussion on the prevalence of uncertainty in SPS risk analysis and reasons for this, *see* Mark Powell, *Science in Sanitary and Phytosanitary Dispute Resolution*, Discussion Paper 97–50, RESOURCES FOR THE FUTURE, 5–11 (1997).

[306] It should be noted that some countries, such as the United States, prefer the term "precautionary approach" in order to avoid the implication that an overriding general principle of law has emerged in this respect. In addition, there is a difference of opinion among Members, particularly the EC and the U.S., regarding at which stage of risk analysis (i.e. risk assessment or risk management) precaution should play a role.

precautionary principle. Article 5.7 provides:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

However, the question arises whether this provision represents the only scope for the precautionary principle in the SPS Agreement. In *EC—Hormones*, the EC had categorized its SPS measure as final, rather than provisional and thus did not rely on Article 5.7. Nevertheless, it contended that scientific uncertainty existed regarding the health effects of growth hormones in beef. Therefore, it tried to rely on the precautionary principle outside the framework of Article 5.7, as a general customary rule of international law or at least a general principle of law, applying to the interpretation of both risk assessment and risk management disciplines in the SPS Agreement.[307]

The Appellate Body in this case expressed its doubts as to whether the precautionary principle has developed into a principle of general or customary international law, outside the field of international environmental law, but found it unnecessary to decide this issue.[308] The Appellate Body stated:

> The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international *environmental* law. Whether it has been widely accepted by Members as a principle of *general* or *customary international law* appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.[309]

Further, the Appellate Body stated that Article 5.7 does not exhaust the relevance of the precautionary principle, which it found to be reflected also in the sixth paragraph of the

[307] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 16. It is interesting to note that the EC Commission's recent Communication on the Precautionary Principle, adopted partly as a reaction to the Appellate Body decision in *EC—Hormones* reflects a departure from the view that the precautionary principle applies to both phases of risk analysis. The communication (at 15) states that the appropriate role for the precautionary principle is in risk management decisions, where scientific uncertainty precludes a full risk assessment. It distinguishes this situation from the prudential approach that scientists take in their assessment of data, in order to deal with the scientific uncertainties inherent in risk assessment. It identifies certain prudential techniques adopted by risk assessors to deal with uncertainties, for example the use of animal models to establish potential effects in humans, adopting a safety factor when evaluating an acceptable daily intake to take account of inter- and intra-species variability, not adopting an acceptable daily intake for recognised carcinogens, etc. *See* European Commission, *Communication from the Commission on the Precautionary Principle,* COM(2000)1, Brussels, February 2, 2000. It seems that the Commission's change in approach is a reaction to the Appellate Body's refusal in its report in *EC—Hormones* to see the precautionary principle as allowing deviation from the explicit provisions of Article 5.1 on risk assessment, except as provided for in Article 5.7. It thus cannot influence the application of the risk assessment disciplines. The Commission thus now prefers to view the principle as a risk management tool.

[308] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 123.

[309] *Id.*

Preamble to the SPS Agreement and Article 3.3.[310] However, we wonder what the Appellate Body might have meant with this statement. The sixth paragraph of the Preamble and Article 3.3 both refer to the right of Members to set their own level of protection, even if it is higher than that embodied in international standards. However, these provisions are in our opinion not reflections of the precautionary principle. Logically, *before* a Member can decide on the level of protection it wants to achieve with regard to a particular risk, it needs to conduct a risk assessment on the basis of scientific information to determine if a risk exists. On grounds of this scientific evaluation, the Member takes the risk management decision regarding a level of protection. However, the precautionary principle is precisely at issue where a lack of scientific evidence hinders the conduct of a proper risk assessment, yet prompt action is necessary to address suspected risks. Thus, the fact that a Member may determine its own level of protection when the risk is certain does nothing to incorporate the precautionary principle into SPS disciplines.[311]

The Appellate Body then held that the precautionary principle (presumably whatever its legal status in international law) could not override the explicit requirements of Articles 5.1 and 5.2, in cases of scientific uncertainty.[312] On the relationship between the "precautionary principle" and the SPS Agreement, the Appellate Body noted the following four elements:

> First, the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*. (. . .) 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. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.[313]

This statement follows the traditional view of the hierarchy of norms in international law, according to which customary international law norms (unless they have developed into mandatory rules of *ius cogens*) do not override the express terms of treaty provisions but are only useful in interpreting treaty provisions. In the *Gabcikovo—Nagymaros* case,[314] referred to by the Appellate Body,[315] the International Court of Justice ("ICJ") declined to

[310] *Id.* ¶ 124.

[311] The Appellate Body appears to be confusing the precautionary principle with the protective principle. The latter principle is a forerunner of the precautionary principle, dealing with the duty of governments to provide protection from risks that have been *established scientifically*. Thus the ability of a government to set a high level of protection once a risk has been proved falls under the protective principle. The precautionary principle represents a step forward in that it requires government action in the face of suspected risks that *cannot* be scientifically proven in the current state of scientific knowledge. It evolved precisely due to the need to address the regulatory paralysis that results from a lack of scientific certainty. *See* H. HOHMANN, PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW 10 (1994).

[312] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 125, where it held, "We accordingly agree with the finding of the Panel that the precautionary principle does not override the provisions of the *SPS Agreement*."

[313] *Id.* ¶ 124.

[314] *Case Concerning the Gabcícovo-Nagymaros Project (Hungary/Slovakia)* I.C.J. Judgment, September 25, 1997 paras 111–114 (not yet reported in the I.C.J. Reports), 37 I.L.M. 162 (1998)

[315] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 123 and n.93.

find that newly developed norms and standards in environmental law could override treaty obligations. Instead it emphasized the principle of *pacta sunt servanda*. In a separate, concurring opinion, Judge Korma held that the ICJ's ruling "represents a significant statement by the Court rejecting the argument that obligations assumed under a validly concluded treaty can no longer be observed (. . .) as a result of the emergence of a new wave of legal norms, *irrespective* of their legal character or quality."[316] Clearly then, in terms of this view, the question whether the precautionary principle has evolved into a customary international law norm would not affect the fact that it is subordinate to the express provisions agreed upon by Members in the SPS Agreement and thus cannot override clear provisions in the Agreement.[317]

Even if the view were taken that customary international law norms are equal in status to, and thus can override, express treaty provisions, the limited mandate of panels and the Appellate Body prevents them from relying on non-WTO norms or rules to overturn express treaty provisions. Article 3.2 of the Dispute Settlement Understanding ("DSU") expressly provides that the recommendations and rulings of the Dispute Settlement Body "cannot add to or diminish the rights and obligations provided in the covered agreements."

However, the matter does not end here. If the precautionary principle can be said to have developed into a principle of customary international law or a general principle of international law, it has the effect of guiding the interpretation of treaty articles.[318] It is a customary international law principle of interpretation that, as parties to a treaty are presumed not to have intended to violate other relevant norms of international law, including customary international law, the treaty provisions are interpreted as far as possible in conformity with these norms. This general international law principle of interpretation is known as the presumption against conflicts,[319] and finds reflection in Article 31.3(c) of the Vienna Convention on the Law of Treaties (the "Vienna Convention"), which requires that *any* relevant rule of international law applicable in the relations between the parties to a treaty be taken into account together with the context in which the treaty must be interpreted. Article 31 of the Vienna Convention has been recognized by the Appellate Body[320] as constituting part of the "customary rules of interpretation of public

[316] Emphasis added.

[317] There is wide support for the view that there is no inherent hierarchy of norms in international law, and thus that treaty provisions do not necessarily have precedence over customary international law norms or general principles of international law. However, Pauwelyn argues that genuine conflicts between treaty law and custom or general principles of law are exceptional, due to the fact that custom and general principle emerge gradually over time and therefore constitute more a "process" which interacts with other norms of international law, rather than a "rule" with which other norms of international law can conflict. *See* Pauwelyn, *supra* note 128, at 60–62.

[318] In *U.S.—Shrimp/Turtle*, the Appellate Body recognised that its task is to interpret the language of WTO agreements "seeking additional interpretative guidance, as appropriate, from the general principles of international law". Report of the Appellate Body, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (1998), ¶ 158.

[319] This general principle of treaty interpretation was recognised by the Appellate Body in *Guatemala-Cement* and by a panel in *Indonesia-Automobiles* with regard to conflicts between different WTO Agreements. Report of the Appellate Body, *Guatemala—Anti-Dumping Investigation Regarding Portland Cement from Mexico,* WT/DS60/AB/R (1998), ¶ 65; Report of the WTO Panel, *Indonesia—Certain Measures Affecting the Automobile Industry,* WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, (1998), ¶ 14.28.

[320] In *U.S.—Gasoline*, the Appellate Body held that Article 31.1 of the *Vienna Convention* constitutes customary rules of interpretation of public international law. Report of the Appellate Body, *United States—Standards for Reformulated and Conventional Gasoline,* WT/DS2/AB/R, (1996), 17. This finding was confirmed and extended to include the whole of Article 31 and Article 32 of the Vienna Convention in *Japan—Alcoholic Beverages* and *EC—Computer Equipment.* Report of the Appellate Body *Japan—Taxes on Alcoholic Beverages*,

international law" which panels and the Appellate Body are bound to apply in clarifying the provisions of the covered agreements under Article 3.2 of the DSU. Thus the Appellate Body's statement that ". . . the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation"[321] reveals a misunderstanding of the issue at stake. In fact, it is precisely the "normal principles of treaty interpretation"[322] referred to by the Appellate Body, that require that the precautionary principle be used to guide the interpretation of the provisions of the SPS Agreement, *if* it can be shown that this principle is now a customary international law norm or a general principle of international law.[323]

For this reason, we argue that the Appellate Body was wrong to state that it was "unnecessary" for it to take a position on this question.[324] In fact, the answer to this question is crucial to the determination of the role of the precautionary principle in the SPS Agreement. While it could not result in the non-application of treaty obligations, the precautionary principle could be important in giving meaning to vague terms in the SPS Agreement, such as the "sufficient scientific evidence" requirement[325] in Article 2.2, or the requirement that SPS measures be "based on" a risk assessment, "as appropriate to the circumstances" in Article 5.1. Most importantly, if a customary international law precautionary principle or a general principle of international law has emerged, its content would be a crucial guide to the interpretation of Article 5.7 itself.

Since, despite the absence of a precedent system in WTO dispute settlement, it is the practice of panels and the Appellate Body to follow the interpretations adopted in previous decisions, the Appellate Body's decision with respect to the role of the precautionary principle in the SPS Agreement is likely to be definitive on this issue. As the case law now stands, the Appellate Body's decision in effect limits the applicability of the precautionary principle under the SPS Agreement to the situation covered by Article 5.7.[326] It is therefore necessary to examine the provisions of Article 5.7 SPS to determine to what extent they give expression to this principle and deal with the exigencies it was developed to address.

WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (1996), 11–12; Report of the Appellate Body, *European Communities-Customs Classification of Certain Computer Equipment*, WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R (1998), ¶ 84.

[321] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 124.

[322] The normal principles of treaty interpretation that are part of customary international law must be used in the interpretation of the provisions of the WTO Agreements, according to Article 3.2 of the DSU.

[323] This is due to the fact, set out above, that Article 31.3(c) of the Vienna Convention on the Law of Treaties provides that "any relevant rules of international law applicable in the relations between the parties" are part of the "context" which guides the interpretation of treaty provisions. Clearly, customary international law rules are rules of international law that apply to the relations between Members of the WTO and must thus be taken into account.

[324] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 123.

[325] It is perhaps arguable that the Appellate Body itself recognised this possibility, in a confusing *obiter* statement in *EC—Hormone*s that in interpreting Article 2.2, a panel should bear in mind that responsible governments act "from perspectives of prudence and precaution" in case of risks of irreversible damage to human health. Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 124. (quoted *supra* in text accompanying note 122). Although the interpretation of Article 2.2 was not at issue in this case, the Appellate Body seems to have recognised the possibility of interpreting this article in the light of a rather restrictive formulation of the precautionary principle.

[326] And possibly, to a limited extent, to the interpretation of Article 2.2 SPS. *See supra* note 325.

2. Conditions for Application of Article 5.7

The requirements of Article 5.7 were set out in *Japan—Agricultural Products*. The Appellate Body held that Article 5.7 lays down four requirements for provisional measures. Under the first sentence, the measure may be imposed if it is:

(1) imposed in respect of a situation where "relevant scientific information is insufficient"; and
(2) adopted "on the basis of available pertinent information."

Under the second sentence, the measure may not be maintained unless the Member:

(3) seeks to "obtain the additional information necessary for a more objective assessment of risk"; and
(4) reviews the measure accordingly "within a reasonable period of time".

These requirements were held to be cumulative. The Appellate Body rejected Japan's claim that the words "except as provided for in Article 5.7" in Article 2.2 refer only to the first sentence of Article 5.7, holding that the text of Article 2.2 does not support this proposition as it refers to Article 5.7 as a whole.[327] Thus, all four conditions of Article 5.7 must be met in order to avoid the scientific disciplines of Articles 2.2 and 5.1 of the SPS Agreement.

When the four requirements of Article 5.7 are met, Members may take provisional measures. Provided that these requirements are interpreted in a flexible way to allow recourse to precautionary measures when science gives no clear-cut answers and a plausible case can be made for the existence of a risk on the basis of existing information, Article 5.7 would seem to provide an adequate vehicle for the incorporation of the precautionary principle into SPS disciplines, to the extent that they apply to risk management decisions.

(a) Insufficiency of Relevant Scientific Evidence. The first requirement, namely that "relevant scientific evidence is insufficient", is what triggers the application of Article 5.7. Where this requirement is not met, there is no legitimate reason for resort to provisional measures.[328] It is thus crucial to determine in what circumstances this criterion will be met. For reasons of judicial economy, the Panel in *Japan—Agricultural Products* had found it unnecessary to decide this issue. The Appellate Body upheld this decision.[329]

In *Japan—Apples,* the first requirement of Article 5.7 was addressed for the first time in the case law, making this a particularly interesting case for the understanding of the role of the precautionary principle in the SPS Agreement.

In this case, the Panel held that the fact that a measure has been found to be maintained "without sufficient scientific evidence" under Article 2.2 does not automatically mean

[327] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 90.

[328] It would thus seem logical to start the analysis of the requirements of Article 5.7 in dispute settlement cases by examining whether this criterion is met. However, in *Japan—Agricultural Products* the Panel began by examining the requirements of the second sentence of Article 5.7 and the Appellate Body did not take issue with this order of analysis.

[329] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 91. While it is clear that, since the requirements of the second sentence of Article 5.7 were not met, Japan could not rely on Article 5.7 to justify its measure and it was unnecessary to go on to investigate whether Japan complied with other two requirements of Article 5.7, it would seem more logical to have started the analysis by determining whether Article 5.7 is applicable to the case at all. For this purpose, it would have been useful to examine the first requirement, which triggers the application of this article when "scientific evidence is insufficient." The EC expressed the view in its third party submission before the Appellate Body in *Japan—Agricultural Products* that both the requirements of the first sentence are the triggers for the operation of Article 5.7 and should therefore be examined first. *Id.* ¶ 64.

that "relevant scientific evidence is insufficient" under Article 5.7, which is a separate question.[330] The sufficiency requirement under Article 2.2 requires that the evidence *supporting* the SPS measure applied be sufficient, whereas the evidence to be considered under Article 5.7 "includes not only evidence supporting Japan's position, but also evidence supporting other views."[331] In this case, the Panel found that a wealth of relevant, high quality, scientific evidence was available[332] on the matter at issue and that this was thus "clearly not the type of situation Article 5.7 was intended to address."[333] According to the Panel, Article 5.7 was instead "obviously designed to be invoked where little, or no, reliable evidence was available on the subject matter at issue."[334] It thus concluded that the first requirement of Article 5.7 was not met and that Japan's measure could therefore not be justified under this Article.[335]

Japan challenged the Panel's finding of non-compliance with the first requirement of Article 5.7 on appeal, arguing that the insufficiency of the evidence should be interpreted to relate to a *particular* measure or a *particular* risk, but not to the subject matter *in general*. The Appellate Body, on the contrary, held that Japan's reliance on this distinction was misplaced.[336] Instead, the Appellate Body identified a contextual link between the first requirement of Article 5.7 and the obligation to perform a risk assessment in Article 5.1.[337] Thus, relevant scientific evidence will be "insufficient" for purposes of Article 5.7 if it "does not allow, in qualitative or quantitative terms, the performance of an adequate assessment of risks as required under Article 5.1."[338] According to the Appellate Body, the factual findings of the Panel showed that the scientific evidence available *did* permit the performance of a risk assessment under Article 5.1 and the relevant scientific evidence was thus not insufficient within the meaning of Article 5.7.

Japan also appealed the Panel's finding that Article 5.7 is intended only to address situations where little, or no, reliable evidence is available on the subject matter at issue. Japan argued that this would not provide for situations of "unresolved uncertainty". According to Japan, Article 5.7 covers not only situations of "new uncertainty" (where a new risk is identified) but also "unresolved uncertainty" (where there is considerable scientific evidence but still uncertainty remains). The Appellate Body, however, upheld the Panel's finding, pointing out that Article 5.7 "is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence".[339] Moreover, it held that the Panel's finding referred to the availability of *reliable* evidence, and thus

[330] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 8.215.
[331] *Id.*, ¶ 8.216. The Panel later concluded that the term "insufficient scientific evidence" in Article 5.7 refers to evidence in general on the SPS question at issue (in this case the risk of transmission of fire blight through apple fruit). *Id.*, ¶ 8.218.
[332] The Panel noted that much relevant evidence had been submitted by the parties and panel experts, and scientific studies and practical experience on the matter had accumulated for the past 200 years. *Id.*, ¶¶ 8.216 and 8.219.
[333] *Id.*, ¶ 8.219.
[334] *Id.*, ¶ 8.219.
[335] *Id.*, ¶ 8.222.
[336] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 179.
[337] The Appellate Body found these contextual elements in the following: first, the concepts of relevance and insufficiency in Article 5.7 imply a relationship between scientific evidence and something else; second, Article 5.1, obliging Members to base their measures on a risk assessment, contains a key discipline under Article 5 and informs the other provisions of Article 5; and third, Article 5.7 itself refers to "a more objective assessment of risks". *Id.*, ¶ 179.
[338] *Id.*, ¶ 179.
[339] *Id.,* ¶ 184.

did not exclude cases "where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results."[340]

This analysis of the first requirement of Article 5.7 is groundbreaking. It clarifies the role of Article 5.7, establishing that it is there to address situations where there is a true lack of sufficient scientific evidence regarding the risk at issue, either due to the small quantity of evidence on new risks, or due to the fact that accumulated evidence is inconclusive or unreliable. In either case, the insufficiency of the evidence must be such as to make the performance of an adequate risk assessment impossible. Thus Article 5.7 cannot be used to justify measures that are adopted in disregard of existing scientific evidence. The Panel and Appellate Body's findings establish the fact that the precautionary principle, as embodied in Article 5.7, does not create a broad loophole in the scientific disciplines of the SPS Agreement through which protectionist measures can slip. Rather, it creates a limited exception for cases where there is a true lack of relevant and reliable scientific evidence on the risk at issue.

(b) Based on Available Pertinent Information. The second criterion contained in Article 5.7 requires that the provisional measure be adopted "on the basis of available pertinent information." Judicial economy made it unnecessary to examine this requirement in *Japan—Agricultural Products*[341] and in *Japan—Apples*.

The Appellate Body's interpretation of "based on" in Article 5.1 suggests, however, that under Article 5.7, the SPS measure adopted must be reasonably supported by whatever information exists. In other words, the available information must support a reasonable concern that harm could result.[342] Obviously, the information need not amount to conclusive evidence otherwise recourse to Article 5.7 would not be necessary. However, the measure may not be contrary to what little information is available. Where contradictory information is present, it would appear that the measure need not reflect the preponderance of evidence, but could be based on a minority view that a potential for harm exists, provided this view is held by qualified and respected scientists.[343]

The word "pertinent" indicates that the information must have a bearing upon or be relevant to the suspected risk. It would appear to indicate that the risk must be at least theoretically plausible on the basis of what evidence exists. However, it is unlikely that the term "pertinent" will be interpreted to require an indication of a certain threshold level of risk, since this is also not required for SPS measures based on a proper risk assessment as required by Article 5.1.

The question whether the available pertinent information must indicate a certain level or seriousness of risk can be further elucidated by reference to the developing concept

[340] *Id.*, ¶ 185.

[341] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 91, where the Appellate Body held: "We, therefore, conclude that the Panel did not err in its application of Article 5.7 by first examining whether the varietal testing requirement meets the requirements of the second sentence of Article 5.7. Having established that the requirements of the second sentence of Article 5.7 are not met, there was no need for the Panel to examine the requirements of the first sentence."

[342] This requirement is embodied in most treaties that incorporate the precautionary principle. *See* James Cameron and Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 Boston College International and Comparative Law Review 1 (1991), for a brief discussion of the treaties that incorporate the precautionary principle.

[343] The EC Commission supports this view (COM(2000)1, *supra* note 207, at 17), referring to the following statement by the Appellate Body: "In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty." Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 194.

of the precautionary principle in international law.[344] In earlier environmental treaties embodying the precautionary principle, the available evidence had to indicate a threat of serious or irreversible harm before recourse to the precautionary principle was justified.[345] However, more recently there has been a tendency to lower this evidentiary threshold or leave it out altogether.[346] It would appear that the average evidentiary threshold now required is a non-negligible threat of harm, but beyond that the formulation of the principle in the relevant treaty depends on the relevant context of its negotiation.[347] As Article 5.7 in the SPS Agreement incorporates the precautionary principle with respect to human, animal and plant life and health, rather than environmental protection, it seems clear, in the absence of an explicit provision requiring a stricter standard in Article 5.7, that no more than a non-negligible threat should be required to be indicated by the available information.[348]

(c) Obtain Information Necessary. Article 5.7 further prohibits the maintenance of a provisional measure unless a Member "seeks to obtain the information necessary for a more objective assessment of the risk." The term "more objective assessment" seems to imply that there must have been an original evaluation of the risk before the provisional measure was imposed, although this need not have been altogether objective.[349] The Member is then required to try to gather the information necessary to enable it to conduct a proper risk assessment that would meet the requirements of Article 5.1–5.3.

In *Japan—Agricultural Products*, Japan argued that the requirement to seek additional information was met by gathering information through the experience of the successful importation of varieties, specifically by requiring exporting countries to submit data when

[344] The argument that the precautionary principle, to the extent that it has developed into a principle of customary international law, should guide due interpretation of the SPS Agreement, and particularly Article 5.7, was developed *supra*, Part II(E)(1).

[345] It could perhaps be argued that the Appellate Body seemed to support this high evidentiary threshold for the use of the precautionary principle outside the framework of Article 5.7, to interpret the requirement of "sufficient scientific evidence" in Article 2.2 when it stated that panels should bear in mind that governments act with precaution when *serious (irreversible) threats to human health* are at stake. Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 124, discussed *supra* note 325.

[346] For example, while the Bergen Ministerial Declaration on Sustainable Development in the ECE Region (Bergen, May 16, 1990) required the threat of "serious or irreversible" damage for the application of the precautionary principle (in Article 7), the Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (Bamako, January 29, 1991, 30 I.L.M. 773) incorporates the precautionary principle (in Article 4(3)(f)) without requiring the threat of serious or irreparable harm. Similarly, the Cartagena Protocol on Biosafety (Cartagena, January 28, 2000), not yet in force pending ratification) refers only to "potential adverse effect." Both the latter conventions specifically relate to threats to humans as well as the environment, which could explain the lower threshold. *See* further P. SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW I—FRAMEWORKS, STANDARDS AND IMPLEMENTATION 210–211 (1995).

[347] James Cameron and Juli Abouchar, *The Status of the Precautionary Principle in International Law* in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION, 44 (Freestone and Hey eds. 1996).

[348] In its *Communication on the Precautionary Principle*, the EC Commission suggests that recourse to the precautionary principle should be allowed when it can be concluded from an evaluation of existing information that the desired level of protection could potentially be jeopardized by inaction. COM(2000)1, *supra* note 307, at ¶ 6.2.

[349] *Id*. ¶ 4. The EC Commission recommends that the evaluation of existing evidence constitute as complete a scientific evaluation as possible, encompassing both an inventory of existing evidence and an identification of the possible gaps in knowledge as well as the degree of scientific uncertainty at each stage (*Id.* ¶ 6.1).

applying for the approval of additional varieties. It claimed that Members are obliged to seek information but no actual results are required.[350] The United States submitted that the information sought by Japan was not relevant to the question whether different varieties of products have different sorption levels. It thus did not enable Japan to review its measure and therefore did not meet the third requirement.[351] The Appellate Body held in this regard:

> Neither Article 5.7 nor any other provision of the *SPS Agreement* sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is to "seek to obtain" additional information. However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct "a more objective assessment of risk". Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied. We note that the Panel found that the information collected by Japan does not "examine the appropriateness" of the SPS measure at issue and does not address the core issue as to whether "varietal characteristics cause a divergency in quarantine efficacy".[352] In the light of this finding, we agree with the Panel that Japan did not seek to obtain the additional information necessary for a more objective risk assessment.[353]

Thus, although this element of Article 5.7 seems to embody an obligation of endeavor rather than of result, it does require the Member maintaining a provisional measure to attempt to obtain information that would enable it to conduct a proper risk assessment. Engaging in general information collection exercises is not sufficient.

(d) Review within a Reasonable Period of Time. The last requirement contained in Article 5.7 is the obligation to review the measure within a "reasonable period of time." Article 5.7 therefore creates only a limited exemption from the normal SPS disciplines, pending review of the measure in the light of new evidence.

The Appellate Body in *Japan—Agricultural Products* had to decide on what constitutes a "reasonable period of time" within which to review the measure. It held:

> In our view, what 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. In the present case, the Panel found that collecting the necessary additional information would be relatively easy. Although the obligation "to review" the varietal testing requirement has only been in existence since 1 January 1995, we agree with the Panel that Japan has not reviewed its varietal testing requirement "within a reasonable period of time".[354]

The requirement of review within a reasonable period of time is clearly linked to the provisional nature of the SPS measure allowed by this article. In *Australia—Salmon*, the Panel noted:

[350] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 13.
[351] *Id.* ¶ 26.
[352] The Panel pointed out that the information provided by exporting countries was based on studies designed and carried out to *comply* with Japan's varietal testing requirement. Thus they did not examine the appropriateness of the requirement itself. Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 56, ¶ 8.56. [Footnote added by authors].
[353] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 92.
[354] *Id.* ¶ 93.

> Only Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment, namely "in cases where relevant scientific evidence is insufficient" . . . In this dispute Australia has not invoked Article 5.7. Nor do we consider that this provision applies to the measure in dispute, given the fact that it was imposed more than 20 years ago and can thus hardly be seen as a measure "provisionally" adopted.[355]

While there is no time limit expressed in Article 5.7 on the existence of a "provisional measure", it seems logical that an indirect time limit is inherent in the requirement of review within a reasonable period. Thus, it is not the length of time for which a measure has been in existence that is crucial to its "provisional" nature, but rather the review thereof, within a reasonable period, which indicates that the measure is not final. It would have made more sense, therefore, for the Panel to highlight this aspect to support its finding that the measure was not "provisional" within the meaning of Article 5.7 rather than focus on the time of its existence, *per se*.

It is interesting to note in this regard that, in its *Communication on the Precautionary Principle*,[356] the European Commission interpreted the requirement of review "within a reasonable period of time" to include the time needed for completion of the necessary scientific work as well as the time needed for performance of a risk assessment based on the conclusions drawn there from. Thus, the provisional nature of measures under Article 5.7 was argued to be dependent on the development of scientific knowledge, rather than on a specific time limit.[357] This interpretation is partially supported by the Appellate Body's finding that one of the factors to be considered in the determination of what constitutes a reasonable period of time in a given case is the difficulty of obtaining the additional information necessary for the review. Clearly, the state of scientific knowledge has a direct impact on the difficulty of obtaining the required information and would thus affect the determination whether a "reasonable period" has elapsed. This is significant in that it waters down the temporary nature of measures allowed under Article 5.7 and makes provision for circumstances where scientific uncertainty persists for extended periods or where the risks involved are only expected to materialize in the long term.

However, it is important to note that the difficulty of obtaining information is not the sole criterion. The specific circumstances of the case will be evaluated, including factors such as the characteristics of the SPS measure at stake, amongst others, in order to establish whether the requirement of review within a reasonable period has been met.[358] Nonetheless, it seems important to make sure that the determination of what constitutes a "reasonable period" in each case be made with particular regard to the reality that the state of scientific knowledge has a decisive influence on whether a "more objective assessment of risk" can be conducted. Therefore, artificially linking the requirement of review within a "reasonable period of time" to specific deadlines should be avoided. In this way, Members need not fear that reliance on Article 5.7 to justify their measures will compromise their ability to maintain the measure as long as is necessary for scientists to find clear answers.[359]

[355] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.57.
[356] COM(2000) 1, *supra* note 307, at ¶ 6.3.5.
[357] *Id*.
[358] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 93.
[359] The fact that the EC supports this interpretation of a "reasonable period of time" could explain why it has changed its approach from the one it followed in *EC—Hormones* (where it did not rely on Article 5.7 and thus did not classify its ban on hormone treated meat as a "provisional measure"—fearing

3. Relationship between Article 5.7 and Article 2.2

As has been mentioned, Article 2.2 refers explicitly to Article 5.7, stating that measures may not be maintained without sufficient scientific evidence, except as provided in Article 5.7. The Appellate Body in *Japan—Agricultural Products* addressed the relationship between Article 5.7 and Article 2.2, emphasizing that Article 5.7 is only a *qualified* exemption from the scientific discipline in Article 2.2 and warning that an overly flexible interpretation of Article 2.2 would deprive Article 5.7 of meaning.[360] Thus the Appellate Body seems to regard a less-flexible interpretation of the rather vague requirement of "sufficient scientific evidence" in Article 2.2 as justifiable or even necessary due to the possibility provided in Article 5.7 for an exemption from this requirement.

While there are indications, from the interpretation given to those elements of Article 5.7 addressed in the case law so far, that Article 5.7 will be interpreted in a flexible way and will thus adequately take account of the precautionary principle in risk management decisions, this does not exhaust the relevance of this principle. In our opinion, precaution also plays a role in the scientific aspect of the regulatory process, and may determine the assumptions used and rules of thumb followed in risk assessment in dealing with the gaps and uncertainties inherent in scientific analysis. For this reason, the evolving concept of the precautionary principle in international law could usefully be drawn upon in the interpretation of the requirement of "sufficient scientific evidence" in Article 2.2 and the qualification that measures be based on risk assessments "as appropriate to the circumstances" in Article 5.1. This should not "render Article 5.7 meaningless" as suggested by the Appellate Body, since Article 5.7 deals with a different application of the precautionary principle, namely in respect of the situation where uncertainties in science make a risk assessment either impossible to conduct or too inconclusive to form the basis for an SPS measure.

F. Risk Management (Article 5.3–5.6)

1. Determination of the Appropriate Level of Protection (Annex A, paragraph 5)

A Member's "appropriate level of protection" is defined in paragraph 5 of Annex A as "[t]he level of protection *deemed appropriate by the Member* establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." (emphasis added). Thus, the SPS Agreement recognizes a Member's right to choose its own appropriate level of protection, or in other words to decide freely what standard of sanitary and phytosanitary protection it will aim at with its SPS measures.

that the temporary nature of such a measure would undermine its hormones regime). More recently, in statements claiming that it is now in compliance with the Appellate Body's ruling in *EC—Hormones,* the EC averred that its continued ban on meat treated with the relevant hormones (except 17-beta oestradiol, for which it adopted a permanent ban based on conclusions from new studies in 2000) is a provisional measure in terms of Article 5.7, pending the results of studies to determine the effects of the relevant hormones on human health. ICTSD, *Dispute Settlement, EC Move Fans the Flames under Beef Row,* 21(4) BRIDGES WEEKLY TRADE NEWS DIGEST (2000). An additional seventeen studies were conducted regarding the toxicological aspects, potential abuse and control problems and environmental aspects of the six relevant hormones, on the basis of which the EU Scientific Committee on Veterinary Measures relating to Public Health confirmed its previous opinions concluding that no acceptable daily intake could be established for any of the hormones evaluated. *See* European Commission, Press Releases, *Growth Promoting Hormones Pose Health Risk to Consumers, Confirms EU Scientific Committee,* IP/02/604, April 24, 2002.

[360] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 80, quoted *supra* Part II(B)(2)(b).

Therefore the determination of an appropriate level of protection (risk management) must be clearly distinguished from the evaluation of risk (risk assessment), which is subject to scientific disciplines.[361] This was not done by the Panel in *Australia—Salmon* which stated:

> . . . we consider that a risk assessment, on which to base an import prohibition in accordance with Article 5.1, cannot be premised on the concept of "zero risk". Otherwise, all import prohibitions would be based on a risk assessment since there is a risk (i.e., a *possibility* of an adverse event occurring), however remote, associated with most (if not all) imports.[362]

The Appellate Body in that case, noted to the contrary:

> . . . it is important to distinguish—perhaps more carefully than the Panel did—between the evaluation of "risk" in a risk assessment and the determination of the appropriate level of protection. As stated in our Report in *European Communities—Hormones*, the "risk" evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is "not the kind of risk which, under Article 5.1, is to be assessed." This does not mean, however, that a Member cannot determine its own appropriate level of protection to be "zero risk".[363]

Once it is established that there is scientific evidence of risk, Members are free to choose their own appropriate level of protection. The choice of a particular level of protection is what is typically called a *risk management* decision. Such decisions are taken by national administrations on grounds of societal value judgments on issues such as what level of risk is considered acceptable, what is economically or technically feasible or what consumers prefer, not purely on the basis of scientific analysis of risk. In other words, once it has scientifically been established that a health risk exists and what the likelihood or potential of that risk occurring is, by means of a risk assessment, other policy issues come into play in the actual crafting of the regulation. SPS measures seldom have the protection of health as their sole objective. Instead several other significant factors are incorporated into the decision. The decision is at core a political one, reflecting societal value choices. The SPS Agreement recognizes this by not requiring a scientific basis for the choice of the appropriate level of protection. Thus, particularized national health measures result even where the scientific basis for the measures is the same everywhere.[364]

2. Limits to the Right to Determine the Appropriate Level of Protection (Article 5.4 and 5.5)

The choice of an appropriate level of protection is, however, subject to some limitations. These limitations are set out in Articles 5.4 and 5.5. Article 5.4 provides:

> Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

The use of the word "should" rather than "shall" indicates that this is not a mandatory provision but rather a recommendation. The effect of this provision was explained by the

[361] *See contra* Victor, *supra* note 154, at 883, where he argues that the requirement that measures be based on risk assessments could be interpreted as a requirement that a Member's appropriate level of protection also be based on a risk assessment. He states, "Indeed, how can one logically assess the risks of SPS measures without assessing the risks associated with the level of protection as well? Levels and measures are two sides of the same coin."

[362] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.81.

[363] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 125.

[364] This point is made by Atik, *supra* note 210, at 737.

EC—Hormones Panel as follows:

> 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 negative trade effects has nonetheless to be taken into account in the interpretation of other provisions of the SPS Agreement.[365]

Article 5.5, in contrast, creates both a long-term goal and a binding obligation with respect to a Member's choice of an appropriate level of protection.[366] It provides:

> With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

What are precisely the disciplines embodied in Article 5.5? In *EC—Hormones*, the Appellate Body found:

> The objective of Article 5.5 is formulated as the "achieving [of] consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection". Clearly, the desired consistency is defined as a goal to be achieved in the future. To assist in the realization of that objective, the Committee on Sanitary and Phytosanitary Measures is to develop *guidelines for the practical implementation of Article 5.5*, bearing in mind, among other things, that ordinarily, people do not voluntarily expose themselves to health risks. Thus, we agree with the Panel's view that the statement of that goal [consistency] does not establish a *legal obligation* of consistency of appropriate levels of protection. We think, too, that the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided.[367]

Therefore, it is clear that there is no immediate obligation of consistency in appropriate levels of protection. This is only a long-term goal. However, Members are obliged to ensure that the distinctions in the levels of protection they choose meet the requirements

[365] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.169; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.166.

[366] After five years of deliberation, at its meeting on March 15–16, 2000, the SPS Committee drew up a final draft of guidelines for the implementation of Article 5.5. These guidelines are not legally binding but are intended as aids to assist officials in applying Article 5.5 when deciding on appropriate levels of protection or adopting and implementing SPS measures. These guidelines were provisionally adopted at the following meeting of June 21–22, and Members having objections to the final adoption were asked to make these known by July 14. Since no objections were raised by that date, the guidelines are now adopted. Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 5.5*, G/SPS/15, July 18, 2000. *See* WTO *SPS Committee Completes Draft on Risk "Consistency"* 45 FOCUS NEWSLETTER Mar.–Apr. 2000 at 12; and ICTSD *WTO Meets on SPS and Risk Management*, 4(25) BRIDGES WEEKLY TRADE NEWS DIGEST, June 27, 2000.

[367] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 213.

of Article 5.5, namely that they are not arbitrary or unjustifiable and do not lead to discrimination or disguised trade restrictions.

(a) Elements of Article 5.5. The Appellate Body in *EC—Hormones*[368] set out the elements required for a violation of Article 5.5 to be shown. These are that: (1) the Member has set its own level of protection in different situations; (2) the levels of protection show arbitrary or unjustifiable differences in their treatment of different situations; and (3) these arbitrary or unjustifiable differences lead to discrimination or a disguised restriction on trade (referring to the effect of the measure used to reflect the particular level of protection).[369] These elements were found to be cumulative, thus proof of different treatment of different situations is not sufficient, though it might serve as a warning signal that the measure might be discriminatory or a disguised restriction on trade.[370]

It is obvious that not all health risks can or should be treated in the same way. Thus, with regard to the first element for proving a violation of Article 5.5, the Appellate Body in *EC—Hormones* found that to compare the different levels of protection deemed appropriate by a Member, the situations dealt with must be comparable, that is, have some common element or elements.[371] On this issue, the Appellate Body stated:

> Clearly, comparison of *several* levels of sanitary protection deemed appropriate by a Member is necessary if a panel's inquiry under Article 5.5 is to proceed at all. The situations exhibiting differing levels of protection cannot, of course, be compared unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable. If the situations proposed to be examined are *totally* different from one another, they would not be rationally comparable and the differences in levels of protection cannot be examined for arbitrariness.[372]

In this case the Panel found that two situations, namely the treatment given to natural hormones administered for growth-promotion purposes and the treatment given to hormones occurring endogenously in meat and other foods or administered for therapeutic or zootechnical purposes, were comparable as the same substance was involved (natural hormones) and the same adverse health effect was at stake in both cases (namely carcinogenicity).[373] In addition, although different substances were involved, the Panel regarded as comparable the treatment given by the EC to the synthetic hormones in dispute and the treatment given to natural hormones occurring endogenously in meat and

[368] *Id.* ¶ 214.
[369] These elements were reiterated in the Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 140.
[370] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 215.
[371] The Panel in *EC—Hormones* noted that both parties agreed that Article 5.5 covers situations which deal with the same substance or the same averse health effect. Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.179; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.176.
[372] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 217.
[373] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.189–8.190; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.186–8.187.

other foods due to their common adverse health effect (carcinogenicity).[374] Lastly, the Panel held that the treatment given to five of the six hormones[375] in dispute was comparable to that given to carbadox and olaquindox,[376] two antimicrobial growth promoters used in swine production, as they also both had carcinogenicity in common as an adverse health effect.[377]

Similarly, the Appellate Body in *Australia—Salmon* was faced with the question of the comparability of "different situations". In this case, the situations compared were the treatment applied to imports of Canadian adult, wild, ocean-caught salmon for human consumption and that applied to whole frozen herring used as bait and ornamental finfish. The Appellate Body stated:

> Situations which involve a risk of entry, establishment or spread of the same or a similar disease have some common elements sufficient to render them comparable under Article 5.5. Likewise, situations with a risk of the same or similar associated potential biological and economic consequences also have some common elements sufficient to render them comparable under Article 5.5. We, therefore, consider that for "different" situations to be comparable under Article 5.5, there is no need for both the disease *and* the biological and economic consequences to be the same or similar.[378]

The Appellate Body further stated:

> We believe that for situations to be comparable under Article 5.5, it is sufficient for these situations to have in common a risk of entry, establishment or spread of *one* disease of concern. There is no need for these situations to have in common a risk of entry, establishment or spread of *all* diseases of concern.[379]

In this case, the situations were deemed comparable as the potential consequences of the risk occurring were the same, regardless of whether the disease entered Australia via salmon or herring.

In response to Australia's argument that a "situation" cannot be compared under Article 5.5 if no risk assessment has been made in respect of it, the Panel in *Australia—Salmon* noted:

> . . . we consider that even though Australia has not yet conducted import risk analyses for the other products compared under Article 5.5, Australia does, nevertheless, have a level of protection it considers to be appropriate for these other products. Australia currently has a sanitary regime, imposing specific sanitary measures or refraining from such regulation, for these other products. This sanitary regime (whether or not specific measures are enacted) reflects a level of protection. To have a specific level of protection, there is no need to first complete a risk assessment . . . Article 5.5 directs us to compare for different situations the related levels of protection as they are currently considered to be appropriate by Australia and this whether or not the sanitary measures enacted to achieve that level are based on a risk assessment. Of course, such comparison would be easier and more accurate if for both situations

[374] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.211–8.212; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.208–8.209.

[375] The hormone MGA was dealt with separately.

[376] The U.S. complaint dealt only with carbadox, not olaquindox, whereas the Canadian complaint dealt with both.

[377] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.223–8.224; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.221.

[378] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 146.

[379] *Id.* ¶ 152.

> an appropriate risk assessment were available. However, according to Article 5.5 and our mandate set out in Article 11 of the DSU (to make an "objective assessment of the matter before [us], including an objective assessment of the facts of the case"), we are called upon in this case to make this comparison and to do so on the basis of the evidence before us.[380]

To establish if the first element has been met, it is furthermore necessary to determine whether the Member has imposed *different* levels of protection in different (but comparable) situations. The Panel in *EC—Hormones* found that there was a difference in the levels of protection applied by the European Communities in the comparable situations of administered hormones and naturally-occurring hormones or those administered for therapeutic or zootechnical purposes as in the former case a "no-residue level" (a ban) was applied, whereas in the latter an unlimited-residue level was permitted (complete tolerance).[381] Similarly, the Panel identified differences between a no-residue level of protection and an unlimited-residue level of protection applied respectively to synthetic hormones as opposed to natural hormones occurring endogenously in meat and other foods,[382] as well as to the hormones in dispute as opposed to the relevant antimicrobial agents used in swine production.[383]

With regard to how to determine whether Australia imposed *different* levels of protection for the situations compared, the Panel in *Australia—Salmon* stated:

> . . . the appropriate level of sanitary protection will normally be reflected in the sanitary measures imposed for a specific situation. We consider, moreover, that the level of protection achieved by a specific sanitary measure will also depend on the degree of risk against which that measure is intended to protect. In that sense, we agree with Australia that imposing the same sanitary measure for different situations does not necessarily result in the same level of protection. Indeed, in many situations (e.g., situations representing different risks) the same sanitary measure might result in different levels of protection. On the other hand, different sanitary measures for different situations might ensure the same level of protection. Indeed, one given situation might only represent a small risk for which a lenient sanitary measure will achieve a high level of protection, whereas another situation might pose very high risks requiring a very strict and different sanitary measure in order to meet that same high level of protection.
>
> To determine whether Australia makes a distinction in the levels of protection it considers to be appropriate for the situations compared, we thus need to examine the sanitary measures Australia currently imposes for these different situations . . . Since we have found that these situations are comparable as "different situations" under Article 5.5 . . . and since we will consider the potential difference in the degree of risk posed by these different situations under the second element of Article 5.5, we will for present purposes assume that if there is a difference in the sanitary *measures* imposed for the different situations we compare under Article 5.5, this difference does reflect a distinction in *levels of protection* achieved in—and considered to be appropriate by—Australia.[384]

[380] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.126.
[381] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.193–8.194; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.190–8.191.
[382] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.214–8.215; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.211–8.212.
[383] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.229; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.226.
[384] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶¶ 8.123–8.124.

This finding was not appealed.[385] However, in dealing with the determination of the appropriate level of protection under Article 5.6, the Appellate Body in *Australia—Salmon* noted that nothing in the SPS Agreement or the DSU permits a panel or the Appellate Body to imply the Member's appropriate level of protection from the measure it applies to attain that level of protection.[386]

Regarding the second element, namely that of arbitrary or unjustifiable differences in the levels of protection, the Appellate Body in *EC—Hormones* disagreed with the Panel's finding that both the added hormones and naturally-occurring hormones pose the same risks and practical difficulties of control,[387] and that the difference in the level of protection must therefore be arbitrary. The Appellate Body stated as follows:

> . . . 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 it 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.[388]

Regarding this same element, the Panel in *Australia—Salmon* found that the different levels of protection applied by Australia against risks from imports of salmon and from imports of other fish were "arbitrary or unjustifiable". It based its finding on the fact that since the level of protection in the case of salmon was higher, one could expect that a higher risk was present for salmon than for other fish. However, the evidence pointed to the opposite conclusion, namely that there was ". . . a higher risk of disease introduction associated with imports of bait fish and live ornamental fish than the risk posed by imports of salmon products for human consumption."[389] Thus, Canada had raised a presumption in this regard which had not been rebutted by Australia. The Panel therefore held that the differences in levels of protection applied by Australia were arbitrary and unjustifiable, a finding upheld by the Appellate Body. This is the only case thus far where a finding was made of a violation of Article 5.5.

The fact that the second element of Article 5.5 limits the prohibition to *arbitrary or unjustifiable* distinctions, not all distinctions,[390] is sensible in the light of the exigencies of health protection decision-making. Regulators make decisions regarding the level of protection to be secured on a case-by-case basis, as the need arises. The difficulty in evaluating the justifiability of distinctions lies in the problem of explaining why a society accepts some risks but not others or values some goals more than others. This fact

[385] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, n. 106.
[386] *Id.*, ¶¶ 199–200. This issue is dealt with further *infra* Part II(F)(3)(b).
[387] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.190; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.187.
[388] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 221 (footnote omitted). When comparing the levels of protection for hormones used for growth promotion purposes and hormones used for therapeutic and zootechnical purposes—a comparison not further pursued by the panels—the Appellate Body, referring to the differences in frequency and scale of the two treatments and the strict mode of administration of the latter treatment, found that the distinction in levels of protection "is not, in itself, 'arbitrary or unjustifiable"'. *See* ¶¶ 222–225.
[389] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.137.
[390] As emphasised in Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 213.

was explicitly recognized by the drafters in their direction to the SPS Committee to take into account "the exceptional character of human health risks to which people voluntarily expose themselves" in the Committee's formulation of guidelines for the implementation of Article 5.5.[391]

Even if it is shown that the different levels of protection chosen by a Member in different but comparable situations are arbitrary or unjustifiable, it is necessary to show that they result in discrimination or disguised trade restrictions, under the third element of Article 5.5, before a violation of this Article can be said to exist. According to the Appellate Body in *EC—Hormones,* the third element of Article 5.5 is the "most important".[392]

On the relationship between the second and third elements of the three-pronged test, the Appellate Body in *EC—Hormones* stated:

> The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element—the arbitrary or unjustifiable character of differences in *levels of protection* considered by a Member as appropriate in differing situations — may in practical effect operate as a 'warning' signal that the implementing *measure* in its application *might* be a discriminatory measure or *might* be a restriction on international trade disguised as an SPS measure for the protection of human life or health. Nevertheless, the measure itself needs to be examined and appraised and, in the context of the differing levels of protection, shown to result in discrimination or a disguised restriction on international trade.[393]

On the third requirement of Article 5.5, the Appellate Body in *EC—Hormones* disagreed with the Panel's finding that the decisions in *U.S.—Gasoline*[394] with respect to Article XX of the GATT 1994 and that in *Japan—Alcoholic Beverages*[395] regarding Article III:2 of GATT 1994 can be used as precedents for the interpretation of Article 5.5.[396] It reversed

[391] In its guidelines on Article 5.5, the SPS Committee has noted that reasons for a significant difference in the appropriate level of protection for human health "may, in exceptional circumstances, include a risk which humans voluntarily accept. Such circumstances might arise with respect to traditional foods or some other products for which consumers knowingly accept a higher risk than that generally considered to be appropriate for food products." Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 5.5*, G/SPS/15, July 18, 2000, ¶ A.8.

[392] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 240.

[393] *Id.* ¶ 215.

[394] Report of the Appellate Body, *United States-Standards for Reformulated and Conventional Gasoline, supra* note 320, ¶ 22.

[395] Report of the Appellate Body, *Japan-Taxes on Alcoholic Beverages*, *supra* note 320.

[396] In the Report of the Appellate Body, *United States-Standards for Reformulated and Conventional Gasoline, supra* note 320, ¶ 22, the Appellate Body had found that "arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction on international trade" in Article XX impart meaning to each other and that the fundamental theme is the purpose and object of avoiding abuse or illegitimate use of the exceptions in Article XX. Thus the same considerations used to determine if a measure amounts to arbitrary or unjustifiable discrimination can be used to decide if the measure is a disguised restriction on international trade. The Appellate Body in *EC—Hormones* found that the structural differences between the *chapeau* of Article XX of GATT 1994 and Article 5.5 of the SPS Agreement are too great for this analogous interpretation to be made. In its argument, the EC pointed out that the three elements of the chapeau of Article XX of GATT 1994 are in the alternative, whereas those in Article 5.5 of the SPS Agreement are cumulative. *See* Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 239. In the Report of the Appellate Body, *Japan-Taxes on Alcoholic Beverages, supra* note 320, it was held that a large difference in the taxation applied to imports and that applied to domestic products could be sufficient to prove that it was applied so as to afford protection to domestic products, contrary to Article III of GATT 1994. The Appellate Body in *EC—Hormones*, ¶ 239, distinguished the reasoning in the Report of the Appellate Body, *Japan-Taxes on Alcoholic Beverages*, regarding tax differentials from the different question in this case regarding different levels of health protection. As tax is always expressed quantitatively

the Panel's finding, on the basis of the degree of difference in levels of protection in certain comparable situations, that the EC measure in question constituted discrimination or a disguised restriction on international trade, finding that:

> . . . the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. Thus, we do not think that the difference between a "no residues" level and "unlimited residues" level is, together with a finding of an arbitrary or unjustifiable difference, sufficient to demonstrate that the third, and most important, requirement of Article 5.5 has been met . . . Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case.[397]

In *Australia—Salmon*, the Panel had relied on what it called three "warning signals" (i.e., elements which are "not conclusive in [their] own right"[398]) and three "other factors more substantial in nature" or "additional factors"[399] taken cumulatively, to support its finding that the third element of Article 5.5 was met.[400] The three warning signals identified by the Panel were (1) "the arbitrary character of the differences in levels of protection";[401] (2) "the rather substantial difference in levels of protection";[402] and (3) its earlier "two findings of inconsistency (with both Article 5.1 and 2.2)" which make it "seem that the measure at issue constitutes an import prohibition, i.e., a restriction on international trade, 'disguised' as a sanitary measure".[403]

The Appellate Body in this case addressed Australia's contention, on appeal, that the Panel had erroneously regarded proof of arbitrary and unjustifiable distinctions in the levels of protection, that is the second element of Article 5.5, as evidence that the third element, that of discrimination or a disguised restriction on trade, was met. The Appellate Body held:

> According to Australia, the Panel erred in according the first "warning signal", the status of evidence which demonstrates that the measure results in a disguised restriction on international trade. We note however, that it appears clearly from the Panel Report, and in particular, from the reference therein to our Report in *European Communities—Hormones*, that the Panel considered the arbitrary or unjustifiable character of differences in levels of protection as a "warning signal" for, and not as "evidence" of, a disguised restriction on international trade.[404]

and affects the competitiveness of imports, a tax differential necessarily protects domestic products. There is no such link between differences in levels of health protection and the issue of discrimination or a disguised restriction on international trade. The extent of the difference is only one factor among others to be taken into account in determining whether there is discrimination or a disguised restriction on trade. Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, at n.251. Regard must be had to the circumstances of each case.

[397] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 240.

[398] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.151.

[399] *Id.* ¶ 8.152.

[400] *Id.* ¶ 8.159.

[401] *Id.* ¶ 8.149.

[402] *Id.* ¶ 8.150.

[403] *Id.* ¶ 8.151.

[404] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 162.

Thus, it is clear that while the fact that the second element is established can be one indication (or a "warning signal") that the third element is also met, the former cannot be regarded as conclusive proof of the latter. This is so even if the distinction in levels of protection is great. Instead, each element must be determined separately and its existence must be determined on a case-by-case basis, taking into account all relevant circumstances.

However, the degree of difference in level of protection has been recognized to constitute a separate "warning signal" that the third element for a violation of Article 5.5 may be met. The Appellate Body in *Australia—Salmon* agreed with the Panel that the rather substantial difference in levels of protection provided by an import prohibition on ocean-caught Pacific salmon, as opposed to the tolerance of both imports of herring used as bait and imports of live ornamental fish, was a separate (second) warning signal.[405] It held that the degree of difference in the level of protection justified this factor being treated as a separate warning signal distinct from the first.

The Appellate Body also agreed with the Panel in respect of the third warning signal, stating:

> We note that a finding that an SPS measure is not based on an assessment of the risks to human, animal or plant life or health—either because there was no risk assessment at all or because there is an insufficient risk assessment—is a strong indication that this measure is not really concerned with the protection of human, animal or plant life or health but is instead a trade-restrictive measure taken in the guise of an SPS measure, i.e., a "disguised restriction on international trade".[406]

The Panel also took account of three "additional factors" in its decision on the third element of Article 5.5. It derived these "additional factors" from the architecture and structure of the measures applied to implement the different chosen levels of protection. The "additional factors" were: (1) that the two substantially different SPS measures (import prohibition versus import tolerance) applied by Australia lead to discrimination between salmon on the one hand and herring used as bait and live ornamental finfish on the other; (2) that there was a sudden, unexplained change in the conclusion of Australia's earlier Draft Report (which recommended the conditional allowing of the importation of ocean-caught Pacific salmon) and the Final Report (which recommended the import prohibition); and (3) the absence of controls on internal movement of salmon products within Australia compared to the import prohibition with respect to ocean-caught Pacific salmon.[407] On the basis of these considerations, the Panel held that Article 5.5 and, for that reason, also Article 2.3, was violated.[408]

The Appellate Body agreed with the Panel's conclusion,[409] although it reversed the Panel's finding in respect of the first additional factor, holding that it was no different from the first "warning signal" and should be excluded from consideration as a separate factor.[410]

[405] *Id.* ¶ 164.
[406] *Id*. ¶ 166.
[407] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶¶ 8.153–8.158.
[408] *Id.* ¶ 8.160.
[409] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 177.
[410] *Id.* ¶¶ 167–169. The Panel noted that the substantial distinctions in the *levels of protection* applied by Australia to salmon products and to herring and finfish were expressed in two different implementing *measures*, namely import prohibition and import tolerance. It found that as the two products were considered

Whether different levels of protection resulted in discrimination or a disguised restriction on trade also arose as an issue in *EC—Hormones.* In this case, the Panel in support of its finding that the difference in the level of protection for hormones and that for anti-microbial agents, Carbadox and Olaquindox, resulted in discrimination or a disguised restriction on trade, pointed to certain factors. These were: (1) the great difference in level of protection (a no-residue level for the relevant hormones as opposed to an unlimited-residue level for Carbadox and Olaquindox); (2) the absence of a plausible justification for this significant difference; and (3) the nature of the EC measure, an import prohibition, which necessarily restricts international trade.[411]

The Panel in *EC—Hormones* also looked at three "additional factors", namely: (1) the objectives, besides health protection, it believed the European Communities had in mind when enacting and maintaining the ban, which it deduced from the fact that the preambles of the relevant directives, the reports of the European Parliament, and the opinions of the EC Social and Economic Committee indicated that the measure was aimed at harmonization of laws within the European Communities, the removal of distortions of competition and barriers to intra-Community trade, the increase of beef consumption and the reduction of internal surpluses; (2) the fact that before the coming into force of the ban, fewer animals were treated with hormones for growth promotion in the European Communities than in Canada and the United States; and (3) that the hormones are used in the bovine sector, where the European Communities wants to limit supply, whereas Carbadox and Olaquindox are used in the pork sector, where the EC has no surpluses.[412]

The Appellate Body rejected the Panel's conclusion, stating that it did not attach the same importance as the Panel to the multiple objectives of the measure. It pointed to the demonstrated concerns within the EC regarding the studies showing the carcinogenicity of hormones, consumer concerns and the problems of abuse. It stated that the harmonization of regulations was a result of the EC's mandate to establish a Common Market and that the reduction of beef surpluses not only benefited the EC but also other non-hormone beef producers. It thus concluded that it did not agree with the Panel's inference that the import ban was aimed at restricting beef imports from Canada and the United States rather than protecting the EC's population from the risk of cancer.[413] The Panel's finding that there was a violation of Article 5.5 was thus reversed.[414] The Appellate Body's decision makes it clear that the mere incorporation of various non-scientific considerations in the decision to impose a certain health measure is not sufficient to invalidate the measure by rendering it a "disguised restriction on trade". This decision implies a positive recognition by the

comparable (as "different situations" under Article 5.5) and the risk arising therefrom was the same, the different implementing measures suggested that Australia was effectively discriminating between salmon products on the one hand and herring and finfish on the other. The Panel viewed "disguised restriction on international trade" under Article 5.5 as including restrictions amounting to arbitrary or unjustifiable discrimination *between products*. Australia contended that the Panel's concept of discrimination under Article 5.5 was wrong, as discrimination here refers to discrimination *between countries*.

411 Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶ 8.244; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶ 8.241.

412 Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.245–8.246; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.242–8.243.

413 Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 245.

414 *Id.* ¶ 246.

Appellate Body of the important role of societal value judgments in the making of risk management decisions.

(b) Relationship between Article 5.5 and Article 2.3. As mentioned previously, Article 5.5 can be regarded as a specific application of the general obligation contained in Article 2.3. The Panel and Appellate Body in *EC—Hormones* found that Article 5.5 must be read together with the basic obligation of Members to avoid discrimination and disguised restrictions on trade in Article 2.3.[415] Article 2.3 reiterates the obligations set out in the *chapeau* (headnote) to Article XX of GATT 1994.[416] The Appellate Body in *EC—Hormones* held regarding the relationship between Article 5.5 and Article 2.3:

> Article 5.5 must be read in context. An important part of that context is Article 2.3 of the *SPS Agreement*, . . .
>
> When read together with Article 2.3, Article 5.5 may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3.[417]

The most concrete reflection of Article 2.3 is found in the third element of Article 5.5. Regarding the relationship between the third element of Article 5.5 and Article 2.3, the Appellate Body in *EC—Hormones* noted:

> . . . We also recall our interpretation that Article 5.5 and, in particular, the terms "discrimination or a disguised restriction on international trade", have to be read in the context of the basic obligations contained in Article 2.3, which requires that "sanitary . . . *measures* shall not be *applied in a manner which would constitute a disguised restriction on international trade*". (emphasis added)[418]

There is thus a close link between these two articles and a violation of Article 5.5 will necessarily imply a violation of the broader obligation of Article 2.3.

3. Requirement of the Least-Trade Restrictive Measure (Article 5.6)

Another aspect of the risk management process is the choice of a measure to achieve the level of protection deemed appropriate by the government. Measures are typically chosen with regard not only to their technical effectiveness, but also to considerations of cost and ease of application. It is clear that the characteristics of the measure chosen can have a significant effect on trade. While a Member has the right to determine for itself the level of protection it deems appropriate, its choice of a measure can be subject to disciplines to ensure that the trade effect is limited. To this purpose, Article 5.6 of the SPS Agreement provides:

> Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

This amounts to a discipline on the choice of measure rather than on the selection of an appropriate level of protection.

[415] *Id.* ¶ 212.
[416] Article 2.3 of the SPS Agreement is discussed *supra* Part II(B)(2)(c).
[417] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 70, ¶ 212.
[418] *Id.* ¶ 238.

In a footnote, the SPS Agreement defines what is meant by "a measure not more trade restrictive than required". This footnote provides:

> For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

In *Australia—Salmon*[419] the Panel set out the three elements of this definition, which it held to be cumulative, namely that a measure is more trade restrictive than required only if there is another SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member's appropriate level of sanitary protection; and (3) is significantly less trade restrictive than the contested measure. The Appellate Body agreed with this three-pronged test[420] and added:

> 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 is not fulfilled, 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.[421]

This finding was reiterated by the Appellate Body in *Japan—Agricultural Products*.[422] It is now useful to examine each of these requirements in turn to determine what needs to be proved if a measure is challenged under Article 5.6.

(a) No Alternative Measure that is Reasonably Available. The first element of the three-pronged test is that another SPS measure is reasonably available taking into account technical and economic feasibility. It is important to note that in determining the existence of an alternative measure within the meaning of Article 5.6 both the *technical* and *economic* feasibility of the measure must be taken into account. This reflects the recognition that an alternative less-trade-restrictive measure could have high regulatory or compliance costs or could be impractical to implement.[423] This is particularly significant for developing countries. It seems logical that the question of economic and technical feasibility will be determined on the basis of the resources and capacity of the importing Member, rather than by looking in abstract at the alternative measures. This should result in greater flexibility in the application of this discipline to developing countries.

In *Australia—Salmon*, the Panel stated as follows with regard to options considered in the relevant risk assessment as technically and economically feasible alternatives:

> . . . all four alternative options . . . were presented in the 1996 Final Report itself as options which merit consideration and this in contrast to two other options—removal of all quarantine restrictions and banning the importation of all salmon products—which were thought of as options which could not "reasonably be considered as appropriate, having regard to associated quarantine risks" and were therefore "not discussed further". In our view, this

[419] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 95.
[420] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 194.
[421] *Id.*
[422] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 95.
[423] Goh and Ziegler, *supra* note 87, at 280.

> implies that the 1996 Final Report put forward the four alternatives we examine as technically and economically feasible policy options. Nothing in the 1996 Final Report—nor any other evidence before us—implies that any of these four alternatives would be technically or economically unfeasible.[424]

The compliance Panel in *Australia—Salmon*, when examining one of the four alternatives proposed by Canada for the challenged Australian measure, stated as follows:

> . . . [s]ince one can assume that current Australian requirements are "reasonably available taking into account technical and economic feasibility", also a regime without the consumer-ready requirements [the current Australian requirements] . . . would be so. Given that inspection and control to release from quarantine only product that meets the consumer-ready requirements would no longer be necessary, a regime without the consumer ready requirements would be even more reasonably available in the sense of Article 5.6.[425]

In *Japan—Agricultural Products*, the Panel also examined whether testing by product was a technically and economically feasible alternative to the measure at issue, namely varietal testing, and found this to be so.[426] This issue was not appealed. From the above findings it is clear that a panel will look concretely at the facts of each case, including the characteristics of the SPS measure actually applied and the alternative measures considered in the risk assessment, to determine which measures can be considered feasible alternatives.

(b) No Alternative Measure which Achieves the Appropriate Level of Protection. The Panel in *Australia—Salmon*[427] examined the second element required for proof that a measure is more trade restrictive than required, namely that an alternative measure achieves the Member's appropriate level of protection. It found that the level of protection deemed appropriate by a Member could be implied from the level reflected in the SPS measure it adopts. Thus it must be determined whether the alternative measures meet the level of protection achieved by the measure actually imposed. The Appellate Body disagreed, holding as follows:

> We do not believe that Article 11 of the DSU, or any other provision of the DSU or of the *SPS Agreement*, entitles the Panel or the Appellate Body, for the purpose of applying Article 5.6 in the present case, to substitute its own reasoning about the implied level of protection for that expressed consistently by Australia. 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 concerned and not of a panel or of the Appellate Body.[428]

The Appellate Body distinguished the appropriate level of protection, which is an objective, and the measure used to achieve that level, which is an instrument to attain this objective.[429] It continued:

[424] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 56, ¶ 8.171. The Appellate Body noted the panel's "factual finding" in this respect and considered, therefore, that the first element was met. Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 195.
[425] Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon, Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.146–7.149.
[426] Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 57, ¶ 8.78
[427] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon, supra* note 57, ¶ 8.173.
[428] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 199.
[429] *Id.* ¶ 200.

> It can be deduced from the provisions of the *SPS Agreement* that the determination by a Member of the "appropriate level of protection" logically precedes the establishment or decision on maintenance of an "SPS measure".[430]

The Appellate Body noted that the correlation between the appropriate level of protection and the relevant SPS measure is most clearly illustrated by Article 5.6 and held:

> . . . The words of Article 5.6, in particular the terms "*when establishing or maintaining* sanitary . . . protection", demonstrate that the determination of the level of protection is an element in the decision-making process which logically *precedes* and is *separate* from the establishment or maintenance of the SPS measure. It is the appropriate level of protection which determines the SPS measure to be introduced or maintained, not the SPS measure introduced or maintained which determines the appropriate level of protection. To imply the appropriate level of protection from the existing SPS measure would be to assume that the measure always achieves the appropriate level of protection determined by the Member. That clearly cannot be the case.[431]

Thus the appropriate level of protection determines what SPS measure will be used, not *vice versa*.[432] Applying this finding to the case at hand, the Appellate Body stated:

> We note that, in this case, the level of protection *reflected* in the SPS measure at issue, i.e., the import prohibition, is undisputedly a "zero-risk level" of protection. However, Australia determined explicitly that its *appropriate* level of protection is:
>
> > . . . a high or "very conservative" level of sanitary protection aimed at reducing risk to "very low levels", 'while not based on a zero-risk approach.[433]
>
> It is clear, in this case, that the *appropriate* level of protection as determined by Australia is definitely *not* at least as high as the level of protection *reflected* in the SPS measure at issue".[434]

Further, the Appellate Body held that although there is no explicit obligation on Members to determine their appropriate level of protection, this obligation is implicit in paragraph 3 of Annex B, and Articles 4.1, 5.4 and 5.6. It found:

> We do not believe that there is an obligation to determine the appropriate level of protection in quantitative terms. This does not mean, however, that an importing Member is free to determine its level of protection with such vagueness or equivocation that the application of the relevant provisions of the *SPS Agreement,* such as Article 5.6, becomes impossible. It would obviously be wrong to interpret the *SPS Agreement* in a way that would render nugatory entire articles or paragraphs of articles of this Agreement and allow Members to escape from their obligations under this Agreement. While in this case Australia determined its appropriate level of protection, and did so with sufficient precision to apply Article 5.6, we believe that in cases where a Member does not determine its appropriate level of protection, or does so with insufficient precision, the appropriate level of protection may be established by panels on the basis of the level of protection reflected in the SPS measure actually applied. Otherwise, a Member's failure to comply with the implicit obligation to determine its appropriate level of protection—with sufficient precision—would allow it to escape from its obligations under this Agreement and, in particular, its obligations under Articles 5.5 and 5.6.[435]

[430] *Id.* ¶ 201.
[431] *Id.* ¶ 203.
[432] *Id*.
[433] (Footnote in original) Panel Report, ¶ 8.107.
[434] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 197.
[435] *Id.* ¶¶ 205–207.

Thus, if a Member does not determine its appropriate level of protection, or does so with insufficient clarity, panels may determine the appropriate level based on the level reflected in the measure actually applied.

This finding is important in that it prevents the discipline in Article 5.6 from limiting the ability of governments to adopt measures that achieve the level of protection they have chosen. It recognizes that the choice of level of protection is the sole prerogative of national decision-makers. Thus alternative measures must always be judged against the Members' own chosen level of protection and not simply compared to the measure currently in place. Only in cases where a government does not adequately determine its level of protection, may a panel infer it from the measure applied in order to prevent the avoidance of disciplines under the SPS Agreement.

This approach was followed in *Japan—Agricultural Products*, where the Panel, when dealing with the second element of Article 5.6, stated:

> Both parties agree that it is up to Japan to determine its appropriate level of phytosanitary protection with respect to codling moth. We agree since the SPS Agreement (in paragraph 5 of Annex A) defines the "appropriate level of . . . phytosanitary protection" as "[t]he level of protection *deemed appropriate by the Member* establishing a . . . phytosanitary measure to protect . . . plant life or health within its territory",[436] *in casu*, the level deemed appropriate by Japan.[437]

(c) No Alternative Measure which is Significantly Less Restrictive to Trade. With regard to the third requirement, it is notable that the alternative measure must be *significantly* less trade-restrictive before a Member's measure will be deemed "more trade-restrictive than required." Thus a small difference in the trade impacts of the two measures is not sufficient to oblige a Member to adopt the alternative measure.

This requirement was examined by both the Panel and the compliance Panel in *Australia—Salmon*, and by the Panel in *Japan—Agricultural Products.*[438] It appears from these cases that the issue relates to whether market access will be substantially improved under an alternative measure as compared to the measure currently imposed. This examination turns on the relevant facts of the case. For example, in *Japan—Agricultural Products,* Japan did not contest that two alternative measures, namely testing the efficacy of the quarantine treatment by product rather than by each variety of the product;[439] and determining the sorption levels of different varieties of products,[440] were significantly less trade-restrictive than its varietal-testing requirement. The Panel agreed, noting that market access would be obtained either automatically or significantly more easily under the alternatives.[441] In *Australia—Salmon*, the Panel found that even the most stringent

[436] (Footnote in original) Emphasis added.

[437] Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 57, ¶ 8.81.

[438] Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.182; Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon*, *Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.150–7.153; Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 56, ¶¶ 8.79, 8.89, 8.95–8.96 and 8.103–8.104.

[439] In other words, once the efficacy of quarantine treatment for a product has been shown and the product has been approved, no further testing would be required for any other varieties of the product. Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 57, ¶ 8.73.

[440] This would require that once a particular variety of a product is approved, if it can be demonstrated that the sorption level of an additional variety is not higher than that of the initial variety, the same treatment can be applied to both varieties without further testing or approval requirements. If the sorption level of the additional variety is demonstrated to be higher, further testing could be required. *Id.* ¶ 8.96.

[441] With regard to the alternative of testing by product, the Panel noted that market access for additional varieties would be automatic as no additional testing would be required. *Id.* ¶ 8.79. Regarding the alternative

of the four alternative measures examined (requiring retail-ready filleting, evisceration, beheading and gilling of salmon before importation) would be significantly less trade-restrictive than Australia's requirement of heat treatment for salmon, as this amounted to a prohibition on the importation of fresh, chilled or frozen salmon.[442] Australia changed its requirements with respect to the importation of salmon after its measures were judged in violation of the SPS Agreement.[443] With respect to its new measure, and in particular the "consumer-ready" requirement for the importation of salmon,[444] the compliance Panel found that the alternatives proposed[445] would result in significantly more salmon products being allowed for direct release from quarantine.[446] On the basis of evidence before it, the compliance Panel found that demand existed in Australia for non-consumer ready salmon, for use in hotels, restaurants and institutions as well as large families. Therefore, increased market access would result from the alternative measures.[447]

G. Other Substantive Provisions

1. Equivalence (Article 4)

In order to ensure the protection of human, animal and plant health in its territory, a country needs to be satisfied that imported products meet its SPS standards. However, there may be marked differences in the SPS regulations applied as well as the control and inspection systems in place to ensure that the local standards are met in the country where the products are produced as compared to those in the importing country. These differences are not only due to differences in the levels of health protection deemed appropriate by the importing and exporting countries, they may also be due to differences

of determination of sorption levels, the Panel noted that if the determination showed no higher sorption level for other varieties, no additional testing would be necessary, thus resulting in market access being obtained significantly more easily. If a higher sorption level was shown, additional testing could be required, in which case market access would be obtained in circumstances no more difficult than under the current regime. *Id.* ¶ 8.96.

[442] As the Panel in this case incorrectly viewed the requirement of heat-treatment for salmon products as the measure at issue (as opposed to the ban on fresh, chilled or frozen salmon), it proceeded to discuss how heat treatment changes the nature of the product and limits its use since heat-treated salmon cannot be consumed as fresh salmon. In contrast, eviscerated, headless and filleted salmon can be consumed as fresh or cooked salmon. Thus the latter requirement is significantly less trade restrictive. Report of the WTO Panel, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 57, ¶ 8.182.

[443] The Appellate Body overturned the Panel's finding with regard to Article 5.6 since the Panel had made its finding on the wrong premise—that the SPS measure at issue was the heat-treatment requirement. There were insufficient factual findings for the Appellate Body to reach a conclusion on whether the actual SPS measure at issue (the import prohibition) was consistent with Article 5.6. Report of the Appellate Body, *Australia Measures Affecting the Importation of Salmon*, *supra* note 141, ¶¶ 213 and 241–242.

[444] This entailed that only salmon ready for household use (defined as cutlets of less than 450g, skinless fillets of any weight, skin-on fillets of less than 450g, eviscerated, headless pan-size fish of less than 450g or products processed even further) could be released from quarantine. Other salmonid products were required to be processed to a consumer-ready stage at an approved processing plant before release from quarantine. These requirements aimed to avoid the risk that imported salmon would be processed commercially in Australia, leading to substantial concentrations of waste material (skin, fins etc) that would create the risk of pests or diseases.

[445] Canada proposed as alternatives either the current Australian regime *without* the consumer-ready requirements or the current regime with *different* consumer-ready requirements (in particular, removing the weight limitations and requiring the product to be individually and commercially wrapped).

[446] In particular, skin-on salmon weighing more than 450g would be able to be imported for direct sale.

[447] Report of the WTO Compliance Panel, *Australia—Measures Affecting the Importation of Salmon*, *Recourse to Article 21.5 by Canada*, *supra* note 65, ¶¶ 7.150–7.151.

in the conditions prevalent in each country[448] which may affect the efficacy of particular SPS measures and make it possible for alternative measures to be used which result in the same level of health protection.[449] As a result, it is possible for importing countries to rely on the SPS measures and control and inspection systems in place in exporting countries, even where these may be different from their own, when such measures or systems have been demonstrated to achieve the level of protection sought by the importing Member, *i.e.*, to be equally effective in reducing risk. This is known as the recognition or acceptance of "equivalence".

Countries can accept the equivalence of different SPS measures on an *ad hoc* basis or by means of bilateral or regional equivalence agreements. The acceptance of equivalence on an *ad hoc* basis commonly occurs with regard to specific products or technical aspects of SPS measures.[450] In equivalence agreements criteria are often set out for the acceptance of different SPS measures as equivalent on either a system-wide or product-by-product basis. Further, agreements can be concluded in which countries agree that the standards and food safety systems used by each are sufficient to guarantee the level of protection each aims to secure. As a result, they mutually bind themselves to allow each other's products to enter their respective markets despite differences in the SPS measures or control systems applied. The latter type of agreement is known as a "mutual recognition agreement"[451] and may be concluded for specific food or agricultural products or all food and agricultural products and may apply to only certain food safety requirements (for example only conformity assessment procedures or only food safety standards) or to all such requirements.[452] If effectively implemented, equivalence could reduce the barriers created by onerous, but legitimate SPS measures. It is a useful method of eliminating the trade restrictive effect[453] of SPS measures in the absence of complete harmonization.[454]

[448] For example, the prevalence of particular pests or diseases may differ, as may climatic conditions that may be more or less conducive to the proliferation of pests or the spread of diseases. In addition it has been noted that developing countries may face rather different developmental and technological conditions which also result in differences in SPS measures. *See* Simonetta Zarrilli, WTO Sanitary and Phytosanitary Agreement: Issues for Developing Countries, T.R.A.D.E. Working Paper 3, 17, South Centre (1999).

[449] Digby Gascoine, *Harmonisation, Mutual Recognition and Equivalence—How and What Is Attainable?* Paper presented at the Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition, Melbourne Australia, October 11–15, 1999, at 6.

[450] This fact was emphasized in discussions on equivalence in the SPS Committee. Such acceptance occurs on a technical level and is not reflected in formal bilateral agreements. *See* Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001. An example of this is the determination of the United States Department of Agriculture on December 14, 1999, that 32 of the 36 countries exporting meat and poultry to the United States had an inspection system equivalent to that of the U.S. See USDA, Office of the Inspector General, Food Safety and Inspection Service, *Imported Meat and Poultry Inspection Process Phase 1*, Rep. No. 24099-3-Hy (2000).

[451] An example of a mutual recognition agreement is that signed by the EU and Argentina in June 1996, where they agreed to full mutual recognition of each other's sanitary and phytosanitary standards. *See Argentina and EU Sign SPS Agreement,* 351 Animal Pharm 14, 14 (1996).

[452] *See* Gascoine, *supra* note 448, at 5.

[453] *See* Victor, *supra* note 154, at 877–878, where the author notes, "Assuming that exporters have an interest in identifying the least trade restrictive measure, this "equivalence" requirement could automatically ensure that SPS rules are not more discriminatory than necessary (. . .)". It may perhaps be more correct to say that the result would be rules that are least trade-restrictive, since SPS measures need not be discriminatory at all to fall under the SPS Agreement.

[454] This may be the case either where no international standards exist in the specific area or where the existing international standards are inappropriate since they do not achieve the level of protection chosen by the importing Member. In these cases the principle of equivalence could nevertheless result in open markets. It should be noted that the SPS Committee has emphasized that equivalence does not replace the need for

As has been discussed above,[455] Members are not obliged to adopt harmonized standards where these do not meet their chosen levels of protection. However, by recognizing as equivalent divergent SPS measures that meet the relevant appropriate level of protection, Members can avoid creating unnecessary trade barriers while continuing to provide the level of protection they deem appropriate. This is of particular importance to developing countries since their SPS measures and food safety systems often differ from those in place in importing developed countries, due to the developmental and technological constraints faced by developing countries. If their measures nonetheless achieve the level of protection aimed at by the importing country, they should be recognized as equivalent.[456]

However, the recognition of equivalence is not to be used as an instrument for discrimination between countries nor should it result in additional barriers to trade. Neither is it intended to replace the need for the development and use of international standards.[457]

Article 4 of the SPS Agreement aims to promote the recognition of equivalence, both on an *ad hoc* basis and by means of equivalence agreements, and in this way minimize the trade barriers caused by divergent SPS measures.

(a) Acceptance of Equivalence (Article 4.1). Article 4 of the SPS Agreement makes provision for acceptance by WTO Members of the equivalence of different SPS measures provided that the measure achieves the appropriate level of protection chosen by the importing Member. In paragraph 1, it obliges Members to accept as equivalent different SPS measures that have been proven to achieve their chosen level of health protection.

(b) Conditions. In order for Members to be obliged to recognize the equivalence of other Members' SPS measures, Article 4.1 requires that the exporting Member "objectively demonstrate" to the importing Member that its SPS measures achieve the latter's appropriate level of protection. The burden of proof is on the exporting Member to adduce scientific proof that its measure is equally effective in reducing the health risk posed by its export. In addition, the exporting Member must allow reasonable access to the importing Member on request, to conduct its own inspections, tests and other procedures to verify the efficacy of the measure.

(c) Agreements on Recognition of Equivalence (Article 4.2). It is possible for the recognition of equivalence to occur not only on an *ad hoc* basis but also by means of bilateral,

the development and use of international standards. Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 3. *See also* Victor, *supra* note 154, at 878, where he refers to the similar concept of "mutual recognition" in the context of the EC single market which "created a strong market-opening dynamic by allowing legal production from any European country into any other European national market." In this regard he refers to Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL LAW REVIEW 692, 708–729 (1998).

[455] *See supra* Part II(C).

[456] In the meetings of Members in the SPS Committee regarding equivalence, it was stressed that the purpose of equivalence is to facilitate trade and that the recognition of equivalence should enhance developing country access to export markets, including those in developed countries, by allowing them to meet the importer's chosen level of protection by means of alternative measures. *See* Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 7.

[457] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 3.

regional or multilateral agreements[458] in which criteria are set out for acceptance of different SPS measures as equivalent. Therefore, the SPS Agreement, in Article 4.2, encourages the conclusion of equivalence agreements between Members by obliging Members to enter into consultations to this end upon request. However, there is no obligation to actually conclude such agreements.

Some Members are reluctant to enter into negotiations for the conclusion of formal equivalence agreements due to the lengthy and costly nature of such negotiations. However, once in place, formal agreements can make the subsequent recognition of equivalence easier and less costly as the general criteria and conditions for the recognition of equivalence are already established in such agreements.[459]

(d) Procedure. Article 4 does not provide for specific procedures for the recognition of equivalence or the conclusion of equivalence agreements. It is thus left to Members to determine how they will give effect to this provision, in particular what procedures they will establish and which criteria they will apply for the recognition of equivalence.[460] Although these procedures may be laid down in formal equivalence agreements, the Chairman of the SPS Committee made clear in his 2001 Report to the General Council that equivalence does not necessarily require formal equivalence agreements but can be achieved on different levels. He noted:

> In the Committee's discussions in November 2000, Members recognized that there were several different levels of equivalence, which ranged from (i) formal agreements recognizing the equivalence of sanitary and phytosanitary systems; to (ii) agreements of equivalence for specific products; to (iii) acceptance, on an ad hoc basis, of the equivalence of specific technical aspects of certain sanitary and phytosanitary measures. In the March 2001 discussions, it was also suggested that equivalence could be considered for either: (i) inspection and control systems; (ii) processing techniques; and (iii) for product standards.[461]

The Chairperson also reported that delegations had stressed that regardless of the level at which equivalence is recognized, certain obligations exist for both the importing country and the exporting country. These obligations stem from the fact that the SPS measures of the exporting country, in order to be accepted as equivalent, must meet the appropriate level of protection of the importing country. Therefore, the importing country must clearly identify the level of protection its measure aims to achieve and the exporting country must provide appropriate, science-based technical information to

[458] Johanson and Bryant have noted that, "[i]n practice, the definition of equivalency and criteria for recognizing equivalent practices is likely to emerge from bilateral consultations, regional agreements, and the exchange of views encouraged by the Sanitary and Phytosanitary Committee. . . ". David S. Johanson and William L. Bryant, *Eliminating Phytosanitary Trade Barriers: The Effects of the Uruguay Round Agreements on California Agricultural Exports,* 6 SAN JOAQUIN AGRICULTURAL LAW REVIEW 1, 6 (1996).

[459] Argentina has suggested that all formal equivalence agreements should contain a section establishing general principles, aims and requirements for the recognition of equivalence, and deal with specific products in annexes to the agreement. *See* Committee on Sanitary and Phytosanitary Measures, *Equivalence—Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures,* G/SPS/GEN/268, August 15, 2001. *See also* Zarrilli and Musselli, *supra* note 28, at 8.

[460] The Decision on Equivalence, discussed *infra*, provides some guidelines with regard to the procedure to be followed.

[461] Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 4.

demonstrate that its alternative measure meets this level of protection.[462] The Secretariat has noted that, in identifying their appropriate level of protection, Members should take into account the Guidelines to Further the Practical Implementation of Article 5.5,[463] which were adopted by the SPS Committee in June 2000.[464] The question of a Member's identification of its chosen level of protection is addressed in these Guidelines as follows:

> A Member should indicate the level of protection which it considers to be appropriate with respect to risks to human life or health, to animal life or health or to plant life or health in a sufficiently clear manner so as to permit examination of the extent to which any sanitary or phytosanitary measure achieves that level.
>
> Such an indication may be contained in a published statement or other text generally available to interested parties. The statement of the appropriate level of protection may be qualitative or quantitative, and should serve to guide its consistent implementation over time, and also to increase the transparency of the sanitary or phytosanitary regime. Examples might include government policy statements with regard to appropriate levels of protection in response to certain risks, or documents on animal health protection objectives or with respect to plant protection. The use of quantitative terms, where feasible, to describe the appropriate level of protection can facilitate the identification of arbitrary or unjustified distinctions in levels deemed appropriate in different situations.[465]

The Guidelines also indicate,[466] as decided by the Appellate Body in *Australia—Salmon*,[467] that although the SPS Agreement contains no express obligation on a Member to determine its appropriate level of protection, this obligation is implicit in several provisions including Article 4.

Once the appropriate level of protection of the importing Member is known, and the exporting Member produces evidence to support its claim that its SPS measure achieves this level of protection, the importing Member makes its determination of equivalence. The equivalence of different types of SPS measures (such as ban on a potential host of a pest and a requirement of fumigation treatment prior to importation) could be determined by examining the effectiveness of each by means of scientific evidence. In contrast, when different control and inspection systems are compared, a more subjective element is present as the quality of the system and qualifications of personnel are evaluated.[468]

(e) Notification. The notification of equivalence agreements or *ad hoc* recognition of equivalence is not mandatory under the SPS Agreement. In the informal discussions on equivalence in the SPS Committee, several Members expressed concern regarding the lack of transparency with regard to equivalence agreements.[469] A notification obligation

[462] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 6; Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001.

[463] Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 5.5,* G/SPS/15, July 18, 2000. These non-binding guidelines relate to the objective of consistency in the choice of appropriate level of protection and are discussed *supra* Part II(F)(2).

[464] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 11.

[465] Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 5.5,* G/SPS/15, July 18, 2000, ¶ A.1.

[466] *Id*. ¶ B

[467] Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 205.

[468] This point is made by Johanson and Bryant, *supra* note 457, at 6.

[469] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 19.

would facilitate the recognition of equivalence of SPS measures of developing countries by enabling developing countries to make a request to become party to a notified equivalence agreement by showing that they meet the conditions set out therein. A notification obligation would also facilitate the recognition of equivalence by making it easier for developing countries to conclude a similar bilateral agreement with the importing country. However, it was pointed out in the Committee meeting that all Members' national Enquiry Points[470] are obliged to respond to questions regarding, *inter alia* the *ad hoc* recognition of equivalence and equivalence agreements.[471] Nevertheless, the SPS Committee endorsed a conclusion stating that Members will inform the SPS Committee of their recognition of the equivalence of the SPS measures of other Members.[472] The Secretariat proposed a format for the notification of determinations of equivalence and equivalence agreements, where such recognition of equivalence may have a significant effect on the trade of the Member that requested the determination or on the trade of other Members.[473] The SPS Committee adopted the recommended procedures and format for the notification of equivalence agreements at its meeting of June 25–26, 2002.[474]

(f) Examples. In practice, the recognition of equivalence most often takes place informally, on a technical or administrative level for specific products. An example of such recognition of equivalence is that of Australia with regard to Switzerland's measures applicable to hard cheeses. Australia requires pasteurization or thermization of milk in the production of cheeses in order to achieve its "safe food use" level of protection for cheese consumption. Switzerland sought to demonstrate that its manufacturing process for cheeses achieved Australia's level of protection by means of a risk assessment. The risk assessment showed, according to Australia, that hard cheeses made following the Swiss process achieved the same level of pathogen destruction as hard cheese subject to pasteurization, but this was not the case with soft cheeses. Australia thus recognized Emmental, Sbrinz and Gruyere as safe due to the equivalence of the Swiss process with regard to hard cheeses.[475]

Currently, the recognition of equivalence by means of formal agreements is taking place in very limited cases, in the context of bilateral or regional agreements. In particular, it occurs between the Member States of the European Union, the Members of NAFTA, and between Australia and New Zealand.[476] In addition, in certain cases Members have

[470] The Enquiry Points will be discussed *infra* Part III(A)(4).

[471] This obligation is contained in Annex B.3(d) and was confirmed by the SPS Committee in its meeting of March 13, 2001. Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 11(ii).

[472] *Id*. ¶ 11(iii).

[473] Committee on Sanitary and Phytosanitary Measures, *Proposed Format for the Notification of Agreements of Equivalence,* G/SPS/W/114/Rev.1, May 21, 2002.

[474] Committee on Sanitary and Phytosanitary Measures, *Notification of Determination of the Recognition of Equivalence of Sanitary or Phytosanitary Measures, Decision by the Committee. Addendum,* G/SPS/7/Rev.2/Add.1, July 25, 2002.

[475] Committee on Sanitary and Phytosanitary Measures, *An Example of Equivalence: Statement by Australia at the Meeting of 14–15 March, 2001,* G/SPS/GEN/243, April 9, 2001. Other examples of *ad hoc* recognition of equivalence were provided by New Zealand. *See* Committee on Sanitary and Phytosanitary Measures, *Experience in Recognizing Equivalence of Phytosanitary Measures: Submission by New Zealand,* G/SPS/GEN/232, February 28, 2001.

[476] For examples of the recognition of equivalence in the EU and NAFTA and the mutual recognition agreement between Australia and New Zealand (which has since been replaced by a joint food authority, the ANZFA), *see* Zarrilli, *supra* note 447, at 17–18. The recognition of equivalence by the United States of the new Australian meat inspection system is discussed in J.J. Kastner and R.K. Pawsey, *Harmonising*

negotiated agreements laying down the conditions and requirements for the recognition of each other's SPS measures as equivalent for specific products or sectors. An example of such an equivalence agreement is that concluded between the European Union and Canada, where they have established a mechanism, laying down procedures and criteria for the recognition of equivalence of sanitary measures relating to trade in live animals and animal products.[477]

(g) Problems with Implementation. The implementation of Article 4 of the SPS Agreement to date leaves much to be desired. Developing countries have repeatedly raised the concern that developed countries demand "sameness" rather than equivalence of standards and control and inspection systems.[478] This deprives countries of the flexibility in their choice of measures that Article 4 intends to achieve. In addition, some Members[479] are of the opinion that the negotiation of formal equivalence agreements or determinations is too time consuming and resource intensive, imposing administrative burdens on both the importing and the exporting countries, whereas the gains in trade achieved thereby are limited. They therefore hold the view that recourse to other provisions of the SPS Agreement (such as the rules on risk assessment, transparency, technical assistance and control and inspection procedures) would yield more immediate trade benefits in the form of market access.[480] However, other Members note that although importing countries may view the administrative burden of an equivalence agreement as unjustified with regard to the limited trade benefits it can bring, the improved market access through recognition of equivalence can be very important for developing countries.[481] This is because developing country exports are often limited to a small range of products and involve few enterprises. Thus the recognition of equivalence with regard to the few products of export interest to a developing country could have great benefits for its export trade, while being less costly and burdensome than if equivalence negotiations across a wide range of products were necessary.

In its first periodic review of the implementation of the SPS Agreement,[482] the SPS Committee noted that although there had been an increase in the recognition of equivalence and in the negotiations towards bilateral agreements in this respect, greater efforts in this area were necessary. The Committee pointed in this regard to the importance of the recognition of equivalence for developing countries. The Committee requested Members

Sanitary Measures and Resolving Trade Disputes through the WTO-SPS Framework. Part II: A Case Study of the U.S.—Australia Determination of Equivalence in Meat Inspection, 13 FOOD CONTROL 57 (2002).

[477] *Agreement between the European Community and the Government of Canada on Sanitary Measures to Protect Public and Animal Health in respect of Trade in Live Animals and Animal Products*, OJ L071, 3, 1999/03/18. Similar agreements have been concluded with the United States, New Zealand and the Czech Republic.

[478] World Trade Organization, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 5.

[479] *See* Committee on Sanitary and Phytosanitary Measures, *Equivalence: Submission from the United States,* G/SPS/GEN/212, November 7, 2000, ¶ 16.

[480] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 5. *See also* Committee on Sanitary and Phytosanitary Measures, *Equivalence: Submission from the United States,* G/SPS/GEN/212, November 7, 2000, ¶ 20.

[481] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Note by the Secretariat,* G/SPS/W/111, July 4, 2001, ¶ 6.

[482] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures: Report of the Committee* G/SPS/12, March 11, 1999, ¶ 20.

to provide more information on equivalence agreements that they have concluded bilaterally. In addition, the work of Codex and other international organizations to promote the recognition of equivalence was welcomed by the SPS Committee.[483]

(h) International Guidelines on Equivalence. Since the SPS Agreement does not lay down specific procedures or criteria for the recognition of equivalence, international guidelines in this regard would be useful. They would also reduce the costs of equivalence negotiations by providing a framework against which equivalence can be judged.[484]

In order to facilitate the recognition of equivalence among trading partners,[485] the Codex Alimentarius Commission has established international guidelines on the development of equivalence agreements,[486] on the design, operation, assessment and accreditation of food import and export inspection and certification systems,[487] and for the judgment of equivalence of sanitary measures associated with food inspection and certification systems.[488] The Equivalence Decision[489] mandates the SPS Committee to formally encourage the Codex Alimentarius Committee to complete its work with regard to equivalence as expeditiously as possible, and to formally encourage the OIE and IPPC to elaborate guidelines on equivalence as appropriate.

The SPS Committee has done so, and the International Committee of the OIE has since adopted the Guidelines for Reaching a Judgment on Equivalence of Sanitary Measures.[490] The Interim Commission on Phytosanitary Measures of the IPPC took note of the request of the SPS Committee and agreed to include, as priorities in its work programme, work on the equivalence and efficacy of measures, which is considered a pre-requisite to an international standard for phytosanitary measure on equivalence.[491] Such work is currently underway.

(i) The Equivalence Decision. At its Special Session on Implementation on October 18, 2000, the General Council referred the issue of implementation of Article 4 to the SPS

[483] Gretchen Stanton, *A Review of the Operation of the SPS Agreement*, Paper presented at the Conference on Agriculture and the New Trade Agenda in the WTO 2000 Negotiations, Geneva, October 1–2, 2000, at 5.
[484] It has been noted that in the absence of guidelines on the methodology for judging equivalence, specific bilateral issues are more likely to arise and the methodological concerns of developing countries are more likely to be neglected. Zarrilli and Musselli, supra note 28, at 8.
[485] One of the recommendations resulting from an FAO conference in 1999, under the heading "Food trade and implementation of WTO Agreements," was the recognition of the urgency of the development of Codex guidelines on the judgment of equivalence, initially in a generic sense and subsequently in relation to specific topics such as equivalence of inspection and certification systems and food hygiene measures. *See* Food and Agriculture Organization, REPORT OF THE CONFERENCE ON INTERNATIONAL FOOD TRADE BEYOND 2000: SCIENCE-BASED DECISIONS, HARMONIZATION, EQUIVALENCE AND MUTUAL RECOGNITION, Melbourne, Australia, October 11–15, 1999, at Appendix II A.2. In addition, in discussions on equivalence in the SPS Committee, Members noted with regard to the concern about the time and resources needed to conclude equivalence agreements, that international guidelines for systemic application of the principle would be useful. The progress made by the CAC in this regard was noted. *See* Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 7.
[486] CAC/GL/34-1999, adopted by the CAC in its 23rd Session in 1999.
[487] CAC/GL/26-1997, adopted by the CAC in its 22nd Session in 1997.
[488] ALINORM 03/03A, Appendix II, ¶¶ 8–16, adopted by the CAC in its 25th session in 2003.
[489] *See infra* Part II(G)(1)(i).
[490] These guidelines were adopted at the 71st General Session of the OIE, which took place in Paris, France, on May 18–23, 2003.
[491] This occurred at the 5th Session of the Interim Commission on Phytosanitary Measures, held in Rome, Italy, on April 7–11, 2003.

Committee.[492] The SPS Committee held informal and special meetings on equivalence and also addressed the issue in its regular meetings.[493] The result of these discussions[494] was the adoption in November 2001 of the Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter the Equivalence Decision)[495] by the SPS Committee.[496]

The Equivalence Decision[497] sets out some guidelines for any Member who requests the recognition of equivalence of their SPS measures and for the importing Member who is the addressee of such a request. In particular, the importing Member should, on request, supply information regarding the aim and rationale of its SPS measure, clearly identify the risks it addresses and indicate its chosen appropriate level of protection. The explanation should be accompanied by a copy of the underlying risk assessment for the measure or a technical justification based on a relevant international standard, guideline or recommendation. The importing Member must respond in a timely manner to the request for recognition of equivalence, normally within six months. The exporting Member must provide science-based and technical information to show that its measure achieves the level of protection chosen by the importing Member, and provide reasonable access for testing and inspection. The importing Member should evaluate the scientific and technical information with a view to determining if the SPS measure of the exporting Member achieves its level of protection and must give full consideration to requests for technical assistance for the implementation of Article 4.[498] The procedure for determining equivalence must be accelerated for products historically imported from the exporting Member. The consideration of equivalence may not be a reason to disrupt or suspend

[492] The General Council requested the SPS Committee "to examine the concerns of developing countries regarding the equivalence of SPS measures and to come up with concrete options as to how to deal with them." *See* General Council, *Minutes of Meeting: Special Session on Implementation*, WT/GC/M/59, October 18, 2000, ¶ 12.

[493] The informal meetings on equivalence were held on November 7, 2000, March 13, 2001 and July 9, 2001. The formal meetings where equivalence was considered were those of November 8–9, 2000 and July 10–11, 2001. In addition, two Special Meetings on equivalence were held on September 18–19, and October 24, 2001.

[494] The discussions on equivalence are summarized in Committee on Sanitary and Phytosanitary Measures, *Equivalence: Consideration of Article 4 of the SPS Agreement: Summary of Informal Discussions on Equivalence. Second Report by the Chairman,* G/L/445, March 21, 2001, ¶ 7.

[495] Committee on Sanitary and Phytosanitary Measures, *Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures,* G/SPS/19, October 24, 2001.

[496] The Ministerial Conference at Doha took note of this Decision. Ministerial Conference, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001, ¶ 3.3.

[497] The legal status of the Equivalence Decision brings up interesting questions. It was adopted under the authority of the SPS Committee to carry out the functions necessary to implement and further the objectives of the SPS Agreement under Article 12.1 SPS. However, the question arises whether this decision can be enforced in dispute settlement, since it is not a "covered agreement" for purposes of the DSU, and only claims pursuant to a "covered agreement" fall within the jurisdiction of panels or the Appellate Body. *See* Articles 1.1, 3.1 and 3.2 DSU. The Equivalence Decision cannot be the legal basis for a complaint of violation before panels or the Appellate Body. However, this does not mean that the Equivalence Decision could not be considered in the interpretation of Article 4 of the SPS Agreement. Arguably, it could constitute a subsequent agreement between the parties regarding the interpretation of the SPS Agreement and should thus be considered together with the context for interpreting the agreement in terms of Article 31.3(a) of the Vienna Convention on the Law of Treaties, which reflects customary international law with regard to treaty interpretation.

[498] This technical assistance may be in the form of help in identifying and implementing equivalent measures, otherwise enhancing market access opportunities, or the development and provision of science-based information to support the recognition of equivalence requests.

on-going imports of the relevant product from the exporting Member. Members must actively participate in the work of the international standard-setting organizations on equivalence and are encouraged to notify bilateral equivalence agreements to the SPS Committee.

The Equivalence Decision also creates obligations for the SPS Committee. It must revise its notification procedures to provide for the notification of equivalence agreements[499] and must reinforce the obligation of national Enquiry Points to provide information in this regard. Further, it must formally encourage the international standard-setting organizations to develop guidelines on equivalence. It must also develop a program to further the implementation of Article 4, with particular regard for the problems encountered by developing countries.

At its meeting of March 19–21, 2002, the SPS Committee adopted a program for further work on equivalence,[500] setting out the main issues for discussion in 2002 and 2003. The work program included discussions regarding the clarification of the following paragraphs of the Equivalence Decision: paragraph 5 (regarding accelerated steps for determining equivalence for products historically imported from the exporting Member); paragraph 6 (with respect to the relationship between current imports and potential compliance problems) and paragraph 7 (regarding the examination of scientific and technical information to determine equivalence of SPS measures). These discussions have taken place in steps, culminating in the adoption of clarifying texts.[501]

The SPS Committee completed the work programme on equivalence in March 2004. However, it agreed to keep equivalence as a standing item on the agenda of its meetings. A second, revised, version of the Equivalence Decision was adopted in 2004, providing updated information on the actions that have been undertaken pursuant to the Decision.[502]

2. Adaptation to Regional Conditions (Article 6)

The prevalence of pests and diseases is not determined by national boundaries, and may differ between various regions within a country. This may be the case either due to variations in climatic, environmental or geographic conditions within a country, or due to the efforts of the regulatory authorities to eradicate a pest or disease from specific areas. In practice, however, it is common to ban products from an entire country where it has been established that a pest or disease of significance for the importing country occurs, even if its prevalence is limited to certain regions.[503] If importing countries were instead to adapt their SPS measures to the conditions prevailing in the region of origin of the product,

[499] As mentioned above, the SPS Committee has since adopted a notification procedure for equivalence agreements or determinations. Committee on Sanitary and Phytosanitary Measures, *Notification of Determination of the Recognition of Equivalence of Sanitary or Phytosanitary Measures, Decision by the Committee. Addendum,* G/SPS/7/Rev.2/Add.1, July 25, 2002.

[500] Committee on Sanitary and Phytosanitary Measures, *Equivalence—Programme for Further Work, Decision by the Committee,* G/SPS/20. March 21, 2002.

[501] Clarifications to ¶¶ 5 and 6 of the Equivalence Decision were adopted by the SPS Committee at its meeting of November 7–8, 2002. These clarifications are contained in G/SPS/19/Add.1. In June 2003, a clarification to ¶ 7 was adopted (contained in G/SPS/A/Add.2) and a further clarification to ¶ 5 was adopted in March 2004 (G/SPS/19/Add.3).

[502] Committee on Sanitary and Phytosanitary Measures, *Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, Revision,* G/SPS/19/Rev.2, July 23, 2004.

[503] For example, in 1995 Ecuador banned the importation of fruit hosts of the oriental fruit fly from the United States after a few oriental fruit flies had been detected in Southern California. This example was noted in Johanson and Bryant, *supra* note 457.

this could greatly improve market access possibilities. Article 6.1 therefore requires that Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area from which the product originated and to which the product is destined. This adaptation of SPS measures to regional conditions is especially significant for large developing countries where conditions vary greatly from region to region, as the costs of eradicating a pest or disease or keeping pest- or disease-free status can be limited by focusing on specific areas.

(a) Factors to Be Taken into Account (Article 6.1). In determining what the sanitary or phytosanitary characteristics of a region are, Article 6.1 obliges Members to take into account the level of prevalence of specific pests or diseases, and the existence of eradication or control programs and guidelines developed by international organizations. This is not an exhaustive list of factors.

It is significant that international guidelines are mentioned as a factor that must be considered. The OIE has specific procedures in place pursuant to which, after an investigation and evaluation of the evidence, it officially recognizes the disease-free status of a country or region with regard to foot-and-mouth disease,[504] rinderpest and contagious bovine pleuropneumonia.[505] The Director General publishes a list of countries that meet the requirements for disease free status. With regard to these and other diseases the OIE lays down guidelines according to which a country can declare itself, or a *zone* within the country, free of a particular disease. To do so, the country must provide epidemiological information that conforms to the standards laid down in the *Animal Health Code,* to the importing country in support of its declaration. The IPPC has also laid down guidelines for the establishment of pest-free status[506] and for the determination of pest status in an area.[507] Further, the IPPC has created guidelines for the establishment of pest-free production sites and areas of production.[508] All these guidelines should facilitate the implementation of Article 6, as they clarify what is meant by a pest- or disease-free country or region and how this can be established.

However, concerns have been raised that even the official recognition of a Member as disease-free by the OIE is in practice not accepted by other Members as proof of disease-free status and the exporting Member is required to supply anew all the evidence it has in support of its claim of disease-free status to the importing country.[509] This situation seems to be contrary to the aim of Article 6.

(b) Recognition of Pest- or Disease-free Areas or Areas of Low Pest or Disease Prevalence (Article 6.2). Annex A, paragraph 6 defines a pest- or disease-free area as an area which

[504] OIE International Committee, *Establishment of a list of foot and mouth disease (FMD) free countries where vaccination is not practiced*, Resolution XI and *Procedure for the recognition of the foot and mouth disease status of Member Countries*, Resolution XII, 63rd General Session, (1995)

[505] A specific procedure for recognition of disease-free status was created for rinderpest and contagious bovine pleuropneumonia and will soon also be created for BSE. It should be noted that with regard to rinderpest, only whole countries and not regions can be officially recognised as rinderpest-free by the OIE.

[506] International Plant Protection Convention, *Requirements for the Establishment of Pest Free Areas*, ISPM 4, FAO (1996).

[507] International Plant Protection Convention, *Determination of Pest Status in an Area*, ISPM 8, FAO (1998).

[508] International Plant Protection Convention, *Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites*, ISPM 10, FAO (1999).

[509] Committee on Sanitary and Phytosanitary Measures, *Articles 6(2), 6(3) and Annex A(3)(B): Recognition of the Concept of Pest- or Disease-Free Areas as an International Standard, Guideline or Recommendation: Submission by South Africa,* G/SPS/GEN/139, November 2, 1999.

can be all or part of a country or of several countries, as identified by the competent authorities, in which a pest or disease does not occur. This area may adjoin an area where the pest or disease does occur, but is subject to regional control measures such as protection, surveillance or buffer zones that confine or eradicate the pest or disease. An area of low pest- or disease prevalence is defined as an area, which can be all or part of a country or of several countries, as identified by the competent authorities, in which a pest or disease occurs at low levels and is subject to effective surveillance, control or eradication measures.

Article 6.2 specifically creates the obligation on Members to recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. These areas shall be determined with regard to factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of SPS controls.

(c) Obligations on Exporting Members (Article 6.3). In terms of Article 6.3, an exporting Member that claims that regions within its territory are pest- or disease-free or have low pest or disease prevalence must provide the necessary evidence to objectively demonstrate this fact to the importing Member. For this purpose, it must give the importing Member reasonable access for inspection, testing and other relevant procedures.

Once again, it can be argued that the official recognition of the pest-free status of a country by the OIE and the publication of this status in the official Bulletin of the OIE should be accepted as constituting the "necessary evidence" for an objective demonstration of disease-free status. Members that refuse to accept such evidence could therefore be challenged under Article 6.

(d) Ongoing Work on Regionalization. Several Members, particularly developing countries, have raised concerns that the full benefits of regionalization, as provided for in Article 6, are not being reaped due to problems with the implementation of this provision. These Members have emphasized the importance of regionalization in reducing barriers to trade. As a result, the SPS Committee is currently conducting work in this area. Informal meetings of the SPS Committee have been held, dedicated to the regionalization issue, where the submissions of Members have been discussed,[510] and representatives of the OIE and IPPC have made presentations.[511] At these meetings, Members have stressed the crucial role of the international organizations in creating specific standards in this area, in order to facilitate the recognition of pest- and disease-free areas and areas of low pest and disease prevalence. Chile has submitted a proposal, later revised, regarding the

[510] Submissions were made by Mexico, Argentina, Chile and Peru (G/SPS/GEN/388, G/SPS/GEN/440, G/SPS/GEN/417, G/SPS/GEN/418, G/SPS/GEN/445, G/SPS/W/129, G/SPS/W/140, G/SPS/GEN/381, G/SPS/GEN/433), followed later by other Members.

[511] The OIE representative indicated that in May 2004, the OIE would consider for adoption simplified definitions and procedures for regionalization, which would provide Members with recommendations on regionalization for a broad range of diseases of terrestrial animals. Similar work would be undertaken with regard to aquatic animals but was delayed due to the complexity of the issue. The concept of regionalization is part of existing OIE recommendations for how countries could achieve, maintain, and regain pest-free status for most major diseases. The IPPC representative described the ongoing efforts to develop standards related to the designation of pest-free areas and areas of low pest prevalence. The relevant existing standards are ISPM 4 (containing detailed requirements for the establishment of pest-free areas) and ISPM 10 (containing information on pest-free areas of production) and the draft standard on requirements for the establishment, maintenance and verification of areas of low pest prevalence. However, there is as yet no IPPC procedure for officially recognizing pest-free areas. *See* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 17–18 March 2004, Note by the Secretariat*, G/SPS/R/33, May 7, 2004, ¶¶ 109–110.

adoption of procedural guidelines for the implementation of regionalization measures by the SPS Committee.[512] This proposal has been supported by several Members, who suggest that the Committee address the regionalization issue in a similar way to the work it has done on equivalence and transparency.[513] Although the SPS Committee agreed that further work on regionalization is necessary, there was no consensus on whether the Committee should develop guidelines and procedures. The Chairman thus proposed that work continue in informal mode on this issue.

III. Institutional and Procedural Provisions of the SPS Agreement

The SPS Agreement contains several provisions dealing with institutional or procedural matters. Some of these provisions impose obligations of an institutional or procedural nature on Members, for example those requiring Members to follow certain procedures and set up certain institutions with respect to notification and transparency and those disciplining Members' use of control, inspection and approval procedures, in order to minimize their trade effects. Other provisions deal, instead, with the institutions and procedures necessary for the smooth and effective implementation of the SPS Agreement. Both these categories of institutional and procedural provisions have an important impact on the effectiveness of the SPS Agreement in achieving its goals, and will be discussed in detail below.

A. Transparency (Articles 5.8 and 7, and Annex B)

An important hurdle faced by exporters of food and agricultural products is a lack of transparency regarding SPS measures with which they must comply. SPS measures are often complex and subject to change, as a result of which exporters have no certainty that their products will have access to the markets in the country of destination. Obtaining the necessary information regarding the SPS measures with which they must comply is often a costly and burdensome process for exporters. In addition, the lack of information regarding SPS measures is problematic for Members whose exporters are faced with SPS barriers to trade, as they need to obtain full information about these measures in order to identify whether they are legitimate measures or whether they could be challenged under the SPS Agreement.

For these reasons, the transparency and notification obligations in the SPS Agreement are crucial in facilitating market access for exports since the cost and difficulty of obtaining information on their trading partners' SPS measures are thereby greatly reduced. In addition, the transparency obligations make it possible for Members to become acquainted with proposed SPS measures before they come into force, enabling them to raise their concerns regarding these measures at an early enough stage to influence the final measure adopted.

1. Scope of Application of Notification Obligation

It is useful to start by identifying when the notification obligation applies. Article 7 of the SPS Agreement obliges Members to notify changes in their SPS measures and to provide

[512] Committee on Sanitary and Phytosanitary Measures, *Draft Decision on the Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures, Proposal by Chile, Revision,* G/SPS/W/140/Rev.1, October 30, 2003.

[513] Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 17–18 March 2004, Note by the Secretariat*, G/SPS/R/33, May 7, 2004, ¶¶ 115.

information on their SPS measures in accordance with Annex B. In terms of Annex B.1, Members must publish all adopted "SPS regulations" in a way that enables all interested Members to become acquainted with them. A footnote to this paragraph defines "SPS regulations" as SPS measures such as laws, decrees or ordinances of general application. The Appellate Body in *Japan—Agricultural Products* noted with regard to this definition:

> We consider that the list of instruments contained in the footnote to paragraph 1 of Annex B is, as is indicated by the words "such as", not exhaustive in nature. The scope of application of the publication requirement is not limited to "laws, decrees or ordinances", but also includes, in our opinion, other instruments which are applicable generally and are similar in character to the instruments explicitly referred to in the illustrative list of the footnote to paragraph 1 of Annex B.
>
> The object and purpose of paragraph 1 of Annex B is "to enable interested Members to become acquainted with" the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures. In our opinion, the scope of application of the publication requirement of paragraph 1 of Annex B should be interpreted in the light of the object and purpose of this provision.[514]

Further, Annex B.5 provides that Members must notify proposed new SPS measures in cases where no international standard, guideline or recommendation exists or where the Member's SPS measure is "not substantially the same" as the international standard, and the measure may have a significant effect on trade. The question arises whether a measure that is substantially the same as an international standard for purposes of Annex B.5 and thus does not have to be notified is a measure "based on" an international standard under Article 3.1, or a measure that "conforms to" an international standard under Article 3.2. It would appear that a measure "not substantially the same" as an international standard is a measure that does not "conform to" the international standard under Article 3.2, although the reason for the difference in terminology is not clear. This view is supported by the fact that measures which do "conform to" international standards benefit from a presumption of consistency with the SPS Agreement and thus also with its Annexes, including the transparency provisions of Annex B, whereas measures that are simply "based on" international standards do not. Therefore, if a measure is merely "based on" an international standard, it seems likely that it will be regarded as "not substantially the same" as the international standard for purposes of Annex B.5 and will have to be notified.

In addition, the notification procedures of Annex B.5 apply only if the relevant SPS measure "may have a significant effect on trade of other Members". The Secretariat has established non-binding guidelines for what is meant by a "significant effect on trade".[515] According to these guidelines, this term may refer to the import-enhancing or import-reducing effect on trade in a specific product, group of products or products in general of a single SPS measure or various SPS measures in combination, between two or more Members. The guidelines further set out various factors that Members should take into account when determining if there is a significant effect on trade.[516]

[514] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 92, ¶¶ 105–106.

[515] Committee on Sanitary and Phytosanitary Measures, *Recommended Notification Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7),* G/SPS/7/Rev.2, April 2, 2002, ¶ 6.

[516] These include the value or importance of the imports for the importing and/or exporting Members concerned, the potential development of these imports and difficulties for producers, particularly in developing countries, to comply with the proposed SPS measure.

In *Japan—Apples,* the issue arose whether certain changes in Japan's measure "may have a significant effect on trade of other Members" and should thus have been notified. The Panel referred to the guidelines on this concept adopted by the SPS Committee and held that:

> . . . the most important factor in this regard is whether the change affects the conditions for market access for the product concerned, that is, would the exported product (apple fruit from the United States in this case) still be permitted to enter Japan if they complied with the prescription contained in the previous regulations. If this is not the case, then we must consider whether the change could be considered to potentially have a *significant* effect on trade of other Members. In this regard it would be relevant to consider whether the change has resulted in any increase in production, packaging and sales costs, such as more onerous treatment requirements or more time-consuming administrative formalities.[517]

The crux of the issue is therefore whether the changes have an actual or potential effect on the conditions for market access. If so, the changes must be notified.

When all the conditions of Annex B.5 are met, Members have to comply with the notification procedure set out in the rest of the Annex.

2. Notification Procedure

Annex B.5–10 sets out the notification procedure to be followed. In terms of this procedure, the proposal for a new measure must be published early enough to allow other Members to become acquainted with the proposal. In addition, the products to be covered and the objective and rationale for the proposed measure must be notified to other Members through the WTO Secretariat,[518] allowing a reasonable time for comments from other Members. These comments must be discussed upon request and must be taken into account by the Member imposing the SPS measure. In urgent cases, Members may follow a shorter procedure under Annex B.6. Members are not obliged to disclose confidential information that could hamper the enforcement of their SPS measures or prejudice the legitimate interests of enterprises.[519]

A special meeting of the SPS Committee on the operation of the transparency provisions of the SPS Agreement was held five years after the coming into force of the SPS Agreement.[520] The Secretariat has established guidelines on transparency, contained in the handbook *How to Apply the Transparency Provisions of the SPS Agreement*.[521] These are particularly aimed at helping developing countries comply with their transparency obligations. In addition, the Secretariat has established detailed guidelines for notifications under both the normal and the urgent procedure, including a specific format to be

[517] Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 8.314. After comparing the two existing measures (which predated the SPS Agreement) with the two new measures, the Panel did not consider that the changes in one measure could have a significant effect on the trade of other Members, and was unable to determine if the changes to the second measure were strictly editorial or introduced substantial changes. It therefore found that the US had failed to make a *prima facie* case of violation of Article 7 SPS.

[518] Notifications received by the Secretariat are circulated to Members as part of the official document series G/SPS/N/*.

[519] Annex B.11(b).

[520] Committee on Sanitary and Phytosanitary Measures, *Summary of the Special Meeting of the SPS Committee on the Transparency Provisions of the SPS Agreement, 9 November 1999, Note by the Secretariat,* G/SPS/R/16, January 20, 2000.

[521] Published in November 2000, available at: www.wto.org/english/tratop_e/sps_e/spshand_e.pdf. The guidelines are non-binding and are not intended as a legal interpretation of the relevant provisions of the SPS Agreement.

used when notifying new SPS measures.[522] These guidelines have since been revised.[523] The new guidelines state that where previously notified measures are changed so as to apply to new Members or new products they should be re-notified by means of the submission of a Revision. An additional sixty days are allowed for comments. The revision was originally proposed by New Zealand in response to an implementation proposal of Brazil,[524] which called for the re-notification of measures if they may have negative trade effects on trade opportunities of developing countries.[525]

Other proposals being considered for the amendment of the notification guidelines relate to the notification of special and differential treatment. These are, first, the proposal of Egypt to include a box on special and differential treatment in the notification formats, where Members should indicate *ex ante* what special treatment they are providing to affected developing countries.[526] Second, there is a Canadian proposal to oblige Members, *ex post*, to notify requests for special and differential treatment arising from their notified measures, indicating whether such treatment has been provided, giving reasons in case of a refusal to do so.[527] It is interesting to note that the Secretariat is obliged, under paragraph 9 of Annex B, to draw the attention of developing country Members to any notifications relating to products of particular interest to them. As it is difficult for the Secretariat to establish which notifications affect products significant to developing countries, it fulfils this obligation by circulating, to all Members, monthly lists of notifications.

3. Request for Reasons for SPS Measures (Article 5.8)

An additional provision in the SPS Agreement that contributes to transparency is Article 5.8. According to this provision, an exporting Member may request an importing Member to provide reasons for the latter's SPS measure where it is not based on international standards and it constrains or could potentially constrain exports. The importing Member is then obliged to provide such reasons.

This obligation is significant as it can assist a Member in establishing a *prima facie* case that another Member's SPS measure is not based on a risk assessment or sufficient scientific evidence. In *Japan—Agricultural Products*, the Appellate Body noted the

[522] Committee on Sanitary and Phytosanitary Measures, *Recommended Notification Procedures,* G/SPS/7/Rev.1, November 26, 1999.

[523] Committee on Sanitary and Phytosanitary Measures, *Recommended Notification Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7),* G/SPS/7/Rev.2, April 2, 2002. This revision was adopted at the SPS Committee meeting of meeting of March 19–21, 2002.

[524] Committee on Sanitary and Phytosanitary Measures, *Agreement on the Application of Sanitary and Phytosanitary Measures. Proposal by Brazil,* G/SPS/W/108, June 22, 2001.

[525] Brazil's proposal followed a dispute with Canada in February 2001 due to a ban by Canada of Brazilian beef imports due to BSE concerns. The ban was based on a previously notified regulation and was therefore not notified to the WTO although it was applied to Brazil for the first time. ICTSD, *SPS Committee Resolves Implementation Issue, Discusses Biotech,* 6(11) BRIDGES WEEKLY TRADE DIGEST March 26, 2002.

[526] This proposal was supported by many developing countries, who believe it would encourage developed countries to build into their measures leniency for developing countries, such as longer compliance periods. Developed countries (EC, Canada, U.S.) questioned whether this would be effective in ensuring special and differential treatment.

[527] The Egyptian proposal was carried forward to the next meeting of the SPS Committee, where Canada set out its proposal (contained n G/SPS/W/127) that the special and differential treatment provided by a Member be notified later, by means of an addendum to the original notification. After amendments to this proposal following comments by Members, the revised proposal was adopted at the meeting of March 24, 2004 (G/SPS/W/132/Rev.2) provided no objections were raised. Malaysia objected to the adoption, due to the fact that it places the onus on the developing country to raise its concerns regarding the notified measure. At the SPS Committee meeting of June 22–23, 2004, Members again failed again to reach agreement on the Canadian proposal due to opposition of Malaysia.

following with respect to the establishment of a *prima facie* case under Article 2.2:

> (. . .) The United States could have requested Japan, pursuant to Article 5.8 of the *SPS Agreement*, to provide "an explanation of the reasons" for its varietal testing requirement, in particular, as it applies to apricots, pears, plums and quince. Japan would, in that case, be obliged to provide such explanation. The failure of Japan to bring forward scientific studies or reports in support of its varietal testing requirement as it applies to apricots, pears, plums and quince, would have been a strong indication that there are no such studies or reports.[528]

4. Infrastructure for Transparency

Members are further required to create the infrastructure necessary for the implementation of their notification obligations. Under Annex B.10, Members must designate a single central government authority as responsible for implementing the notification procedures in Annex B.5–8 on a national level. The Secretariat regularly updates and circulates lists of Members' National Notification Authorities.[529]

Also as part of the infrastructure necessary for transparency, the SPS Agreement obliges each Member to establish a national Enquiry Point. The Secretariat maintains an updated list of Enquiry Points, which it circulates to Members.[530] A Member's national Enquiry Point must provide answers to all reasonable questions from other Members as well as provide relevant documents regarding: any adopted or proposed SPS measures in its territory; the risk assessment basis for the measure; control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures; and the Member's participation in international or regional SPS systems as well as bilateral or multilateral agreements within the scope of the SPS Agreement. Requested copies of documents must be supplied to other Members at the same price as to nationals.

By June 18, 2004, of the then 147 WTO Members, 127 had established National Notification Authorities and 136 had established Enquiry Points.[531]

In order to address the problems that Members experience with the operation of Enquiry Points, the SPS Committee has held a special meeting on this issue in June 2003. Prior to the meeting, a questionnaire was circulated by the Secretariat on the operation of Enquiry Points and National Notification Authorities, to which eighty responses were received. At the meeting, officials from Members' Enquiry Points and National Notification Authorities came together for in-depth discussions focusing on the problems encountered with the operation of these bodies and the identification of possible solutions.[532] The Secretariat will use the information gathered to identify best practice models to help developing countries operate their Enquiry Points effectively.

B. Control, Inspection and Approval Procedures (Article 8 and Annex C)

In addition to imposing SPS standards, countries also have mechanisms in place to check compliance with these standards and to approve new products. Where these mechanisms

[528] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 100, ¶ 137.
[529] These can be found in the G/SPS/NNA/* series of official WTO documents.
[530] These can be found in the G/SPS/ENQ/* series of official WTO documents.
[531] These numbers include the 25 Member States of the European Union, together with the European Communities, in respect of which a single Notification Authority, the European Commission Directorate General for Health and Consumer Protection, is responsible for notifications. Separate Enquiry Points have been notified for the European Communities and each of its Member States. See Committee on Sanitary and Phytosanitary Measures, *Implementation of the Transparency Obligations as of 18 June 2004, Note by the Secretariat, Revision,* G/SPS/GEN/27/Rev.13, June 21, 2004.
[532] Committee on Sanitary and Phytosanitary Measures, *Special Meeting of the SPS Committee on the Operation of Enquiry Points held on 31 October 2003,* G/SPS/R/32, February 6, 2004.

are complex and lengthy, they may effectively restrict market access. They may also be duplicative of domestic conformity assessment procedures in the exporting country, unnecessarily adding to the costs of exportation. Thus the SPS Agreement establishes rules in Article 8 and Annex C to prevent Members from using technical procedures to monitor compliance with their SPS standards as a way to restrict the importation of foreign products. According to Article 8, Members must comply with Annex C as well as the other provisions of the SPS Agreement in the operation of their control, inspection and approval procedures. This includes their national systems for approval of additives and establishment of tolerances for contaminants in food, beverages and feedstuffs.

Annex C contains the detailed rules applicable to control, inspection and approval procedures. These are mainly aimed at ensuring that the procedures are not more lengthy or burdensome than reasonable and necessary and do not discriminate between imports and like domestic products. In addition, Members may not charge fees for the control, inspection or approval procedures that are higher than the actual cost of the service. A review procedure must be in place for complaints regarding the operation of the control, inspection or approval procedure. Where Members require approval for the use of additives or have a system in place for the determination of tolerances for contaminants, they are encouraged to use the relevant international standard as the basis for allowing importation until a final determination is made.[533] In addition, exporting Members are obliged to facilitate the work of other Members' controlling authorities on their territories where the SPS measure relates to control at the level of production.

The relevance of these disciplines on control, inspection and approval procedures can be illustrated by the following example. In a meeting of the SPS Committee in November 2000, Thailand raised its concerns in respect of Australia's pre-shipment inspection requirements for durian fruit. Australia required that for shipments of less than 1000 fruits, samples of 450 fruits be randomly selected and cut open to check for the presence of seed borers and for shipments of more than 1000 fruits, samples of 600 fruits be thus cut open. The result was that, in many cases, for each fruit to be exported to Australia, a pre-shipment volume of two fruits was necessary, thus doubling the cost of durian in each shipment. Due to the existence of disciplines on control, inspection and approval procedures in the SPS Agreement, Thailand was able to raise its concerns before the SPS Committee regarding the compatibility of this measure with the provision in Annex C.1(e) which stipulates that any requirements for control, inspection and approval of individual specimens of a product must be limited to what is reasonable and necessary.[534] In its response to Thailand's statement,[535] Australia noted that its cutting requirement was in accordance with the internationally accepted approach. However, it noted that due to Thailand's concerns, the Australian authority had amended the proposed cutting

[533] This provision takes into account the fact that it is common practice among regulatory authorities to prohibit products containing new additives or contaminants until the exporter has established the safety of the additive or the tolerance level for the contaminant to the satisfaction of the authority in the country of import. Once the additive is approved or a tolerance level established for the contaminant, the product may be imported.

[534] Committee on Sanitary and Phytosanitary Measures, *Australia's Import Restrictions on Durian: Statement by Thailand at the Meeting of 8–9 November, 2000,* G/SPS/GEN/217, November 22, 2000, ¶ 3.1.

[535] Committee on Sanitary and Phytosanitary Measures, *Australia's Import Restrictions on Durian. Response from Australia to Thailand's Statement at the Meeting of 8–9 November 2000*, G/SPS/GEN/218, November 22, 2000 ¶¶ 6–7.

requirement to allow culled fruits to be included in the samples taken from the export shipment, thus reducing its economic impact.[536]

C. The SPS Committee (Article 12)

1. Composition

A Committee on Sanitary and Phytosanitary Measures (the "SPS Committee") is established under Article 12.1 of the SPS Agreement. The SPS Committee consists of representatives of all WTO Members[537] and takes its decisions by consensus. Observer status[538] is granted to governments that have observer status in higher WTO bodies as well as representatives from certain international intergovernmental organizations with a mandate in this area. Observers may be invited to speak at meetings and table papers, but do not participate in decision-making in the Committee. The SPS Committee is serviced by the Agriculture and Commodities Division of the WTO Secretariat. The SPS Committee usually holds three meetings per year, and may convene informal meetings as necessary.

2. Functions

In terms of Article 12.1, the SPS Committee has as its goal to provide a regular forum for consultations and further the implementation of the SPS Agreement and the achievement of its aims, in particular the harmonization of SPS measures.[539] The specific tasks of the SPS Committee in the fulfillment of these objectives are elaborated in the other paragraphs of Article 12.

(a) Forum for Consultations (Article 12.1). Article 12.2 mandates the SPS Committee to encourage and facilitate consultations between Members on specific SPS issues. Coupled with the transparency obligations, this provision may go a long way towards helping countries to solve SPS conflicts in a low-cost manner, without resort to dispute settlement. Discussions on notified changes in SPS legislation take place, with concerns being raised by exporting Members and clarifications given by the Member imposing the measure.[540] This could lead to the revision of the notified measure or further bilateral consultations between the Members involved. In this way, disputes can be resolved without recourse to the expensive and time-consuming process of formal dispute settlement. In a

[536] However, at a recent meeting of the SPS Committee in June 2002, Thailand reiterated its concern regarding the cutting requirement and the excessive sample size. Australia indicated that it was willing to consider alternatives to destructive sampling if their efficacy was shown. Joint trials indicated that x-ray technology was promising and Australia agreed to keep the SPS Committee informed in this regard. *See* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25–26 June 2002, Note by the Secretariat*, G/SPS/R/27, August 2, 2002, ¶¶ 133–134.

[537] Members may send representatives of their choice, and normally send officials from their food safety authorities or veterinary or plant health officials.

[538] Criteria used in decisions to grant observer status are: the mandate, scope and area of work of the applicant organization and reciprocity with regard to the grant of observer status to the WTO. Committee on Sanitary and Phytosanitary Measures, *Criteria for Observer Status,* G/SPS/GEN/229, February 23, 2001.

[539] In terms of this power, the SPS Committee adopted the Equivalence Decision in 2001, in order to facilitate the implementation of Article 4 of the SPS Agreement. This decision is further discussed *supra* Part II(G)(1)(i).

[540] The Secretariat provides a summary of all specific trade-related concerns raised in the SPS Committee, together with an indication of the resolution of the issue, if notified. Committee on Sanitary and Phytosanitary Measures, *Specific Trade Concerns: Note by the Secretariat. Revision,* G/SPS/GEN/204/Rev.2, February 15, 2002.

recent study[541] it was shown that approximately 120 SPS issues have been raised in the SPS Committee, almost half involving complaints by developing countries or transition economies.[542]

(b) Monitoring and Encouraging the Process of Harmonization (Article 12.2–12.6). Article 12 of the SPS Agreement allocates various tasks to the SPS Committee regarding the process of international harmonization of SPS standards. It must encourage the use of international standards, guidelines and recommendations by all Members, and sponsor technical consultation and study in this regard.[543] It must also maintain close contact with the three main international standard-setting organizations in order to obtain the best possible scientific advice for the administration of the SPS Agreement and avoid duplication of effort.[544] Further, the SPS Committee must develop a procedure to monitor the process of international harmonization and the use of international standards.[545] A provisional procedure was established[546] and extended three times.[547] In conformity with this procedure,[548] the SPS Committee draws up annual reports based on information and comments from Members and international standard-setting organizations regarding the use of existing international standards, the need for new international standards and work on the adoption of such standards. Further, to avoid duplication, Article 12.5 allows the SPS Committee to use information gathered by the international organizations. Finally, on the initiative of a Member the Committee may, in terms of Article 12.6, invite the international organizations to examine specific matters with regard to a particular standard, guideline or recommendation, including the basis for explanations of non-use of the standard.

(c) Periodic Review of the Operation and Implementation of the SPS Agreement (Article 12.7). The SPS Committee is obliged by Article 12.7 to review the operation and implementation of the SPS Agreement three years after its entry into force, and thereafter as the need arises. Where appropriate, the SPS Committee may make proposals to the Council for Trade in Goods regarding amendments to the SPS Agreement. The SPS Committee established a procedure for this review[549] and the first review was conducted in 1998, resulting in a report of the SPS Committee.[550] However, no amendments were

[541] Micheal Friis Jensen, *Reviewing The SPS Agreement: A Developing Country Perspective,* Working Paper 02.3, Centre for Development Research (2002), at 18, table 1.
[542] It is however, significant that almost all developing country complaints come from the developing countries that are part of the Cairns group of agricultural exporting Members and from India and Mexico, while African and least-developed country complaints are almost non-existent. *Id*.
[543] Article 12.2 of the SPS Agreement.
[544] Article 12.3 of the SPS Agreement.
[545] Article 12.4 of the SPS Agreement.
[546] Committee on Sanitary and Phytosanitary Measures, *Procedure to Monitor the Process of International Harmonization: Decision of the Committee,* G/SPS/11, October 22, 1997.
[547] Committee on Sanitary and Phytosanitary Measures, *Decision to Extend the Provisional Procedure to Monitor the Process of International Harmonization: Decision of the Committee of 8 July, 1999,* G/SPS/14, July 12, 1999; Committee on Sanitary and Phytosanitary Measures, *Decision to Extend the Provisional Procedure to Monitor the Process of International Harmonization,* G/SPS/17, July 19, 2001.
[548] *Procedure to Monitor the Process of International Harmonization, supra* note 545, ¶ 10.
[549] Committee on Sanitary and Phytosanitary Measures, *Procedure to Review the Operation and Implementation of the Agreement,* G/SPS/10, October 21, 1997.
[550] Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures: Report of the Committee,* G/SPS/12, March 11, 1999.

proposed as a result of this review. The SPS Committee noted that the review had not been comprehensive and recognized that Members could raise any issue for the consideration of the Committee at any time.

The Ministerial Decision on Implementation adopted in Doha, instructs the SPS Committee to review the operation and implementation of the SPS Agreement at least once every four years.[551]

The WTO Secretariat has noted that, as a result, the report of the next review should be prepared for the Sixth Session of the Ministerial Conference. It has therefore proposed a procedure for the review process, in consultation with the Chairman of the SPS Committee. This procedure consists of a series of informal meetings, back-to-back with the regular SPS Committee meetings, where issues identified by Members will be discussed. Members will be invited to submit papers in advance of the meetings and the Chairman will report on the results of the meetings to the each regular SPS Committee meeting.[552]

3. Overview of Work (1995–2002)

Each year, the SPS Committee holds an average of three regular committee meetings. In addition, it holds informal meetings to discuss specific issues as the need arises. At each regular meeting, specific trade concerns raised by Members are discussed, often in response to notifications received and circulated by the SPS Committee under the transparency provisions of Article 7 and Annex B.[553] In addition, there are standing items on the agenda of SPS Committee meetings relating to technical assistance and special and differential treatment for developing countries and the use of international standards, and Members are encouraged to raise concerns they may have in these areas and report on progress made.

Since the entry into force of the SPS Agreement through October 1, 2003, the SPS Committee received and circulated over 3,600 notifications of SPS measures.[554] In addition, it adopted non-binding guidelines for the implementation of Article 5.5.[555] The Committee adopted and revised recommended procedures for notification,[556] including notification of equivalence agreements,[557] as well as a procedure for the monitoring of harmonization. It has drawn up six annual reports on the monitoring of harmonization. The SPS Committee maintains close working relationships with the CAC, OIE and IPPC and receives regular updates of their activities. The SPS Committee also conducts informal consultations with various international intergovernmental organizations on the recognition of their observer status at meetings of the SPS Committee. Regular observer status has been granted to the CAC, OIE, IPPC, Food and Agriculture Organization, World Health Organization, International Organization for Standardization, International Trade

[551] Ministerial Conference, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001 ¶ 3.4.

[552] Committee on Sanitary and Phytosanitary Measures, *Proposed Process for the Review of the Operation and Implementation of the Agreement, Note by the Secretariat,* G/SPS/W/147, June 10, 2004.

[553] The specific trade concerns raised are summarized in revisions of document G/SPS/GEN/204 (in revision 4 at the time of writing).

[554] World Trade Organization, *Report (2003) on the Activities of the Committee on Sanitary and Phytosanitary Measures,* G/L/661, November 18, 2003, ¶ 6. This report also notes that in the period January 1, 2003 to October 1, 2003, over 650 notifications were received.

[555] *See supra* note 366.

[556] *See supra* note 522.

[557] Committee on Sanitary and Phytosanitary Measures, *Notification of Determination of the Recognition of Equivalence of Sanitary or Phytosanitary Measures, Decision by the Committee. Addendum,* G/SPS/7/Rev.2/Add.1, July 25, 2002.

Center, United Nations Conference on Trade And Development, World Bank, International Monetary Fund and observer status on an *ad hoc* meeting-by-meeting basis to the group of African, Caribbean and Pacific countries, European Free Trade Association, Inter-American Institute for Cooperation on Agriculture, Organization for Economic Cooperation and Development, Regional International Agricultural Health Organization, and Latin American Economic System. Existing requests for observer status from the International Organization for Vine and Wine, the Asia Pacific Coconut Community, and the Convention on Biodiversity and its Cartagena Protocol on Biosafety[558] continued to be considered.

In 2001, the Committee adopted the Equivalence Decision in terms of its powers under Article 12.1 and has adopted a future work program on the subject of equivalence. In terms of this work program, the Committee, as discussed above, has adopted clarifications to the Equivalence Decision.[559] As mentioned above, work regarding regionalization under Article 6 of the SPS Agreement is currently ongoing. The SPS Committee also circulated a questionnaire in July 1999 on the subject of technical assistance, to gather information on technical assistance that Members have asked for, received and provided in relation to the implementation of the SPS Agreement.[560] In October 2001, a second questionnaire was circulated to identify the technical assistance needs of developing countries.[561] The SPS Committee has also considered various proposals regarding special and differential treatment which the General Council referred to it in May 2003, and has established a work plan for the consideration of these proposals. It has reported to the General Council on the progress made in this regard.[562]

At its meetings of November 7–8, 2002, and October 29–30, 2003, the SPS Committee conducted a transitional review, under paragraph 18 of the Protocol of Accession of the Peoples Republic of China. Under this review, Members put questions in writing to China regarding its implementation of the SPS Agreement. China responded both to these questions and to others raised in the meeting.[563]

D. Dispute Settlement (Article 11)

In order to enforce their rights under the SPS Agreement, Article 11.1 provides that Members can have recourse to the dispute settlement system of the WTO, as embodied in Articles XXII and XXIII of GATT 1994 and elaborated in the Dispute Settlement Understanding (the "DSU"), except as otherwise specifically provided in the SPS Agreement. Thus, the DSU applies fully and unconditionally to disputes under the SPS Agreement.[564] In addition, Article 11.3 provides that nothing in the SPS Agreement impairs Members' rights under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations

[558] World Trade Organization, *Report (2003) on the Activities of the Committee on Sanitary and Phytosanitary Measures,* G/L/661, November 18, 2003, ¶ 11.
[559] *See supra* note 500.
[560] Committee on Sanitary and Phytosanitary Measures, *Questionnaire on Technical Assistance: Note by the Secretariat,* G/SPS/W/101, July 23, 1999.
[561] Committee on Sanitary and Phytosanitary Measures, *Questionnaire on Technical Assistance,* G/SPS/W/113, October 15, 2001.
[562] These reports were circulated as G/SPS/27 and G/SPS/30.
[563] World Trade Organization, *Report (2003) on the Activities of the Committee on Sanitary and Phytosanitary Measures,* G/L/661, November 18, 2003, ¶ 10.
[564] The dispute settlement system is discussed in detail in Chapters 25 *et seq.* of this book. Here attention will only be given to specific aspects applicable to SPS disputes.

or established under any international agreement. In addition to the normal rules of the DSU, the SPS Agreement contains a special provision with regard to dispute settlement, dealing with the authority of panels to seek expert advice.[565]

Three issues regarding the settlement of disputes arising under the SPS Agreement deserve particular attention: the burden of proof; the standard of review; and the use of scientific experts and expert review groups.

1. Special Dispute Settlement Rules and Procedures

(a) Burden of Proof. Due to the complexity of the facts and scientific evidence in SPS disputes, the question of which party bears the evidentiary burden is particularly significant in cases involving health measures. In *EC—Hormones* the Appellate Body emphasized the importance of this issue, in the light of the "multiple and complex issues of fact" that may arise under the SPS Agreement.[566]

The Appellate Body first set out the burden of proof rules generally applicable in WTO disputes in *U.S.—Wool Shirts and Blouses*.[567] There it recognized that various international tribunals and most national jurisdictions apply the rule that the party that asserts a fact, whether plaintiff or respondent, must prove it. Once a party has adduced sufficient evidence to create a presumption that what is claimed is true, in other words has established a *prima facie* case, the evidentiary burden shifts to the other party who must rebut the presumption or lose the case. In *EC—Hormones* the Appellate Body held that this rule applies equally to disputes under the SPS Agreement. It rejected the Panel's finding that the SPS Agreement allocates the burden of proof to the Member imposing the SPS measure.[568]

The question of the burden of proof under the SPS Agreement arose again in *Japan—Agricultural Products.*[569] The Panel found that Japan's varietal testing requirement was maintained without "sufficient scientific evidence" contrary to Article 2.2, with regard to apples, cherries, nectarines and walnuts.[570] However, it did not consider that there was sufficient evidence before it to extend this finding to apricots, pears, plums and quince. This was due to the fact that the parties had not submitted any evidence for the latter products. The Panel had also asked the experts advising it whether their statements

[565] Article 11.2 of the SPS Agreement, discussed *infra* Part III(D)(b). Article 1.2 of the DSU provides that its rules and procedures apply subject to such additional rules and procedures on dispute settlement as are identified in Annex 2 to the DSU. Article 11.2 of the SPS Agreement is one of the provisions identified in Annex 2 of the DSU.

[566] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 97.

[567] Report of the Appellate Body, *United States—Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R (1997), 14–16.

[568] In *EC—Hormones*, *supra* note 70, ¶¶ 102–105, the Appellate Body dealt with the three grounds for the Panel's finding in turn. First, it rejected the Panel's conclusion that the fact that many SPS provisions are worded "Members shall ensure that . . . " has any logical connection to the allocation of the evidentiary burden. Second, contrary to the Panel's ruling, it held that Article 5.8 (pursuant to which a Member may ask for an explanation of an SPS measure from another Member and the latter is obliged to comply with the request) does not address burden of proof issues. Instead Article 5.8 is most likely to be used in pre-dispute situations in order to enable a Member to acquire information that it could later use to meet its burden of proof. Third, the Appellate Body dismissed as a *non-sequitur* the reverse inference made by the Panel from Article 3.2, that if a measure does not conform to international standards, the Member imposing the measure bears the burden of proving its consistency with the SPS Agreement in case of a challenge.

[569] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶¶ 132–139.

[570] Report of WTO the Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 57, ¶ 8.45.

with regard to the former group of products applied to the latter as well. The experts affirmed this but did not elaborate. Thus the Panel found that the United States had not adduced sufficient evidence to raise a presumption (i.e. make a *prima facie* case) that the measure was maintained without sufficient scientific evidence with regard to apricots, pears, plums and quince.

The United States appealed this ruling, arguing that the Panel's interpretation imposed on it an impossible burden of proof, requiring it to prove a negative (namely that there were no relevant studies or reports supporting Japan's measure). The United States contended that the Panel's finding amounted to holding that because there was insufficient evidence of the existence or relevance of varietal differences, the Panel could not find that there was insufficient evidence to support the measure.[571] The Appellate Body rejected this argument, finding that the United States was not being required to prove a negative, but merely to raise a presumption that there were no relevant studies or reports. According to the Appellate Body, this is not an impossible burden. The United States could have requested Japan, under Article 5.8, to provide an "explanation of the reasons" for its measure as it related to the products at issue. The failure of Japan to do so would have amounted to a strong indication that such studies or reports did not exist. Further, the United States could have questioned the Panel's experts or submitted an opinion of its own experts on the question whether such reports exist. Instead, the United States submitted no evidence on the point. Therefore, the Appellate Body agreed with the Panel's refusal to find a violation of Article 2.2 with regard to the products at issue.[572]

This decision is significant as it establishes that it is the challenging Member's duty to make a *prima facie* case for the absence of scientific evidence in support of an SPS measure. Only once this has occurred does the defending Member have to submit evidence to rebut this presumption. A mere contention that scientific evidence is lacking and an omission to submit any evidence are insufficient to create a duty of rebuttal. It would be too onerous to require Members to defend their SPS measures on the basis of scientific evidence without any indication that the measures violate the SPS Agreement.

The issue of burden of proof arose again in *Japan—Apples*. In that case, the US had argued that there was insufficient scientific evidence, for purposes of Article 2.2, that mature, symptomless apples could form a transmission pathway for fire blight. To counter these arguments, Japan averred that, due to failures in export control systems, infected or immature apples could be exported, and these apples could serve as a pathway for fire blight. The US limited its arguments to the issue of mature, symptomless apples. On the basis of the scientific evidence presented to it, the Panel agreed with the US that Japan's measure, as it applied to mature, symptomless apples, was maintained without sufficient scientific evidence and concluded that it had not been established with sufficient scientific evidence that infected or immature apples could serve as a pathway for the transmission of fire blight.[573] On appeal, Japan argued that the Panel had erred in shifting the burden of proof to Japan in respect of infected or immature apples before the US had made a *prima facie* case in that regard. The Appellate Body rejected Japan's contention, holding:

[571] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 38.
[572] *Id.* ¶ 137.
[573] This was due to the fact that Japan did not present sufficient scientific evidence that the last stage of the transmission pathway of fire blight from the infected imported apple to the host plant, was likely to be completed. Report of the WTO Panel, *Japan—Measures Affecting the Importation of Apples, supra* note 57, ¶ 8.168.

> It is important to distinguish, on the one hand, the principle that the complainant must establish a *prima facie* case of inconsistency with a provision of a covered agreement from, on the other hand, the principle that the party that asserts a fact is responsible for providing proof thereof. In fact, the two principles are distinct. In the present case, the burden of demonstrating a *prima facie* case that Japan's measure is maintained without sufficient scientific evidence, rested on the United States. Japan sought to counter the case put forward by the United States by putting arguments in respect of apples other than mature, symptomless apples being exported to Japan as a result of errors of handling or illegal actions. It was thus for Japan to substantiate those allegations; it was not for the United States to provide proof of the facts asserted by Japan. Thus, we disagree with Japan's assertion that "the shift of the burden of proof to Japan was made prematurely *before* the demonstration of a *prima facie* case by the United States." There was no "shift of the burden of proof" with respect to allegations of fact relating to apples other than mature, symptomless apples, for Japan was solely responsible for providing proof of the facts it had asserted. Moreover, it was only after the United States had established a *prima facie* case that Japan's measure is maintained without sufficient scientific evidence, that the Panel had to turn to Japan's attempts to counter that case.[574]

This finding is useful in clarifying the issue of the burden of proof in cases where there are several hypotheses regarding the perceived risks underlying an SPS measure. It is not necessary for the complainant to address all possible hypotheses and establish that there is insufficient evidence of risk for each.[575] According to the Appellate Body in this case, the Panel had evidently found it sufficient for the US to address whether mature symptomless apples could serve as a transmission pathway for fire blight. It noted, referring to its previous finding in *US-Wool Shirts and Blouses* that "the nature and scope of evidence required to establish a *prima facie* case 'will necessarily vary from measure to measure, provision to provision, and case to case.'"[576]

Once a *prima facie* case is established, the respondent will bear the burden of proving the allegations it makes to refute the complainant's case.

Aside from the general issue of the burden of proof under the SPS Agreement, the harmonization provision contained in Article 3 presents interesting specific burden of proof issues. In *EC—Hormones* the Panel derived, from the presumption of consistency in favor of a measure that conforms to an international standard in Article 3.2 and from its finding of a rule/exception relationship between Articles 3.1 and 3.3, a burden of proof for a defending Member whose SPS measure deviates from the relevant international standard.[577] The Appellate Body rejected this finding as having no textual basis. It denied that Article 3.3 embodies an exception to the general rule contained in Article 3.1, finding that the relationship between Articles 3.1, 3.2 and 3.3 is qualitatively different from that between Articles I or III (non-discrimination obligations) and Article XX, (exceptions) of GATT 1994. Instead, it held that Article 3.1 of the SPS Agreement merely excludes from its scope situations falling under Article 3.3. Article 3.3 contains an autonomous option available to Members and it is for the challenging Member to prove the failure

[574] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 157 (footnotes omitted).
[575] This was argued by Japan but rejected by the Appellate Body. *Id.*, ¶ 159.
[576] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 160. In footnote, the Appellate Body referred to the Appellate Body Report, p. 14, DSR 1997:I, 323, at 335
[577] Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by the United States, *supra* note 53, ¶¶ 8.54 and 8.87–7; Report of the WTO Panel, *EC—Measures Concerning Meat and Meat Products (Hormones),* Complaint by Canada, *supra* note 53, ¶¶ 8.57 and 8.89–8.90.

to meet conditions laid down in Article 3.3 with respect to SPS measures not based on international standards.[578] To hold otherwise would result in penalizing a Member who chooses a higher level of protection than that aimed at by the international standard, a right expressly recognized in the Preamble of the SPS Agreement.[579] The Appellate Body's ruling on the burden of proof pursuant to Article 3 is particularly important in the light of the problematic aspects, discussed elsewhere, of standard setting by international bodies.[580]

A second question raised by Article 3 is that of the consequences of the presumption of consistency with the SPS Agreement and GATT 1994, for measures that conform to the relevant international standards contained in Article 3.2. Clearly, this provision is intended to encourage Members to adopt international standards, thus resulting in increasing harmonization of SPS measures and promoting free trade. In *EC—Hormones*, the Appellate Body held this presumption to be rebuttable.[581] However, it would seem that a higher standard of proof would be required from the challenging Member due to this presumption than would be the case if the challenging Member only had to establish a *prima facie* case of inconsistency. Bearing in mind the difficulties of meeting the requirements for a risk assessment under the SPS Agreement, particularly for developing countries that often lack the necessary scientific expertise, this constitutes a considerable advantage and thus a strong incentive to adopt international standards.

(b) Consultation with Experts (Article 11.2). Disputes between WTO Members, including those under the SPS Agreement, are heard by dispute settlement panels, which are usually composed of trade diplomats or academics with an expertise in international trade law.[582] In SPS disputes, these panelists are often faced with complex scientific issues of fact. An attempt to deal with the lack of scientific expertise of panelists is reflected generally in Article 13 of the DSU, and for SPS matters more specifically in Article 11.2 of the SPS Agreement. Article 13.1 of the DSU authorizes panels to seek information and technical advice from any individual or body. Article 13.2 allows panels to seek information from any source and to consult experts or request advisory reports.[583] Article 11.2 of the SPS Agreement states that in SPS disputes involving scientific or technical issues, a panel should consult experts chosen by it in consultation with the parties. For this purpose, the panel may set up advisory technical experts groups or consult relevant international organizations.

In *EC—Hormones*[584] the Appellate Body affirmed the panel's right to receive opinions from experts in their individual capacity rather than set up expert review groups. Articles

[578] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 104.

[579] ¶ 6 of the Preamble to the SPS Agreement provides: "Desiring to further the use of sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by international organizations. . . without requiring Members to change their appropriate level of protection of human, animal or plant life or health."

[580] Certain concerns regarding the standard setting process in international organisations have been mentioned *supra* Part II(C)(1)(a). *See* also *infra* Part IV(B)(1) regarding the problems that developing countries face in participating effectively in international standard setting.

[581] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 170.

[582] The composition of panels is dealt with in Article 8 of the DSU.

[583] The rules and procedures applying to expert review groups are laid down in Appendix 4 of the DSU.

[584] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 147.

11.2 and Article 13.2 of the DSU, together with Appendix 4, do not limit this right. These provisions leave it to the discretion of the panel to determine whether an expert review group should be established. Both provisions require the panel to consult the parties to the dispute in the selection of experts. Since experts were chosen in terms of procedures agreed upon by the parties in this case, the Appellate Body found that the Panel had acted consistently with the Article 13.2 and Appendix 4 of the DSU and Article 11.2 of the SPS Agreement.

To date, in all three disputes heard under the SPS Agreement, the panels have consulted individual experts rather than set up expert review groups. This was partly due to the time constraints in the dispute settlement procedure. If time had to be provided for an expert review group to reach an agreement on scientific issues, it is probable that the tight deadlines within which panels should reach a decision would be far exceeded. In addition, panelists were interested in hearing the individual opinions of the scientists consulted in each case. In this regard, it should be noted that scientists consulted individually are more likely to provide a clear picture of the state of scientific knowledge on an issue, particularly when there is a divergence in scientific opinion. The views of scientists reflect the scientific tradition of which they are a part.[585] It is therefore important for the panel to hear from a variety of scientists rather than only hear a final consensus opinion arrived at within an expert review group. An expert review group is less conducive to understanding the range of possible interpretations of scientific data.[586]

In *Japan—Agricultural Products*[587] the Appellate Body examined the interaction between the obligation of a party to prove a *prima facie* case of inconsistency and the investigative authority of a panel. The United States argued that Japan's varietal testing requirement was more trade restrictive than required to meet Japan's appropriate level of protection, contrary to Article 5.6. It claimed that testing by product was an alternative measure, meeting the Article 5.6 requirements. The Panel found that this measure would not meet Japan's appropriate level of protection. However, it went on to deduce another alternative measure, namely the determination of sorption levels, which had neither been claimed nor argued by the United States, from the opinions given by its expert advisors.[588] Although the Panel acknowledged that the United States had not argued that the determination of sorption levels met any of the three requirements of Article 5.6, it held that it could be presumed that the requirements were met and that the United States had offered views consistent with this.

This finding was appealed and the Appellate Body found that the United States was obliged to establish a *prima facie* case that an alternative measure exists meeting all three requirements of Article 5.6. Since the United States had not claimed that determination of sorption levels was such a measure, it had not complied with this obligation. The Appellate Body recognized that a panel is entitled under Article 13 of the DSU to seek

[585] According to Atik, *supra* note 201, at 757, scientists are more likely to recognize a scientific justification for a measure where the scientific assertion is accepted in the scientific community to which they belong. *See* Wirth for an interesting discussion on the problematic nature of adjudication in respect of scientific controversies. Wirth, *supra* note 23, at 841–845.

[586] *Contra see* Joost Pauwelyn, *The Use of Experts in WTO Dispute Settlement*, 51 INTERNATIONAL AND COMPARATIVE LAW QUARTERLY 325, 327–329 (2002) and Theofanis Christoforou, *Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, NEW YORK UNIVERSITY ENVIRONMENTAL LAW JOURNAL 622 (2000).

[587] Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶¶ 120–131.

[588] Report of the WTO Panel, *Japan—Measures Affecting Agricultural Products*, *supra* note 57, ¶ 8.74.

information from any relevant source and to consult experts, and that it is instructed under Article 11.2 of the SPS Agreement to seek expert advice in technical and scientific matters. However, it held that this authority cannot be used to rule in favor of a party that has not established a *prima facie* case of inconsistency. The expert advice sought by the Panel is intended to help it understand and evaluate the evidence submitted and arguments made by the parties, not to make the complainant's case for it.

In *Japan—Apples*, Japan referred to this finding by the Appellate Body to challenge on appeal the Panel's use of experts. Japan argued that the US had not made claims or submitted evidence in respect of the risk of transmission of fire blight by apples other than mature symptomless apples, yet the Panel had made findings of fact with regard to these "other" apples. Japan claimed that the Panel had thus exceeded the bounds of its investigative authority.[589] The Appellate Body rejected Japan's argument, finding that the Panel had acted within the limits of its investigative authority, as "it did nothing more than assess the relevant allegations of fact asserted by Japan, in the light of the evidence submitted by the parties and the opinions of the experts."[590] It thus clarified that a panel may use the evidence of its experts to assist it in assessing not only the claims of the complaining Member, but also the allegations of the responding Member. In doing so, it cannot be said to be exceeding its authority under Article 11.2.

These findings are important in clarifying the respective roles of the panel, the experts and the parties. It establishes that a panel procedure is adversarial, with the panel acting as an impartial arbiter, rather than the inquisitor, A panel's investigative authority is meant only to help its own understanding and evaluation of the case presented by the parties. Thus the role of panel experts is limited to assisting the panel in its understanding of the complex issues before it. The evidence of these experts cannot be used to make the case for one of the parties.

(c) Standard of Review. The issue of the appropriate standard of review is important, as it raises the question of whether panels are entitled to interfere in a Member's regulatory determinations, or whether they must defer to such decisions and confine themselves to the question of whether procedural rules related to decision-making have been followed. This is crucial to establishing the limits of regulatory review and deference to national standards under the SPS Agreement.

In *EC—Hormones*[591] the question of the appropriate standard of review was first examined. The EC argued that the Panel had failed to apply the appropriate standard of review, which it asserted to be a "deferential reasonableness standard", as exists for the Anti-Dumping Agreement.[592] Under such a standard, the panel is not to substitute its judgment for that of the national investigative authority that led to the establishment of the measure. It must limit itself to determining whether the procedure set by WTO rules has been followed. Thus, if the Member has properly established the facts and conducted an objective, unbiased examination thereof, its conclusions should be deferred to by the panel, even if the panel would have reached a different conclusion based on the facts. The EC argued that the Panel had instead undertaken a *de novo* standard of review, under

[589] *Id.*, ¶ 158.
[590] *Id.*.
[591] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 133.
[592] Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade, Annex 1A to t he Marrakesh Agreement, reprinted in THE RESULTS OF THE URUGUAY ROUND, *supra* note 24, at 168–196, ("Anti-Dumping Agreement") at Article 17.6(i).

which it exercised complete freedom to examine the factual and procedural validity of the decision and to come to a different conclusion.

The Appellate Body rejected the application of the standard of review set in the Anti-Dumping Agreement to the SPS Agreement,[593] holding that this standard is textually specific to the former agreement and there is no evidence of an intention to adopt it in the latter agreement.[594] Instead, it focused on the need for the standard of review applied to the SPS Agreement to reflect the balance created in that agreement between the jurisdictional competences transferred by Members to the WTO and those retained by them. Neither a panel nor the Appellate Body is authorized to change this balance.[595]

The Appellate Body found that although the SPS Agreement is silent on the issue of the standard of review, Article 11 of the DSU articulates this standard both for the determination of the facts and the legal characterization of these facts.[596] The standard of review established by this article is neither total deference nor *de novo* review, but rather the "objective assessment of the facts" (with respect to fact-finding) and an objective assessment of the matter, including the applicability of and conformity with the relevant covered agreements (with respect to legal issues).

The issue of whether the appropriate standard of review was used thus depends, according to the Appellate Body in *EC—Hormones*, on whether there was an objective assessment of the matter, including an objective assessment of the facts.[597] It held that failure to conduct an objective assessment requires proof that there has been deliberate disregard of or refusal to consider submitted evidence or willful distortion or misrepresentation of the evidence.[598] These do not indicate a mere error of judgment but imply an egregious error, which calls into question the good faith of the panel. It is apparent that the Appellate Body will not lightly find that this element of bad faith is present, as can be seen from its findings in *EC- Hormones* that although the Panel had misquoted and misinterpreted the evidence,[599] its actions had not been

[593] This refusal to extend the standard of review laid down in the Anti-Dumping Agreement to other WTO agreements was affirmed in the Report of the Appellate Body, *United States—Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom,* WT/DS138/AB/R (2000), ¶ 51, where the Appellate Body held that Article 11 of the DSU sets the standard of review for disputes under the Agreement on Subsidies and Countervailing Measures.

[594] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70,¶ 114. Further, this standard applies only to the factual assessment of the matter and not to the legal analysis applied thereto.

[595] *Id.* ¶ 115.

[596] *Id.* ¶ 116.

[597] The utility of this "objective assessment" standard has been criticized on the grounds that it does not clarify the required standard of review. *See* Axel G. Desmedt, *Hormones: "Objective Assessment" and (or as) Standard of Review,* 1 JOURNAL OF INTERNATIONAL ECONOMIC LAW 695, 698 (1998).

[598] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 133.

[599] The Appellate Body in *EC—Hormones* agreed with the EC that the Panel had misquoted the evidence of an EC expert, Dr. Lucien. Further, in response to the EC's contention that the panel had distorted the views of Dr. André by stating that they supported those of the other panel experts when, in fact, they rather supported the views of EC scientists, the Appellate Body stated, "Whether or not the views of Dr. André support the statements made by the other Panel experts or the opinions expressed by the EC scientists may be an issue of fact; it does require some technical expertise to deal with it. However, even if the Panel has interpreted the views of Dr. André incorrectly, we see no reason, and no reason was advanced, to consider this mistake as a *deliberate disregard* or *distortion* of evidence." Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶¶ 138–139. Provided the mistake is not deliberate, it would appear that the Appellate Body grants some leeway to the panel based on its lack of "technical expertise".

deliberate and there had thus been no failure to make an objective assessment of the facts.[600]

Due to the scope given by the Appellate Body to the obligation to conduct an objective assessment, it is clear that panels have broad discretion in assessing the evidence before them and that it is difficult for parties to a dispute to challenge the assessment of the evidence made by panels. This is problematic when one bears in mind the composition of panels and their lack of expertise in scientific matters. The lack of certainty that often exists in the scientific arena means that a panel's ability to consult experts does not constitute a real safeguard against the possibility of mistakes. In *EC—Hormones*[601] the Appellate Body recognized that the panel had misrepresented the statements of its own expert advisors on the potential for abuse in a regime where the use of hormones was allowed. However as the mistake was not egregious, it did not amount to a failure to make an objective assessment of the facts.

The Appellate Body's decision on the standard of review thus has two problematic aspects. Firstly, the decision that the applicable standard of review is an "objective assessment" of the factual and legal aspects of the case, without a precise definition of what this standard entails, gives cause for concern. While this was held to mean neither complete deference nor *de novo* review, what it does mean is not clear aside from the fact that a panel must act in good faith. Secondly, since only "willful distortion" or "deliberate disregard" of evidence will constitute a failure to make an "objective assessment" of the facts, the situation could arise that a case is incorrectly decided on the basis of a good faith misunderstanding of scientific evidence by a panel, without this mistake constituting a ground for overturning the panel decision.

This is problematic since the disciplines of the SPS Agreement are primarily science-based, and thus cases decided under its provisions will most likely turn on the evaluation of scientific evidence. Since the Appellate Body may not review issues of fact on appeal, an appeal will not be able to correct this situation but will instead be decided on the basis of this mistaken understanding of the facts. In order to avoid this unacceptable situation, it seems imperative that the question of the appropriate standard of review under the SPS Agreement be reassessed to allow for deference to national decisions regarding the quality and weight of scientific evidence. Provided that the scientific support for a measure is plausible and comes from respected sources, and that a Member has met all the procedural requirements relating to the conduct of a risk assessment and setting an appropriate level of protection, a panel should refrain from evaluating the scientific evidence itself, a task for which it is demonstrably poorly suited.

An additional issue which arises with regard to the standard of review to be applied, is whether the precautionary principle should guide a panel's evaluation of the evidence before it. This issue arose in *Japan—Apples*. Japan argued, on appeal, that the Panel had failed to adequately take into account the precautionary principle in its evaluation of the evidence. The panel experts in this case had recognized the need for caution with respect to the elimination of the phytosanitary measures protecting Japan from fire blight. According to Japan, this fact should have been given greater weight by the Panel

[600] This trend continued in both *Australia—Salmon* and *Japan—Agricultural Products*, where errors of the Panel in the appreciation of evidence were not characterized by the Appellate Body as failures to make an objective assessment of the facts, due to lack of an egregious nature. *See* Report of the Appellate Body, *Australia—Measures Affecting the Importation of Salmon*, *supra* note 141, ¶ 266, and Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, *supra* note 97, ¶ 142.

[601] Report of the Appellate Body, *EC—Measures Concerning Meat and Meat Products (Hormones), supra* note 70, ¶ 144.

in considering the evidence regarding the completion of the transmission pathway for fire blight.[602] The Appellate Body noted that Japan did not argue that the precautionary principle should have been applied as distinct from the provisions of the SPS Agreement, nor did it argue that the Panel should have used the precautionary principle as part of its interpretative analysis of the Agreement. Instead, it understood Japan to argue that the principle was embodied in the cautionary opinions of the experts and *should have been given greater weight* in the Panel's conclusions on the completion of the pathway. The Appellate Body then noted that it is established case law that the credibility and weight to be properly ascribed to a particular piece of evidence is in the discretion of a panel as the trier of facts. This discretion is limited only by a panel's duty to make an "objective assessment" of the facts. Since Japan made no argument challenging the objectivity of the Panel's assessment, it failed to establish a violation of Article 11.[603]

This finding of the Panel reinforces the conclusion that the possible relevance of the precautionary principle for purposes of the SPS Agreement is limited to the particular formulation it has been given in Article 5.7. Outside this article, the precautionary principle plays no role, according to the case law, in guiding the interpretation of the SPS Agreement or the evaluation of the evidence. The standard of review to be applied by panels remains an "objective assessment" of the matter, even in cases of scientific uncertainty.

2. Overview of Dispute Settlement Relating to the SPS Agreement

To date (July 2004), there have been thirty formal complaints under the SPS Agreement regarding twenty-six separate issues, three of which only involved minor SPS issues. No African country or LDC has initiated a complaint under the SPS Agreement. Consultations are still pending in fifteen cases. A mutually agreed solution has been reported in six cases.[604] Eight disputes,[605] regarding five separate issues, have proceeded to adjudication by a panel under the SPS Agreement[606] and four panel reports have thus far been issued.[607] All of these have been appealed, resulting in four Appellate Body reports.[608]

[602] This evidence was considered for purposes of the Panel's finding under Article 2.2 SPS.

[603] Report of the Appellate Body, *Japan—Measures Affecting the Importation of Apples, supra* note 112, ¶ 283.

[604] *Korea—Measures Concerning the Shelf-Life of Products (Complaint by the United States)*, WT/DS5; *Korea—Measures Concerning Bottled Water (Complaint by Canada)*, WT/DS20; *Australia—Measures Affecting the Importation of Salmonids (Complaint by the United States)*, WT/DS21; *India—Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products (Complaint by the European Communities)*, WT/DS96; *Turkey—Certain Import Procedures for Fresh Fruit (Complaint by Ecuador)*, WT/DS237; and *Mexico—Certain Measures Preventing the Importation of Black Beans from Nicaragua (Complaint by Nicaragua)*, WT/DS284.

[605] These eight disputes are the separate complaints by the United States and Canada in *EC—Hormones* (WT/DS48, WT/DS26) that were heard by separate panels, composed of the same panelists, which issued separate but largely identical reports; the complaint by the United States in *Japan—Agricultural Products II* (WT/DS76); the complaint by Canada in *Australia—Salmon* (WT/DS18); the complaint by the United States in *Japan—Apples*, (WT/DS245), and the separate complaints by the United States, Canada and Argentina in *EC—Biotech* (WT/DS291, WT/DS292, WT/DS293) which is being heard by a single panel. This count does not include the compliance disputes under Article 21.5 DSU in *Australia—Salmon* (WT/DS18) and *Japan—Apples* (WT/DS245).

[606] The dispute *EC—Asbestos* (WT/DS135) also proceeded to adjudication by a panel and the Appellate Body, but the claims under the *SPS Agreement* were not pursued in the adjudication process.

[607] See the WTO Panel Reports in *EC—Hormones, Australia—Salmon, Japan—Agricultural Products,* and *Japan—Apples*. The findings in these cases have been discussed in previous sections where relevant.

[608] See the Appellate Body Reports in *EC—Hormones, Australia—Salmon, Japan—Agricultural Products,* and *Japan—Apples*. The findings in these cases have been discussed in previous sections where relevant.

One dispute is currently still before a panel.[609] Developing countries[610] have been involved in thirteen disputes, in nine cases as complainant[611] and in nine as defendant.[612] In only one of these disputes involving developing countries, namely *EC—Biotech Products*, has the dispute proceeded to adjudication.[613]

IV. Developing Countries and the SPS Agreement

The general disciplines of the SPS Agreement apply equally to developed and developing countries. However, the SPS Agreement does take into account the financial and technical resource constraints that developing countries face. This consideration finds its first reflection in the preamble to the SPS Agreement, which recognizes that:

> (. . .) developing country Members may encounter special difficulties in complying with sanitary and phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories, and desiring to assist them in their endeavors in this regard; . . . [614]

For this reason, special provisions exist that take into account the special position of developing countries. These provisions relate to the provision of technical assistance to developing countries as well as to special and differential treatment in favor of developing countries. In addition, some of the disciplines in the SPS Agreement contain elements of flexibility that can be used to the benefit of developing countries.[615]

[609] A panel was established on to address the complaints of the US, Argentina and Canada against the EC's measure with regard to the products of biotechnology (WT/DS291, 292 and 293).

[610] Developing countries here is interpreted broadly to include economies in transition.

[611] *Croatia—Measure Affecting Imports of Live Animals and Meat Products (Complaint by Hungary),* WT/DS297; *European Communities—Measures Affecting the Approval and Marketing of Biotech Products (Complaint by Argentina)*, WT/DS293; *Mexico—Certain Measures Preventing the Importation of Black Beans from Nicaragua (Complaint by Nicaragua)*, WT/DS284; *Australia—Certain Measures Affecting the Importation of Fresh Pineapple (Complaint by the Philippines),* WT/DS271; *Australia—Certain Measures Affecting the Importation of Fresh Fruit and Vegetables (Complaint by the Philippines),* WT/DS270; *Turkey—Import Ban on Pet Food from Hungary (Complaint by Hungary),* WT/DS256; *Turkey—Certain Import Procedures for Fresh Fruit (Complaint by Ecuador),* WT/DS237; *Egypt—Import Prohibition on Canned Tuna with Soybean Oil (Complaint by Thailand),* WT/DS205; and *EC—Restrictions on Certain Import Duties on Rice (Complaint by India),* WT/DS134.

[612] *Croatia—Measures Affecting Imports of Live Animals and Meat Products (Complaint by Hungary),* WT/DS297; *Mexico—Certain Measures Preventing the Importation of Black Beans from Nicaragua (Complaint by Nicaragua)*, WT/DS284; *India—Import Restrictions Maintained Under the Export and Import Policy 2002–2007 (Complaint by the European Communities),* WT/DS279; *Turkey—Import Ban on Pet Food from Hungary (Complaint by Hungary),* WT/DS256; *Turkey—Certain Import Procedures for Fresh Fruit (Complaint by Ecuador),* WT/DS237; *Egypt—Import Prohibition on Canned Tuna with Soy Oil (Complaint by Thailand),* WT/DS205; *Mexico—Measures Affecting Trade in Live Swine (Complaint by the United States),* WT/DS203, *Slovak Republic—Measures Concerning the Importation of Dairy Products and the Transit of Cattle (Complaint by Switzerland),* WT/DS133; and *India—Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Imports (Complaint by the European Communities),* WT/DS96.

[613] In *Australia—Certain Measures Affecting the Importation of Fresh Fruit and Vegetables (Complaint by the Philippines)*, WT/DS270, the Philippines requested the establishment of a panel once, on July 10, 2003. This panel request was blocked by Australia. The Philippines has not yet submitted its second panel request to the DSB (at which time the decision to establish a panel would be taken by reverse consensus in the DSB and could therefore not be blocked), and thus no panel has yet been established to hear this dispute. In *Turkey—Certain Import Procedures for Fresh Fruit (Complaint by Ecuador)*, WT/DS237, a panel request was submitted by Ecuador on June 14, 2002, but a mutually agreed solution was subsequently reached.

[614] In the 7th preambular paragraph of the SPS Agreement.

[615] For example, Article 5.1 requires a risk assessment "as appropriate to the circumstances" and Article 5.6 allows technical and economic feasibility to be taken into account in the choice of an SPS measure.

A. Technical Assistance (Article 9)

The technical assistance needs of developing countries encompass not only the improvement of their understanding of the rules applicable under the SPS Agreement, but also the acquisition of the technical and scientific capacity required to meet their obligations and enforce their rights under the SPS Agreement, and to comply with the SPS measures imposed by their trading partners. Thus technical assistance is a broad term, including: the provision of information to enhance Members' understanding of their rights and obligations under the SPS Agreement; the provision of practical and detailed training on the operation of the SPS Agreement; the provision of "soft" infrastructure (training and formation of technical and scientific personnel and the development of national regulatory frameworks); and "hard" infrastructure (laboratories, equipment, veterinary services and the establishment of disease free areas).[616]

The provision of technical assistance to developing countries involves several actors, including other WTO Members, the WTO Secretariat, as well as other international organizations such as the FAO (including Codex and the IPPC), the WHO, the OIE and the World Bank. It should be noted that the active participation and contribution of developing countries in this process is essential in order to ensure that the provision of technical assistance is effective and demand-driven.

Under Article 9.1, Members agree to facilitate the provision of technical assistance to other Members, especially developing countries, either bilaterally or through international organizations. This assistance may take various forms, including advice, credits, and grants and donations, and may be in the areas of processing technologies or research and infrastructure, including the creation of national regulatory bodies. Such assistance may also aim at helping developing countries adjust to and comply with SPS measures affecting their export markets.

Article 9.2 refers specifically to the case where the SPS measures put in place by an importing Member necessitate substantial investments in order for a developing country exporting Member to be able to comply with these measures. In such a case, the importing Member must consider providing technical assistance that will enable the developing country Member to maintain and expand its market access opportunities for that product. However, there is no obligation to actually provide such technical assistance.

Technical assistance is a standing item on the agenda of SPS Committee meetings, where Members are encouraged to identify specific technical assistance needs and report on technical assistance activities. The SPS Committee[617] has undertaken a survey of technical assistance needs and activities by means of questionnaires,[618] and drawn up a technical assistance typology.[619] In addition, informal discussions on technical assistance

[616] This typology was drawn up by the WTO Secretariat. Committee on Sanitary and Phytosanitary Measures, *Technical Assistance Typology: Note by the Secretariat,* G/SPS/GEN/206, October 18, 2000.

[617] A compilation of all documents submitted to and drafted by the SPS Committee on this issue was circulated to all Members. Committee on Sanitary and Phytosanitary Measures, *Technical Assistance and Capacity Building in the Context of the SPS Committee, Note by the Secretariat,* G/SPS/GEN/332, June 24, 2002.

[618] In July 1999, a questionnaire was circulated to Members by the Secretariat, to gather information on technical assistance requested, received or provided under the SPS Agreement but few developing countries replied. Committee on Sanitary and Phytosanitary Measures, *Questionnaire on Technical Assistance: Note by the Secretariat,* G/SPS/W/101, July 23, 1999. In October 2001 a second questionnaire was circulated regarding technical assistance needs to which 35 Members have responded to date. Committee on Sanitary and Phytosanitary Measures, *Questionnaire on Technical Assistance,* G/SPS/W/113, October 15, 2001. *See* addenda to Committee on Sanitary and Phytosanitary Measures, *Technical Assistance—Responses to the Questionnaire,* G/SPS/GEN/295, February 6, 2002.

[619] *See supra* note 553.

and co-operation have been held in the SPS Committee. In these discussions, concrete proposals were put forward to improve the effectiveness of the technical assistance provisions, including creating a coherent program for the provision of technical assistance, regardless of the source of the assistance, and placing emphasis on the development of human resources.[620] Further, high-level as well as technical meetings have been held between the WTO and other international organizations to co-ordinate the provision of technical assistance.[621] In November 2002, prior to the SPS Committee meeting, the WTO Secretariat organized a seminar on SPS-related technical assistance and capacity building. At this seminar, information was presented by international and regional organizations as well as developing country Members regarding their experiences with technical assistance in the SPS area.[622]

The Doha Development Agenda recognizes the importance of technical assistance and capacity building for developing countries in order to enable these Members to benefit fully from the multilateral trading system. For this reason, a Doha Development Agenda Trust Fund has been established, to which donor countries have pledged 30 million Swiss francs. The WTO Secretariat regularly provides technical assistance to developing countries for the implementation of the SPS Agreement, in particular through training programs organized by the WTO or through WTO participation in training programs organized by other organizations or institutions.[623] However, it should be noted that the role of the WTO Secretariat in the provision of technical assistance is necessarily limited. Other international organizations, and in particular the three standard-setting organizations (CAC, OIE and IPPC) as well as the World Bank, with which the WTO co-operates closely, are better suited to the provision of technical assistance in areas requiring scientific or technical expertise, such as building regulatory systems or strengthening infrastructure in the SPS sector.[624]

[620] The first meeting was held in July 2001. Committee on Sanitary and Phytosanitary Measures, *Discussion on Technical Assistance and Cooperation—Informal Meeting of the SPS Committee of 9 July, 2001,* G/SPS/GEN/267, July 16, 2001 and the second on March 18, 2002 (no report yet derestricted).

[621] General Council, Special Session on Implementation, *Actions to Increase the Participation of Developing Country Members in the Work of the Relevant International Standard-Setting Organizations: Report by the Director-General,* WT/GC/42, December 11, 2000; General Council, *Actions to Increase the Participation of Developing Country Members in the Work of Relevant International Standard-Setting Organizations—Information from Financial Institutions,* WT/GC/46/Rev.1, July 16, 2001; General Council, *Actions to Increase the Participation of Developing Country Members in the Work of Relevant Sanitary and Phytosanitary International Standard-Setting Organizations,* WT/GC/54, November 7, 2001; General Council, Special Session on Implementation, *Actions to Increase the Participation of Developing Country Members in the Work of Relevant Sanitary and Phytosanitary International Standard-Setting Organizations: Second Report by the Director General,* WT/GC/45, March 7, 2001.

[622] WTO SEMINAR ON TECHNICAL ASSISTANCE AND CAPACITY BUILDING RELATED TO THE SPS AGREEMENT, November 5, 2002, Geneva. The PowerPoint presentations delivered at this seminar are available at: www.wto.org/english/tratop_e/sps_e/sem_nov02_e/programme_e.htm.

[623] WTO Secretariat, ANNUAL REPORT 2002 (2002). For a list of planned technical assistance activities in the SPS area for 2003, see Committee on Trade and Development, *2003 Technical Assistance Activities, Note by the Secretariat. Revision*, WT/COMTD/W/104/Add.1/Rev.1, November 7, 2002, at 33.

[624] In this context, it is worth mentioning that, on September 27, 2002, the World Bank and the WTO established a new fund, called the *Standards and Trade Development Facility* ("STDF"). This fund aims to provide funding to assist developing countries to meet SPS standards. The World Bank has pledged US$ 300 000 to this fund and the WTO has contributed to it from the Doha Development Trust Fund. In its list of technical assistance activities for 2003, the WTO Secretariat proposed a contribution of CHF 100 000 to the STDF (*see supra* note 567). The fund will be administered by the WTO. The FAO, WHO and OIE are part of this initiative. *See* Committee on Sanitary and Phytosanitary Measures, *The Standards and Trade Development Facility, Note by the Secretariat*, G/SPS/GEN/371, February 18, 2003. *See also* WTO Press Release 314 *World Bank Grant Kicks off Bank-WTO Assistance on Standards,* September 27, 2002.

B. Special Rules for Developing Countries (Articles 10 and 14 and Annex B)

1. Special and Differential Treatment (Article 10)

Special and differential treatment in the SPS Agreement relates to the aim of ensuring that the special constraints faced by developing countries are taken into account in the implementation certain provisions of the SPS Agreement. This may refer to the implementation of provisions of the agreement in a manner favorable to developing countries by other Members, additional flexibility in the obligations contained in the SPS Agreement for developing countries, or actions by the SPS Committee or Secretariat to assist developing countries.

Article 10.1 obliges Members to take account of the special needs of developing country Members, and in particular least-developed country Members when preparing and applying SPS measures. However, there is no obligation to adapt the SPS measure or its application to address developing country needs. This can therefore be characterized as a "best endeavor" obligation.

Article 10.2 makes provision for phased-in introduction of new SPS measures. It encourages Members, without obliging them, to allow longer time frames for compliance with new SPS measures for developing country Members, where the appropriate level of protection of the importing Member allows scope. This is aimed at allowing developing countries to maintain their export opportunities while adjusting to the new measures.

Article 10.3 allows the SPS Committee to grant developing countries, upon request, specified, time-limited exemptions from all or some of their obligations under the SPS Agreement. This is done with the aim of enabling developing countries to comply with their obligations by giving them extra time to adjust to their new obligations, and takes account of their financial, trade and development needs. However, to date no developing country has requested an exemption under Article 10.3 despite the fact that certain developing countries remain in breach of certain obligations under the SPS Agreement, such as the obligation to establish a National Notification Authority and Enquiry Point, or to publish and notify all new SPS measures.

According to Article 10.4, Members should encourage and facilitate the active participation of developing countries in relevant international organizations. This is clearly a reference to the international standard-setting organizations. The issue of developing country participation in international standard setting is very contentious. Participation in the numerous committees of the international organizations where standards are developed and proposed for adoption requires not only financial and human resources, but also technical capabilities for the formulation of positions regarding standards of interest to the country. Although in recent years the number of developing country delegates attending meetings of the standard-setting organizations has increased and their participation has been more active, there remains considerable room for improvement. This has led to assertions that the standards set by the international organizations do not cover areas of interest for developing countries and do not reflect a level of protection that is realistic or desirable for developing countries. However, Article 10.4 is purely hortatory and contains no binding obligations. It should, nevertheless, be noted that the international standard-setting organizations themselves are taking steps to address this problem.[625]

[625] For instance, in the Codex Alimentarius Commission's Strategic Framework, adopted at its 24th Session in 2001, the issue of improving developing country participation is included as an objective. Codex Alimentarius Commission, *Report of the 24*th *Session*, July 2–7, 2001 ALINORM 01/41, Appendix II, ¶ 16. The objectives of the Strategic Framework will be implemented through a Medium Term Plan for

2. Reasonable Adaptation Period (Annex B, paragraph 2)

Under paragraph 2 of Annex B, Members are obliged to allow a reasonable period between the publication of an SPS measure and its entry into force for exporting Members (especially developing countries) to adapt to the new measure, except in cases of urgency. Although this provision is not a special and differential treatment provision in that the reasonable adaptation period must be granted equally to both developed and developing country exporting Members, it does hold particular advantages for developing countries as they often face more difficulties in adapting to new SPS measures than do their developed counterparts. For this reason, the provision makes specific reference to developing countries.

3. Special Provisions on Notification (Annex B, paragraphs 8 and 9)

Compliance with the transparency obligations of the SPS Agreement can be costly and burdensome for developing countries. Under the transparency provisions of Annex B, paragraph 8, developing countries are exempted from the obligation to provide copies of the documents, or in case of lengthy documents, summaries of the documents covered by a specific notification in one of the official languages of the WTO. This exemption from translation and summarizing obligations is clearly an attempt to reduce the burden on developing countries that results from compliance with the transparency provisions.

In addition, developing countries do not always benefit from increased transparency if they do not have the skilled manpower to monitor the notifications and identify those of interest to them. For this reason, under Annex B.9, the Secretariat is obliged to draw the attention of developing countries to any notifications relating to products of interest to them. In this way, developing countries can benefit fully from the increased transparency resulting from the disciplines of the SPS Agreement despite the fact that they may lack the resources to keep track of all notifications. As it is difficult to determine which notifications may be of interest to each developing countries Member, the Secretariat implements this obligation by circulating monthly lists of notified SPS measures to all WTO Members.[626] Further, in order to address the problems Members face in translating proposed regulations of other Members into a language in which they can work, the Secretariat has recently established a mechanism to circulate information on the availability of unofficial translations of draft regulations notified by Members.[627]

4. Transitional Periods (Article 14)

Article 14 of the SPS Agreement made provision for delayed implementation of the obligations under the Agreement for developing and least-developed country Members. Least-developed Members were granted a five-year period, from the entry into force of

2003–2007. In addition, on February 14, 2003 at the Extraordinary Meeting of the Codex Alimentarius Commission, the Directors General of the FAO and WHO officially launched the *FAO/WHO Trust Fund for Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius Commission*, which is expected to run for 12 years on a budget of $40 million and aims to help developing countries and countries in transition increase their participation in Codex activities. *See* Codex Alimentarius Commission, *Trust Fund for the Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius Commission, FAO/WHO Project and Fund for Enhanced Participation in Codex. Progress Report*, ALINORM 03/25/4, February 13–15, 2003.

[626] Committee on Sanitary and Phytosanitary Measures, *Electronic Transmission of Notifications to national Enquiry Points. Note by the Secretariat,* G/SPS/GEN/136, August 9, 1999. These lists can be found in the series G/SPS/GEN/* by searching under the keyword “notifications”.

[627] Committee on Sanitary and Phytosanitary Measures, *Unofficial Translation, Note by the Secretariat,* G/SPS/GEN/487, April 23, 2004.

the WTO Agreement, for delayed implementation of their obligations. Other developing Members were given a two-year grace period, where lack of technical expertise, infrastructure or resources prevented immediate implementation of their obligations. However, this possibility did not extend to their transparency and information obligations. The period for delayed application expired in January 2000 for least-developed Members and in January 1997 for other developing Members.

C. Problems with Implementation

Despite the existence of these provisions on technical assistance and special and differential treatment, developing countries have often raised concerns that their needs are not taken into account by developed country Members. These concerns form part of the broader discussion on implementation of the WTO agreements, which has been going on since the Seattle Ministerial Conference and, in a more concrete fashion, during the preparations for the Doha Ministerial Conference. The SPS Committee was asked by the General Council to examine implementation concerns relating to the SPS Agreement, and the Committee held discussions on this issue.[628] During these discussions, developing countries have complained that the provisions on technical assistance and special and differential treatment are either couched in non-mandatory language or constitute at most "best-endeavor" obligations without being fully operational.[629] In particular, they have noted that additional time for compliance with new SPS measures has seldom been granted and that they do not receive technical assistance to facilitate adjustment to SPS measures that affect their trade. In addition, their continued problems with regard to effective participation in international standard setting have been pointed out.

These and other concerns of developing countries with regard to implementation of the WTO agreements have been the focus of special sessions in the General Council,[630] which have resulted in the adoption of the Decision on Implementation-Related Issues and Concerns (the "Decision on Implementation") on November 14, 2001 at the Ministerial Conference in Doha.

D. Doha Decision on Implementation

The Decision on Implementation adopted at the Ministerial Conference in Doha urges the WTO Director-General to continue co-operative efforts with the international standard-setting organizations to facilitate the provision of technical and financial assistance to ensure the effective participation of least-developed countries.[631] In addition, Members

[628] As background to these discussions, the Secretariat prepared a document summarizing implementation concerns raised at SPS Committee meetings. Committee on Sanitary and Phytosanitary Measures, *Special and Differential Treatment: Note by the Secretariat,* G/SPS/W/105, May 9, 2000.

[629] *See e.g.*, the statement by India on this point. Committee on Sanitary and Phytosanitary Measures, *Implementation of the Provisions for Special and Differential Treatment: Statement by India at the Meeting of 21–22 June, 2000,* G/SPS/GEN/197, July 21, 2000.

[630] On May 3, 2000, the General Council adopted a decision to meet in special sessions to address outstanding implementation issues. Special Sessions were held in October and December 2000 and April, July and October 2001. Specific issues were referred to the relevant WTO bodies, including the SPS Committee for further work, which resulted in reports from these bodies to the General Council.

[631] At the Doha Ministerial Conference, the Director-Generals of the WTO, FAO, and OIE and the President of the World Bank declared their commitment to promote the participation of developing countries in international standard setting. Ministerial Conference, *Participation of Developing Countries in the Development and Application of International Standards, Guidelines and Recommendations on Food Safety,*

are urged to provide technical and financial assistance to least-developed countries to enable them to respond to SPS measures that may negatively affect their trade as well as to ensure that technical assistance is provided to these countries in response to the special problems they face in implementing the SPS Agreement.[632]

The Decision on Implementation establishes a longer time frame for compliance under Article 10.2—"normally a period of not less than 6 months" where there is scope for phased introduction of the new measure. Where such phased introduction is not possible, if a Member identifies specific problems it faces with regard to the new measure, the importing Member must enter into consultations with a view to reaching a mutually satisfactory solution, while continuing to achieve the importing Member's appropriate level of protection.[633]

In addition, the Decision on Implementation sets the reasonable adaptation period under Annex B.2 at "normally a period of not less than 6 months," but notes that the particular circumstances of the measure and the actions needed for its implementation must be considered. In addition, it clarifies that the entry into force of SPS measures that liberalise trade should not be unnecessarily delayed.[634] This takes into account the fact that some new SPS measures may establish lower or easier requirements than existing ones.

The Decision on Implementation represents a step towards the strengthening of the provisions in the SPS Agreement in favor of developing countries. However, much remains to be done if these special provisions are to be fully operationalized. For this reason, work is ongoing in the Special Session of the Committee on Trade and Development with respect to the identification of ways to make the special and differential treatment provisions in WTO agreements more effective.[635] The Doha Ministerial Declaration provides that outstanding implementation issues are to be addressed as a matter of priority by the relevant WTO bodies. In May 2003, the General Council referred five proposals, containing twelve specific recommendations, on special and differential treatment to the SPS Committee. The Committee adopted a work programme with regard to these proposals on June 25, 2003.[636] The SPS Committee has held an informal meeting on special and differential treatment. The proposals on special and differential treatment are also a standing item on the agenda of SPS Committee meetings. At the meeting of March 2004, no comments were made regarding these proposals.[637]

Animal and Plant Health: Joint Statement Circulated by the Directors-General of the Food and Agriculture Organization of the United Nations, the Office International Des Epizooties, the World Health Organization, the World Trade Organization and the President of the World Bank, WT/MIN(01)/ST/97, November 11, 2001.

[632] Ministerial Conference, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001, ¶¶ 3.5–3.6.

[633] *Id.* ¶ 3.1

[634] *Id*. ¶ 3.2

[635] This ongoing work in the area of special and differential treatment is mandated in the Doha Ministerial Declaration, which endorses the Work Programme on special and differential treatment set out in the Implementation Decision. Ministerial Conference, Fourth Session, Ministerial Declaration, Adopted on November 14, 2001, WT/MIN(01)/DEC/1, November 20, 2001, ¶ 44; Ministerial Conference, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001, ¶ 12.1. The outstanding issues are to be found in a Secretariat compilation. WTO Secretariat, *Compilation of Outstanding Implementation Issues Raised by Members, Revision,* JOB(01)/152/Rev.1, October 27, 2001.

[636] The work programme is contained in G/SPS/26.

[637] Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 17–18 March 2004, Note by the Secretariat*, G/SPS/R/33, May 7, 2004, ¶ 100.

V. Conclusion

A. An Evaluation of the SPS Agreement as a Balancing Act

An evaluation of the SPS Agreement must logically examine its effectiveness in achieving its aims. As was discussed in the introduction to this Chapter, the SPS Agreement has the objective of balancing the right of Members to impose measures for the protection of human, plant and animal life or health, with the goal of liberalization of trade in the food and agricultural sector. This is an extremely delicate balance, as on one side of the scale is a policy area of significant public concern, namely that of health. Health issues tend to be emotionally charged and politically sensitive. Members need to have sufficient flexibility to be able to respond to the legitimate demands of their citizens for effective protection in this area. On the other side of the scale is another important goal, namely that of market access for food and agricultural products, creating economic growth and prosperity. The importance of this value is often underplayed by critics of the SPS Agreement who see the protection of health as trumping all other considerations. However, when one bears in mind the crucial importance of the agricultural sector for the export trade of developing countries, and takes into account the fact that the export revenue earned in this sector is necessary to finance basic services such as education and health, it becomes clear that market access considerations should also be given sufficient weight in the balancing process. For these reasons, it is critical that this balance be finely struck.

A complicating factor in evaluating the balance struck between these competing aims is the fact that WTO Members have vastly different levels of economic development. This affects a variety of factors of relevance to the disciplines of the SPS Agreement. First, it plays a role in the level of SPS protection expected by citizens and thus the demands that they make on their regulators. Second, it affects the export interests of Members, with developing countries being much more dependent on the food and agricultural sector for their export earnings than industrialized countries. Third, the level of development of a Member is often reflected in the strength and efficacy of the sanitary and phytosanitary systems, consisting of both regulations and infrastructure, in place in that country to secure a particular level of SPS protection. The ability of a Member to guarantee the safety and pest- or disease-free status of its food and agricultural products and meet the requirements of its trading partners is dependent on the effectiveness of its SPS system. Finally, the ability of a Member to enforce its rights and meet its obligations under the SPS Agreement is conditional on the availability of financial and human resources which can be dedicated to this purpose by that Member. For these reasons, a realistic evaluation of the SPS Agreement must determine whether it takes sufficient account of the varying levels of economic development of WTO Members and has effective mechanisms in place to ensure that all Members benefit from its disciplines.

B. Evaluation of the Balance Achieved

In respect of allowing sufficient scope for Members to regulate in the area of human, animal or plant life and health, the SPS Agreement represents a significant achievement as compared to the situation under the GATT 1947. Now the imposition of SPS measures is no longer viewed as an exceptional situation requiring justification. By recognizing the right of Members to regulate in this area, the SPS Agreement has shifted the burden of proof to the Member who wishes to challenge an SPS measure. In addition, the SPS Agreement recognizes the right of Members to set the level of protection they deem fit,

even if this level of protection is higher than that embodied in international standards. Also this possibility is regarded as an autonomous right rather than an exception from the harmonization disciplines. Thus it is for the challenging Member to show that relevant measure is not scientifically justified.

It is with the disciplines on Members' right to regulate in the SPS area, that the balance struck in the SPS Agreement becomes apparent. The Agreement represents an innovation from the previous GATT approach in that it uses *science* to mediate the conflict between the competing values of health protection and free trade. Some concerns arise in connection with the scientific disciplines in the SPS Agreement. Given the strict interpretation that has been given to the requirement of a risk assessment, the lack of clarity regarding the requirement of "sufficient scientific evidence" and the limitation of the role of the precautionary principle to the provisions of Article 5.7, concerns can be raised regarding the ability of the SPS Agreement, as it has been interpreted in the case law, to deal with the uncertainties inherent in scientific analysis. By using science as if it were a neutral benchmark against which SPS measures can be tested for legitimacy, the SPS Agreement may reflect a naïve and outdated view of the nature of science. The Appellate Body has gone some way towards taking into account the realities of risks in the real world, rather than looking only at laboratory science, and has also accepted that divergent risk assessments can occur in a particular situation and that SPS measures can legitimately be based on minority opinions. However, it has stopped short of allowing the presence of unknown factors and uncertainties to influence the interpretation of the requirements for a risk assessment or sufficient scientific evidence, of the evaluation by panels of the scientific evidence before them.

It is argued here that account should be taken of the prevalence of uncertainties and differing scientific opinions in all aspects of the regulatory process, not just the risk management stage. For this reason, the emerging concept of the precautionary principle, to the extent that it develops into a general principle of international law or a customary international law principle, should be taken into account in interpreting the requirements of "sufficient scientific evidence" and of risk assessment "as appropriate to the circumstances". However, this taking into account must be carefully circumscribed to avoid introducing unpredictability into the trade regime in this area and shifting the carefully negotiated balance in the SPS Agreement too far towards the side of health protection, undermining the market access achievements of the disciplines in the Agreement.

Another area that merits attention with respect to how the balance is struck in the SPS Agreement relates to the use of international standards set by the "three sisters" as reference standards. The possibility of deviating from international standards without a shift in the burden of proof ensures that Members' right to choose their own level of protection is respected. At the same time, the harmonization of standards holds real benefits in terms of facilitating market access and is particularly useful for developing countries that lack the resources and infrastructure to set their own standards. However the standard-setting process leaves much to be desired. Until such time as these international standard-setting organizations have effectively resolved the problems of developing country participation in standard setting and the politicization of the standard-setting process, the standards they set are of doubtful legitimacy as the touchstone against which SPS measures are judged for presumptive validity with the SPS Agreement and the GATT. Reforms to the standard-setting process are necessary to ensure that these standards reflect the needs of all Members, including developing countries.

Perhaps one of the most significant achievements of the SPS Agreement is the improvement it has brought about with regard to transparency of SPS measures. This has

increased predictability in the international market for food and agricultural products, by enabling exporters to determine, in advance, what requirements their products have to meet. The requirement of a reasonable interval between publication of a measure and its entry into force[638] gives exporters time to adjust to new measures. In addition, the transparency requirement of advance notification of new non-harmonized measures to allow for comments as well as the possibility to discuss notified measures in the SPS Committee enables Members to raise their concerns regarding SPS measures that affect their exports and to try to get these measures amended before they come into force. This means that disagreements regarding SPS measures can be resolved quickly and simply without recourse to the more costly process of dispute settlement.

However, the full potential of the transparency obligations to enhance market access has not been realized due to the flexibility in the transparency provisions. Although the Doha Decision on Implementation has taken a step towards tightening these obligations, a lot remains to be done. It has been pointed out that the content and quality of the information provided in notifications varies between countries, the period allowed for comments on proposed measures is sometimes insufficient, comments are often not taken into account and documentation is sometimes not promptly provided.[639] Further work in the area of notification is thus necessary.

Other disciplines that hold significant potential for increasing market access for food and agricultural products, without bringing into question the level of protection maintained by an importing Member, are those relating to the recognition of equivalence and adaptation to regional conditions. These provisions make it possible for Members to limit the negative effects of legitimate SPS measures of their trading partners on their exports. This can be done either by requesting that the effectiveness of their own different measures in achieving the appropriate level of protection of the importing Member be recognized or by proving that regional conditions in their territories (such as pest- or disease-free status) justify an adaptation (or non-application) of the measure with regard to that region. Due to the best-endeavor nature of these provisions, they have been dogged by problems of lack of implementation. The SPS Committee's Equivalence Decision and the clarification thereto adopted through the work programme in this area, have gone some way towards clarifying and operationalizing the provision on equivalence. It now remains to be seen whether this work will bear fruit, in promoting the recognition of equivalence in practice. Similarly, it is hoped that the informal discussions initiated on the regionalization provision will lead to a similar work programme for the establishment of procedural guidelines to further the full use of this provision.

It is now necessary to evaluate whether the disciplines of the SPS Agreement sufficiently take account of the special constraints faced by developing countries. The rules of the SPS Agreement entail high costs for developing countries first of all in terms of establishment of the infrastructure required for transparency and risk assessment, but also in terms of participation in the SPS Committee, participation in international standard-setting and enforcement of SPS disciplines in dispute settlement. In order for developing countries to be able to meet these costs and thus benefit from the Agreement, it is important that the rules on technical assistance and special and differential treatment in the SPS Agreement be effectively implemented by developed Members. As most of these provisions are either non-mandatory or at best create best-endeavor obligations,

[638] As discussed *supra* Part IV(D), this period has been specified in the Doha Decision on Implementation as normally not less than six months.
[639] Zarilli, *supra* note 447, at 19.

many complaints have been raised regarding the inadequate implementation of these provisions.[640] It is clear that a tightening of these rules is necessary if developing countries are to reap the full benefits of the SPS Agreement.

C. Context for Possible Clarifications or Amendments

The SPS Agreement is *not* on the agenda for negotiations for the Doha Round. This would appear to be due to the difficulty in reaching agreement in this contentious area. Members thus prefer to work with the disciplines they have already negotiated in this area, rather than risk reopening the Agreement and not being able to reach agreement on the amendment of its provisions.[641] However, this does not mean that it will not be possible to agree on amendments to or clarifications of specific provisions of the SPS Agreement either in the context of other negotiations that form part of the Doha Development Agenda or through the SPS Committee outside the Doha Round.[642]

In the first place, SPS concerns have been raised in the context of the ongoing agriculture negotiations. Three facts could be regarded as opening the door for this possibility: first, the reference to the SPS Agreement in Article 14 of the Agreement on Agriculture;[643] second, the identification of market access (which in principle includes non-tariff barriers such as SPS measures) as one of the "three pillars"[644] of the ongoing agriculture negotiations; and third the explicit reference in Article 20 of the Agreement on Agriculture to "non-trade concerns"[645] as one of the elements to be taken into account in the mandated negotiations. Already several proposals in the area of agriculture contain

[640] That is not to say that no technical assistance relating to SPS concerns has been delivered. In fact several Members have submitted papers to the SPS Committee documenting the technical assistance they have provided to developing countries. Amongst others, *see* G/SPS/GEN/181;Committee on Sanitary and Phytosanitary Measures, *Discussion on Technical Assistance and Cooperation—Informal Meeting of the SPS Committee of July 9, 2001,* G/SPS/GEN/267, July 16, 2001; Committee on Sanitary and Phytosanitary Measures, *Summary of the Replies to the Questionnaire on Technical Assistance: Note by the Secretariat,* G/SPS/GEN/143/Rev.1/Add.1, June 16, 2000; Committee on Sanitary and Phytosanitary Measures, *Technical Assistance to Developing Countries Provided by the United States: Submission by the United States,* G/SPS/GEN/181, June 15, 2000; Committee on Sanitary and Phytosanitary Measures, *Technical Cooperation and Assistance: Submission by the United States,* G/SPS/GEN/78, June 9, 1998; Committee on Sanitary and Phytosanitary Measures, *Quarantine and Other Sanitary and Phytosanitary Capacity Building and Training Activities Undertaken by Australia: Submission by Australia,* G/SPS/GEN/124, June 15, 1999; Committee on Sanitary and Phytosanitary Measures, *Technical Assistance to Developing Countries: Statement by the European Communities at the Meeting of March 14–15, 2001,* G/SPS/GEN/244, April 27, 2001. What remains a concern is the inadequacy of the technical assistance given thus far to overcome the barriers to developing country products created by stringent SPS standards. *See* Committee on Sanitary and Phytosanitary Measures, *Special and Differential Treatment and Technical Assistance: Submission Made by India at the Meeting of June 10–11, 1998,* G/SPS/GEN/85, July 23, 1998, at 4.

[641] This does not mean that the possibility that the SPS Agreement could be reopened for negotiation in this Round is entirely excluded, as the negotiations may go beyond the initial agenda set. However, for the reasons mentioned, this would be unlikely in this case.

[642] *See* Denise Prévost and Mariëlle Matthee, *The SPS Agreement as a Bottleneck in Agricultural Trade between the European Union and Developing Countries: How to Solve the Conflict*, 29 LEGAL ISSUES OF ECONOMIC INTEGRATION 43, 44–45 (2002).

[643] Article 14 states that Members agree to give effect to the SPS Agreement. This serves to underscore the link between the SPS Agreement and the Agreement on Agriculture.

[644] The other two pillars are export competition and domestic support.

[645] Food-safety issues (including issues such as GMO labeling, the application of the precautionary principle and consumer concerns) have been identified in some proposals as one of the non-trade concerns relevant to the agriculture negotiations.

references to SPS issues and could serve to open the door for discussion of SPS matters.[646] Perhaps amendments to specific provisions of the SPS Agreement could be agreed upon and included in the results of the Doha Round without the need to reopen the whole SPS Agreement for negotiation.

Second, the SPS Committee views its mandate under Article 12.1 of the SPS Agreement to "carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives" as encompassing the power to make binding rules, clarifying the provisions of the SPS Agreement. It has already exercised this power in adopting the Equivalence Decision.[647] While the enforceability of such decisions in dispute settlement remains an open question, at the very least they will be taken into account by panels and the Appellate Body in interpreting the provisions of the Agreement as either "subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" under Article 31.3(b) of the Vienna Convention on the Law of Treaties[648] or as a "rule of international law applicable to the relations between the parties" pursuant to Article 31.3(c) thereof. It is therefore possible that certain ambiguous obligations could be given content by decisions of the SPS Committee, provided these do not go as far as to amend the rules or create new obligations.

Third, the SPS Agreement itself, in Article 12.7, provides a mechanism for review of the Agreement and the proposal of amendments to the Council for Trade in Goods. This Council would then forward the proposed amendments to the Ministerial Conference for adoption under the amendment mechanism contained in Article X of the WTO Agreement. While Article 12.7 provides that after the first review of the SPS Agreement reviews shall take place "as the need arises", the Doha Decision on Implementation now obliges the SPS Committee to undertake such reviews at least once every four years.[649] Members could usefully have recourse to this possibility to address remaining concerns with the rules of the SPS Agreement.

D. Key Issues for the Future

Equivalence and regional adaptation remain key issues. The work done by the SPS Committee in the area of equivalence will hopefully ensure that the provisions on equivalence live up to their potential in respect to increasing market access.[650] A similar exercise has been initiated with regard to regionalization. It should encompass clarifications to the procedure and requirements that Members should follow in order to have pest- or disease-free status recognized. In particular, it is important to specify that once a Member

[646] *See e.g.*, G/AG/NG/W/37, G/AG/NG/W/142, G/AG/NG/W/136, G/AG/NG/W/94, G/AG/NG/W/98, G/AG/NG/W/96, G/AG/NG/W/90, and G/AG/NG/W/97 (including Corr. 1 and 2).

[647] This Decision is discussed *supra* Part II(F)(1).

[648] Articles 31 and 32 of the *Vienna Convention* are regarded as a codification of customary rules of public international law with regard to treaty interpretation. Thus panels and the Appellate Body are bound to apply them in interpreting provisions of the WTO agreements under Article 3.2 of the Dispute Settlement Understanding.

[649] Ministerial Conference, Fourth Session, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001, ¶ 3.4.

[650] Informal discussions by the SPS Committee have focused on the Work Programme on equivalence, and in particular on clarifications of paragraphs 5–7 of the Equivalence Decision. For a summary of the Chairman's report on these discussions, *see* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25–26 June 2002, Note by the Secretariat*, G/SPS/R/27, August 2, 2002, ¶ V(a). As mentioned *supra* Part III(C)(3), the SPS Committee agreed to clarifications to ¶¶ 5 and 6 of the Equivalence Decision at its meeting of November 7–8, 2002. *See supra* note 500.

(or a region in its territory) has officially been declared pest- or disease free by the relevant international organization, other Members should recognize such a declaration and not require that proof of pest- or disease-free status be provided from scratch.

The gaps in the notification obligations are also an important area for future work. The notification guidelines issued by the SPS Committee are a useful tool in specifying the procedures and requirements of notification but these guidelines are non-binding and failure to comply with them can thus not be challenged in dispute settlement. It is therefore suggested that binding rules in this respect should be worked out by Members in the SPS Committee as part of the next review of the SPS Agreement and submitted to the Council for Trade in Goods, under the possibility for amendment of the SPS Agreement created in Article 12.7 thereof.

With respect to special and differential treatment for developing countries, we have noted that the implementation problems encountered with regard to special and differential treatment provisions in WTO agreements were the subject of discussions in the General Council. On the basis of these discussions, the Decision on Implementation was adopted at the Doha meeting of the Ministerial Conference.[651] This Decision instructs the Committee on Trade and Development ("CTD") of the WTO to examine the possibility of making mandatory those special and differential treatment provisions that are currently non-mandatory as well as other ways of improving the effectiveness of these provisions. The CTD was asked to report to the General Council with clear recommendations for a decision by July 31, 2002.[652] For this purpose, the Special Session of the CTD was established. Discussions in the Special Session of the CTD on this issue were contentious and it was difficult to reach agreement on key issues.[653] Three proposals were received with respect to the special and differential treatment provisions of the SPS Agreement.[654] On July 24, 2002, the Members in the Special Session of the CTD reached agreement on a report[655] that was presented at the meeting of the General Council on July 31, 2002. In this report, the deadline for recommendations for a decision on special and differential treatment was postponed until December 2002.[656] In addition, the report recommended *inter alia* that the Special Session of the CTD be instructed to continue its examination of Agreement-specific proposals, utilizing, as appropriate, the expertise available in other WTO bodies.[657] Subsequently, on February 10, 2003 the CTD adopted a report requesting the General Council to clarify its mandate regarding special and differential treatment negotiations. The General Council failed to adopt this report due to opposition from

[651] This Decision is discussed *supra* Part IV(D).

[652] Ministerial Conference, Fourth Session, *Implementation-Related Issues and Concerns, Decision of 14 November 2001,* WT/MIN(01)/17, November 20, 2001, ¶ 12.1. This work program was endorsed in the Doha Ministerial Declaration. Ministerial Conference, Fourth Session, Ministerial Declaration. *Adopted on 14 November 2001*, WT/MIN(01)/DEC/1, November 20, 2001

[653] These issues deal with basic matters such as the timeline, the relationship between two tracks that have been identified for the discussions, namely agreement-specific issues and cross-cutting issues and the question whether agreement-specific issues would be more appropriately dealt with in the relevant WTO bodies responsible fort he various agreements. ICTSD, *Arduous Process Yields Agreement on S&D Report,* 6(28) BRIDGES WEEKLY TRADE DIGEST July 24, 2002.

[654] These proposals were from India (TN/CTD/W/6), the African Group (TN/CTD/W/3/Rev.1 and 2, not yet derestricted), and the Like-Minded Group, consisting of Cuba, the Dominican Republic, Egypt, Honduras, India, Indonesia, Kenya, Mauritius, Pakistan, Sri Lanka, Tanzania, and Zimbabwe (TN/CTD/W/2).

[655] Committee on Trade and Development, Special Session, *Report to the General Council,* TN/CTD/3 and Corr.1, July 26, 2002.

[656] *Id.* ¶ 14.

[657] *Id.* ¶ 15.

developed countries and the negotiations were[658] deadlocked. With the failure of the Cancun Ministerial Conference in September 2003, progress in negotiations on special and differential treatment stalled. Since the adoption of the new framework text on the Doha work program by the General Council in Geneva on July 31, 2004, negotiations are restarting. Although no agreement was reached on the adoption of amendments to special and differential treatment provisions as part of the 'July package', the text includes an instruction by the General Council to the Special Session of the Committee on Trade and Development to expeditiously complete its condideration of proposals in this regard and to report to the General Council, with clear recommendations for a decision, as soon as possible and no later than July 2005. Similarly, the Council instructs all WTO bodies to which proposals have been referred, to expeditiously complete the consideration of these proposals and report to the General Council with clear recommendations by July 2005.

Since special and differential treatment is a standing agenda item for SPS Committee meetings, and certain proposals on special and differential treatment have been forwarded to the SPS committee under the Doha mandate discussions on this topic between the delegates to the SPS Committee who have specific expertise in this area could provide useful input for the Special Session of the CTD.[659] It is to be hoped that with regard to the special and differential treatment provisions in the SPS Agreement, Members will succeed in agreeing to new rules or to the tightening of existing provisions to fully operationalize these provisions.[660]

The issue of technical assistance is also of fundamental importance and is currently receiving attention not only within the SPS Committee,[661] but also in other international

[658] *See* ICSTD, *S&D Review in Limbo as General Council Fails to Adopt Report* 7(5) BRIDGES WEEKLY TRADE NEWS DIGEST, February 12, 2003.

[659] Until recently, developing countries made little use of this possibility to raise concerns or make suggestions under this agenda item, preferring to keep discussions on special and differential treatment within the CTD. However, it is interesting to note the recent Egyptian and Canadian proposals in the SPS Committee on ways to enhance transparency regarding the provision of special and differential treatment under the SPS Agreement by modifying the recommended notification format to include information on the provision of special and differential treatment, either *ex ante* (Egyptian proposal) or *ex post* by means of an Addendum to the notification after bilateral discussions on this issue between the importing and exporting Members (Canadian proposal) . Committee on Sanitary and Phytosanitary Measures, *Enhancing Transparency of Special and Differential (S&D) Treatment within the SPS Agreement, Submission by Canada,* G/SPS/W/127, October 30, 2002. *See* further *supra* note 524.

[660] At time of writing, prospects for this seem bleak, as discussions in the CTD regarding the relevant provisions in the SPS Agreement have not led to progress in reaching agreement. Developed countries have indicated that they regard developing country proposals in this regard as unrealistic or impractical, placing too many restrictions on the implementation of SPS measures, thus endangering health, or requiring unlimited funding for technical assistance. Instead, they suggest more effective use of the current provisions on special and differential treatment and further consultations in the SPS Committee when new SPS measures are likely to cause difficulties for developing countries. In addition, developed countries oppose changes to the language of special and differential treatment provisions in the agreements, as this would alter the balance of rights and obligations. Developing countries counter that their proposals do not require lowering SPS standards but rather meaningful and mandatory technical and financial assistance in order to meet new SPS measures. According to developing countries, the current under-utilisation of special and differential treatment provisions is due to the vagueness of the language used therein, which is precisely what was meant to be addressed under the CTD's mandate. *See* ICTSD, *WTO: S&D Review Struggles for Agreement* 6(39) BRIDGES WEEKLY TRADE NEWS DIGEST, November 14, 2002.

[661] The relevant discussions and documents circulated in the SPS Committee on technical assistance and capacity building are summarized in a Secretariat document. *See* Committee on Sanitary and Phytosanitary Measures, *Technical Assistance and Capacity Building in the Context of the SPS Committee, Note by the Secretariat,* G/SPS/GEN/332, June 24, 2002.

organizations and bilaterally.[662] Much is being done by the WTO Secretariat to encourage the effective implementation of technical assistance provisions.[663] Informal discussions have taken place in the SPS Committee on this issue and specific proposals were discussed.[664] Some of the suggestions put forward were the integration of all technical assistance into a single coherent framework, irrespective of the source of the assistance; placing emphasis on improving human resources, aiming technical assistance at the establishment or improvement of national regulatory systems in the area of SPS, as well as assisting developing countries to meet the SPS standards of their trading partners.[665] It would be of great consequence if these discussions were to result in a coherent framework for the provision of technical assistance.[666]

Finally, with respect to the problems of standard setting in international organizations, it should be borne in mind that this is outside the scope of action of the WTO. The standard-setting organizations are fully independent of the WTO and operate according to their own rules and statutes. Any initiatives for reform of the standard setting process must thus come from these organizations themselves or Members acting in their capacity as members of the standard-setting organizations. It is interesting to note that an evaluation of the Joint FAO/WHO Food Standards Program has recently been conducted. This involved a review of the Codex standard-setting process and the problems of participation of developing countries. The results of this review were discussed within the Codex[667] and recommendations were made to the FAO and WHO governing bodies regarding reforms to the Codex structure and decision-making process. Consequently several important changes to the CAC Rules of Procedure were considered at the twenty-seventh session of the CAC in 2004. Similarly, the IPPC established a trust fund for technical assistance in 2003, aimed at helping developing countries to participate in standard-setting activities and meetings and to implement resulting standards.[668] In addition, a Trust Fund for the

[662] At the SPS Committee meeting of June 2002, the U.S.A., EC, Codex, ITC and IICA highlighted some of their recent technical assistance activities. *See* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25–26 June 2002, Note by the Secretariat*, G/SPS/R/27, August 2, 2002, paras 102–106. More detailed information on some of these activities can be found in G/SPS/GEN/181/Add.2, G/SPS/GEN/335, G/SPS/GEN/344 and G/SPS/GEN/333.

[663] For example, by the gathering of information on the technical assistance needs of developing countries by means of questionnaires. *See supra* Part IV(A). In the June 2002 meeting of the SPS Committee, the Secretariat drew Members' attention to the Coordinated WTO Secretariat Annual Technical Assistance Plan for 2002 and indicated that it will do its best to include in its 2003 program the technical assistance requests that emerge from the responses to the questionnaire. However, it pointed out that due to resource constraints, most technical assistance requests would have to be addressed bilaterally or by other international organizations. *See* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25–26 June 2002, Note by the Secretariat*, G/SPS/R/27, August 2, 2002, ¶ 97.

[664] *See supra* Part IV(A).

[665] Committee on Sanitary and Phytosanitary Measures, *Discussion on Technical Assistance and Cooperation—Informal Meeting of the SPS Committee of 9 July, 2001,* G/SPS/GEN/267, July 16, 2001.

[666] In addition, it should be noted that the Agriculture and Commodities Division of the WTO Secretariat is participating in the creation of a technical assistance database. *See* Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25–26 June 2002, Note by the Secretariat*, G/SPS/R/27, August 2, 2002, ¶ 97.

[667] Extraordinary sessions of the Codex Alimentarius Commission and its Executive Committee were convened in Geneva on February 10–15, 2003, to discuss the conclusions and recommendations emanating from this evaluation. A statement resulting from these discussions was adopted for submission to the governing bodies of the FAO and WHO. Further work will be undertaken by the Commission in this regard. See Codex Alimentarius Commission, *Report of the 25th (Extraordinary) Session*, February 13–15, 2003 ALINORM 03/25/5, Appendix II.

[668] Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 17–18 March 2004, Note by the Secretariat*, G/SPS/R/33, May 7, 2004, ¶ 140.

Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius Commission[669] was launched on February 14, 2002.[670]

In conclusion, we argue that the SPS Agreement represents a significant achievement in addressing the potential for conflict between trade liberalization and the protection of health. It is the first WTO agreement to deal specifically with the interface between free trade and a specific social policy area. As any such new initiative, it contains both promises and pitfalls. The experience gained during the nine years of existence of the SPS Agreement has served to highlight these two aspects of the Agreement, and can be usefully examined in order to address the issue of whether, and if so which, reforms to the Agreement or clarifications thereof may be necessary. It is hoped that the discussion in this Chapter may stimulate thinking and debate in this area.

[669] *See supra* note 623.

[670] At the SPS Committee meeting of March 17–18, 2004, the CAC representative reported that the contributions to the FAO/WHO Trust Fund have reached the threshold of US$500,000 needed to operationalize it. However, as this amount is insufficient to significantly increase developing country participation in the work of the CAC, he encouraged further contributions.