International and Regional Trade Law: The Law of the World Trade Organization

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Unit IX: Sanitary and Phytosanitary Measures (SPS)

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1. Introduction

1.1. Overview

http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

SANITARY AND PHYTOSANITARY MEASURES: INTRODUCTION

Understanding the WTO Agreement on Sanitary and Phytosanitary Measures

May 1998

The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations.

This introduction discusses the text of the SPS Agreement as it appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in Marrakesh on 15 April 1994. This agreement and others contained in the Final Act, along with the General Agreement on Tariffs and Trade as amended (GATT 1994), are part of the treaty which established the World Trade Organization (WTO). The WTO superseded the GATT as the umbrella organization for international trade.

The WTO Secretariat has prepared this text to assist public understanding of the SPS Agreement. It is not intended to provide legal interpretation of the agreement.

INTRODUCTION

The Sanitary and Phytosanitary Measures Agreement

Problem: How do you ensure that your country’s consumers are being supplied with food that is safe to eat — "safe" by the standards you consider appropriate? And at the same time, how can you ensure that strict health and safety regulations are not being used as an excuse for protecting domestic producers?

The Agreement on the Application of Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health standards.

It allows countries to set their own standards. But it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. And they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary.

The agreement still allows countries to use different standards and different methods of inspecting products.
Key Features

All countries maintain measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants. These sanitary and phytosanitary measures can take many forms, such as requiring products to come from a disease-free area, inspection of products, specific treatment or processing of products, setting of allowable maximum levels of pesticide residues or permitted use of only certain additives in food. Sanitary (human and animal health) and phytosanitary (plant health) measures apply to domestically produced food or local animal and plant diseases, as well as to products coming from other countries.

Protection or protectionism?

Sanitary and phytosanitary measures, by their very nature, may result in restrictions on trade. All governments accept the fact that some trade restrictions may be necessary to ensure food safety and animal and plant health protection. However, governments are sometimes pressured to go beyond what is needed for health protection and to use sanitary and phytosanitary restrictions to shield domestic producers from economic competition. Such pressure is likely to increase as other trade barriers are reduced as a result of the Uruguay Round agreements. A sanitary or phytosanitary restriction which is not actually required for health reasons can be a very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge.

The Agreement on Sanitary and Phytosanitary Measures (SPS) builds on previous GATT rules to restrict the use of unjustified sanitary and phytosanitary measures for the purpose of trade protection. The basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

Justification of measures

The SPS Agreement, while permitting governments to maintain appropriate sanitary and phytosanitary protection, reduces possible arbitrariness of decisions and encourages consistent decision-making. It requires that sanitary and phytosanitary measures be applied for no other purpose than that of ensuring food safety and animal and plant health. In particular, the agreement clarifies which factors should be taken into account in the assessment of the risk involved. Measures to ensure food safety and to protect the health of animals and plants should be based as far as possible on the analysis and assessment of objective and accurate scientific data.

International standards

The SPS Agreement encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations. This process is often referred to as "harmonization". The WTO itself does not and will not develop such standards. However, most of the WTO’s member governments (132 at the date of drafting) participate in the development of these standards in other international bodies. The standards are developed by leading scientists in the field and governmental experts on health protection and are subject to international scrutiny and review.

International standards are often higher than the national requirements of many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose not to use the international standards. However, if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate.

Adapting to conditions
Due to differences in climate, existing pests or diseases, or food safety conditions, it is not always appropriate to impose the same sanitary and phytosanitary requirements on food, animal or plant products coming from different countries. Therefore, sanitary and phytosanitary measures sometimes vary, depending on the country of origin of the food, animal or plant product concerned. This is taken into account in the SPS Agreement. Governments should also recognize disease-free areas which may not correspond to political boundaries, and appropriately adapt their requirements to products from these areas. The agreement, however, checks unjustified discrimination in the use of sanitary and phytosanitary measures, whether in favour of domestic producers or among foreign suppliers.

**Alternative measures**

An acceptable level of risk can often be achieved in alternative ways. Among the alternatives — and on the assumption that they are technically and economically feasible and provide the same level of food safety or animal and plant health — governments should select those which are not more trade restrictive than required to meet their health objective. Furthermore, if another country can show that the measures it applies provide the same level of health protection, these should be accepted as equivalent. This helps ensure that protection is maintained while providing the greatest quantity and variety of safe foodstuffs for consumers, the best availability of safe inputs for producers, and healthy economic competition.

**Risk Assessment**

The SPS Agreement increases the transparency of sanitary and phytosanitary measures. Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved, and, if requested, make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable. Although many governments already use risk assessment in their management of food safety and animal and plant health, the SPS Agreement encourages the wider use of systematic risk assessment among all WTO member governments and for all relevant products.

**Transparency**

Governments are required to notify other countries of any new or changed sanitary and phytosanitary requirements which affect trade, and to set up offices (called "Enquiry Points") to respond to requests for more information on new or existing measures. They also must open to scrutiny how they apply their food safety and animal and plant health regulations. The systematic communication of information and exchange of experiences among the WTO’s member governments provides a better basis for national standards. Such increased transparency also protects the interests of consumers, as well as of trading partners, from hidden protectionism through unnecessary technical requirements.

A special Committee has been established within the WTO as a forum for the exchange of information among member governments on all aspects related to the implementation of the SPS Agreement. The SPS Committee reviews compliance with the agreement, discusses matters with potential trade impacts, and maintains close co-operation with the appropriate technical organizations. In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

**QUESTIONS AND ANSWERS**

*What are sanitary and phytosanitary measures? Does the SPS Agreement cover countries’ measures to protect the environment? Consumer interests? Animal welfare?*
For the purposes of the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

- to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
- to protect human life from plant- or animal-carried diseases;
- to protect animal or plant life from pests, diseases, or disease-causing organisms;
- to prevent or limit other damage to a country from the entry, establishment or spread of pests.

These include sanitary and phytosanitary measures taken to protect the health of fish and wild fauna, as well as of forests and wild flora.

Measures for environmental protection (other than as defined above), to protect consumer interests, or for the welfare of animals are not covered by the SPS Agreement. These concerns, however, are addressed by other WTO agreements (i.e., the TBT Agreement or Article XX of GATT 1994).

*Weren’t a nation’s food safety and animal and plant health regulations previously covered by GATT rules?*

Yes, since 1948 national food safety, animal and plant health measures which affect trade were subject to GATT rules. Article I of the GATT (see note 1), the most-favoured nation clause, required non-discriminatory treatment of imported products from different foreign suppliers, and Article III required that such products be treated no less favourably than domestically produced goods with respect to any laws or requirements affecting their sale. These rules applied, for instance, to pesticide residue and food additive limits, as well as to restrictions for animal or plant health purposes.

The GATT rules also contained an exception (Article XX:b) which permitted countries to take measures "necessary to protect human, animal or plant life or health," as long as these did not unjustifiably discriminate between countries where the same conditions prevailed, nor were a disguised restriction to trade. In other words, where necessary, for purposes of protecting human, animal or plant health, governments could impose more stringent requirements on imported products than they required of domestic goods.

In the Tokyo Round of multilateral trade negotiations (1974-79) an Agreement on Technical Barriers to Trade was negotiated (the 1979 TBT Agreement or "Standards Code") (see note 2). Although this agreement was not developed primarily for the purpose of regulating sanitary and phytosanitary measures, it covered technical requirements resulting from food safety and animal and plant health measures, including pesticide residue limits, inspection requirements and labelling. Governments which were members of the 1979 TBT Agreement agreed to use relevant international standards (such as those for food safety developed by the Codex) except when they considered that these standards would not adequately protect health. They also agreed to notify other governments, through the GATT Secretariat, of any technical regulations which were not based on international standards. The 1979 TBT Agreement included provisions for settling trade disputes arising from the use of food safety and other technical restrictions.

*What is new in the SPS Agreement?*
Because sanitary and phytosanitary measures can so effectively restrict trade, GATT member governments were concerned about the need for clear rules regarding their use. The Uruguay Round objective to reduce other possible barriers to trade increased fears that sanitary and phytosanitary measures might be used for protectionist purposes.

The SPS Agreement was intended to close this potential loophole. It sets clearer, more detailed rights and obligations for food safety and animal and plant health measures which affect trade. Countries are permitted to impose only those requirements needed to protect health which are based on scientific principles. A government can challenge another country’s food safety or animal and plant health requirements on the grounds that they are not justified by scientific evidence. The procedures and decisions used by a country in assessing the risk to food safety or animal or plant health must be made available to other countries upon request. Governments have to be consistent in their decisions on what is safe food, and in responses to animal and plant health concerns.

**How do you know if a measure is SPS or TBT? Does it make any difference?**

The scope of the two agreements is different. The SPS Agreement covers all measures whose purpose is to protect:

- human or animal health from food-borne risks;
- human health from animal- or plant-carried diseases;
- animals and plants from pests or diseases;

whether or not these are technical requirements.

The TBT (Technical Barriers to Trade) Agreement covers all technical regulations, voluntary standards and the procedures to ensure that these are met, except when these are sanitary or phytosanitary measures as defined by the SPS Agreement. It is thus the type of measure which determines whether it is covered by the TBT Agreement, but the purpose of the measure which is relevant in determining whether a measure is subject to the SPS Agreement.

TBT measures could cover any subject, from car safety to energy-saving devices, to the shape of food cartons. To give some examples pertaining to human health, TBT measures could include pharmaceutical restrictions, or the labelling of cigarettes. Most measures related to human disease control are under the TBT Agreement, unless they concern diseases which are carried by plants or animals (such as rabies). In terms of food, labelling requirements, nutrition claims and concerns, quality and packaging regulations are generally not considered to be sanitary or phytosanitary measures and hence are normally subject to the TBT Agreement.

On the other hand, by definition, regulations which address microbiological contamination of food, or set allowable levels of pesticide or veterinary drug residues, or identify permitted food additives, fall under the SPS Agreement. Some packaging and labelling requirements, if directly related to the safety of the food, are also subject to the SPS Agreement.

The two agreements have some common elements, including basic obligations for non-discrimination and similar requirements for the advance notification of proposed measures and the creation of information offices ("Enquiry Points"). However, many of the substantive rules are different. For example, both agreements encourage the use of international standards. However, under the SPS Agreement the only justification for not using such standards for food safety and animal/plant health protection are scientific arguments resulting from an assessment of
the potential health risks. In contrast, under the TBT Agreement governments may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors.

Also, sanitary and phytosanitary measures may be imposed only to the extent necessary to protect human, animal or plant health, on the basis of scientific information. Governments may, however, introduce TBT regulations when necessary to meet a number of objectives, such as national security or the prevention of deceptive practices. Because the obligations that governments have accepted are different under the two agreements, it is important to know whether a measure is a sanitary or phytosanitary measure, or a measure subject to the TBT Agreement.

How do governments and the interested public know who is doing what?

The transparency provisions of the SPS Agreement are designed to ensure that measures taken to protect human, animal and plant health are made known to the interested public and to trading partners. The agreement requires governments to promptly publish all sanitary and phytosanitary regulations, and, upon request from another government, to provide an explanation of the reasons for any particular food safety or animal or plant health requirement.

All WTO Member governments must maintain an Enquiry Point, an office designated to receive and respond to any requests for information regarding that country’s sanitary and phytosanitary measures. Such requests may be for copies of new or existing regulations, information on relevant agreements between two countries, or information about risk assessment decisions. The addresses of the Enquiry Points can be consulted electronically at the WTO’s home page (http://www.wto.org, "Documents on Line", search document symbol "SPS/ENQ/").

Whenever a government is proposing a new regulation (or modifying an existing one) which differs from an international standard and may affect trade, they must notify the WTO Secretariat, who then circulates the notification to other WTO Member governments (over 700 such notifications were circulated during the first three years of implementation of the SPS Agreement). The notifications are also available to the interested public and can be consulted on the WTO web site (search document symbol "G/SPS/N/"). Alternatively, notifications can be requested from the Enquiry Point of the country which is proposing the measure.

Governments are required to submit the notification in advance of the implementation of a proposed new regulation, so as to provide trading partners an opportunity to comment. The SPS Committee has developed recommendations on how the comments must be dealt with.

In cases of emergency, governments may act without delay, but must immediately notify other Members, through the WTO Secretariat, and also still consider any comments submitted by other WTO Member governments.

Does the SPS Agreement restrict a government’s ability to establish food safety and plant and animal health laws? Will food safety or animal and plant health levels be determined by the WTO or some other international institution?

The SPS Agreement explicitly recognizes the right of governments to take measures to protect human, animal and plant health, as long as these are based on science, are necessary for the protection of health, and do not unjustifiably discriminate among foreign sources of supply. Likewise, governments will continue to determine the food safety levels and animal and plant
health protection in their countries. Neither the WTO nor any other international body will do this.

The SPS Agreement does, however, encourage governments to "harmonize" or base their national measures on the international standards, guidelines and recommendations developed by WTO member governments in other international organizations. These organizations include, for food safety, the joint FAO/WHO Codex Alimentarius Commission; for animal health, the Office International des Epizooties; and for plant health, the FAO International Plant Protection Convention. WTO member governments have long participated in the work of these organizations — including work on risk assessment and the scientific determination of the effects on human health of pesticides, contaminants or additives in food; or the effects of pests and diseases on animal and plant health. The work of these technical organizations is subject to international scrutiny and review.

One problem is that international standards are often so stringent that many countries have difficulties implementing them nationally. But the encouragement to use international standards does not mean that these constitute a floor on national standards, nor a ceiling. National standards do not violate the SPS Agreement simply because they differ from international norms. In fact, the SPS Agreement explicitly permits governments to impose more stringent requirements than the international standards. However, governments which do not base their national requirements on international standards may be required to justify their higher standard if this difference gives rise to a trade dispute. Such justification must be based on an analysis of scientific evidence and the risks involved.

**What does harmonization with international food safety standards mean? Will this result in a lowering of health protection, i.e., downward harmonization?**

Harmonization with international food safety standards means basing national requirements on the standards developed by the FAO/WHO Joint Codex Alimentarius Commission (see note 3). Codex standards are not "lowest common denominator" standards. They are based on the input of leading scientists in the field and national experts on food safety. These are the same government experts who are responsible for the development of national food safety standards. For example, the recommendations for pesticide residues and food additives are developed for Codex by international groups of scientists who use conservative, safety-oriented assumptions and who operate without political interference. In many cases, the standards developed by Codex are higher than those of individual countries, including countries such as the United States. As noted in the reply to the previous question, governments may nonetheless choose to use higher standards than the international ones, if the international standards do not meet their health protection needs.

**Can governments take adequate precautions in setting food safety and animal and plant health requirements? What about when there may not be sufficient scientific evidence for a definitive decision on safety, or in emergency situations? Can unsafe products be banned?**

Three different types of precautions are provided for in the SPS Agreement. First, the process of risk assessment and determination of acceptable levels of risk implies the routine use of safety margins to ensure adequate precautions are taken to protect health. Second, as each country determines its own level of acceptable risk, it can respond to national concerns regarding what are necessary health precautions. Third, the SPS Agreement clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. This also permits immediate measures to be taken in emergency situations.
There are many examples of bans on the production, sale and import of products based on scientific evidence that they pose an unacceptable risk to human, animal or plant health. The SPS Agreement does not affect a government’s ability to ban products under these conditions.

**Can food safety and animal and plant health requirements be set by local or regional governments? Can there be differences in requirements within a country?**

It is accepted in the SPS Agreement that food safety and animal and plant health regulations do not necessarily have to be set by the highest governmental authority and that they may not be the same throughout a country. Where such regulations affect international trade, however, they should meet the same requirements as if they were established by the national government. The national government remains responsible for implementation of the SPS Agreement, and should support its observance by other levels of government. Governments should use the service of non-governmental institutions only if these comply with the SPS Agreement.

**Does the SPS Agreement require countries to give priority to trade over food safety, or animal and plant health?**

No, the SPS Agreement allows countries to give food safety, animal and plant health priority over trade, provided there is a demonstrable scientific basis for their food safety and health requirement. Each country has the right to determine what level of food safety and animal and plant health it considers appropriate, based on an assessment of the risks involved.

Once a country has decided on its acceptable level of risk, there are often a number of alternative measures which may be used to achieve this protection (such as treatment, quarantine or increased inspection). In choosing among such alternatives, the SPS Agreement requires that a government use those measures which are no more trade restrictive than required to achieve its health protection objectives, if these measures are technically and economically feasible. For example, although a ban on imports could be one way to reduce the risk of entry of an exotic pest, if requiring treatment of the products could also reduce the risk to the level considered acceptable by the government, this would normally be a less trade restrictive requirement.

**Can national food safety and animal and plant health legislation be challenged by other countries? Can private entities bring trade disputes to the WTO? How are disputes settled in the WTO?**

Since the GATT began in 1948, it has been possible for a government to challenge another country’s food safety and plant and animal health laws as artificial barriers to trade. The 1979 TBT Agreement also had procedures for challenging another signatory’s technical regulations, including food safety standards and animal and plant health requirements. The SPS Agreement makes more explicit not only the basis for food safety and animal and plant health requirements that affect trade but also the basis for challenges to those requirements. While a nation’s ability to establish legislation is not restricted, a specific food safety or animal or plant health requirement can be challenged by another country on the grounds that there is not sufficient scientific evidence supporting the need for the trade restriction. The SPS Agreement provides greater certainty for regulators and traders alike, enabling them to avoid potential conflicts.

The WTO is an inter-governmental organization and only governments, not private entities or non-governmental organizations, can submit trade disputes to the WTO’s dispute settlement
procedures. Non-governmental entities can, of course, make trade problems known to their government and encourage the government to seek redress, if appropriate, through the WTO.

By accepting the WTO Agreement, governments have agreed to be bound by the rules in all of the multilateral trade agreements attached to it, including the SPS Agreement. In the case of a trade dispute, the WTO’s dispute settlement procedures (click here for an introduction, click here for details) encourage the governments involved to find a mutually acceptable bilateral solution through formal consultations. If the governments cannot resolve their dispute, they can choose to follow any of several means of dispute settlement, including good offices, conciliation, mediation and arbitration. Alternatively, a government can request that an impartial panel of trade experts be established to hear all sides of the dispute and to make recommendations.

In a dispute on SPS measures, the panel can seek scientific advice, including by convening a technical experts group. If the panel concludes that a country is violating its obligations under any WTO agreement, it will normally recommend that the country bring its measure into conformity with its obligations. This could, for example, involve procedural changes in the way a measure is applied, modification or elimination of the measure altogether, or simply elimination of discriminatory elements.

The panel submits its recommendations for consideration by the WTO Dispute Settlement Body (DSB), where all WTO Member countries are represented. Unless the DSB decides by consensus not to adopt the panel’s report, or unless one of the parties appeals the decision, the defending party is obliged to implement the panel’s recommendations and to report on how it has complied. Appeals are limited to issues of law and legal interpretations by the panel.

Although only one panel was asked to consider sanitary or phytosanitary trade disputes during the 47 years of the former GATT dispute settlement procedures, during the first three years of the SPS Agreement ten complaints were formally lodged with reference to the new obligations. This is not surprising as the agreement clarifies, for the first time, the basis for challenging sanitary or phytosanitary measures which restrict trade and may not be scientifically justified. The challenges have concerned issues as varied as inspection and quarantine procedures, animal diseases, "use-by" dates, the use of veterinary drugs in animal rearing, and disinfection treatments for beverages. Dispute settlement panels have been requested to examine four of the complaints; the other complaints have been or are likely to be settled following the obligatory process of bilateral consultations.

**Who was responsible for developing the SPS Agreement? Did developing countries participate in the negotiation of the SPS Agreement?**

The decision to start the Uruguay Round trade negotiations was made after years of public debate, including debate in national governments. The decision to negotiate an agreement on the application of sanitary and phytosanitary measures was made in 1986 when the Round was launched. The SPS negotiations were open to all of the 124 governments which participated in the Uruguay Round. Many governments were represented by their food safety or animal and plant health protection officials. The negotiators also drew on the expertise of technical international organizations such as the FAO, the Codex and the OIE.

Developing countries participated in all aspects of the Uruguay Round negotiations to an unprecedented extent. In the negotiations on sanitary and phytosanitary measures, developing countries were active participants, often represented by their national food safety or animal and plant health experts. Both before and during the Uruguay Round negotiations, the GATT Secretariat assisted developing countries to establish effective negotiating positions. The SPS
Agreement calls for assistance to developing countries to enable them to strengthen their food safety and animal and plant health protection systems. FAO and other international organizations already operate programmes for developing countries in these areas.

Was there public participation in the Uruguay Round negotiations? Were private sector interests or consumer interests excluded?

GATT was an intergovernmental organization and it was governments which participated in GATT trade negotiations; neither private business nor non-governmental organizations participated directly. But as the scope of the Uruguay Round was unprecedented, so was the public debate. Many governments consulted with both their public and private sectors on various aspects of the negotiations, including the SPS Agreement. Some governments established formal channels for public consultation and debate while others did so on a more ad hoc basis. The GATT Secretariat also had considerable contact with international non-governmental organizations as well as with the public and private sectors of many countries involved in the negotiations. The final Uruguay Round results were subject to national ratification and implementation processes in most GATT member countries.

The WTO is, likewise, an intergovernmental organization. Private business and non-governmental organizations do not directly participate in its work, but can influence the work of the WTO through their contacts with their own governments. In addition, the WTO Secretariat regularly has contacts with many non-governmental organizations.

What is the SPS Committee and who is on it? What does it do?

The SPS Agreement established a Committee on Sanitary and Phytosanitary Measures (the "SPS Committee") to provide a forum for consultations about food safety or animal and plant health measures which affect trade, and to ensure the implementation of the SPS Agreement. The SPS Committee, like other WTO committees, is open to all WTO Member countries. Governments which have an observer status in the higher level WTO bodies (such as the Council for Trade in Goods) are also eligible to be observers in the SPS Committee. The Committee has agreed to invite representatives of several international intergovernmental organizations as observers, including Codex, OIE, IPPC, WHO, UNCTAD and the International Standards Organization (ISO). Governments may send whichever officials they believe appropriate to participate in the meetings of the SPS Committee, and many send their food safety authorities or veterinary or plant health officials.

The SPS Committee usually holds three regular meetings each year. It also holds occasional joint meetings with the TBT Committee on notification and transparency procedures. Informal or special meetings may be scheduled as needed.

During its first year, the SPS Committee developed recommended procedures and a standardized format for governments to use for the required advance notification of new regulations. Over 700 notifications of sanitary and phytosanitary measures were submitted and circulated by the end of 1997. The Committee considered information provided by governments regarding their national regulatory procedures, their use of risk assessment in the development of sanitary and phytosanitary measures and their disease-status, notably with respect to foot-and-mouth disease and fruit-fly. In addition, a considerable number of trade issues were discussed by the SPS Committee, in particular with regard to bovine spongiform encephalopathy (BSE). As required by the SPS Agreement, the SPS Committee developed a provisional procedure to monitor the use of international standards. The SPS Committee is continuing to work on guidelines to ensure
consistency in risk management decisions, in order to reduce possible arbitrariness in the actions taken by governments. In 1998, the SPS Committee will review the operation of the SPS Agreement.

**Who benefits from the implementation of the SPS Agreement? Is the agreement in the interest of developing countries?**

**Consumers** in all countries benefit. The SPS Agreement helps ensure, and in many cases enhances, the safety of their food as it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions. More information will increasingly become available to consumers as a result of greater transparency in governmental procedures and on the basis for their food safety, animal and plant health decisions. The elimination of unnecessary trade barriers allows consumers to benefit from a greater choice of safe foods and from healthy international competition among producers.

Specific sanitary and phytosanitary requirements are most frequently applied on a bilateral basis between trading countries. **Developing countries** benefit from the SPS Agreement as it provides an international framework for sanitary and phytosanitary arrangements among countries, irrespective of their political and economic strength or technological capacity. Without such an agreement, developing countries could be at a disadvantage when challenging unjustified trade restrictions. Furthermore, under the SPS Agreement, governments must accept imported products that meet their safety requirements, whether these products are the result of simpler, less sophisticated methods or the most modern technology. Increased technical assistance to help developing countries in the area of food safety and animal and plant health, whether bilateral or through international organizations, is also an element of the SPS Agreement.

**Exporters** of agricultural products in all countries benefit from the elimination of unjustified barriers to their products. The SPS Agreement reduces uncertainty about the conditions for selling to a specific market. Efforts to produce safe food for another market should not be thwarted by regulations imposed for protectionist purposes under the guise of health measures. **Importers** of food and other agricultural products also benefit from the greater certainty regarding border measures. The basis for sanitary and phytosanitary measures which restrict trade are made clearer by the SPS Agreement, as well as the basis for challenging requirements which may be unjustified. This also benefits the many processors and commercial users of imported food, animal or plant products.

**What difficulties do developing countries face in implementing the SPS Agreement? Will they receive any assistance in this regard? Are there special provisions for developing countries?**

Although a number of developing countries have excellent food safety and veterinary and plant health services, others do not. For these, the requirements of the SPS Agreement present a challenge to improve the health situation of their people, livestock and crops which may be difficult for some to meet. Because of this difficulty, the SPS Agreement delayed all requirements, other than those dealing with transparency (notification and the establishment of Enquiry Points), until 1997 for developing countries, and until 2000 for the least developed countries. This means that these countries are not required to provide a scientific justification for their sanitary or phytosanitary requirements before that time. Countries which need longer time periods, for example for the improvement of their veterinary services or for the implementation of specific obligations of the agreement, can request the SPS Committee to grant them further delays.
Many developing countries have already adopted international standards (including those of Codex, OIE and the IPPC) as the basis for their national requirements, thus avoiding the need to devote their scarce resources to duplicate work already done by international experts. The SPS Agreement encourages them to participate as actively as possible in these organizations, in order to contribute to and ensure the development of further international standards which address their needs.

One provision of the SPS Agreement is the commitment by members to facilitate the provision of technical assistance to developing countries, either through the relevant international organizations or bilaterally. FAO, OIE and WHO have considerable programmes to assist developing countries with regard to food safety, animal and plant health concerns. A number of countries also have extensive bilateral programmes with other WTO Members in these areas. The WTO Secretariat has undertaken a programme of regional seminars to provide developing countries (and those of Central and Eastern Europe) with detailed information regarding their rights and obligations stemming from this agreement. These seminars are provided in cooperation with the Codex, OIE and IPPC, to ensure that governments are fully aware of the role these organizations can play in assisting countries to meet their requirements and fully enjoy the benefits resulting from the SPS Agreement. The seminars are open to participation by interested private business associations and consumer organizations. The WTO Secretariat also provides technical assistance through national workshops and to governments through their representatives in Geneva.

http://www.wto.org/english/news_e/news07_e/spc_ims_oct07_e.htm

WTO: 2007 NEWS ITEMS19 October 2007

SANITARY AND PHYTOSANITARY MEASURES
Food safety and animal-plant health data now easier to find

A new comprehensive system for searching for information on WTO member governments’ sanitary and phytosanitary measures — food safety and animal and plant health and safety — has been launched.

The SPS Information Management System (SPS IMS) is a comprehensive source allowing users to track and obtain information on measures that member governments have notified to the WTO (an obligation for WTO members), specific trade concerns that they have raised, documents of the WTO’s Sanitary and Phytosanitary Measures Committee, member governments’ national enquiry points and their authorities handling notification.

The internal version of the system helps the Secretariat produce official documents such as SPS notifications, and in undertaking faster and more comprehensive analyses and reporting on SPS matters.

The public version of the system, now available through the WTO website, aims to help member governments and other interested people find SPS information according to their specific needs.

For example, the system allows searches to be based on a variety of criteria such as geographic groupings, product codes, comment periods, keywords, etc.

The SPS Information Management System is at http://spsims.wto.org.
Read the SPS Agreement.

Ask yourself why the TBT and SPS Agreements have been concluded. Why were Art. III and XX GATT not considered sufficient?

**AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES**

*Members,*

*Reaffirming* that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

*Desiring* to improve the human health, animal health and phytosanitary situation in all Members;

*Noting* that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

*Desiring* the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

*Recognizing* the important contribution that international standards, guidelines and recommendations can make in this regard;

*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

*Recognizing* that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;
Desiring therefore 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)1;

Hereby agree as follows:

**Article 1**

**General Provisions**

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

3. The annexes are an integral part of this Agreement.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

**Article 2**

**Basic Rights and Obligations**

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.

4. 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).

**Article 3**

1 In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.
Harmonization

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. 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.

Article 4

Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or

2 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.
phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

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.

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

5. 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.

6. 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.3

3 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
7. 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.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7

Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

significantly less restrictive to trade.
Article 8

Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9

Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10

Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.
Article 11

Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

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

Article 12

Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

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

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported
products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

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

Article 13

Implementation

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

Article 14

Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or
imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A

DEFINITIONS

1. **Sanitary or phytosanitary measure** - 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.

2. **Harmonization** - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. **International standards, guidelines and recommendations**

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

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

4 For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.
for plant health, the international standards, guidelines and recommendations
developed under the auspices of the Secretariat of the International Plant
Protection Convention in cooperation with regional organizations operating
within the framework of the International Plant Protection Convention; and

for matters not covered by the above organizations, appropriate standards,
guidelines and recommendations promulgated by other relevant international
organizations open for membership to all Members, as identified by the
Committee.

4. **Risk assessment** - The evaluation of the likelihood of entry, establishment or spread of a
pest or disease within the territory of an importing Member according to the sanitary or
phytosanitary measures which might be applied, and of the associated potential biological and
economic consequences; or the evaluation of the potential for adverse effects on human or animal
health arising from the presence of additives, contaminants, toxins or disease-causing organisms
in food, beverages or feedstuffs.

5. **Appropriate level of sanitary or phytosanitary protection** - The 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.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. **Pest- or disease-free area** - An area, whether all of a country, part of a country, or all or
parts of several countries, as identified by the competent authorities, in which a specific pest or
disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area -
whether within part of a country or in a geographic region which includes parts of or all of several
countries - in which a specific pest or disease is known to occur but is subject to regional control
measures such as the establishment of protection, surveillance and buffer zones which will
confine or eradicate the pest or disease in question.

7. **Area of low pest or disease prevalence** - An area, whether all of a country, part of a
country, or all or parts of several countries, as identified by the competent authorities, in which a
specific pest or disease occurs at low levels and which is subject to effective surveillance, control
or eradication measures.

ANNEX B

TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

**Publication of regulations**

1. Members shall ensure that all sanitary and phytosanitary regulations which have been
adopted are published promptly in such a manner as to enable interested Members to become
acquainted with them.

5 Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the generally.

6 When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.
proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

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

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

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.
ANNEX C

CONTROL, INSPECTION AND APPROVAL PROCEDURES

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

   (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

   (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

   (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

   (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

   (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

   (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;

   (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

   (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

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7 Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.
(i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.
2. EC -- Measures Concerning Meat and Meat Products (Hormones)

What is the legal relationship between the GATT and the SPS Agreement?

What are the main differences in the approaches taken by the panel and the AB?

Can you think of why the Appellate Body overruled the panel on the procedural requirements for adopting an SPS measure? Work out for yourself what the AB meant by “rational relationship.”

Which arguments could be made in favour of the AB/ in favour of the panel approach?

Is the Appellate Body’s rejection of the concept of “risk management” plausible?

2-1. Panel Report, WT/DS26/R/USA, 18 August 1997

Chairman: Mr. Thomas Cottier, Panellists: Mr. Jun Yokota, Mr. Peter Palecka

http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm

Editorial comment: The footnotes have been omitted from this report.

(...)  

II. FACTUAL ASPECTS

1. The measures at issue


2.2. Directive 81/602/EEC prohibits the administering to farm animals of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action; the placing on the market or slaughtering of farm animals to which these substances have been administered; the placing on the market of meat from such animals; the processing of meat from such animals and the placing on the market of meat products prepared from or with such meat (…)

2.3. Directive 88/146/EEC extends the prohibition imposed by Directive 81/602/EEC to the administration to farm animals of trenbolone acetate and zeranol for any purpose, and oestradiol-17β, testosterone and progesterone for fattening purposes. However, the Directive maintains the permission to administer these three natural hormones to animals for therapeutic and zootechnical purposes under prescribed conditions (…)

2. The substances at issue (hormones)

2.8. Of the six hormones involved in this dispute, three are naturally occurring hormones produced by humans and animals: oestradiol-17β, progesterone and testosterone (hereafter also referred to as natural hormones). Oestradiol-17β is a sex steroidal hormone with oestrogenic action (i.e., responsible for female characteristics); testosterone is a sex steroidal hormone with androgenic action (i.e., responsible for male characteristics); progesterone is a sex steroidal hormone with gestagenic action (i.e., responsible for
maintaining pregnancy). These three hormones are produced throughout the lifetime of each individual and are required for normal physiological functioning and maturation. Hormone levels vary with the tissue, with the species of animal and with the sex and individual. Hormone levels vary most dramatically with puberty, pregnancy and castration.

2.9. The other three hormones involved in this dispute are artificially produced hormones: trenbolone, zeranol and melengestrol acetate (MGA) (hereafter also referred to as synthetic hormones). These hormones mimic the biological activity of the natural hormones. Trenbolone mimics the action of testosterone; zeranol mimics the action of oestradiol-17β; and MGA mimics progesterone.

2.10 In the United States, the three natural hormones may be used for medical treatment (therapeutic). Oestradiol-17β is also permitted for zootechnical purposes. In the United States the six hormones are also approved for growth promotion purposes (…)

3. The Codex Alimentarius standards

2.11. The SPS Agreement makes reference, in a number of provisions, to "the relevant international standards, guidelines and recommendations”. Annex A:3(a) of the SPS Agreement states that the international standards, guidelines and recommendations relevant for food safety are those established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.

2.12 The Codex Alimentarius Commission (hereafter the "Codex Commission") is a joint FAO/WHO advisory body established to implement the Joint FAO/WHO Food Standards Programme. The purpose of this programme is to protect the health of consumers and to ensure fair practices in food trade through the elaboration of food standards. These standards, together with notifications received from governments with respect to their acceptance or otherwise of the standards, constitute the Codex Alimentarius. The Codex Alimentarius (hereafter "the Codex") is thus a collection of internationally adopted food standards presented in a uniform manner.

2.13 Membership of the Codex Commission is open to all member Nations and Associate members of FAO and/or WHO and is composed of government representatives of these members. Most of its members, including the United States and the EC member States, are WTO Members (…)

2.14 The technical and scientific analysis of veterinary drugs, food additives and some other substances in foods and beverages is not undertaken by the Codex Commission itself but independently by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"). The JECFA is composed of independent scientists who serve in their individual capacities as experts, not as representatives of their governments or organizations. The goal of the JECFA evaluation of veterinary drugs is:

"to establish safe levels of intake by setting Acceptable Daily Intakes (ADI) and to develop maximum residue limits when veterinary drugs are used in accordance with good veterinary practice".

(...)
(a) The elaboration of Codex standards

2.16 The Codex Commission keeps under review and may revise Codex standards, generally following procedures similar to those used for the elaboration of standards. Codex standards are published and sent to governments for acceptance and to international organizations to which competence in the matter has been transferred by their EC member States. Acceptance of the standards is voluntary and Codex members are not required to indicate formal acceptance of Codex standards, guidelines or recommendations. The implementation of Codex standards at the national level is the responsibility of members.

(b) Codex standards for five hormones at issue

2.17 Codex standards for veterinary drugs are normally stated in terms of an Acceptable Daily Intake ("ADI") and a Maximum Residue Limit ("MRL"). An ADI is "an estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg)" (…)

2.18 A Codex MRL is one of the tools for ensuring that intake does not exceed the ADI and that "Good Practice in the use of Veterinary Drugs" ("GPVD") is observed. It is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in μg/kg or μg/kg on a fresh weight basis) that is recommended by the Codex Commission to be legally permitted or recognized as acceptable in or on a food (…)

2.19 "Good Practice in the Use of Veterinary Drugs" (GPVD), is defined as:

"the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions." (…)

2.22 The 32nd JECFA Report of 1988 ("1988 JECFA Report"), on which the Codex standards are based, concluded that residues arising from the use of testosterone and oestradiol-17β as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health and that the amount of exogenous progesterone ingested in meat from treated animals would not be capable of exerting an hormonal effect, and therefore, any toxic effect, in human beings. (…)

4. History of events

2.26 European consumers' concern over the use of hormones for growth promotion purposes in livestock grew steadily throughout the 1970s as the result of the illegal use of diethylstilboestrol, commonly known as DES (see paragraph 4.123), in veal production in France and incidents, particularly in Italy, where adolescents had been reported to be suffering from hormonal irregularities and veal had come under suspicion as a possible cause. European consumer organizations called for a boycott of veal, and the market for veal was severely affected. On 20 September 1980, the EC Council of (Agriculture) Ministers adopted a declaration in favour of a ban on the use of oestrogen and endorsed the principle of greater harmonisation of legislation on veterinary medicines and of greater control on animal rearing, both at the production and slaughtering stages.
2.27 On 31 October 1980, the EC Commission proposed legislation aimed at banning the use of all hormone products (COM (80) 614), except for therapeutic purposes (...) On 13 February 1981, the European Parliament adopted the "Nielsen Report" approving the Commission proposals (...) 

2.28 The EC Council of Ministers adopted its first Directive on the issue (81/602/EEC) on 31 July 1981. In that Directive, and in regard to five of the hormones at issue (all but MGA), the Council directed the Commission to provide, not later than 1 July 1984, a report on the experience acquired and scientific developments, accompanied, if necessary, by proposals taking into account these developments. Accordingly, the Commission set up a Scientific Group on Anabolic Agents in Animal Production, chaired by Professor G.E. Lamming (the "Lamming Group") (...) 

"The Scientific Working Group is of the opinion that the use of oestradiol-17β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application would not present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals (...) 

"Proper programmes to control and monitor the use of anabolic agents are essential (...) 

2.29 The EC Scientific Veterinary Committee (...) Committees supported the conclusions and recommendations of the Lamming Report, but stressed the need to lay down provisions regarding the establishment of proper programmes to control and monitor the use of anabolic agents with regard, in particular, to instructions for use, surveillance programmes and analysis methods (...) However, the European Parliament, the EC Economic and Social Committee and the EC Council of Ministers rejected the Commission's proposal. (...) 

2.31 Following reports of significant use of illegal growth-promoting hormonal substances in a number of EC member States, on 26 September 1988 the European Parliament established a "Committee of Enquiry into the Problem of Quality in the Meat Sector". The Report of this Committee (the "Pimenta Report") endorsed the ban on the use of hormones and was adopted by the European Parliament on 29 March 1989 (see paragraphs 4.36-4.39) (...) 

(i) this was the only way to restore consumer confidence in the meat sector; (...) 

(iii) The scientific conclusions regarding the use of natural hormones rested upon strict conditions of use which it believed could not in reality be attained. The Committee was of the opinion that use of the natural/nature-identical hormones carries the risk of inexperienced application, incorrect dosage and unsupervised injection which could pose a risk to the animal and the consumer, and also noted doubts with regard to long-term cumulative and interactive potential carcinogenicity (...) 

(v) The Committee believed that the Commission should promote the concept of animal welfare in agricultural production (...) 

2.33 The EC Commission organized a scientific conference on this subject in Brussels from 29 November to 1 December 1996. With regard to the natural hormones, the 1995 EC Scientific Conference on Growth Promotion in Meat Production (the "1995 EC Scientific Conference") concluded that:
"At present, there is no evidence for possible health risks to the consumer due to the use of natural sex hormones for growth promotion, since:

Residue levels of these substances measured in meat of treated animals fall within the physiological range observed in meat of comparable untreated animals.

The daily production of sex hormones by humans is much higher than the amounts possibly consumed from meat, even in the most sensitive humans (prepubertal children and menopausal women).

Due to an extensive first-pass metabolism, the bioavailability of ingested hormones is low, thus providing a further safety margin."

With regard to the synthetic hormones, zeranol and trenbolone, the 1995 EC Scientific Conference concluded that:

"At the doses needed for growth promotion, residue levels [of trenbolone and zeranol] are well below the levels regarded as safe (the MRLs). There are, at present, no indications of a possible human health risk from the low levels of covalently-bound residues of trenbolone."

(…)

IV. ARGUMENTS OF THE PARTIES

2. The SPS Agreement

(a) Article 2.2 of the SPS Agreement

4.24 The United States claimed that while the negotiators had not defined precisely "scientific principles", at a minimum this term incorporated the scientific method, which represented those principles and processes universally regarded as necessary for scientific investigation, in particular procedures for:

(i) the observation of phenomena in nature or under controlled conditions;

(ii) the systematic classification of empirical data;

(iii) the measurement of empirical quantities and for calculating probable errors and significant deviations;

(iv) forming a hypothesis;

(v) analysing experimental results using logic and mathematics; and

(vi) many other related techniques and processes.

4.25 The European Communities responded that the US explanation of the concept of "scientific principles" was a caricature of "the scientific method"(…) There were many theories of science and the "scientific method"(…) Measures must be based on scientific principles, as opposed to non-scientific ones, such as superstition (…) If, for example, the measure was aimed at eliminating a pathogenic organism from a food, there were several
methods, e.g. heating, salting, pickling, etc. which could be scientifically proven to be effective. If, however, a Member required prayers to be said over the food, or a ritual dance to be performed around it, that would not be compatible with the SPS Agreement because such methods could not be scientifically proven to be effective.

4.26 The European Communities further argued that (...) What was important was whether, in the scientific research employed by the EC scientists (or the scientific reports to which they made reference in their reports), the minimal attributes of scientific inquiry were respected (…)

4.42 (...) Indeed, in response to the 1995 EC Scientific Conference Proceedings, EC Agriculture and Rural Affairs Commissioner Fischler had confirmed that these hormones did not pose a danger to health when used in beef production. However, rather than deciding to modify the ban to reflect the scientific evidence, Mr. Fischler had indicated that this was a political matter and had noted that a 10 million ECU advertising campaign extolling the virtues of eating hormone-free meat had been launched and that the EC Council would be pressed to introduce tougher monitoring measures (…)

4.46 The United States replied that conclusions of any scientific review could not be absolute because science was not absolute. Experimental results might either disprove or lend support to a particular hypothesis, but never prove it, and certainly would never prove it "beyond doubt". Yet the European Communities appeared to claim for itself the right to maintain their ban because scientific reports had not "established beyond doubt" that the use of these hormones for growth promotion was safe. Science could be used to determine whether there was a risk associated with the use of a particular substance; it could not eliminate the possibility that a potential risk might be found in the future (…)

(c) Article 3.1 of the SPS Agreement

4.73 The United States claimed that, contrary to the requirements of Article 3.1 to base its sanitary measures on international standards, guidelines or recommendations where they exist, the EC ban was not based on the relevant international standards. The relevant international standards in this respect were those of the Codex Commission. The Codex standards for oestradiol-17β, progesterone and testosterone in foods of bovine origin stated that there was no need to set any Acceptable Daily Intake level (ADI) or any Maximum Residue Limit (MRL).

4.77 The European Communities argued that (...) the Codex standards on the five hormones at issue had been adopted by a majority of only 33 votes in favour, 29 votes against and 7 abstentions (i.e. a minority of those participating), that was a very close vote in favour of the adoption of the standards. There were, therefore, at least 14 countries other than the 15 EC member States which had voted against the standard. This close vote clearly indicated that the issue of hormones had been, and continued to be, very controversial both from the scientific and the regulatory policy point of view (…)

4.78 The European Communities added that Article 3.1 made it plainly clear that there was no absolute obligation on Members to always follow standards on SPS measures adopted by Codex. There was no doubt that the two systems of the Codex and the SPS Agreement did not interact properly, because a member of Codex, which had different views about other considerations (e.g. health concerns of consumers) and in good faith abstained from blocking the adoption of a Codex standard knowing in advance that in
doing so it would not be required to follow the standard whose adoption it did not block, would later find itself to have an obligation to follow under the SPS Agreement. This was an inherent contradiction in the functioning of the two systems, of which both Codex and WTO Members were well aware and efforts were now being made to resolve it in an appropriate way.

(d) Article 3.3 of the SPS Agreement

4.85 The European Communities argued that (…) Codex and the other relevant international organisations mentioned in the SPS Agreement might issue standards, guidelines or recommendations, but they were relevant only for those Members which chose to follow them and base their measures on them. If a Member elected not to follow them because it had a different level of sanitary protection, the Member was entitled to take another type of measure necessary to achieve its chosen level of protection (…)

4.94 The United States claimed that the EC ban was not designed to, nor did it, achieve any particular level of protection. Meat naturally had widely varying residues of the endogenous hormones, and many foods had levels of residues which were orders of magnitude greater than that found in the banned meat (as shown in the following tables).

(...)

Comparative Oestrogen Intakes from Food Sources

<table>
<thead>
<tr>
<th>Food</th>
<th>Unit Weight (g)</th>
<th>Oestrogen Intake (nano gram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unimplanted Steer Meat</td>
<td>500</td>
<td>61.1</td>
</tr>
<tr>
<td>Oestradiol-Implanted Steer Meat</td>
<td>500</td>
<td>11.4</td>
</tr>
<tr>
<td>Zeranol-Implanted Steer Meat</td>
<td>500</td>
<td>7*</td>
</tr>
<tr>
<td>Cow Meat</td>
<td>500</td>
<td>75*</td>
</tr>
<tr>
<td>Hen’s Egg</td>
<td>50-60</td>
<td>1,750*</td>
</tr>
<tr>
<td>Cabbage</td>
<td>100</td>
<td>2,400*</td>
</tr>
<tr>
<td>Peas</td>
<td>100</td>
<td>400*</td>
</tr>
<tr>
<td>Wheat Germ</td>
<td>10</td>
<td>200*</td>
</tr>
<tr>
<td>Soybean Oil</td>
<td>10 ml</td>
<td>20,000*</td>
</tr>
<tr>
<td>Milk</td>
<td>500 ml</td>
<td>75*</td>
</tr>
</tbody>
</table>

* Oestradiol Equivalents

(...)

(e) Articles 5.1 and 5.2 of the SPS Agreement

4.110 The United States claimed that the European Communities had never performed any risk assessment, or relied on any risk assessment, that could serve as a basis for its ban with respect to the six hormones (…)

4.111 The United States claimed that the European Communities could not just assert that there was a risk associated with these six hormones when used for growth promotion and then prohibit their use (…)

4.113 The European Communities responded that Codex had not developed risk assessment techniques. In the absence of such international guidelines, each Member must apply its own methodology. That followed by the European Communities was, and had been
throughout the consideration of the hormone issue, to obtain the best scientific information available, to have that information evaluated by technical experts and for the EC Commission to make a proposal based on an assessment of that scientific and technical advice (…)

4.122 (…) The European Communities had suggested that it had adopted "zero risk" as the appropriate level of protection, and this "zero risk" level would justify its measures under Article 3.3. The United States submitted that an "appropriate level of sanitary protection" was a level of protection from a risk and that the European Communities had not identified any particular risk from these hormones, which were all safe.

4.123 The European Communities claimed that it was not required to accept only the two scientific reports which the United States contended had carried out a proper risk assessment, i.e. the Lamming Report and the Codex assessment. These were just two reports of a certain scientific orientation, but there were other scientific reports by individual scientists, scientific conferences, (e.g. the 1995 EC Scientific Conference) and responsible international institutions (eg. IARC) which did not entirely agree with them. Some of the scientific reports on which the European Communities had based its measures questioned the very basic scientific assumptions on which the reports supported by the United States were founded, including the carcinogenic effects of these hormones when used for animal growth promotion (…)

(ii) Metabolites

4.166 The European Communities asserted that there were scientists who argued that knowledge about the toxicity of the metabolites of these hormones was as yet very limited. Moreover, metabolites of such substances which, even in low concentrations, might have highly toxic effects were generated in the human body. These scientists argued that "the use of hormones in growth promotion of animals should not be allowed, as it cannot be excluded that unchanged agents, their metabolites and, above all, unknown highly effective and toxic metabolites are distributed with the meat which is purchased by consumers" (…)

4.167 The United States argued that EC claim that there were health risks arising from metabolites of the hormones were unfounded. The European Communities appeared to simply rely on the fact that "there are scientists who argue" that "knowledge is very limited" and metabolites "may have adverse effects", with no evidence of any such adverse effects, much less in relation to specific hormones or to the levels of exposure from the use of hormones for growth promotion purposes (…)

(v) Administration and use of hormones

4.194 The European Communities claimed that there were additional risks to human and animal health arising from the administration and potential misuse of hormones. At the 1995 EC Scientific Conference, it had been observed that a misuse could be hazardous to consumers, if instead of the authorized implant cheaper black-market products were administered to the animals via injections at undefined parts of the animals' bodies. Moreover, injection could be given in addition to an authorized implant (…)

4.195 The United States rejected the EC attempt to justify its ban on the grounds that it could not be sure that the hormones would always be administered correctly. It was not clear to the United States how this differed from the purported "detection and control risks", since in both cases the European Communities claimed to be concerned that
unauthorized meat would slip past its detection. In any event, the same problems applied to this category of purported risk as applied to the EC detection and control concerns. The European Communities did not identify any particular risk, nor did it produce any risk assessment or evidence of risk (…)

(g) Article 5.5 of the SPS Agreement

4.218 The European Communities argued that (…) Article 5.5 did not require Members to achieve consistency between the level of protection which they chose against different hazards to human, animal and plant life and health. This would in any case be an illogical requirement; no Member protected individual plants to the same extent that it protected individual humans. Consistency of application meant that Members must in all circumstances apply measures which were capable of achieving the same level of protection against a given hazard unless there was justifiable reason in a particular situation to apply difference measures to achieve a different level of protection.

4.220 (…) The European Communities in fact applied different levels of protection to different meat. The European Communities had suggested that its appropriate level of protection with respect to the six hormones when used for growth promotion purposes was "zero risk". However, it had chosen a different, less stringent, level of protection with respect to carbadox. Carbadox was a substance that the European Communities permitted to be used for growth promotion purposes in the production of swine. It was a feed additive that was a known genotoxic carcinogen, unlike the six hormones. The experts advising the Panel all confirmed that carbadox was genotoxic. Genotoxic meant that scientists considered carbadox to induce cancer (…)

VIII. FINDINGS

A. CLAIMS OF THE PARTIES

8.1 This dispute arises essentially from the following facts. In 1981 the Council of the European Communities ("EC Council") adopted Directive 81/602/EEC, inter alia, requiring the EC member States of the European Communities to prohibit the administration to farm animals of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action. Directive 81/602/EEC further provided that pending adoption of a decision of the EC Council on the administration to farm animals for growth promotion purposes of oestradiol-17β, testosterone, progesterone, zeranol and trenbolone EC member States could continue to apply the national regulations in force concerning those substances. In 1988 the EC Council adopted Directive 88/146/EEC which brought the administration to farm animals for growth promotion purposes of these five hormones within the general prohibition imposed by Directive 81/602/EEC. The 1988 Directive also required the prohibition of importation from third countries of animals and of meat from animals to which substances with thyrostatic, oestrogenic, androgenic or gestagenic action have been administered. (…) On 29 April 1996, the EC Council adopted Directive 96/22/EC (repealing and replacing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC) which confirms and extends the above-mentioned prohibitions. This 1996 Directive will enter into force on 1 July 1997.

8.2 The United States claims that the European Communities, by banning the importation of meat and meat products from animals to which any of six specific hormones have been administered for purposes of promoting the growth of the animals, has acted inconsistently with the Agreement
on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), in particular Articles 2, 3 and 5; the Agreement on Technical Barriers to Trade ("TBT Agreement"); and the General Agreement on Tariffs and Trade 1994 ("GATT"), in particular Articles I and III.

8.3 The European Communities rejects these claims.

8.4 The six hormones in dispute are: oestradiol-17β, testosterone, progesterone, zeranol and trenbolone (the five hormones mentioned above which were brought within the general prohibition required by Directive 81/602/EEC by Directive 88/146/EEC) and melengestrol acetate ("MGA"; a sixth hormone falling under the general prohibition of Directive 81/602/EEC). Oestradiol-17β is a natural hormone with oestrogenic action (i.e., responsible for female characteristics); testosterone is a natural hormone with androgenic action (i.e., responsible for male characteristics); progesterone is a natural hormone with gestagenic action (i.e., responsible for maintaining pregnancy); zeranol is a synthetic hormone with oestrogenic action (which mimics the action of oestradiol-17β); trenbolone is a synthetic hormone with androgenic action (which mimics the action of testosterone); and MGA is a synthetic hormone with gestagenic action (which mimics the action of progesterone). Natural hormones are hormones which are produced endogenously in animals and humans. Synthetic hormones are hormones which are artificially produced. Oestradiol-17β, testosterone and progesterone are hereafter also referred to as the three natural hormones; zeranol, trenbolone and MGA are hereafter also referred to as the three synthetic hormones.

C. GENERAL INTERPRETATIVE ISSUES

(...)

2. Application of the SPS Agreement, the TBT Agreement and GATT

8.20 The United States invokes arguments relating to three different agreements: the SPS Agreement, the TBT Agreement and GATT. The European Communities, in turn, invokes the same three agreements in its defense. We next examine which of these agreements apply to the present dispute.

8.21 With respect to the SPS Agreement, both parties agree that the EC measures in dispute are paragraph 1(b) of Annex A defines a sanitary measure as

"any measure applied 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".

Footnote 4 to Annex A specifies that "contaminants" include, for the purposes of Annex A, "pesticide and veterinary drug residues and extraneous matter". Since the six hormones in dispute are veterinary drugs, the parties agree that the alleged risks at issue arise from contaminants.

8.22 We agree with the parties that the EC measures in dispute are "applied to protect human ... life or health" within the territory of the European Communities from risks arising from "contaminants", namely residues of six specific hormones, in foods (according to paragraph 1(b) of Annex A). That the contested EC measures are, inter alia, "applied to protect human ... life or health" can be inferred from the preambles to, and legislative history of, Directives 81/602/EEC and 88/146/EEC. Since both parties agree that the contested EC measures are "sanitary
measures", we see no need to further examine in this dispute the definition of measures "applied to protect human ... life or health".

8.23 Both parties also agree that, according to Article 1.1 of the SPS Agreement, the SPS Agreement is applicable to this dispute. Article 1.1 provides that the SPS Agreement "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade".

We agree with the parties that the EC measures "may, directly or indirectly, affect international trade". It cannot be contested that an import ban affects international trade.

(…)

8.28 Thus, we find that the SPS Agreement is applicable to this dispute.

8.29 In respect of the applicability of the TBT Agreement to this dispute, we note that Article 1.5 of the TBT Agreement reads as follows:

"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".

Since the measures in dispute are sanitary measures, we find that the TBT Agreement is not applicable to this dispute.

8.30 We finally note that this dispute relates to trade in goods (in casu imports of meat and meat products) and that on its face GATT applies. In this context, we note that the United States only invokes GATT after having addressed the SPS Agreement and that the European Communities does not invoke any GATT provision other than Article XX(b) as a justification for the EC measures in dispute.

3. Relationship between the SPS Agreement and GATT

8.31 Since both the SPS Agreement and GATT apply to this dispute, we next examine the relationship between these two agreements.

(…)

8.35 In examining the relationship between GATT and the SPS Agreement, we recall the fundamental rules of treaty interpretation set out in the Vienna Convention. Article 31 of the Vienna Convention prescribes that a treaty has to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

8.36 We first consider the wording of Article 1.1 of the SPS Agreement which reads as follows:

"This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement".

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. 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.

8.37 We further note that the distinction proposed by the European Communities between "substantive" and "procedural" provisions of the SPS Agreement has no basis in the text of that Agreement and would, in any event, seem to be difficult to apply to most provisions contained therein. For example, the obligation to base a sanitary measure on a risk assessment in accordance with Article 5 of the SPS Agreement includes both substantive and procedural elements.

8.38 Moreover, 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" and to "improve the human health, animal health and phytosanitary situation in all Members". 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).

8.39 We note in this respect that the general approach adopted in Article XX(b) of GATT is fundamentally different from the approach adopted in the SPS Agreement. Article XX(b), which is not limited to sanitary or phytosanitary measures, provides for a general exception which can be invoked to justify any violation of another GATT provision. The SPS Agreement, on the other hand, provides for specific obligations to be met in order for a Member to enact or maintain specific types of measures, namely sanitary and phytosanitary measures.

8.40 The conclusion that the SPS Agreement contains obligations which are not already imposed by GATT is confirmed in Article 2.4 of the SPS Agreement which provides that "[s]anitary 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)". Indeed, to presume that one set of obligations (in casu GATT) is met because another set of obligations (in casu the SPS Agreement) has been fulfilled, seems to imply that the latter set of obligations imposes at least as many as, and probably more obligations than, the former. Support for this conclusion is also found in Article 3.2 of the SPS Agreement which provides that "[s]anitary 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" (emphasis added). While both agreements may apply in a given factual situation, the foregoing provision nonetheless establishes the SPS Agreement as an agreement which imposes obligations which are different from those imposed by GATT.
8.41 We therefore find that, in accordance with the ordinary meaning to be given to the terms of the SPS Agreement in their context and in the light of its object and purpose (in conformity with Article 31 of the Vienna Convention), there is no requirement, in any of the provisions of the SPS Agreement, that a prior violation of a GATT provision need be established before the SPS Agreement applies.

8.42 Having reached the conclusion that we are not per se required to address GATT claims prior to those raised under the SPS Agreement, we must then decide which of the two agreements we should examine first in this particular dispute. 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.

D. THE SPS AGREEMENT

(...)  

2. Burden of proof

(...)  

8.49 The United States argues that the SPS Agreement, inter alia, requires the European Communities to base its sanitary measures on a risk assessment and prohibits the European Communities from maintaining such measures without scientific evidence. (...) The United States seems, therefore, to conclude that it is up to the European Communities to provide evidence that there is a risk to be protected against and that there has been a risk assessment. It is not up to the United States to prove that there is no risk or that the European Communities did not carry out a risk assessment.

8.50 The European Communities argues that the burden of proof should rest on the party challenging the consistency of sanitary measures with the SPS Agreement (in casu the United States). The European Communities claims, inter alia, that it is up to the United States to provide evidence that the use of the hormones in dispute for growth promotion is safe and without risk.

8.51 In addressing the burden of proof under the SPS Agreement, we consider that, as is the case in most legal proceedings, the initial burden of proof rests on the complaining party in the sense that it bears the burden of presenting a prima facie case of inconsistency with the SPS Agreement. It is, indeed, for the party that initiated the dispute settlement proceedings to put forward factual and legal arguments in order to substantiate its claim that a sanitary measure is inconsistent with the SPS Agreement. In other words, it is for the United States to present factual and legal arguments that, if unrebutted, would demonstrate a violation of the SPS Agreement. Once such a prima facie case is made, however, we consider that, at least with respect to the obligations imposed by the SPS Agreement that are relevant to this case, the burden of proof shifts to the responding party.
8.52 In our view, the allocation of evidentiary burden under the SPS Agreement to the Member imposing a sanitary or phytosanitary measure flows directly from the wording of many of the provisions contained in that Agreement and in particular the first three words thereof: "Members shall ensure that..." (e.g. Articles 2.2, 2.3, 5.1 and 5.6 of the SPS Agreement; emphasis added).

8.53 Moreover, the wording of Article 5.8 (although this provision relates more to transparency than to any requirement of legal justification) further supports our reading of this assignment of burden of proof to the party imposing the measure:

"When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure" (emphasis added).

8.54 Finally, we note that this assignment of burden of proof to the party imposing the measure is also supported by Article 3.2 which introduces a presumption of consistency with the SPS Agreement for sanitary measures which conform to international standards, guidelines or recommendations. Article 3.2 states the following:

"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".

Introducing a general presumption of consistency with an agreement in favour of a party (in casu the party imposing the measure) in the event that certain conditions are met, seems, indeed, to presuppose that the burden of proof under that agreement in principle (i.e., in cases where these specific conditions are not met) rests on that party.

8.55 We thus find that, for the purposes of this dispute, the United States bears the burden of presenting a prima facie case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the European Communities to demonstrate that its measures in dispute meet the requirements imposed by the SPS Agreement.

3. Article 3.1: sanitary measures based on international standards.

8.56 Article 3.1 of the SPS Agreement reads as follows:

"To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary and 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".

The first question we must address is whether there exist any "international standards, guidelines or recommendations" with respect to the administration of any of the six hormones in dispute for growth promotion purposes. For food safety, the health concern at issue in this dispute, paragraph 3(a) of Annex A of the SPS Agreement defines "international standards, guidelines or
recommendations” as "the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice" (emphasis added).

8.57 In line with Article 3.1, we consider that if such Codex Alimentarius Commission standards, guidelines or recommendations ("Codex standards") exist with respect to the administration of any of the six hormones in dispute for growth promotion purposes, a sanitary measure taken by a Member should either be based on these standards or be justified under Article 3.3 of the SPS Agreement.

(a) Codex standards

8.58 Within the scope of the measures in dispute, we note that Codex standards exist for five of the six hormones at issue (i.e., for all hormones at issue other than MGA). We will accordingly examine the definition and scope of application of these Codex standards and determine whether they apply to the EC measures in dispute.

8.59 The Codex Alimentarius Commission ("Codex"), an international body of which most WTO Members (including the United States and the EC member States of the European Communities) are members, establishes, inter alia, Acceptable Daily Intakes ("ADIs"), Maximum Residue Limits ("MRLs") and other recommendations for veterinary drugs. It does so on the basis of the advice of the Codex Committee on Residues of Veterinary Drugs in Foods and the recommendations of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"). While Codex is composed of government representatives of EC member States, JECFA is composed of independent scientists. JECFA makes scientific evaluations and recommendations; Codex takes the decision whether or not to adopt these recommendations. However, once adopted Codex recommendations are, according to the General Principles of Codex, not binding upon Codex members. They are only of an advisory nature. The procedures to be followed to adopt a Codex recommendation have been outlined above.

(…)

8.62 With respect to the three natural hormones in dispute, oestradiol-17β, progesterone and testosterone (classified by Codex as "veterinary drugs"), similar Codex standards apply. For all three hormones, when used for growth promotion purposes, it was considered "unnecessary" to establish an ADI or MRL. For all three hormones the following footnote explained the word "unnecessary": "Establishing an ADI and an [MRL] for a hormone that is produced endogenously at variable levels in human beings was considered unnecessary by the Committee. Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health".

The 32nd JECFA Report of 1988, on which the Codex standards are based, concluded for all three natural hormones administered for growth promotion purposes that the residue levels of each of these hormones when found in meat from animals treated with implants according to good animal husbandry practice are extremely low when compared with the amounts endogenously produced daily in human beings or normally present in the dairy products or tissues of untreated animals or other foods. According to JECFA, the potential toxic effect of residues of these hormones is directly related to their hormonal effect. Since the additional residue levels in treated animals have no hormonal effect, the Report concluded that these residue levels are not
capable of exerting any toxic effect. JECFA further noted that the total residue levels in treated animals fall well within the normal range of levels found in untreated animals of different types and ages. On the basis of this safety assessment and in view of the difficulty of determining the levels of residues attributable to the use of this hormone as a growth promoter in cattle (residues of endogenous natural hormones in meat cannot, according to JECFA, be practically distinguished from those exogenously administered), JECFA concluded that it was “unnecessary” to establish an ADI or MRL for these hormones.

8.63 With respect to two of the three synthetic hormones at issue, zeranol and trenbolone (classified by Codex as "veterinary drugs"), the following Codex standards apply: an ADI of 0-0.5 and 0-0.02 μg/kg body weight, respectively, and an MRL of 2 μg/kg β-trenbolone in bovine muscle and 10 μg/kg α-trenbolone in bovine liver.

(...)

8.66 The European Communities argues that the Codex standards outlined above are not relevant to this dispute. It argues that there are no Codex standards for the use of hormone growth promoters, only Codex standards for maximum residue levels and that since the EC measures in dispute do not set maximum residue levels, there exist no Codex standards on which the EC measures need to be based. Moreover, the European Communities argues, the Codex standards invoked are levels of protection, not measures, and since there is no obligation in the SPS Agreement to adopt Codex recommended levels of protection, the standards invoked are irrelevant for the EC measures in dispute.

8.67 The European Communities also notes that the decision by Codex (of July 1995) to formally adopt the five Codex standards at issue was taken by a majority of only 33 votes in favour, 29 votes against and 7 abstentions; a very close vote which is unusual in Codex practice where proposals are normally adopted by consensus, indicating that the issue of hormone growth promoters has been and continues to be very controversial.

8.68 The European Communities finally argues that the process which led to the adoption of the Codex standards started long before the entry into force of the SPS Agreement and was only completed six months after that date. At the time the standards were discussed, Codex members were, therefore, according to the European Communities, unaware of the fact that the Codex standards, which within the Codex system are only of an advisory nature, would in the future become "binding" by virtue of the SPS Agreement. The European Communities seems to consider this element as a reason to disregard these Codex standards in this dispute.

8.69 In considering these EC arguments, we note 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 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.

8.70 We note that the five Codex standards outlined above are standards relating to veterinary drug residues as required in paragraph 3(a) of Annex A and apply exclusively with respect to cattle and meat and meat products of bovine origin and with respect to five of the six hormones in dispute when these hormones are used for growth promotion purposes. We recall the scope of the EC measures in dispute, in particular that they are limited to the EC ban on imports of meat and meat products of bovine origin from cattle treated with any of six specific hormones if the treatment with any of these substances is carried out for growth promotion purposes. We find, therefore, that international standards exist with respect to the EC measures in dispute, to the extent they relate to five of the six hormones at issue (all but MGA), in the sense of Article 3.1 and paragraph 3(a) of Annex A. We must next determine whether the EC measures are based on these international standards in terms of Article 3.1.

(b) Sanitary measures based on Codex standards

(i) The meaning of based on

8.72 The SPS Agreement does not explicitly define the words based on as used in Article 3.1. However, Article 3.2, which introduces a presumption of consistency with both the SPS Agreement and GATT for sanitary measures which conform to international standards, equates measures based on international standards with measures which conform to such standards. Article 3.3, in turn, explicitly relates the definition of sanitary measures based on international standards to the level of sanitary protection achieved by these measures. Article 3.3 stipulates the conditions to be met for a Member to enact or maintain certain sanitary measures which are not based on international standards. It applies more specifically to measures "which result in a higher level of sanitary ... protection than would be achieved by measures based on the relevant international standards" or measures "which result in a level of sanitary ... protection different from that which would be achieved by measures based on international standards". One of the determining factors in deciding whether a measure is based on an international standard is, therefore, the level of protection that measure achieves. According to Article 3.3 all measures which are based on a given international standard should in principle achieve the same level of sanitary protection. Therefore, if an international standard reflects a specific level of sanitary protection and a sanitary measure implies a different level, that measure cannot be considered to be based on the international standard.

8.73 We find, therefore, that for a sanitary measure to be based on an international standard in accordance with Article 3.1, that measure needs to reflect the same level of sanitary protection as the standard. In this dispute a comparison thus needs to be made between the level of protection reflected in the EC measures in dispute and that reflected in the Codex standards for each of the five hormones at issue.

(ii) Comparison of levels of sanitary protection

(...)
8.75 In this dispute, two of the international standards applicable, namely the Codex standards with respect to zeranol and trenbolone (two synthetic hormones), provide for an ADI of 0-0.5 and 0-0.02 μg/kg of body weight, respectively, and an MRL of 10 μg/kg for bovine liver and 2 μg/kg for bovine muscle for zeranol and an MRL of 10 μg/kg α-trenbolone for bovine liver and 2 μg/kg of β-trenbolone for bovine muscle. These ADIs and MRLs reflect the level of protection set by the Codex standards. (...) Since the EC measures in dispute do not allow the presence of any residues of these two hormones in any meat or meat product or any of these residues to be ingested by humans (imposing what it calls a "no residue" level), the level of protection reflected in the EC measures is significantly different from the level of protection set by the Codex standards (a "no residue" level as opposed to an ADI of maximum 0.5 and 0.02 μg/kg of body weight and an MRL of 2 and 10 μg/kg for, respectively, bovine muscle and bovine liver). The EC measures in dispute, in as far as they relate to zeranol and trenbolone, are, therefore, not based on existing international standards as specified in Article 3.1.

8.76 When establishing the other three Codex standards applicable to the EC measures in dispute, Codex considered it "unnecessary" to set an ADI or MRL for residues of oestradiol-17β, testosterone and progesterone (the three natural hormones). (...) The EC measures in dispute, on the other hand, do not allow the presence of any residues of these three hormones administered for growth promotion purposes (again imposing what the European Communities calls a "no residue" level). The level of protection reflected in the EC measures is, therefore, significantly different from the level of protection reflected in the Codex standards (a "no residue" level as opposed to an unlimited residue level). The EC measures in dispute, in so far as they relate to oestradiol-17β, testosterone and progesterone, are, therefore, not based on existing international standards as specified in Article 3.1.

8.77 We thus find that the EC measures in dispute (except to the extent they relate to the hormone MGA) result in a different level of sanitary protection than would be achieved by measures based on the relevant Codex standards and are, therefore, not based on existing international standards as specified in Article 3.1.

8.78 We next examine whether the EC measures with respect to five of the six hormones in dispute, which are not based on existing international standards, otherwise are consistent with the requirements of the SPS Agreement (sections 4 and 5). We then address the EC measures which relate to the sixth hormone, MGA, for which no international standard exists (section 6).

4. Article 3.3: sanitary measures not based on international standards.

8.79 The fact that the EC measures for oestradiol-17β, testosterone, progesterone, zeranol and trenbolone are not based on existing international standards does not necessarily mean that those measures are inconsistent with the requirements of the SPS Agreement. Article 3.3 reads as follows:

"Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary 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. 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”.

A footnote to Article 3.3, first sentence, then specifies:

"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”.

The concept of an "appropriate level of sanitary protection" is defined in paragraph 5 of Annex A of the SPS Agreement as:

"The level of protection deemed appropriate by the Member establishing a sanitary ... measure to protect human, animal or plant life or health within its territory”.

A Note to this paragraph adds the following:

"Many Members otherwise refer to this concept as the 'acceptable level of risk' ".

(a) Requirements for justification

8.80 For a sanitary measure to be justified under Article 3.3 the measure needs, first of all, to "result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations". We recall the comparison made above between the level of protection reflected in the EC measures and that implied in the Codex standards for each of the hormones at issue, in particular that the level reflected in the EC measures is different from that implied in the Codex standards. For purposes of our analysis under Article 3.3, we assume that the former level is higher than the latter, in line with the first sentence of Article 3.3. In addition, the sanitary measure needs to fulfil one of the following two conditions:

- there is a "scientific justification" for imposing the measure, i.e., the Member imposing the measure has determined "on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of [the SPS] Agreement, ... that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary ... protection" ("the first exception"); or

- the measure is "a consequence of the level of sanitary ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5" ("the second exception").

However, according to the second sentence of Article 3.3, even if one of these conditions is fulfilled, the party imposing the measure must still comply with the other provisions of the SPS Agreement.

8.81 We will consider first whether either the first or the second exception outlined above is met. In doing so, we first address the relationship and difference between these two exceptions. The United States argues that both exceptions have the same effect since both refer to a situation where the basis for departing from the relevant international standard is that the international
standard is not sufficient to achieve the Member’s appropriate level of protection. The European Communities argues that the first exception is fulfilled when the international standard is inadequate, faulty or obsolete from a scientific point of view and that, according to the second exception, a Member is in any case entitled to introduce or maintain measures which aim at achieving its appropriate level of protection, to be determined in accordance with Article 5 of the SPS Agreement.

8.82 We note that both exceptions explicitly refer to other provisions of the SPS Agreement. The first exception contains the following reference: "... on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of [the SPS] Agreement ..." (emphasis added). The second exception refers to "... the relevant provisions of paragraphs 1 through 8 of Article 5" (emphasis added). Article 3.3, second sentence, in turn, explicitly states that even if the sanitary measure at issue falls under one of the two exceptions of Article 3.3, first sentence, the sanitary measure in question still needs to be consistent with all provisions of the SPS Agreement other than Article 3.

8.83 We find, therefore, that, whatever the difference might be between the two exceptions, a sanitary measure can only be justified under Article 3.3 if it is consistent with the requirements contained in Article 5. If we were to find that the EC measures in dispute are inconsistent with the requirements imposed by Article 5, these measures cannot be justified under Article 3.3. However, even if we find that the EC measures at issue are consistent with the requirements imposed by Article 5, this will still not be sufficient for these measures to be justified under Article 3.3 since to reach that conclusion we also need to find that the EC measures in dispute fulfil all provisions of the SPS Agreement other than Articles 3 and 5 (in casu Article 2).

(…)

8.86 One purpose of the SPS Agreement, as explicitly recognized in the preamble, is to promote the use of international standards, guidelines and recommendations. To that end, Article 3.1 imposes an obligation on all Members to base their sanitary measures on international standards except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3 thereof. In this sense, Article 3.3 provides an exception to the general obligation contained in Article 3.1. Article 3.2, in turn, specifies that the complaining party has the burden of overcoming a presumption of consistency with the SPS Agreement in the case of a measure based on international standards. It thereby suggests by implication that when a measure is not so based, the burden is on the respondent to show that the measure is justified under the exceptions provided for in Article 3.3.

8.87 We find, therefore, that once the complaining party provides a prima facie case (i) that there is an international standard with respect to the measure in dispute, and (ii) that the measure in dispute is not based on this standard, the burden of proof under Article 3.3 shifts to the defending party.

8.88 Since in this dispute we have already found that there exist international standards and that the EC measures at issue are not based on these standards, we find that the burden of justifying the measures in dispute under Article 3.3, and in particular under the first sentence thereof, rests on the European Communities.

8.89 In summary, in sections 3 and 4 we have found that: (i) there exist international standards, as defined in Article 3.1 and paragraph 3(a) of Annex A of the SPS Agreement, with respect to the EC measures in dispute to the extent they relate to five of the six
hormones at issue (all but MGA); (ii) the EC measures in dispute, in as far as they relate to these five hormones, are not based on these international standards, as required in Article 3.1; and (iii) the EC measures, to the extent they are not based on these international standards, can only be justified under Article 3.3 if these measures meet, inter alia, the requirements imposed by Article 5.

8.90 In the next section we will, therefore, examine whether the EC measures in dispute with respect to the five hormones at issue for which international standards exist are consistent with the requirements imposed by Article 5.

5. Article 5: "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection"

(a) Risk assessment and risk management

8.91 Article 5 of the SPS Agreement deals mainly with two separate aspects of a Member's decision to enact or maintain a sanitary measure. These two aspects are separated in the SPS Agreement, which provides for specific rights and obligations in respect of each of them.

8.92 The first aspect relates to the exercise of assessing the risks to human, animal or plant life or health against which a sanitary measure is intended to protect. This is referred to in the SPS Agreement as risk assessment. With respect to food safety, the potential adverse effects (if any) related to a specific substance are established together with the probability of occurrence of any such effects.

8.93 According to Article 5.1, a Member needs to ensure that its sanitary measures are based on an assessment of risks. The obligation to base a sanitary measure on a risk assessment may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement which provides that "Members shall ensure that any sanitary ... 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 ..." (emphasis added). Articles 5.1 to 5.3 sum up factors a Member needs to take into account in making this assessment of risks.

8.94 As will be outlined below, an assessment of risks is, at least for risks to human life or health, a scientific examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies.

8.95 The second aspect of a Member's decision to enact or maintain a sanitary measure relates, inter alia, to the determination and application of the appropriate level of sanitary protection by that Member against the risks to human, animal or plant life or health which have been assessed in accordance with Articles 5.1 to 5.3. This aspect is commonly referred to by the parties to this dispute as an essential part of risk management. The Member wishing to impose a sanitary measure must decide the extent to which it can accept the potential adverse effects related to a specific substance which have been identified in the risk assessment.

8.96 Articles 5.4 to 5.6 are particularly relevant to the risk management decision. Article 5.4 establishes the objective of minimizing negative trade effects in the determination by a Member of its appropriate level of protection. Article 5.5 aims at achieving consistency in the application of the concept of appropriate level of protection. Article 5.6, in turn, provides that the sanitary measure which is finally adopted shall not be more trade-
restrictive than required to achieve the appropriate level of protection of the Member concerned. Articles 5.4 to 5.6 may be viewed as specific applications of the basic obligations provided for in Article 2.2 which, \textit{inter alia}, states that "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" (emphasis added) and Article 2.3 which provides that "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail ..." and that "Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade" (emphasis added).

8.97 As will be outlined below, the risk management phase involves non-scientific considerations, such as social value judgments.

(b) Articles 5.1 to 5.3: risk assessment

8.98 According to Article 5.1:

"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".

Paragraph 4 of Annex A of the SPS Agreement defines "risk assessment" with respect to contaminants (including residues of the hormones at issue) as

"the evaluation of the potential for adverse effects on human or animal health arising from the presence of ... contaminants ... in food, beverages or feedstuffs" (emphasis added).

Guided by the wording of these provisions, we consider that, in this dispute, a risk assessment carried out in accordance with the SPS Agreement should (i) identify the adverse effects on human health (if any) arising 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.

8.99 Article 5.1 provides in general terms, without any limitation in time, that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks ...". It does not prevent that with respect to a sanitary measure enacted \textit{before} the entry into force of the SPS Agreement, the risk assessment is carried out or invoked \textit{after} the entry into force of that Agreement (and thus \textit{after} the enactment of the sanitary measure in question). However, the fact that a sanitary measure may be enacted \textit{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. Moreover, the more general obligation contained in Article 2.2 of the SPS Agreement explicitly provides that "Members shall ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not maintained without sufficient scientific evidence ..." (emphasis added).

(…)

8.100 We also recall our finding reached above on the specific burden of proof under Article 3.3, in particular that the burden of proving that the requirements imposed by
Article 3.3 (inter alia, consistency with Article 5) are met, rests with the Member imposing a sanitary measure which deviates from an international standard. Since the EC measures examined in this section (relating to all hormones in dispute other than MGA) are not based on existing international standards and need to be justified under the exceptions provided for in Article 3.3, the European Communities has the burden of proving that its measures are based on a risk assessment in accordance with Article 5.

(...)  

(ii) The existence of a risk assessment

(...)  

8.110 We next consider whether the scientific evidence and attendant evaluation referred to by the European Communities constitutes a risk assessment in the sense of Article 5. We recall that under the SPS Agreement a risk assessment should, for the purposes of this dispute, identify the adverse effects on human health arising from the presence of the specific hormones at issue when used as growth promoters in meat or meat products and, if any such adverse effects exist, evaluate the potential or probability of occurrence of these effects. We further recall that a risk assessment should be a scientific examination of data and studies and that the SPS Agreement sets out factors which need to be taken into account in a risk assessment. We finally recall that no risk assessment techniques, as referred to in Article 5.1, have as yet been formally adopted by Codex. The Agreement does not further specify the requirements of what constitutes a risk assessment in accordance with Article 5.

8.111 We note that the European Communities has invoked several scientific reports which appear to meet these minimum requirements of a risk assessment (in particular the Lamming Report and the 1988 and 1989 JECFA Reports) and that the scientists advising the Panel seemed to consider these reports, from a scientific and technical point of view, to be risk assessments. We shall, therefore, for the purposes of this dispute, assume that the European Communities has met its burden of demonstrating the existence of a risk assessment carried out in accordance with Article 5.

(iii) Sanitary measures to be based on a risk assessment

8.112 Article 5.1 requires Members to "ensure that their sanitary ... measures ... are based on an assessment ... of the risks to human ... life or health". It does not, however, specify how to determine whether a measure is based on a risk assessment. In our view, this determination has both a procedural and a substantive aspect.

Procedural requirements

8.113 Notwithstanding the fact that Article 5 does not contain specific procedural requirements for a Member to base its sanitary measures on a risk assessment, we consider that, according to the ordinary meaning of the words based on put in their context and in light of the object and purpose of Article 5, there is a minimum procedural requirement contained in Article 5.1. In our view, the Member imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment.
8.114 We note that in this dispute the European Communities, which has the burden of proving that it based its measures on a risk assessment, has not provided any evidence that the studies it referred to (in so far as they can be considered as part of a risk assessment) or the scientific conclusions reached therein, have actually been taken into account by the competent EC institutions either when it enacted these measures (in 1981 and 1988) or at any later point in time. We note, in this respect, that none of the preambles to the EC measures at issue mention any of the scientific studies referred to by the European Communities. These preambles only refer to the non-scientific reports and opinions of the European Parliament and the EC Economic and Social Committee, which cannot be considered as part of a risk assessment. 

(…)

8.116 For these reasons, we find that the European Communities has not met its burden of proving that it met the minimal procedural requirement contained in Article 5.1 and that, therefore, the EC measures in dispute are inconsistent with the requirements of Article 5.1.

Substantive requirements

8.117 Even if the European Communities would have fulfilled these minimum procedural requirements, there would still be a need to examine the substantive requirements contained in Article 5.1. From a substantive point of view, we consider that in this dispute we should, in accordance with the ordinary meaning of the words based on put in their context and in light of the object and purpose of Article 5, proceed as follows to determine whether the EC measures at issue are based on a risk assessment: (i) we need to identify the scientific conclusions reached in each of the studies referred to by the European Communities; (ii) we need to identify the scientific conclusion reflected in the EC measures in dispute; and (iii) we need to determine whether the scientific conclusion reflected in the EC measures can be considered as being in conformity with any of those reached in the studies referred to by the European Communities.

8.118 For purposes of this analysis, we first address the studies referred to by the European Communities which specifically address one or more of the hormones in dispute when used for growth promotion purposes before examining the studies which generally relate to one or more of these hormones.

1. Scientific conclusions reached in the studies referred to by the European Communities which specifically address one or more of the hormones in dispute when used for growth promotion purposes

(…)

8.124 As can be deduced from all conclusions outlined above, none of the scientific evidence referred to by the European Communities which specifically addresses the safety of some or all of the hormones in dispute when used for growth promotion, indicates that an identifiable risk arises for human health from such use of these hormones if good practice is followed. All of the scientific studies outlined above came to the conclusion that the use of the hormones at issue (all but MGA, for which no evidence was submitted) for growth promotion purposes is safe; most of these studies adding that this conclusion assumes that good practice is followed. We note that this conclusion has also been confirmed by the scientific experts advising the Panel.
2. Scientific conclusions reached in the studies referred to by the European Communities which generally relate to one or more of the hormones in dispute

(...)

8.134 For these reasons, we find that the European Communities has not demonstrated that the scientific evidence it referred to, which generally addresses the safety of some or all of the hormones in dispute, would indicate that an identifiable risk arises for human health from the use of these hormones for growth promotion purposes if good practice is followed. In this respect we recall that all scientific experts advising the Panel confirmed this conclusion and stated that, as of today, no scientific evidence is available which concludes that an identifiable risk arises from the use of any of the hormones at issue for growth promotion purposes in accordance with good practice.

8.135 The finding we thus make does, of course, not exclude that future scientific developments could require modifications to the scientific conclusions reached in the studies referred to by the European Communities.

3. Scientific conclusion reflected in the EC measures

8.136 The European Communities bans the use for growth promotion purposes of any of the hormones in dispute, including the use of these hormones in accordance with good practice. During the Panel proceedings it has made clear that it considers any residue level of these hormones to be unsafe for human health, setting its level of protection at a "zero residue" level. The scientific conclusion reflected in the EC measures in dispute is thus that the use of the hormones in dispute for growth promotion purposes, even in accordance with good practice, poses an identifiable risk to human health.

4. The conformity of the scientific conclusion reflected in the EC measures with the scientific conclusions reached in the studies referred to

8.137 In our view, the scientific conclusion reflected in the EC measures in dispute, i.e., that the use of the hormones in dispute for growth promotion purposes, even in accordance with good practice, is not safe, does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities. All the evidence referred to by the European Communities which specifically relates to the use of the hormones at issue for growth promotion purposes concludes that the use of these hormones as growth promoters in accordance with good practice is safe. Moreover, none of the evidence referred to by the European Communities which generally deals with one or more of the hormones in dispute contradicts this conclusion. The EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, allegedly necessary to protect human health, in so far as it also applies to meat and meat products from animals treated with any of these hormones in accordance with good practice, is, therefore, not based on the scientific evidence submitted to the Panel.

8.138 The European Communities, however, submits the following additional arguments (sections 5 and 6). We note that these arguments have not been supported by scientific evidence other than the evidence examined above. We consider it nonetheless appropriate to examine whether these arguments demonstrate that the EC measures in dispute are, from a substantive point of view, based on a risk assessment in accordance with Article 5.1.
5. General categories of risks invoked by the European Communities

8.139 The European Communities argues that it has based its ban on the existence of the following categories of risks related to the hormones at issue: (i) risks arising from the nature and mode of action of the hormones; (ii) risks arising from the action of metabolites; (iii) risks arising from the action of combinations (or cocktails) of hormones and from multiple exposure of humans; (iv) risks arising from problems related to detection and control of hormones; (v) risks arising from the administration and use of hormones; and (vi) risks arising from various other parameters, in particular the inherent limits to science.

8.140 The United States argues that the European Communities has never performed an appropriate assessment of these alleged risks and has, in any event, not relied on, nor put forward, any assessment of these risks that could serve as a basis for the EC ban.

8.141 We recall that the European Communities has not referred to any scientific evidence, other than that examined above, in which the categories of risks put forward by the European Communities have been assessed and that none of the scientific evidence referred to by the European Communities reached the conclusion that any of the hormones in dispute when administered for growth promotion purposes in accordance with good practice has an adverse effect on human health.

(...)

8.143 In addition, with respect to the alleged risks arising from problems related to the detection, control, administration and use of the hormones in dispute (i.e., the fourth and fifth category of risks invoked by the European Communities), we note that the European Communities has not referred to evidence, other than that outlined above, in which an assessment is made of the possible adverse health effects related to the potential abuse of these specific hormones when used for growth promotion purposes. The European Communities has restricted itself to pointing out the condition contained in many of the scientific conclusions mentioned above, namely that the safety of the hormones is to a certain extent conditional upon their administration in accordance with good practice, without further providing an assessment of the potential adverse effects related to non-compliance with such practice.

(...)

8.146 With respect to the alleged risks related to the control (or, in other words, the abuse) of the hormones at issue (both natural and synthetic), we further note that even though a Member would seem to be able to take into account risks arising from difficulties of inspecting, sampling or testing which are specific to a particular substance in a particular food, the "relevant inspection, sampling and testing methods" referred to in Article 5.2, do not seem to cover the general problem of control (such as the problem of ensuring the observance of good practice) which can exist for any substance. The risks related to the general problem of control do not seem to be specific to the substance at issue but to the economic or social incidence related to a substance or its particular use (such as economic incentives for abuse). These non-scientific factors should, therefore, not be taken into account in risk assessment but in risk management (...). The experts advising the Panel made clear that the potential for abuse under both regimes would be comparable, some noting that abuse would probably occur more frequently under a regime where the hormones are banned compared to one allowing the controlled use of prescribed products.
in predetermined dosages with well-defined educational programmes, good communication between the different actors involved and appropriate penalties for misuse. In this context, we note, therefore, that banning the use of a substance does not necessarily offer better protection of human health than other means of regulating its use.

(...)

8.148 (…) we find that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones in accordance with good practice, is not based on an assessment of the fourth or fifth category of risks invoked by the European Communities.

8.149 In the sixth general category of risks invoked by the European Communities (risks arising from various other parameters), the European Communities argues that none of the studies it referred to as part of a risk assessment proves beyond doubt or concludes in an unqualified manner that the presence of residues of the hormones in dispute in meat or meat products present no risk whatsoever. (…) The European Communities apparently considers, therefore, that this residual risk, albeit minute and not appreciable, constitutes the risk (derived from a risk assessment) on which the EC ban is based in accordance with Article 5.1, arguing that, according to EC risk management, risk other than zero is not acceptable.

8.150 The United States argues that science can never prove beyond doubt that there is no risk and can only be used to determine whether there is a risk associated with the use of a particular substance; it cannot eliminate the possibility that a potential risk may be found in the future. According to the United States, the SPS Agreement does not allow measures to be maintained without scientific evidence until such time as science proves "beyond doubt" that there is no risk.

8.151 We recall the conclusions we reached above on burden of proof, in particular that the European Communities has, with respect to its measures which deviate from international standards, the burden of proving the existence of a risk assessment (and, derived therefrom, an identifiable risk) on which the EC measures in dispute are based. It is not, in this dispute, for the United States to prove that there is no risk.

8.152 We further note that, according to scientists advising the Panel, science can never provide a certainty, i.e. exclude once and for all that a specific substance can ever have adverse health effects.

(...)

8.154 We finally note that the EC objective of "zero risk" cannot be achieved in practice; not even under the EC ban itself since the European Communities cannot guarantee that there is a zero probability that illegal use of the hormones at issue will occur. Moreover, this "zero risk" objective cannot, as further examined below, in any case be achieved for the three natural hormones in dispute since the European Communities allows the ingestion of these same hormones occurring endogenously in meat and other foods as well as the use of these hormones for therapeutic or zootechnical purposes.

8.155 The EC ban on the use of the hormones in dispute for growth promotion purposes is, therefore, not based on an assessment of the sixth and final category of risks invoked by the European Communities.
8.156 For these reasons, we find that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones in accordance with good practice, is not based on an assessment of any of the six general categories of risks invoked by the European Communities.

6. The precautionary principle

8.157 The European Communities also invokes the precautionary principle in support of its claim that its measures in dispute are based on a risk assessment. To the extent that this principle could be considered as part of customary international law and be used to interpret Articles 5.1 and 5.2 on the assessment of risks as a customary rule of interpretation of public international law (as that phrase is used in Article 3.2 of the DSU), we consider that this principle would not override the explicit wording of Articles 5.1 and 5.2 outlined above, in particular since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement. We note, however, that the European Communities has explicitly stated in this case that it is not invoking Article 5.7.

8.158 We thus find that the precautionary principle cannot override our findings made above, namely that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones in accordance with good practice, is, from a substantive point of view, not based on a risk assessment.

8.159 In summary, in this section we have found that, even assuming that the European Communities has demonstrated the existence of a risk assessment in accordance with Article 5, it has not fulfilled the minimal procedural requirements contained in Article 5.1 to base its sanitary measures on a risk assessment. We have also found that, even if it would have fulfilled these minimal procedural requirements, the European Communities has not met its burden of proving that its measures in dispute, in so far as they also ban the import of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes in accordance with good practice, are, from a substantive point of view, based on a risk assessment. The EC measures in dispute, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, inconsistent with the requirements of Article 5.1. The fact that these measures are not based on existing international standards (contrary to Article 3.1) cannot, therefore, be justified under Article 3.3 which includes as one of the requirements for justification, consistency with Article 5.1. The EC measures, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, also inconsistent with the requirements of Article 3.1.

(c) Articles 5.4 to 5.6: risk management

8.160 We recall that there is a distinction between risk assessment which is a scientific examination and risk management which involves social value judgments. Once the risks have been assessed, i.e., once the risks and their probability of occurrence identified, a Member will need to decide, on the basis of its own value judgments, whether it can accept these risks. In so doing a Member sets its "appropriate level of sanitary protection". The determination and application of the appropriate level of protection by a Member is part of risk management.

(…)

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(ii) Article 5.5: distinctions in levels of protection

8.167 Article 5.5 provides the following:

"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" (emphasis added).

8.168 We note, in this respect, the basic obligations contained in Article 2.3:

"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" (emphasis added).

Article 2.3 deals, in general terms, with sanitary measures which discriminate between Members or which are applied in a manner which would constitute a disguised restriction on international trade. Article 5.5, on the other hand, deals more specifically with distinctions in levels of protection (which will normally be reflected in one or more sanitary measures) which result in discrimination or a disguised restriction on international trade.

8.169 We consider that the first part of the first sentence of Article 5.5 ("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 ..."; emphasis added), unlike the second part, does not impose an obligation upon Members. Consistency is not imposed as an obligation but as an objective which nonetheless has to be taken into account in the interpretation of Article 5.5.

(...)

8.171 The United States argues that the European Communities fails to justify the following differences in regulatory treatment: (i) a ban on natural and synthetic hormones when used for growth promotion purposes as opposed to not setting any limit for residues of the natural hormones present endogenously in untreated meat and other foods (such as milk, cabbage, broccoli or eggs) and residues of these hormones when used for therapeutic or zootechnical purposes; and (ii) a ban on the hormones in dispute when used for growth promotion purposes as opposed to allowing the use of the veterinary drug carbadox as a growth promoter in swine production. Only with respect to the last mentioned difference in treatment does the United States invoke and address Article 5.5.

8.172 The European Communities rejects these claims, arguing that it does not make distinctions in its levels of protection for different situations and that, even if it were to make such
distinctions, these distinctions are justified and do not result in discrimination or a disguised restriction on international trade.

The three elements contained in Article 5.5

8.173 We next examine the elements that must be assessed to determine if a Member's sanitary measure does not conform to the requirements of the second part of the first sentence of Article 5.5. The relevant part of Article 5.5 reads as follows:

"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".

8.174 The first element contained in Article 5.5 is that the Member concerned adopts different appropriate levels of sanitary protection in "different situations". The second element is that the distinction in levels of protection for the different situations is "arbitrary or unjustifiable". The third element is that the distinction in levels of protection results in "discrimination or a disguised restriction on international trade". In order to find a sanitary measure to be inconsistent with Article 5.5 all three elements need to be present.

8.175 As to the first element, the words "different situations" have been interpreted by the parties as follows. The European Communities argues that "different situations" only covers different situations for the same residue or for different residues where the adverse health effect is the same. According to the European Communities, "different situations" cannot mean that the same level of protection must be applied to similar health hazards, whatever their nature or severity, coming from similar substances. The United States argues that the "different situations" referred to in Article 5.5 of necessity must be comparable situations. It argues, for example, that the purported health risk from carbadox and the hormones in dispute, when used for growth promotion, is in both instances, cancer in humans and that, therefore, the different situations invoked by the United States are comparable.

8.176 We note that both parties in dispute agree that the scope of "different situations" contained in Article 5.5 includes situations which deal with the same substance as well as situations which involve the same adverse health effect. For this reason, considering the lack of guidelines by the Committee on Sanitary and Phytosanitary Measures and without further defining or limiting the scope of "different situations", we find that, for the purposes of this dispute, we can compare situations where the same substance or the same adverse health effect is involved as "different situations" in the sense of Article 5.5. For the sake of clarity in this particular case, we will hereafter refer to such "different situations" as "comparable situations" since these situations need to be compared for the purposes of Article 5.5 and are, therefore, "comparable".

8.177 The second element contained in Article 5.5 is that the distinction in levels of protection for comparable situations is "arbitrary or unjustifiable".

8.178 The United States argues that, in the absence of any principle or criterion that accounts for the selection of differing levels of sanitary protection, the distinction in the levels of protection is arbitrary and unjustifiable. The European Communities argues that Article 5.5 clearly states that "arbitrary or unjustifiable" distinctions are to be avoided if, and only if, they result in discrimination or a disguised restriction on trade. If they do not result in discrimination or a disguised restriction on trade, the European Communities concludes, they are not prohibited by Article 5.5.

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8.179 The *third element* contained in Article 5.5 is that the distinction in level of protection results in "discrimination or a disguised restriction on international trade".

8.180 The United States has not presented a claim with respect to the term "discrimination"; only with respect to the term "disguised restriction on international trade". The United States argues that "a disguised restriction on international trade" is present in the context of Article 5.5 where a Member claims a legitimate basis for the difference in the chosen levels of protection being compared, but where instead the differing levels of protection are being employed for commercial reasons to restrict trade. The European Communities argues that the measures in dispute do not result in discrimination and that the fact that sanitary measures affect imports is not a sufficient reason to claim that they restrict trade, or even less, that they discriminate.

(...)

8.184 We consider the reasoning in both Appellate Body Reports [Japan--Alcoholic Beverages and Gasoline] to be equally relevant to the relationship between the three elements contained in Article 5.5. All three elements impart meaning to one another. Nevertheless, in order to give effect to all three elements contained in Article 5.5 and giving full meaning to the text and context of this provision, we consider that all three elements need to be distinguished and addressed separately. However, we also agree that in some cases where a Member enacts, for comparable situations, sanitary measures which reflect different levels of protection, the significance of the difference in levels of protection combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection "result[s] in discrimination or a disguised restriction on international trade" in the sense of Article 5.5 (in line with the argument that the magnitude of the very differential of a dissimilar taxation may be enough to conclude that a dissimilar taxation is applied so as to afford protection, as provided for in the second sentence of Article III:2 of GATT).

8.185 We next examine, in light of the three elements of Article 5.5 outlined above, the distinctions in levels of sanitary protection allegedly made by the European Communities which have been invoked by the United States. In order to conduct our consideration of this dispute under Article 5.5 in the most efficient manner, we first address the alleged differences in treatment provided by the European Communities for the *natural hormones in dispute*. In this examination we compare the treatment of these hormones when used as growth promoters with both the treatment of these hormones occurring endogenously in meat and other foods (such as milk, cabbage, broccoli or eggs) and when used for therapeutic or zootechnical purposes. In a second step, we address the alleged differences in treatment provided by the European Communities for *all hormones in dispute* (other than MGA) when used as growth promoters as opposed to that for *carbadox*, an antimicrobial growth promoter.

**Natural hormones for growth promotion compared to (i) those occurring endogenously in meat and other foods, and (ii) those for therapeutic or zootechnical purposes**

1. Comparable situations with different levels of sanitary protection

8.186 This examination involves a comparison of the levels of protection for the *same substance*, namely, respectively, oestradiol-17β, testosterone and progesterone, in different situations depending on the origin or use of that substance. Since we have found above that we can compare
situations where the *same substance* is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5, we find that the treatment of the three natural hormones in dispute when used for growth promotion purposes as opposed to the treatment of these hormones which (i) occur endogenously in meat and other foods and (ii) which have been administered for therapeutic or zootechnical purposes, constitute comparable situations in the sense of Article 5.5.

8.187 The European Communities argues that the origin of these hormones (whether endogenously produced or exogenously administered) causes these hormones to be different, claiming that the hormones present endogenously in meat and other foods have formed part of the human diet for centuries. We note, however, that the European Communities did not submit any evidence in support of its claim that these hormones have different effects. Moreover, all scientific experts advising the Panel have concluded that residues of the three natural hormones present endogenously in meat and other foods or administered for therapeutic or zootechnical purposes are qualitatively the same as the residues of these hormones administered for growth promotion and that if any differences between these hormones could exist (e.g., differences in pathways taken or metabolites), these differences would in any event not have consequences for the potential adverse effects of these hormones. Therefore, even if these hormones would not be totally identical substances, they pose, in any event, the *same adverse health effect* and can, therefore, according to our finding made above, be considered as comparable situations for the purposes of Article 5.5.

(…)

8.191 We thus find that the level of protection adopted by the European Communities for the three natural hormones in dispute when used for growth promotion and that adopted for the same hormones (i) occurring endogenously in meat and other foods and (ii) used for therapeutic or zootechnical purposes, is *different* ("no residue" level as opposed to an unlimited residue level) and that, therefore, distinctions in levels of protection for these comparable situations exist in the sense of the first element of Article 5.5.

2."Arbitrary or unjustifiable" difference in levels of sanitary protection

8.192 We next examine whether these two distinctions in levels of protection are "arbitrary or unjustifiable". We first address the distinction made between the three natural hormones when used as growth promoters and the same hormones occurring endogenously in meat and other foods. We then examine the distinction made between the three natural hormones when used as growth promoters and the same hormones when used for therapeutic or zootechnical purposes.

8.193 Natural hormones used as growth promoters as opposed to those occurring endogenously in meat and other foods. The European Communities has not provided any reasons, other than those addressed above, why it has adopted a different level of protection for the residues of these two categories of natural hormones. The European Communities has, in particular, not provided any evidence that the risk related to the natural hormones used as growth promoters is in any way higher than the risk related to natural endogenous hormones. We also recall that the experts advising the Panel concluded that both categories of hormones (either exogenously administered to animals or endogenously present in animals, meat, other foods or human beings) pose the same potential adverse effects.

(…)

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8.196 We finally note that even if some form of justification could be deduced from the arguments submitted by the European Communities, such could not, in any event, justify so significant a difference in levels of protection between a "no residue" level for natural hormones administered for growth promotion and an unlimited residue level for natural hormones endogenously present in meat and other foods.

8.197 We thus find that the European Communities has not met its burden of proving that the distinction it makes in levels of protection for residues of the three natural hormones in dispute when administered for growth promotion purposes and residues of the same natural hormones present endogenously in meat and other foods is justifiable and that, therefore, this particular distinction in levels of protection is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

(...)

3. Difference which results in "discrimination or a disguised restriction on international trade"

8.201 We next examine whether the difference in levels of protection between residues of the three natural hormones in dispute when administered for growth promotion purposes and residues of the same natural hormones present endogenously in meat and other foods, results in discrimination or a disguised restriction on international trade within the meaning of the third element of Article 5.5.

8.202 We recall the considerations made above on the relationship between the three elements contained in Article 5.5. We recall, in particular, that in some cases the significance of the difference in levels of protection for comparable situations combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".

8.203 In this case, we note, firstly, the significance of the difference in levels of protection for the three natural hormones in dispute when administered for growth promotion purposes and residues of the same hormones present endogenously in meat and other foods, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with any of the three natural hormones in dispute for growth promotion purposes) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for the three natural hormones in dispute when administered for growth promotion purposes and those present endogenously in meat and other foods, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.204 We consider that this finding is further supported by two additional factors. Firstly, we recall some of the objectives (other than the protection of human health) that the European Communities had in mind when enacting or maintaining the EC ban on the use of the natural hormones for growth promotion purposes, as stated in the preambles of the EC measures in dispute and in the reports of the European Parliament and the opinions of the EC Economic and Social Committee referred to by the European Communities, namely harmonizing the regulatory schemes of the different EC Member States, thereby removing competitive distortions and barriers to intra-Community trade in beef, and bringing about an increase in the consumption of
beef, thereby reducing the internal beef surpluses and providing more favourable treatment to domestic producers.

8.205 Secondly, we note that before the EC ban came into force, the percentage of animals treated with any of the hormones in dispute was significantly lower in the European Communities than in the United States. (...) By banning the internal sale and import of meat treated with natural hormones for growth promotion purposes (which represents a significantly higher proportion of the total US meat supply than of the total European Communities meat supply) but continuing to allow any level of residues of these natural hormones present endogenously in meat, the European Communities favoured the consumption of domestic meat and, therefore, de facto discriminates against US meat in favour of EC meat. In this sense, the difference in levels of protection in the European Communities for residues of hormones present endogenously in meat and other foods and residues of the same natural hormones when administered for growth promotion purposes could be said to result in "discrimination or a disguised restriction on international trade".

8.206 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for residues of the three natural hormones in dispute administered for growth promotion purposes and residues of the same natural hormones present endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to the three natural hormones at issue, are inconsistent with the requirements imposed in Article 5.5.

**Synthetic hormones for growth promotion compared to natural hormones**

8.207 We next examine the alleged different treatment provided by the European Communities for, on the one hand, two of the three synthetic hormones in dispute for which international standards exist (zeranol and trenbolone) and, on the other hand, the natural hormones in dispute occurring endogenously in meat and other foods.

1. Comparable situations with different levels of sanitary protection

8.208 In this examination we compare different substances, namely, respectively, zeranol and oestradiol-17β and trenbolone and testosterone. As outlined above, both synthetic hormones at issue are produced to mimic one of the natural hormones in dispute (zeranol mimics oestradiol-17β and trenbolone mimics testosterone). However, both parties in this dispute and the experts advising the Panel agree that the situations thus compared involve at least the same adverse health effect, namely carcinogenicity.

8.209 Since we decided above that we can compare situations where the same adverse health effect is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5, we find that the treatment of zeranol and trenbolone and the treatment of the natural hormones in dispute which occur endogenously in meat and other foods, are comparable situations in the sense of the first element of Article 5.5.

8.210 We next examine whether the European Communities has adopted different levels of protection for these comparable situations.

8.211 With respect to zeranol and trenbolone, the European Communities adopted a "no residue" level as its appropriate level of protection. As outlined above417, the level of protection in the European Communities for the natural hormones present endogenously in meat and other foods is an unlimited residue level.
8.212 We thus find that the levels of protection adopted by the European Communities for residues of zeranol and trenbolone and that for residues of the natural hormones in dispute which occur endogenously in meat and other foods are different ("no residue" level as opposed to an unlimited residue level) and that, therefore, a distinction in levels of protection for these comparable situations exists in the sense of the first element of Article 5.5.

2."Arbitrary or unjustifiable" difference in levels of sanitary protection

8.213 We next examine whether this difference in levels of protection is "arbitrary or unjustifiable". The European Communities has not provided convincing evidence that the synthetic hormones (which mimic the natural hormones) are inherently more dangerous than the natural hormones. (…) Therefore, even if there could be valid reasons to subject the natural hormones to a treatment different from the synthetic hormones, the European Communities has not provided justification for so significant a difference in levels of protection as between a "no residue" level (for the synthetic hormones at issue) and an unlimited residue level (for the natural hormones endogenously present in meat and other foods). We recall, in particular, that the European Communities has not provided evidence that the use of zeranol or trenbolone for growth promotion purposes in accordance with good practice (for example, the Codex MRLs) is unsafe. In other words, it has not submitted any justification for adopting a "no residue" level, instead of the Codex MRLs.

8.214 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods. For these reasons, we find that the difference in levels of protection thus made by the European Communities is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

3.Difference which results in "discrimination or a disguised restriction on international trade"

8.215 We recall the considerations made above on the relationship between the three elements contained in Article 5.5.424 We recall, in particular, that in some cases the significance of the difference in levels of protection for comparable situations combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".

8.216 In this case, we note, firstly, the significance of the difference in levels of protection for zeranol and trenbolone and that for the natural hormones in dispute which occur endogenously in meat and other foods, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with zeranol or trenbolone) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for zeranol and trenbolone and that for the natural hormones in dispute which occur endogenously in meat and other foods, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.217 We consider that this finding is further supported by the two additional factors outlined above, which are equally valid for the distinction in levels of protection made by the European Communities for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods.
8.218 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to zeranol and trenbolone, are inconsistent with the requirements imposed in Article 5.5.

The hormones in dispute compared to carbadox

8.219 We next examine the alleged different treatment provided by the European Communities for five of the six hormones in dispute (all but MGA) when used for growth promotion purposes and carbadox. We recall that this agent is an antimicrobial growth promoter used as a feed additive in swine production.

(...)  

8.244 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for five of the six hormones at issue (all but MGA) when used as growth promoters and carbadox, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to these five hormones in dispute, are inconsistent with the requirements imposed in Article 5.5.

8.245 In summary, in this section we have found that the EC measures in dispute, both in so far as they relate to the two synthetic hormones (zeranol and trenbolone) and the three natural hormones at issue for which international standards exist, are inconsistent with the requirements contained in Article 5.5. The fact that the EC measures in dispute are not based on existing international standards (contrary to Article 3.1) can, for that reason, not be justified on the basis of Article 3.3. The EC measures, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, also inconsistent with the requirements of Article 3.1.

(...)  

6. Sanitary measures where no international standards exist: melengestrol acetate ("MGA")

8.250 We recall that with respect to the third synthetic hormone in dispute, MGA, no international standard exists. As outlined above, the European Communities is, therefore, not under an obligation to base its sanitary measure in respect of this hormone on an international standard in accordance with Article 3.1.

8.251 However, even though no international standard exists for MGA, the EC measures in dispute relating to MGA still need to comply with the other provisions of the SPS Agreement. The United States has invoked violations of Articles 2 and 5. Since Article 2 provides for basic rights and obligations which are further specified in Article 5, we first examine the consistency of the EC measures in dispute relating to MGA with the requirements of Article 5. The consistency of the EC measures relating to all hormones in dispute (including MGA) with the requirements of Article 2 will be dealt with below.

(...)

64
(b) Articles 5.1 to 5.3: risk assessment

(...)

8.255 With respect to MGA, we note, however, that the European Communities has not submitted any scientific evidence in which the potential for adverse effects on human health of MGA residues is evaluated. Moreover, the scientists advising the Panel have at several occasions stated that they are not aware of any publicly available scientific study which evaluates the safety of MGA; the studies carried out by the United States are proprietary studies which remain confidential.

(...)

8.258 We thus find that the European Communities has not met its burden of demonstrating the existence of a risk assessment with respect to MGA and that, therefore, the EC measures in dispute, in so far as they relate to the hormone MGA, are not based on an assessment of risks in accordance with Article 5.

8.259 We recall, in this respect, that the European Communities has explicitly stated that Article 5.7, which deals with cases where relevant scientific evidence is insufficient and allows a Member to take provisional sanitary measures, does not apply to the measures in dispute, including those relating to MGA.

(...)

(c) Article 5.5: distinctions in levels of protection

8.262 Even if we had found that the European Communities met its burden of proving that its measures relating to MGA are based on an assessment of risks in accordance with Articles 5.1 and 5.2 and even if, for that reason, the European Communities could have adopted an appropriate level of protection against these risks, there would still be a need to examine whether the determination and application of this level of protection is consistent with Article 5.5. In this respect, the United States argues that the European Communities fails to justify the following differences in regulatory treatment: (i) a ban on MGA when used for growth promotion purposes as opposed to not setting any limit for residues of the natural hormones present endogenously in untreated meat and other foods (such as milk, cabbage, broccoli or eggs) or used for therapeutic or zootechnical purposes; and (ii) a ban on MGA when used for growth promotion purposes as opposed to allowing the use of carbadox as a growth promoter in swine production. Only with respect to the last mentioned difference in treatment does the United States explicitly invoke Article 5.5.

8.263 We refer to paragraphs 4.209-4.211 for the arguments submitted by the United States with respect to these distinctions in light of the three elements contained in Article 5.5 and find that the United States meets its burden of presenting a prima facie case of inconsistency with Article 5.5.

(i) MGA for growth promotion compared to the natural hormones occurring endogenously in meat and other foods

8.264 We recall our reasoning and findings reached above with respect to the EC measures in dispute relating to the hormones at issue other than MGA, in particular our finding that the European Communities has not met its burden of justifying the distinction it makes in levels of
protection for residues of zeronol and trenbolone (two of the synthetic hormones in dispute) and residues of the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to zeronol and trenbolone, are inconsistent with the requirements imposed in Article 5.5.

8.265 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA (the third synthetic hormone in dispute). Firstly, the European Communities has adopted different levels of protection (a "no residue" limit as opposed to an unlimited residue level) for comparable situations, in casu situations posing the same adverse health effect (i.e., carcinogenicity), namely for MGA used as a growth promoter and the natural hormones in dispute which occur endogenously in meat and other foods in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

8.266 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for MGA used as a growth promoter and the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, also in so far as they relate to MGA, are inconsistent with the requirements imposed by Article 5.5.

(ii) MGA for growth promotion compared to carbadox

8.267 We further recall our reasoning and findings reached above with respect to the EC measures in dispute relating to the hormones at issue other than MGA, in particular our finding that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for residues of the hormones at issue (other than MGA) when used for growth promotion purposes and residues of carbadox in light of the three elements contained in Article 5.5 and that, therefore, the EC measures in dispute, in so far as they relate to the hormones in dispute (other than MGA), are inconsistent with the requirements imposed by Article 5.5.

8.268 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA. Firstly, the European Communities has adopted different levels of protection (a "no residue" limit as opposed to an unlimited residue level) for comparable situations, in casu situations posing the same adverse health effect (i.e., carcinogenicity), namely for MGA used as a growth promoter and carbadox in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted any evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

8.269 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for MGA used as a growth promoter and carbadox, in
light of the three elements contained in Article 5.5, and that, for this reason, also the EC measures in dispute which relate to MGA are inconsistent with the requirements imposed by Article 5.5.

8.270 In summary, in this section we have found that the EC measures in dispute relating to MGA are inconsistent with the requirements contained in Articles 5.1 and 5.5.

7. Article 2: "Basic Rights and Obligations"

8.271 Since we have found that the EC measures in dispute are inconsistent with the requirements of Articles 3 and 5 of the SPS Agreement and considering that Articles 3 and 5 provide for more specific rights and obligations than the "basic rights and obligations" set out in Article 2, we see no need to further examine whether the EC measures in dispute also violate Article 2.

E. ARTICLES I AND III OF GATT

8.272 Since we have found that the EC measures in dispute are inconsistent with the requirements of the SPS Agreement, we see no need to further examine whether the EC measures in dispute are also inconsistent with Article I or III of GATT.

8.273 As noted above in paragraph 8.0, if we were to find an inconsistency with Article I or III of GATT, we would then need to examine whether this inconsistency could be justified, as argued by the European Communities, under Article XX(b) of GATT and would thus necessarily need to revert to the SPS Agreement under which we have already found inconsistencies. Since the European Communities has not invoked any defence under GATT other than Article XX(b), an inconsistency with Article I or III of GATT would, therefore, in any event, not be justifiable.

F. CONCLUDING REMARKS

8.274 In order to avoid any misunderstanding as to the scope and implications of the findings above, we would like to stress that it was not our task to examine generally the desirability or necessity of the EC Council Directives in dispute. The ability of any Member to take sanitary measures which do not affect international trade was not at issue in the present case. Our examination was confined to those aspects of the EC measures that have been raised by the United States, namely the EC import ban on meat and meat products of bovine origin treated with any of six specific hormones for growth promotion purposes. It was further limited to the specific provisions of GATT and the SPS Agreement which have been invoked by the European Communities in support of this import ban. That is the necessity of the import ban, which the European Communities strictly construed as a sanitary measure, for the protection of human life or health. Likewise, the ability of any Member to enact measures which are intended to protect not consumer health but other consumer concerns was not addressed. In this regard, we are aware that in some countries where the use of growth promoting hormones is permitted in beef production, voluntary labelling schemes operate whereby beef from animals which have not received such treatment may be so labelled.

IX. CONCLUSIONS

9.1 In light of the findings above, we reach the following conclusions:

(i) The European Communities, by maintaining sanitary measures which are not based on a risk assessment, has acted inconsistently with the requirements contained in Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures.
(ii) The European Communities, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations which result in discrimination or a disguised restriction on international trade, has acted inconsistently with the requirements contained in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

(iii) The European Communities, by maintaining sanitary measures which are not based on existing international standards without justification under Article 3.3 of the Agreement on the Application of Sanitary and Phytosanitary Measures, has acted inconsistently with the requirements contained in Article 3.1 of that Agreement.

9.2 We recommend that the Dispute Settlement Body requests the European Communities to bring its measures in dispute into conformity with its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures.
III. Issues Raised in this Appeal

96. This appeal raises the following legal issues:

(a) Whether the Panel correctly allocated the burden of proof in this case;
(b) Whether the Panel applied the appropriate standard of review under the SPS Agreement;
(c) Whether, or to what extent, the precautionary principle is relevant in the interpretation of the SPS Agreement;

(...)

(g) Whether the Panel correctly interpreted Articles 3.1 and 3.3 of the SPS Agreement;
(h) Whether the EC measures are "based on" a risk assessment within the meaning of Article 5.1 of the SPS Agreement;
(i) Whether the Panel correctly interpreted and applied Article 5.5 of the SPS Agreement;

(...)

IV. Allocating the Burden of Proof in Proceedings Under the SPS Agreement

99. The Panel, however, proceeds to make a general, unqualified, interpretative ruling that the SPS Agreement allocates the "evidentiary burden" to the Member imposing an SPS measure.

(...)

101. Lastly, the Panel seeks support for its general interpretative ruling in Article 3.2 of the SPS Agreement, which establishes a presumption of consistency with relevant provisions of that Agreement and of the GATT 1994 for measures that conform to international standards, guidelines and recommendations. From this presumption, the Panel extracts a reverse inference that if a measure does not conform to international standards, the
Member imposing such a measure must bear the burden of proof in any complaint of inconsistency with a provision of the *SPS Agreement*.

102. We find the general interpretative ruling of the Panel to be bereft of basis in the *SPS Agreement* and must, accordingly, reverse that ruling. It does not appear to us that there is any necessary (i.e. logical) or other connection between the undertaking of Members to ensure, for example, that SPS measures are "applied only to the extent necessary to protect human, animal or plant life or health ...", and the allocation of burden of proof in a dispute settlement proceeding. Article 5.8 of the *SPS Agreement* does not purport to address burden of proof problems; it does not deal with a dispute settlement situation. To the contrary, a Member seeking to exercise its right to receive information under Article 5.8 would, most likely, be in a pre-dispute situation, and the information or explanation it receives may well make it possible for that Member to proceed to dispute settlement proceedings and to carry the burden of proving on a *prima facie* basis that the measure involved is not consistent with the *SPS Agreement*. The Panel's last reason involves, quite simply, a *non-sequitur*. The converse or *a contrario* presumption created by the Panel does not arise. 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*.

103. In initiating its discussion on the requirements of Articles 3.1 and 3.3 of the *SPS Agreement*, the Panel turns once more to allocating the burden of proof between the complaining parties and the defending party. The Panel states:

> One purpose of the SPS Agreement, as explicitly recognized in the preamble, is to promote the use of international standards, guidelines and recommendations. To that end, Article 3.1 imposes an obligation on all Members to base their sanitary measures on international standards except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3 thereof. In this sense, Article 3.3 provides an *exception* to the general obligation contained in Article 3.1. Article 3.2, in turn, specifies that the complaining party has the burden of overcoming a presumption of consistency with the SPS Agreement in the case of a measure based on international standards. It thereby suggests by implication that when a measure is not so based, the burden is on the respondent to show that the measure is justified under the exceptions provided for in Article 3.3.

We find, therefore, that once the complaining party provides a *prima facie* case (i) that there is an international standard with respect to the measure in dispute, and (ii) that the measure in dispute is *not* based on this standard, the burden of proof under Article 3.3 shifts to the defending party. (underlining added)
The Panel relies on two interpretative points in reaching its above finding. First, the Panel posits the existence of a "general rule - exception" relationship between Article 3.1 (the general obligation) and Article 3.3 (an exception) and applies to the SPS Agreement what it calls "established practice under GATT 1947 and GATT 1994" to the effect that the burden of justifying a measure under Article XX of the GATT 1994 rests on the defending party. It appears to us that the Panel has misconceived the relationship between Articles 3.1, 3.2 and 3.3, a relationship discussed below, 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. Article 3.3 recognizes the autonomous right of a Member to establish such higher level of protection, provided that that Member complies with certain requirements in promulgating SPS measures to achieve that level. The general rule in a dispute settlement proceeding requiring a complaining party to establish a prima facie case of inconsistency with a provision of the SPS Agreement before the burden of showing consistency with that provision is taken on by the defending party, is not avoided by simply describing that same provision as an "exception". In much the same way, merely characterizing a treaty provision as an "exception" does not by itself justify a "stricter" or "narrower" interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose, or, in other words, by applying the normal rules of treaty interpretation. It is also well to remember that a prima facie case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favour of the complaining party presenting the prima facie case.

Secondly, the Panel relies upon the reverse presumption or implication it discovered in Article 3.2 of the SPS Agreement. As already noted, we have been unable to find any basis for that implication or presumption.

We believe, therefore, and so hold that the Panel erred in law both in its two interpretative points and its finding set out in paragraphs 8.86 and 8.87 of the US Panel Report and paragraphs 8.89 and 8.90 of the Canada Panel Report (quoted above).

The legal interpretations developed and the findings set out above by the Panel appear to have been applied, inter alia, in the following paragraphs that have also been appealed by the European Communities:

We recall the conclusions we reached above on burden of proof, in particular that the European Communities has, with respect to its measures which deviate from international standards, the burden of proving the existence of a risk assessment (and, derived therefrom, an identifiable risk) on which the EC measures in dispute are based. It is not, in this dispute, for the United States to prove that there is no risk.

...
3.3 (inter alia, consistency with Article 5) are met, in order to justify a sanitary measure which deviates from an international standard, rests with the Member imposing that measure. Since the EC measures examined in this section (relating to all hormones in dispute other than MGA) are not based on existing international standards and need to be justified under the exceptions provided for in Article 3.3, the European Communities bears the burden of proving that the determination and application of its level of protection is consistent with Articles 5.4 to 5.6.

108. To the extent that the Panel purports to absolve the United States and Canada from the necessity of establishing a prima facie case showing the absence of the risk assessment required by Article 5.1, and the failure of the European Communities to comply with the requirements of Article 3.3, and to impose upon the European Communities the burden of proving the existence of such risk assessment and the consistency of its measures with Articles 5.4, 5.5 and 5.6 without regard to whether or not the complaining parties had already established their prima facie case, we consider and so hold that the Panel once more erred in law.

109. In accordance with our ruling in United States - Shirts and Blouses, the Panel should have begun the analysis of each legal provision by examining whether the United States and Canada had presented evidence and legal arguments sufficient to demonstrate that the EC measures were inconsistent with the obligations assumed by the European Communities under each Article of the SPS Agreement addressed by the Panel, i.e., Articles 3.1, 3.3, 5.1 and 5.5. Only after such a prima facie determination had been made by the Panel may the onus be shifted to the European Communities to bring forward evidence and arguments to disprove the complaining party’s claim.

V. The Standard of Review Applicable in Proceedings Under the SPS Agreement

(…)

111. In the view of the European Communities, the principal alternative approaches to the problem of formulating the "proper standard of review" so far as panels are concerned are two-fold. The first is designated as "de novo review". This standard of review would allow a panel complete freedom to come to a different view than the competent authority of the Member whose act or determination is being reviewed. A panel would have to "verify whether the determination by the national authority was ‘correct’ both factually and procedurally". The second is described as "deference". Under a "deference" standard, a panel, in the submission of the European Communities, should not seek to redo the investigation conducted by the national authority but instead examine whether the "procedure" required by the relevant WTO rules had been followed.

112. Clearly referring only to an appropriate standard of review of factual determinations by the domestic authorities of a Member, the European Communities submits that the principle of deference has been embodied in Article 17.6(i) of the Anti-Dumping Agreement, which reads as follows:

17.6 In examining the matter referred to in paragraph 5:

(i) in its assessment of the facts of the matter, the panel shall determine whether the authorities'
establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned;

113. The European Communities further urges that the above-quoted standard, which it describes as a "deferential 'reasonableness' standard" is applicable in "all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants", and should have been applied by the Panel in the present case.

(...)

116. We do not mean, however, to suggest that there is at present no standard of review applicable to the determination and assessment of the facts in proceedings under the SPS Agreement or under other covered agreements. In our view, Article 11 of the DSU bears directly on this matter and, in effect, articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements. Article 11 reads thus:

The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided in the covered agreements. Panels should consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution". (underlining added)

117. So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither de novo review as such, nor "total deference", but rather the "objective assessment of the facts". Many panels have in the past refused to undertake de novo review, wisely, since under current practice and systems, they are in any case poorly suited to engage in such a review. On the other hand, "total deference to the findings of the national authorities", it has been well said, "could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU".

118. In so far as legal questions are concerned - that is, consistency or inconsistency of a Member's measure with the provisions of the applicable agreement - a standard not found in the text of the SPS Agreement itself cannot absolve a panel (or the Appellate Body) from the duty to apply the customary rules of interpretation of public international law. It may be noted that the European Communities refrained from suggesting that Article 17.6 of the Anti-Dumping Agreement in its entirety was applicable to the present case. Nevertheless, it is appropriate to stress that here again Article 11 of the DSU is directly on point, requiring a panel to "make an
objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements ...".

119. We consider, therefore, that the issue of failure to apply an appropriate standard of review, raised by the European Communities, resolves itself into the issue of whether or not the Panel, in making the above and other findings referred to and appealed by the European Communities, had made an "objective assessment of the matter before it, including an objective assessment of the facts ...". This particular issue is addressed (in substantial detail) below. Here, however, we uphold the findings of the Panel appealed by the European Communities upon the ground of failure to apply either a "deferential reasonableness standard" or the standard of review set out in Article 17.6(i) of the Anti-Dumping Agreement.

VI. The Relevance of the Precautionary Principle in the Interpretation of the SPS Agreement

(...)

123. 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.

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

125. We accordingly agree with the finding of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement.

(...)

X. The Interpretation of Articles 3.1 and 3.3 of the SPS Agreement
The European Communities appeals from the conclusion of the Panel that the European Communities, by maintaining SPS measures which are not based on existing international standards without justification under Article 3.3 of the SPS Agreement, has acted inconsistently with the requirements contained in Article 3.1 of that Agreement.

It will be seen below that the Panel is actually saying that the European Communities acted inconsistently with the requirements of both Articles 3.1 and 3.3 of the SPS Agreement, a position that flows from the Panel's view of a supposed "general rule - exception" relationship between Articles 3.1 and 3.3, a view we have indicated we do not share.

The above conclusion of the Panel has three components: first, international standards, guidelines and recommendations exist in respect of meat and meat products derived from cattle to which five of the hormones involved have been administered for growth promotion purposes; secondly, the EC measures involved here are not based on the relevant international standards, guidelines and recommendations developed by Codex, because such measures are not in conformity with those standards, guidelines and recommendations; and thirdly, the EC measures are "not justified under", that is, do not comply with the requirements of Article 3.3. En route to its above-mentioned conclusion, the Panel developed three legal interpretations, which have all been appealed by the European Communities and which need to be addressed: the first relates to the meaning of "based on" as used in Article 3.1; the second is concerned with the relationship between Articles 3.1, 3.2 and 3.3 of the SPS Agreement; and the third relates to the requirements of Article 3.3 of the SPS Agreement. As may be expected, the Panel's three interpretations are intertwined.

A. The Meaning of "Based On" as Used in Article 3.1 of the SPS Agreement

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.

(…) We read the Panel's interpretation that Article 3.2 "equates" measures "based on" international standards with measures which "conform to" such standards, as signifying that "based on" and "conform to" are identical in meaning. The Panel is thus saying that, henceforth, SPS measures of Members must "conform to" Codex standards, guidelines and recommendations.

We are unable to accept this interpretation of the Panel. 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.
164. In the second place, "based on" and "conform to" are used in different articles, as well as in differing paragraphs of the same article. Thus, Article 2.2 uses "based on", while Article 2.4 employs "conform to". Article 3.1 requires the Members to "base" their SPS measures on international standards; however, Article 3.2 speaks of measures which "conform to" international standards. Article 3.3 once again refers to measures "based on" international standards. The implication arises that the choice and use of different words in different places in the SPS Agreement are deliberate, and that the different words are designed to convey different meanings. A treaty interpreter is not entitled to assume that such usage was merely inadvertent on the part of the Members who negotiated and wrote that Agreement. (...)

165. In the third place, 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.

166. Accordingly, we disagree with the Panel's interpretation that "based on" means the same thing as "conform to".

167. After having erroneously "equated" measures "based on" an international standard with measures that "conform to" that standard, the Panel proceeds to Article 3.3. According to the Panel, Article 3.3 "explicitly relates" the "definition of sanitary measures based on international standards to the level of sanitary protection achieved by those measures". The Panel then interprets Article 3.3 as saying that "all measures which are based on a given international standard should in principle achieve the same level of sanitary protection", and argues a contrario that "if a sanitary measure implies a different level (from that reflected in an international standard), that measure cannot be considered to be based on the international standard". The Panel concludes that, under Article 3.1, "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".
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.

B. **Relationship Between Articles 3.1, 3.2 and 3.3 of the SPS Agreement**

We turn to the relationship between Articles 3.1, 3.2 and 3.3 of the SPS Agreement. As observed earlier, the Panel assimilated Articles 3.1 and 3.2 to one another, designating the product as the "general rule", and contraposed that product to Article 3.3 which denoted the "exception". This view appears to us an erroneous representation of the differing situations that may arise under Article 3, that is, where a relevant international standard, guideline or recommendation exists.

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; but, as earlier observed, the Member is 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.

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. This is made clear in the sixth preambular paragraph of the SPS Agreement:

*Members,*

...  
*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional
organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;  (underlining added)

As noted earlier, this 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.

C. The Requirements of Article 3.3 of the SPS Agreement

174. The European Communities argues that there are two situations covered by Article 3.3 and that its SPS measures are within the first of these situations. It is claimed that the European Communities has maintained SPS measures "which result in a higher level of ... protection than would be achieved by measures based on the relevant" Codex standard, guideline or recommendation, for which measures "there is a scientific justification". It is also, accordingly, argued that the requirement of a risk assessment under Article 5.1 does not apply to the European Communities. At the same time, it is emphasized that the EC measures have satisfied the requirements of Article 2.2.

175. 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 which 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.

176. 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.
Consideration of the object and purpose of Article 3 and of the SPS Agreement as a whole reinforces our 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. 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. 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. We conclude that the Panel's finding that the European Communities is required by Article 3.3 to comply with the requirements of Article 5.1 is correct and, accordingly, dismiss the appeal of the European Communities from that ruling of the Panel.

XI. The Reading of Articles 5.1 and 5.2 of the SPS Agreement: Basing SPS Measures on a Risk Assessment

179. Article 5.1 of the SPS Agreement provides:

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.

(...)

A. The Interpretation of "Risk Assessment"

180. At the outset, two preliminary considerations need to be brought out. The first is that the Panel considered that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement, which reads as follows:

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. (underlining added)

We agree with this general consideration and would also stress that Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1.

181. The second preliminary consideration relates to the Panel's effort to distinguish between "risk assessment" and "risk management". 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. The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment". 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.

1. Risk Assessment and the Notion of "Risk".

182. Paragraph 4 of Annex A of the SPS Agreement sets out the treaty definition of risk assessment: This definition, to the extent pertinent to the present appeal, speaks of:

... 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. (underlining added)

183. Interpreting the above definition, the Panel elaborates risk assessment as a two-step process that "should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat ..., and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects".

185. In its discussion on a statement made by Dr. Lucier at the joint meeting with the experts in February 1997, the Panel states the risk referred to by this expert is an estimate which "... only represents a statistical range of 0 to 1 in a million, not a scientifically identified risk". The European Communities protests vigorously that, by doing so, the Panel is in effect requiring a Member carrying out a risk assessment to quantify the potential for adverse effects on human health.

186. It is not clear in what sense the Panel uses the term "scientifically identified risk". The Panel also frequently uses the term "identifiable risk", 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 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. 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. 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. A panel is authorized only to determine whether a given SPS measure is "based on" a risk assessment. As will be elaborated below, this means that a panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment.
2. Factors to be Considered in Carrying Out a Risk Assessment.

187. Article 5.2 of the SPS Agreement provides an indication of the factors that should be taken into account in the assessment of risk. Article 5.2 states that:

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.

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 at establishing the scientific basis for the sanitary measure a Member intends to take". 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.

B. The Interpretation of "Based On"

1. A "Minimum Procedural Requirement" in Article 5.1?

188. Although it expressly recognizes that Article 5.1 does not contain any specific procedural requirements for a Member to base its sanitary measures on a risk assessment, the Panel nevertheless proceeds to declare that "there is a minimum procedural requirement contained in Article 5.1". That requirement is that "the Member imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment". The Panel goes on to state that the European Communities did not provide any evidence that the studies it referred to or the scientific conclusions reached therein "have actually been taken into account by the competent EC institutions either when it enacted those measures (in 1981 and 1988) or at any later point in time". (emphasis added) Thereupon, the Panel holds that such studies could not be considered as part of a risk assessment on which the European Communities based its measures in dispute. Concluding that the European Communities had not met its burden of proving that it had
satisfied the "minimum procedural requirement" it had found in Article 5.1, the Panel holds the EC measures as inconsistent with the requirements of Article 5.1.

189. We are bound to note that, as the Panel itself acknowledges, no textual basis exists in Article 5 of the SPS Agreement for such a "minimum procedural requirement". 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.

190. Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measures be "based on an assessment, as appropriate for the circumstances ...". The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization. The "minimum procedural requirement" constructed by the Panel, could well lead to the elimination or disregard of available scientific evidence that rationally supports the SPS measure being examined. This risk of exclusion of available scientific evidence may be particularly significant for the bulk of SPS measures which were put in place before the effective date of the WTO Agreement and that have been simply maintained thereafter. (…)

191. In the course of demanding evidence that EC authorities actually "took into account" certain scientific studies, the Panel refers to the preambles of the EC Directives here involved. The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the panel proceedings

2. Substantive Requirement of Article 5.1 - Rational Relationship Between an SPS Measure and a Risk Assessment.

192. Having posited a "minimum procedural requirement" of Article 5.1, the Panel turns to the "substantive requirements" of Article 5.1 to determine whether the EC measures at issue are "based on" a risk assessment. In the Panel's view, those "substantive requirements" involve two kinds of operations: first, identifying the scientific conclusions reached in the risk assessment and the scientific conclusions implicit in the SPS measures; and secondly, examining those scientific conclusions to determine whether or not one set of conclusions matches, i.e. conforms with, the second set of conclusions. Applying the "substantive requirements" it finds in Article 5.1, the Panel holds that the scientific conclusions implicit in the EC measures do not conform with any of the scientific conclusions reached in the scientific studies the European Communities had submitted as evidence.

193. We consider that, in principle, the Panel's approach of examining the scientific conclusions implicit in the SPS measure under consideration and the scientific conclusion yielded by a risk assessment is a useful approach. 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.

194. 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 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. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. 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.

195. We turn now to the application by the Panel of the substantive requirements of Article 5.1 to the EC measures at stake in the present case. (…)

197. Prescinding from the difficulty raised by the Panel's use of the term "identifiable risk", we agree that the scientific reports listed above do not rationally support the EC import prohibition.

(…)

198. With regard to the scientific opinion expressed by Dr. Lucier at the joint meeting with the experts, and as set out in paragraph 819 of the Annex to the US and Canada Panel Reports, we should note that this opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones. Accordingly, it appears that the single divergent opinion expressed by Dr. Lucier is not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities that related specifically to residues of the hormones in meat from cattle to which hormones had been administered for growth promotion. (…)

200. (…) The 1987 IARC Monographs and the articles and opinions of individual scientists submitted by the European Communities 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.

(…)

202. The evidence referred to above by the European Communities related to the biochemical risk arising from the ingestion by human beings of residues of the five hormones here involved in treated meat, where such hormones had been administered to the cattle in accordance with good veterinary practice. The European Communities also referred to distinguishable but closely related risks – risks arising from failure to observe the requirements of good veterinary practice, in combination with multiple problems relating to detection and control of such abusive failure, in the administration of hormones to cattle for growth promotion.

203. The Panel considers this type of risk and examines the arguments made by the European Communities but finds no assessment of such kind of risk. (…)

205. (…) [W]e agree with the European Communities that the Panel has indeed misconceived the scope of application of Article 5.2. 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.

206. Most, if not all, of the scientific studies referred to by the European Communities, in respect of the five hormones involved here, concluded that their use for growth promotion purposes is "safe", if the hormones are administered in accordance with the requirements of good veterinary practice. Where the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is not followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be "safe". The 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. We disagree with the Panel's suggestion that exclusion of risks resulting from the combination of potential abuse and difficulties of control
is justified by distinguishing between "risk assessment" and "risk management". As earlier noted, the concept of "risk management" is not mentioned in any provision of the SPS Agreement and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the SPS Agreement.

207. The question that arises, therefore, is whether the European Communities did, in fact, submit a risk assessment demonstrating and evaluating the existence and level of risk arising in the present case from abusive use of hormones and the difficulties of control of the administration of hormones for growth promotion purposes, within the United States and Canada as exporting countries, and at the frontiers of the European Communities as an importing country. Here, we must agree with the finding of the Panel that the European Communities in fact restricted itself to pointing out the condition of administration of hormones "in accordance with good practice" "without further providing an assessment of the potential adverse effects related to non compliance with such practice". The record of the panel proceedings shows that the risk arising from abusive use of hormones for growth promotion combined with control problems for the hormones at issue, may have been examined on two occasions in a scientific manner. The first occasion may have occurred at the proceedings before the Committee of Inquiry into the Problem of Quality in the Meat Sector established by the European Parliament, the results of which constituted the basis of the Pimenta Report of 1989. However, none of the original studies and evidence put before the Committee of Inquiry was submitted to the Panel. The second occasion could have been the 1995 EC Scientific Conference on Growth Promotion in Meat Production. One of the three workshops of this Conference examined specifically the problems of "detection and control". However, only one of the studies presented to the workshop discussed systematically some of the problems arising from the combination of potential abuse and problems of control of hormones and other substances. The study presented a theoretical framework for the systematic analysis of such problems, but did not itself investigate and evaluate the actual problems that have arisen at the borders of the European Communities or within the United States, Canada and other countries exporting meat and meat products to the European Communities. At best, this study may represent the beginning of an assessment of such risks.

208. In the absence of any other relevant documentation, we find that the European Communities did not actually proceed to an assessment, within the meaning of Articles 5.1 and 5.2, of the risks arising from the failure of observance of good veterinary practice combined with problems of control of the use of hormones for growth promotion purposes. The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel. We affirm, therefore, the ultimate conclusion of the Panel that the EC import prohibition is not based on a risk assessment within the meaning of Articles 5.1 and 5.2 of the SPS Agreement and is, therefore, inconsistent with the requirements of Article 5.1.

209. Since we have concluded above that an SPS measure, to be consistent with Article 3.3, has to comply with, inter alia, the requirements contained in Article 5.1, it follows that the EC measures at issue, by failing to comply with Article 5.1, are also inconsistent with Article 3.3 of the SPS Agreement.
XII. The Reading of Article 5.5 of the SPS Agreement: Consistency of Levels of Protection and Resulting Discrimination or Disguised Restriction on International Trade

210. The European Communities also appeals from the conclusion of the Panel that, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers appropriate in different situations which result in discrimination or a disguised restriction on international trade, the European Communities acted inconsistently with the requirements set out in Article 5.5 of the SPS Agreement.

A. General Considerations: the Elements of Article 5.

211. Article 5.5 of the SPS Agreement needs to be quoted in full:

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.

212. Article 5.5 must be read in context. An important part of that context is Article 2.3 of the SPS Agreement, which provides as follows:

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.

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.

213. 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 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.

214. Close inspection of Article 5.5 indicates that a complaint of violation of this Article must show the presence of three distinct elements. The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those levels of protection exhibit arbitrary or unjustifiable differences ("distinctions" in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the measure embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade.

215. We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. 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.

216. Different Levels of Protection in Different Situations

We examine the first element set out in Article 5.5, namely, that a Member has established different levels of protection which it regards as appropriate for itself in differing situations. The Panel, interpreting the term "different situations", states in effect that situations involving the same substance or the same adverse health effect may be compared to one another. The European Communities protests this interpretation as erroneous: while it agrees that there must be some common element (e.g. the substance or drug, or the health risk), it argues that such common element is not necessarily sufficient to ensure a rational comparison.

217. There appears no need to examine this matter at any length. 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.
218. In examining the EC measures here involved and at least one other SPS measure of the European Communities, the Panel finds that several different levels of protection were projected by the European Communities:

(i) the level of protection in respect of natural hormones when used for growth promotion;
(ii) the level of protection in respect of natural hormones occurring endogenously in meat and other foods;
(iii) the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes;
(iv) the level of protection in respect of synthetic hormones (zeranol and trenbolone) when used for growth promotion; and
(v) the level of protection in respect of carbadox and olaquindox.

C. Arbitrary or Unjustifiable Differences in Levels of Protection

219. The Panel then proceeds to compare level of protection (i) with, firstly, level of protection (ii) and, secondly, with level of protection (iii). Thereafter, the Panel compares levels of protection (i) and (iv) with level of protection (v). The Panel holds that the differences between levels of protection (i) and (iv) on the one hand, and level of protection (ii) on the other, are arbitrary and unjustifiable. It further held that the differences in levels of protection (i) and (iv) on the one hand, and level (v) on the other, are also arbitrary and unjustifiable. In contrast, the Panel does not undertake to compare level of protection (iii) with level of protection (i). We examine below seriatim what the Panel has done and the results it has obtained.

220. The Panel first compares the levels of protection established by the European Communities in respect of natural and synthetic hormones when used for growth promotion purposes (levels of protection (i) and (iv)) with the level of protection set by the European Communities in respect of natural hormones occurring endogenously in meat and other natural foods (level of protection (ii)). The Panel finds the difference between these levels of protection "arbitrary" and "unjustifiable" basically because, in its view, the European Communities had not provided any reason other than the difference between added hormones and hormones naturally occurring in meat and other foods that have formed part of the human diet for centuries, and had not submitted any evidence that the risk related to natural hormones used as growth promoters is higher than the risk related to endogenous hormones. The Panel adds that the residue level of natural hormones in some natural products (such as eggs and broccoli) is higher than the residue level of hormones administered for growth promotion in treated meat. Furthermore, the Panel states the practical difficulties of detecting the presence of residues of natural hormones in treated meat would also be present in respect of natural hormones occurring endogenously in meat and other foods. The Panel stresses the very marked gap between a "no-residue" level of protection against natural hormones used for growth promotion and the "unlimited-residue" level of protection with regard to hormones occurring naturally in meat and other foods. Much the same reasons are deployed by the Panel in comparing the levels of protection in respect of synthetic hormones used for growth promotion and in respect of natural hormones endogenously occurring in meat and other foods.

221. We do not share the Panel's conclusions that the above differences in levels of protection in respect of added hormones in treated meat and in respect of naturally-occurring hormones in food, are merely arbitrary and unjustifiable. To the contrary, 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. The other considerations cited by the Panel, whether taken separately or grouped together, do not justify the Panel's finding of arbitrariness in the difference in the level of protection between added hormones for growth promotion and naturally-occurring hormones in meat and other foods.

222. Because the Panel finds that the difference in the level of protection in respect of the three natural hormones, when used for growth promotion purposes, and the level of protection in respect of natural hormones present endogenously in meat and other foods is unjustifiable, the Panel regards it as unnecessary to decide whether the difference in the levels of protection set by the European Communities in respect of natural hormones used as growth promoters and in respect of the same hormones when used for therapeutic or zootecchnical purposes, is justified. Because, however, we have reached a conclusion different from that of the Panel, we consider it appropriate to complete the Panel's analysis in order that we may be in a position to review the Panel's conclusion concerning consistency with Article 5.5 as a whole. The matter of therapeutic and zootecchnical uses of hormones was fully argued before the Panel. Although the failure of the Panel to proceed with this comparison was not expressly appealed by the United States, the United States relies markedly upon the fact that the European Communities treats therapeutic and zootecchnical uses of natural hormones differently from growth promotion use of the same hormones.

223. The European Communities has argued that there are two important differences between the administration of hormones for growth promotion purposes and their administration for therapeutic and zootecchnical purposes. The first difference concerns the frequency and scale of the treatment. Therapeutic use is occasional as opposed to regular and continuous use that characterizes growth promotion. Therapeutic use is selective as it concerns only individual sick or diseased animals; growth promotion involves the administration of hormones to all herds and all the members of a herd of cattle. Thus, therapeutic use takes place on a small scale and normally involves cattle intended for breeding and not for slaughter; in contrast, the use of these hormones for growth promotion occurs on a much larger scale and is much more difficult and costly to control. Zootecchnical use may relate to entire herds but would occur only once a year; it is thus clearly distinguishable from the use of hormones continuously and over long periods of time (apparently most of the lifespan of the animals involved). This difference has been stressed in particular by Dr. André, one of the experts advising the Panel.

224. The second difference concerns the mode of administration of hormones. In order to prevent abuse, the European Communities has regulated in substantial detail the conditions under which the administration of natural hormones may be authorized by the Member States of the European Union for therapeutic and zootecchnical purposes. The hormones must, in the first place, be administered by a veterinarian or under the responsibility of a veterinarian. In addition, Directive 96/22/EC specifies detailed conditions, such as, for example: strict withdrawal periods; administration by injection or, in case of varying disfunctions, by vaginal spirals, but not by implants; clear identification of the individual animal so treated; and recording of the details of treatment by the responsible veterinarian (e.g. type of treatment, type of veterinary drug used or authorized, date of treatment, identity of the animals treated).
225. The conclusion we come to, after consideration of the foregoing factors, is that, on balance, the difference in the levels of protection concerning hormones used for growth promotion purposes, on the one hand, and concerning hormones used for therapeutic and zootechnical purposes, on the other, is not, in itself, "arbitrary or unjustifiable".

226. We turn to the Panel's comparison between the levels of protection set by the European Communities in respect of natural and synthetic hormones for growth promotion and with respect to carbadox and olaquindox. Carbadox and olaquindox are anti-microbial agents or compounds which are mixed with the feed given to piglets (maximum age of four months). According to a report of JECFA, submitted to the Panel by the United States, carbadox is a feed additive that is a known genotoxic carcinogen, that is, carbadox induces and does not merely promote cancer. The experts advising the Panel confirmed that carbadox was genotoxic in character.

227. In the panel proceedings, the European Communities sought to justify the difference in the levels of protection in respect of the natural and synthetic hormones (except MGA) and in respect of carbadox and olaquindox. The Panel responds to these arguments and the European Communities has reiterated its original arguments in its appellant's submission. (…)

(…)

235. Having reviewed the above arguments and counter-arguments, we must agree with the Panel that the difference in the EC levels of protection in respect of the hormones in dispute when used for growth promotion, on the one hand, and carbadox and olaquindox, on the other, is unjustifiable in the sense of Article 5.5.

D. Resulting in Discrimination or a Disguised Restriction on International Trade

236. In interpreting this last element or requirement of Article 5.5, the Panel recalls the conclusion of the Appellate Body in United States - Standards for Reformulated and Conventional Gasoline ("United States - Gasoline") to the effect that the terms "arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction on international trade" found in Article XX of the GATT 1994, may be read side-by-side and impart meaning to one another. The Panel also recalls our statement in Japan - Alcoholic Beverages, and in particular the requirement in Article III:2, second sentence, of the GATT 1994 that dissimilar taxation needs to be "applied ... so as to afford protection to domestic production". It quotes the passage stating, in part, that "[the dissimilar taxation] may be so much more that it will be clear from that very differential that the dissimilar taxation was applied ?so as to afford protection'. In some cases, that may be enough to show a violation". The Panel then renders its interpretation of the last requirement of Article 5.5 of the SPS Agreement as follows:

We consider the reasoning in both Appellate Body Reports to be equally relevant to the relationship between the three elements contained in Article 5.5. All three elements impart meaning to one another. Nevertheless, in order to give effect to all three elements contained in Article 5.5 and giving full meaning to the text and context of this provision, we consider that all three elements need to be distinguished and addressed separately. However, we also agree that in some cases where a Member enacts, for comparable situations, sanitary measures which reflect different levels of protection, the significance of the difference in levels of protection combined with the arbitrariness
thereof may be sufficient to conclude that this difference in levels of protection "result[s] in discrimination or a disguised restriction on international trade" in the sense of Article 5.5 (in line with the argument that the magnitude of the very differential of a dissimilar taxation may be enough to conclude that a dissimilar taxation is applied so as to afford protection, as provided for in the second sentence of Article III:2 of GATT.

(underlining added)

237. The European Communities urges that the Panel committed several errors of legal interpretation. Firstly, the Panel disregards the alternative character of the three elements of the chapeau of Article XX of the GATT 1994, and the fact that the three elements of Article 5.5 of the SPS Agreement are additional and cumulative in nature. Secondly, Article III:2, second sentence, of the GATT 1994 is concerned with the impact of a tax on the competitive relations concerning directly competitive or substitutable products. On the other hand, discrimination and disguised restriction in the sense of Article 5.5 of the SPS Agreement are entirely different concepts. Thirdly, and as a consequence of its interpretation of Article 5.5, a "discrimination or a disguised restriction on international trade" is not really, for the Panel, a third or additional requirement at all under Article 5.5.

238. We agree with the Panel's view that "all three elements [of Article 5.5] need to be distinguished and addressed separately". 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)

239. However, we disagree with the Panel on two points. First, in view of the structural differences between the standards of the chapeau of Article XX of the GATT 1994 and the elements of Article 5.5 of the SPS Agreement, the reasoning in our Report in United States - Gasoline, quoted by Panel, cannot be casually imported into a case involving Article 5.5 of the SPS Agreement. Secondly, in our view, it is similarly unjustified to assume applicability of the reasoning of the Appellate Body in Japan - Alcoholic Beverages about the inference that may be drawn from the sheer size of a tax differential for the application of Article III:2, second sentence, of the GATT 1994, to the quite different question of whether arbitrary or unjustifiable differences in levels of protection against risks for human life or health, "result in discrimination or a disguised restriction on international trade".

240. In our view, 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. It is well to bear in mind that, after all, the difference in levels of protection that is characteristic 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. 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.

241. In the present appeal, it is necessary to address this question only with regard to the difference in the levels of protection established in respect of the hormones in dispute and in respect of carbadox and olaquindox.

242. According to the Panel, the "significance" of the "arbitrary or unjustifiable" distinction in the level of protection concerning the hormones in dispute as compared with the level of protection in respect of carbadox and olaquindox results in discrimination or a disguised restriction on international trade. It bases this finding on: (i) the great difference in the levels of protection, namely, the difference between a "no residue" level for the five hormones at issue when used as growth promoters, as opposed to an "unlimited residue" level for carbadox and olaquindox; (ii) the absence of any plausible justification put forward by the European Communities for this significant difference; and (iii) the nature of the EC measure, i.e., the prohibition of imports, which necessarily restricts international trade.

243. The Panel adduces, in support of its finding, three additional factors: (iv) the objectives (apart from the protection of human health) that it believes the European Communities had in mind in enacting or maintaining the EC ban, as reflected in the preambles of the measures in dispute, the reports of the European Parliament and the opinions rendered by the EC Social and Economic Committee. These include the harmonizing of the regulatory schemes of the different Member States of the European Union and the removal of competitive distortions in and barriers to intra-community trade in beef, and the bringing about of an increase in the consumption of beef, thereby reducing the internal beef surpluses, and providing more favourable treatment to domestic producers; (v) before the import ban came into force (in 1987), the percentage of animals treated for growth promotion with the hormones in dispute was significantly lower in the European Communities than in Canada and the United States. The apparent implication, for the Panel, is that the EC measures constitute de facto discrimination against imported beef produced with growth promotion hormones; and (vi) that the hormones at issue are used for growth promotion in the bovine sector "where the European Communities seemingly wants to limit supplies and is arguably less concerned with international competitiveness", whereas carbadox and olaquindox are used for growth promotion in the pork meat sectors "where the European Communities has no domestic surpluses and where international competitiveness is a higher priority".

244. In its appeal, the European Communities stresses that the prohibition of the use of hormones for growth promotion purposes applies equally to beef produced within the European Communities and to imports of such beef. It is also emphasized that the predominant motivation for both the prohibition of the domestic use of growth promotion hormones and the prohibition of importation of treated meat, is the protection of the health and safety of its population. No suggestion has been made that the import prohibition of treated meat was the result of lobbying by EC domestic producers of beef. It is also pointed out that legislation (in representative governments) normally reflects multiple objectives. The fact that there was a higher percentage of beef treated with growth promotion hormones in Canada and in the United States, as compared with the European Communities, was simply a reflection of the fact that Canada and the United States had allowed this practice for a long time while the European Communities had not. The long history of the EC Directives should be recalled in this connection. The import prohibition could not have been designed simply to protect beef producers in the European Communities vis-à-vis beef producers in the United States and Canada, for beef producers in the European Communities were precisely forbidden to use the same hormones for the same purpose. We note,
in this connection, that the prohibition of domestic use also necessarily excludes any exports of treated meat by domestic producers.

245. We do not attribute the same importance as the Panel to the supposed multiple objectives of the European Communities in enacting the EC Directives that set forth the EC measures at issue. The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes clear the depth and extent of the anxieties experienced within the European Communities concerning the results of the general scientific studies (showing the carcinogenicity of hormones), the dangers of abuse (highlighted by scandals relating to black-marketing and smuggling of prohibited veterinary drugs in the European Communities) of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the meat available in its internal market. A major problem addressed in the legislative process of the European Communities related to the differences in the internal regulations of various Member States of the European Union (four or five of which permitted, while the rest prohibited, the use for growth promotion of certain hormones), the resulting distortions in competitive conditions in and the existence of barriers to intra-community trade. The necessity for harmonizing the internal regulations of its Member States was a consequence of the European Communities' mandate to establish a common (internal) market in beef. Reduction of any beef surplus through an increase in the consumption of beef within the European Communities, is not only in the interests of EC farmers, but also of non-hormone using farmers in exporting countries. We are unable to share the inference that the Panel apparently draws that the import ban on treated meat and the Community-wide prohibition of the use of the hormones here in dispute for growth promotion purposes in the beef sector were not really designed to protect its population from the risk of cancer, but rather to keep out US and Canadian hormone-treated beef and thereby to protect the domestic beef producers in the European Communities.

246. Our conclusion, therefore, is that the Panel's finding that the "arbitrary or unjustifiable" difference in the EC levels of protection in respect of the hormones at issue on the one hand and in respect of carbadox and olaquindox on the other hand, "result in discrimination or a disguised restriction on international trade", is not supported either by the architecture and structure of the EC Directives here at stake or of the subsequent Directive on carbadox and olaquindox, or by the evidence submitted by the United States and Canada to the Panel. The Panel's finding is itself unjustified and erroneous as a matter of law. Accordingly, we reverse the conclusion of the Panel that the European Communities has acted inconsistently with the requirements set out in Article 5.5 of the SPS Agreement.

(…)

XIV. Findings and Conclusions

253. For the reasons set out in the preceding sections of this Report, the Appellate Body:

(a) reverses the Panel's general interpretative ruling that the SPS Agreement allocates the evidentiary burden to the Member imposing an SPS measure, and also reverses the Panel's conclusion that when a Member's measure is not based on an international standard in accordance with Article 3.1, the burden is on that Member to show that its SPS measure is consistent with Article 3.3 of the SPS Agreement;

(b) concludes that the Panel applied the appropriate standard of review under the SPS Agreement;
(c) upholds the Panel's conclusions that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2, and that the precautionary principle has been incorporated in, inter alia, Article 5.7 of the SPS Agreement;

(…)

(g) reverses the Panel's conclusion that the term "based on" as used in Articles 3.1 and 3.3 has the same meaning as the term "conform to" as used in Article 3.2 of the SPS Agreement;

(h) modifies the Panel's interpretation of the relationship between Articles 3.1, 3.2 and 3.3 of the SPS Agreement, and reverses the Panel's conclusion that the European Communities by maintaining, without justification under Article 3.3, SPS measures which are not based on existing international standards, acted inconsistently with Article 3.1 of the SPS Agreement;

(i) upholds the Panel's finding that a measure, to be consistent with the requirements of Article 3.3, must comply with, inter alia, the requirements contained in Article 5 of the SPS Agreement;

(j) modifies the Panel's interpretation of the concept of "risk assessment" by holding that neither Articles 5.1 and 5.2 nor Annex A.4 of the SPS Agreement require a risk assessment to establish a minimum quantifiable magnitude of risk, nor do these provisions exclude a priori, from the scope of a risk assessment, factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences;

(k) reverses the Panel's finding that the term "based on" as used in Article 5.1 of the SPS Agreement entails a "minimum procedural requirement" that a Member imposing an SPS measure must submit evidence that it actually took into account a risk assessment when it enacted or maintained the measure;

(l) upholds the Panel's finding that the EC measures at issue are inconsistent with the requirements of Article 5.1 of the SPS Agreement, but modifies the Panel's interpretation by holding that Article 5.1, read in conjunction with Article 2.2, requires that the results of the risk assessment must sufficiently warrant the SPS measure at stake;

(m) reverses the Panel's findings and conclusions on Article 5.5 of the SPS Agreement;

(…)

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3. Case Note on United States – Continued Suspension of Obligations in the EC – Hormones Disputes

By Sungjoon Cho, 103 AJIL 299 (2009)

World Trade Organization—Dispute Settlement Understanding (DSU)—Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)—termination of suspension of concessions (DSU Articles 21–23)—risk assessment (SPS Agreement Article 5.1)—provisional safeguards (SPS Agreement Article 5.7)

UNITED STATES—CONTINUED SUSPENSION OF OBLIGATIONS IN THE EC—HORMONES DISPUTE. WT/DS320/AB/R. At


The transatlantic trade row over hormone-treated beef dates back to as early as the 1980s. In 1987, the United States and the European Communities (EC) failed to resolve their dispute under the Committee on Technical Barriers to Trade of the General Agreement on Tariffs and Trade (GATT). The tension climaxed later that year when President Reagan imposed retaliatory tariffs of 100 percent ad valorem, worth about $100 million, on EC imports. After the new World Trade Organization (WTO) system was launched in 1995, the United States brought its complaint to the WTO’s Dispute Settlement Body (DSB) on the ground that the EC violated the newly agreed Agreement

9 Id.
on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).\(^{10}\) The focus of the U.S. complaint was the EC’s import ban, implemented through Directives 81/602/EEC, 88/146/EEC, 88/299/EEC, and 96/22/EC.\(^{11}\) These directives banned the importation of meat and meat products treated with six specific growth hormones, namely three natural hormones: oestradiol-17β (responsible for female characteristics), testosterone (responsible for male characteristics), and progesterone (responsible for maintaining pregnancy); as well as three synthetic hormones: zeranol, trenbolone acetate (TBA), and melengestrol acetate (MGA), which imitate the actions of the three natural hormones, respectively.\(^{12}\)

In January 1998, the Appellate Body in *EC—Hormones* ruled that the EC had failed to undertake the risk assessment required by SPS Agreement Article 5.1\(^{13}\) to justify scientifically its import ban. The Appellate Body held:

> The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel.\(^{14}\)

Despite its defeat, the EC refused to lift its import ban. Upon the WTO’s authorization, the United States imposed retaliatory tariffs worth $116.8 million on major


\(^{12}\) See Panel Report, *EC—Hormones*, supra note 4, paras. 2.8, 2.9.

\(^{13}\) Article 5.1 provides: “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.”

\(^{14}\) Appellate Body Report, *EC—Hormones*, supra note 4, para. 208 (emphasis added).
imports, such as Bordeaux wines, from the EC countries. In the meantime, after losing the EC—Hormones case in the WTO, the EC commissioned seventeen scientific studies concerning the adverse health risks from hormone-treated beef. Reviewing these studies, the Scientific Committee on Veterinary Measures relating to Public Health of the European Commission (SCVPH) issued a series of opinions (Opinion 1999, Opinion 2000, and Opinion 2002) that concluded that oestradiol-17β was a “complete carcinogen,” but further noted that “no threshold levels could be defined for any of the six [hormones]” and that the “current state of knowledge did not allow a quantitative estimate of the risk” as to the safety of the five other hormones. Based on the SCVPH’s opinions, the EC replaced Directive 96/22/EC with Directive 2003/74/EC, which permanently banned the importation of meat and meat products treated with oestradiol-17β, and provisionally banned the importation of the same products treated with any of the five other hormones. In November 2004, the EC filed a complaint against the United States and Canada for their continued suspension of concessions even after the EC notified the DSB of Directive 2003/74/EC.

On March 31, 2008, a WTO panel issued its report in U.S.—Continued Suspension. The panel determined that the EC had complied with the original EC—Hormones decision when it replaced its old measure, Directive 96/22/EC, with the new one, Directive 2003/74/EC. Therefore, continued retaliation by the United States was tantamount to unilateral determination and redress of a violation, which was prohibited by Dispute Settlement Understanding (DSU) Article 23. As to the EC’s risk assessment on oestradiol-17β, the panel, after consulting scientific experts, found that the EC had

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15 See Arbitrators’ Report, Recourse to Arbitration by the European Communities under Article 22.6 of the DSU, EC—Hormones, WT/DS26/ARB, paras. 83, 84 (July 12, 1999).
17 Appellate Body Report, U.S.—Continued Suspension, supra note 9, paras. 489–90, 622. 18 Id., para. 493.

21 Id., para. 7.251.
failed to evaluate relevant health risks specifically in terms of those originating from residues in meat as a result of growth hormone treatment.\textsuperscript{22} As to the EC’s provisional ban on the five other hormones at issue, the panel held that the EC had failed to meet the condition of insufficient scientific evidence under SPS Agreement Article 5.7,\textsuperscript{23} given that the EC had not demonstrated any “critical mass” of new evidence to justify its provisional ban.\textsuperscript{24} The EC, along with the United States and Canada, appealed the panel decision.

On October 16, 2008, the WTO Appellate Body issued its report, rejecting the panel’s rulings on nearly all grounds. First, the Appellate Body took a diametrically opposite view vis-à-vis the panel on a “unilateral declaration of compliance” by the EC (para. 317). The Appellate Body held that DSU Article 21.5 should be the only channel in which an implementing party may demonstrate its “substantive” compliance under DSU Article 22.8, which could terminate the sanction (suspension of concession) (para. 380).\textsuperscript{25}

Second, the Appellate Body reprimanded the panel for violating the EC’s due process rights (para. 481). According to the Appellate Body, the scientists whom the panel consulted were prejudiced because they were deeply involved in establishing the Codex standards on the hormones at issue from which the EC had deviated when it imposed the new measure (\textit{id.}). Third, the Appellate Body held that the panel interpreted risk assessment under SPS Agreement Article 5.1 too narrowly and had thus failed to take into account those risks from abuse or misuse of oestradiol-17β, which the EC highlighted in justifying its new measure (para. 553). Finally, the Appellate Body found that the panel’s interpretation of the insufficiency requirement under Article 5.7 would require a “paradigm shift” to trigger a provisional ban (para. 703). The Appellate Body

\begin{itemize}
\item[\textsuperscript{22}] \textit{Id.}, para. 7.537.
\item[\textsuperscript{23}] 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.”
\item[\textsuperscript{24}] Panel Report, \textit{U.S.—Continued Suspension, supra} note 9, para. 7.648.
\item[\textsuperscript{25}] For an excellent analysis on the DSU issues (Articles 21–23) arising under this dispute, see Markus Böckenförde, \textit{Hormone Ban in Dispute Again: The WTO Refuses to Reject Either the EC Ban or Canadian/US Trade Sanctions}, ASIL INSIGHTS (Dec. 18, 2008), at \texttt{<http://www.asil.org/insights081218.cfm>}. 
\end{itemize}
concluded that such interpretation would be too narrow and that mere suspicion would be enough to cross the insufficiency hurdle (paras. 703–05).

* * * *

The Appellate Body’s extensive rejection of the panel’s findings in *U.S.—Continued Suspension* appears to be an ostensible effort to broaden a regulating member’s policy space as to risk factors and scientific evidence. The Appellate Body condemned the panel’s alleged oversubscription to mainstream science, symbolized by the panel’s use of relevant international standards, the Codex standards. The Appellate Body attempted to restore a broadened notion of science or scientific justification, in the form of risk assessment, as defined in *EC—Hormones*, which took into account certain nonscientific policy considerations, such as the acceptable level of protection.

Yet, the Appellate Body’s deferentialism tends to come at the expense of science itself. In an unprecedented move, the Appellate Body ruled that the panel violated the EC’s due process rights by consulting certain scientific experts who, the Appellate Body viewed, were prejudiced against the EC’s regulatory position diverging from the Codex standards on the six hormones at issue because these experts authored these very standards (para. 477). The Appellate Body held that “the qualifications and relevant knowledge of Drs. Boisseau and Boobis are not by themselves sufficient guarantees of their independence and impartiality” (para. 459). According to the Appellate Body, the panel’s reliance on these two scientists was so egregious that it could invalidate the panel’s findings under Articles 5.1 and 5.7 (para. 484).

The Appellate Body’s position in seems highly problematic. It might border on the fallacy of “guilt by association” or “ad hominem argument.” The Appellate Body, in essence, censured these scientists’ testimonies not by their professional qualifications or any other ethical misconduct but merely by their “institutional affiliation” and

26 The Appellate Body report explained: “This is problematic in this case because the European Communities’ risk assessment called into question the validity of the [Joint FAO/WHO Expert Committee on Food Additives]’s evaluations and explicitly stated that it would not follow them. In the light of this, it was improper for the Panel to consult with Drs. Boisseau and Boobis, who were directly involved in JECFA’s evaluations” (para. 477).
“participation” in legitimate professional activities carried out pursuant to their affiliation (para. 481). However, as the United States argued, “familiarity and expertise with the matters in dispute are assets . . . .”27 As seen in selection of the DSU Article 21.5 panel, that those original panelists reviewed the same issues in a compliance panel was no concern to the Appellate Body.28

The Appellate Body also sided with the EC’s position on risk assessment by spotlighting opinions of some scientific experts who recognized the possible risks from abuse or misuse of the hormones at issue when not administered according to good veterinary practices (para. 547). More specifically, the report stated: “Indeed, these experts agreed that their conclusions in relation to the risks posed by oestradiol-17β were predicated on good veterinary practices being followed. Accordingly, the abuse or misuse in the administration of oestradiol-17β has a bearing on the particular risks being assessed by the European Communities” (id., emphasis added). Here, the Appellate Body enmeshed an objective risk assessment under Article 5.1 with a subjective policy determination on the level of protection under paragraph 5 of Annex A of the SPS Agreement.29 In principle, whether (or how much) a regulating member may evaluate the potential risk from abuse or misuse belongs to the realm of the determination of the appropriate or acceptable level of protection, which is a separate, and subsequent, stage to risk assessment. The Appellate Body itself recognized that “the chosen level of protection must not affect the rigour or objective nature of the risk assessment, which must remain, in its essence, a process in which possible adverse effects are evaluated using scientific methods” (para. 534). Nonetheless, the Appellate Body subsequently adopted a self-contradictory position by holding that “the risks arising from the abuse or misuse in the administration of hormones can properly be considered as part of a risk assessment” (para. 545).

The Appellate Body’s dilution, or broadening the scope, of objective science continued when it interpreted Article 5.7. While the panel ascribed the existence of

27 Communication from the United States on Concerns Regarding the Appellate Body’s Report, U.S.—Continued Suspension, supra note 9, para. 26 (Nov. 12, 2008).
28 Id.
29 Paragraph 5 of Annex A defines the appropriate level of sanitary or phytosanitary protection as “The 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.”
relevant international standards to the sufficiency of available evidence,\(^{30}\) the Appellate Body undermined such attributive relationship between international standards and the state of evidentiary sufficiency. As noted in its report, “in circumstances where a Member adopts a *higher level of protection* than that reflected in the international standard, the legal test that applies to the ‘insufficiency’ of the evidence under Article 5.7 is not made stricter” (para. 708). Thus, according to the Appellate Body, the EC’s uniquely chosen (higher) level of protection, a zero tolerance of health risks from the consumption of hormone-treated beef, should inform the insufficiency determination (*id.*) in the same manner in which the given level of protection is part of risk assessment (para. 685).\(^{31}\) The Appellate Body even explained that this determination should be the EC’s call, explaining that the “particular insufficiencies in the relevant scientific evidence identified by the European Communities had to be evaluated *on their own terms*” (para. 711, emphasis added).

In the same vein, the Appellate Body lowered the trigger threshold of Article 5.7 from a “paradigm shift,” which the panel had employed, to a mere level of suspicion in a situation with new scientific developments, noting that the paradigm shift was “too high a threshold” and further stating that “it suffices that new scientific developments *call into question* whether the body of scientific evidence still permits . . . a sufficiently objective assessment of risk” (paras. 706, 725, emphasis added). Therefore, the Appellate Body provided the possibility in which a regulating state may predicate its provisional SPS safeguard on any new scientific study that it thinks casts doubt on the conventional version of science (para. 725).

As noted, however, the Appellate Body’s deferentialism tends to encroach upon the rigor of risk assessment obligation under Article 5.1. For example, under Article 5.7, a preliminary question confronted by a regulating member is how to *value* currently available scientific information in its possession (and even the availability itself), and, subsequently, whether to conduct risk assessment under Article 5.1 or to have recourse to

\(^{30}\) Panel Report, *U.S.—Continued Suspension, supra* note 9, para. 7.644.

\(^{31}\) The full quotation from the Appellate Body report in *U.S.—Continued Suspension* is as follows: “[T]he fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as *part of its risk assessment* that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard” (emphasis added).
a provisional measure under Article 5.7. In other words, the preliminary evaluation here centers on the “assessability” of risks, that is, “whether the relevant evidence . . . is sufficient to permit the evaluation” of the risks in question.\footnote{32}{Appellate Body Report, Japan—Measures Affecting the Importation of Apples, WS/DS245/AB/R, para. 179 (Nov. 26, 2003) [hereinafter Appellate Body Report, Japan—Apples].}

According to the Appellate Body’s new construction in \textit{U.S.—Continued Suspension}, this preliminary test of assessability is a \textit{subjective} matter, reserved to the regulating member (para. 711). Under this interpretive structure, the regulating state may, in practice, escape the risk assessment obligation under Article 5.1. The Appellate Body in \textit{EC—Hormones} had noted that a regulating state could rely even on a minority opinion when it conducts risk assessment,\footnote{33}{Appellate Body Report, \textit{EC—Hormones}, supra note 4, para. 194.} and, consequently, when two different scientific views rival each other, the regulating state could simply pick one to assess risks without any concerns for such view’s mainstream status. However, according to the Appellate Body in \textit{U.S.—Continued Suspension}, the regulating state in such a situation may elect not to make any choice and instead may opt for a provisional measure under Article 5.7 if the state defines this situation as a “qualitative” deficiency of available scientific evidence in which two competing scientific views exist in an unreliable and inconclusive manner (para. 712).\footnote{34}{See also Appellate Body Report, \textit{Japan—Apples}, supra note 25, para. 185.} In sum, according to this new construction, subjective or political determinations may overshadow objective scientific investigations harnessed by international standards and risk assessment.

Perhaps the line between objective science (risk assessment) and subjective policy determination (risk management) \textit{is} obscure. Or, more fundamentally, the very concept of science itself might be subjective and thus political. There might be no definite certainties in risk science but only competing paradigms. Then, one might question whether the WTO tribunal could, or \textit{should}, adjudicate such innately dogmatic regulatory positions.\footnote{35}{See generally Sungjoon Cho, \textit{Of the World Trade Court’s Burden} (Mar. 2007), at <http://ssrn.com/abstract=969437> (arguing that the WTO tribunal should not engage in any “substantive” adjudication on issues involving risk science and should instead focus on “procedural” obligations of parties concerned).} Although it rebuked the panel for violating the standard of review as the panel had allegedly taken scientific determination on its own hands, the Appellate Body in \textit{U.S.—}
Continued Suspension seems to have engaged in a certain type of substantivism itself. Knowingly or unknowingly, the Appellate Body relied on substantive opinions of particular scientific experts in an attempt to fault exactly the same type of wrongs committed by the panel (paras. 547, 550, 553).³⁶

At the very end of its report, the Appellate Body urged both parties to launch Article 21.5 proceedings “without delay” to determine whether the EC has actually complied with the original EC—Hormones decision and consequently whether the U.S. sanction remains valid (para. 737). It remains to be seen whether either party will follow the Appellate Body’s recommendation. In the end, interesting questions remain in this long-standing transatlantic dispute: what will be the result if an Article 21.5 panel still finds in favor of the United States after it adheres to the Appellate Body’s instruction on the standard of review? Even then, would any room be left for the Appellate Body to reject the panel’s findings as a matter of law?

³⁶ More specifically, the Appellate Body report in U.S.—Continued Suspension provides: “However, some of the scientific experts consulted by the Panel indicated that risks arising from residues of oestradiol-17β in bovine meat are likely to increase where good veterinary practices in the administration of this hormone are not followed” (para. 547); “In response to another question on the subject posed by the Panel, Dr. De Brabander recognized that ‘[i]mproper administration of implants or misplaced implants create potential hazards to human health’” (para. 550); and “At least two of the scientific experts consulted by the Panel recognized that the misuse or abuse in the administration of the hormones could give rise to adverse effects” (para. 553).
4. Japan -- Measures Affecting the Importation of Apples

When reading this decision ask yourself whether the AB respects Japan’s regulatory autonomy to set the acceptable level of risk. The AB highlights the Panel’s standard of review. Approach this case law from the standpoint of the standard of review in domestic administrative law cases.


Lockhart, Presiding Member; Baptista, Member; Sacerdoti, Member

http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds245_e.htm

I. Introduction

1. Japan and the United States appeal certain issues of law and legal interpretations in the Panel Report, Japan – Measures Affecting the Importation of Apples (the "Panel Report"). The Panel was established to consider a complaint by the United States concerning certain requirements and prohibitions imposed by Japan with respect to the importation of apple fruit from the United States.

(...) 

II. Background

A. The Disease at Issue

8. The following summarizes "factual aspects" set out by the Panel in paragraphs 2.1–2.6 of the Panel Report. The disease targeted by Japan's phytosanitary measure in this dispute is called "fire blight", often referred to by the scientific name for its bacterium, Erwinia amylovora or E. amylovora. Fruits infected by fire blight exude bacterial ooze, or inoculum, which is transmitted primarily through wind and/or rain and by insects or birds to open flowers on the same or new host plants. E. amylovora bacteria multiply externally on the stigmas of these open flowers and enter the plant by various openings. In addition to apple fruit, hosts of fire blight include pears, quince, and loquats, as well as several garden plants. Scientific evidence establishes, as the Panel found, that the risk of introduction and spread of fire blight varies considerably according to the host plant.

38 The Panel defined "disease" as "[a] disorder of structure or function in a plant of such a degree as to produce or threaten to produce detectable illness or disorder … usually with specific signs or symptoms." (Panel Report, para. 2.9)
39 "Infection" was defined by the Panel as "[w]hen an organism (e.g., E. amylovora) has entered into a host plant (or fruit) establishing a permanent or temporary pathogenic relationship with the host." (Ibid., para. 2.12). In contrast, the Panel noted that the term "infestation" would "[r]efer[] to the presence of the bacteria on the surface of a plant without any implication that infection has occurred." (Ibid., para. 2.13 (emphasis added))
40 The Panel defined "inoculum" as "[m]aterial consisting of or containing bacteria to be introduced into or transferred to a host or medium". The Panel explained that "[i]noculation is the introduction of inoculum into a host or into a culture medium. Inoculum can also refer to potentially infective material available in soil, air or water and which by chance results in the natural inoculation of a host." (Ibid., para. 2.14)
41 Panel Report, para. 2.2.
42 Ibid., para. 2.5.
43 Ibid., para. 8.271.
9. The uncontested history of fire blight reveals significant trans-oceanic dissemination in the 200-plus years since its discovery. 44 *E. amylovora*, first reported in New York State in the United States in 1793, is believed to be native to North America. 45 By the early 1900s, fire blight had been reported in Canada from Ontario to British Columbia, in northern Mexico, and in the United States from the East Coast to California and the Pacific Northwest. Fire blight was reported in New Zealand in 1919, in Great Britain in 1957, and in Egypt in 1964. The disease has spread across much of Europe, to varying degrees depending on the country, and also through the Mediterranean region. In 1997, Australia reported the presence of fire blight, but eradication efforts were successful and no further outbreaks have been reported. With respect to the incidence of fire blight in Japan, the parties disputed before the Panel whether fire blight had ever entered Japan; but the United States assumed, for purposes of this dispute, that Japan was, as it claimed, free of fire blight and fire blight bacteria. 46

B. The Product at Issue

10. The United States argued before the Panel that the subject of the United States' challenge to Japan's phytosanitary measure at issue is the sole apple product that the United States exports, that is, "mature, symptomless" apples. The United States claimed that such apples constitute a separate, identifiable category of apples and that its categorization is "scientifically supported". 47 Japan did not accept the United States' categorization, arguing that "mature" and "symptomless" are subjective terms and that the distinction has no scientific basis. 48 Furthermore, Japan argued, its phytosanitary measure addressed the risk arising, not only from mature, symptomless apples that develop and spread fire blight, but also from the accidental introduction of infected or infested apples within a shipment of what are thought to be mature, symptomless apples destined for Japan. 49

11. In the light of this disagreement about the product scope of the dispute, the Panel identified the product that was subject to the measure at issue. The Panel observed that, if it were to consider the "product" to be limited to mature, symptomless apple fruit, as claimed by the United States, "many aspects of the measure at issue might, ipso facto, lose their raison d'être and may become incompatible with the SPS Agreement." 50 If, on the contrary, the Panel were to conclude that the product at issue was "any apple" fruit exported to Japan from the United States, then it would need to address the justification of all the requirements imposed by Japan as a whole. 51 The Panel also noted that it would be "illogical" to accept the United States' characterization because it would prevent the Panel from examining certain aspects of the measure that could be relevant, even if not expressly addressing mature, symptomless apples. 52

44Ibid., para. 2.6.
45Ibid., paras. 2.1 and 2.6.
46Ibid., paras. 4.25-4.26.
48Ibid., paras. 4.99 and 8.26.
49Ibid., para. 8.28(b).
50Panel Report, para. 8.30. As an example of aspects of the measure that might in this manner lose their raison d'être, the Panel refers to the requirements covering pre-harvesting actions to be undertaken with respect to apples. (Ibid.)
51Ibid.
52Ibid., para. 8.31. Aspects of the measure that the Panel thought might be relevant, notwithstanding the fact that they did not focus on mature, symptomless apple fruit, included requirements related to apples that cannot be exported (that is, prohibitions). (Ibid.)
12. In addition, the Panel stated that the request for the establishment of a panel submitted by the United States referred only to "US apples", which is less specific than mature, symptomless apples. The Panel said that the fact that the United States intended to address "only" mature, symptomless apples in its submission did not affect the Panel's mandate. Finally, the Panel observed that scientific methods existed for distinguishing mature apples, and that an apple's susceptibility to fire blight was related to its maturity.

13. Considering the parties' arguments, as well as the experts' views, the Panel determined that the scope of the dispute should not, at a preliminary stage, be limited to mature, symptomless apples. The Panel considered it particularly inappropriate to limit the scope of the dispute before further consideration of the merits of the case in the light of the two assumptions it found to underlie the United States' characterization of the product at issue: (i) that mature, symptomless apple fruit is not a "pathway" for fire blight and (ii) that shipments from the United States to Japan contain only mature, symptomless apples.

C. The Measure at Issue

14. The United States argued before the Panel that, through the operation of various legal instruments, Japan maintains nine prohibitions or requirements imposed with respect to apple fruit imported from the United States. With respect to the United States' description of the requirements for importation of apple fruit from the United States, Japan claimed that two such requirements amounted merely to "procedural steps" common to all phytosanitary measures, and that one of them should actually have been identified as two separate requirements.

53Ibid., para. 8.32.
54The Panel engaged experts in consultation with the parties, as provided for in Article 11.2 of the SPS Agreement. (Ibid., paras. 6.1-6.4)
55We understand the Panel to have used the term "pathway" to describe the steps through which a disease must travel for successful transmission from one plant to a new host plant. We employ the term in this Report in the same manner.
56Panel Report, para. 8.33.
57The Panel identified the following means by which Japan imposed the prohibitions or requirements relevant to this dispute: (i) the Plant Protection Law (Law No. 151; enacted 4 May 1950), as amended; (ii) the Plant Protection Regulations (Ministry of Agriculture, Forestry, and Fisheries Ordinance No. 73, enacted 30 June 1950), as amended; (iii) Ministry of Agriculture, Forestry and Fisheries Notification No. 354 (dated 10 March 1997); and (iv) related detailed rules and regulations, including Ministry of Agriculture, Forestry, and Fisheries Circular 8103. (Panel Report, para. 8.7)
58Panel Report, para. 8.5, citing Request for the Establishment of a Panel by the United States, WT/DS245/2, 8 May 2002; United States' first written submission to the Panel, para. 19; United States' answers to the Additional Questions posed by the Panel, 28 January 2003, para. 2. The nine requirements identified by the United States are as follows:

(a) The prohibition of imported apples from US states other than apples produced in designated areas in the states of Oregon or Washington;
(b) the prohibition of imported apples from orchards in which any fire blight is detected on plants or in which host plants of fire blight (other than apple trees) are found, whether or not infected;
(c) the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard;
(d) the requirement that export orchards be inspected three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight for purposes of applying the above-mentioned prohibitions;
(e) a post-harvest surface treatment of apples for export with chlorine;
(f) production requirements, such as chlorine treatment of containers for harvesting and chlorine treatment of the packing facility;
15. The Panel decided to regard the multiple requirements imposed on imported apple fruit from the United States as a single measure to be reviewed under the *SPS Agreement*. With regard to the precise requirements to be considered as the elements of the single measure, the Panel found that the two requirements claimed by Japan to be "procedural" nevertheless constituted "phytosanitary measures" within the definition of the *SPS Agreement* and formed part of the collective set of conditions to be fulfilled for the importation of apple fruit from the United States. The Panel also appears to have agreed with Japan's claim that one of the requirements identified by the United States should actually be understood as two separate requirements. Therefore, the Panel identified the focus of this dispute to be a measure applied by Japan to the importation of apple fruit from the United States, which measure consists of the following ten cumulatively-applied elements:

(a) Fruit must be produced in designated fire blight-free orchards. Designation of a fire blight-free area as an export orchard is made by the United States Department of Agriculture (USDA) upon application by the orchard owner. Any detection of a blighted tree in this area by inspection will disqualify the orchard. For the time being, the designation is accepted only for orchards in the states of Washington and Oregon;

(b) the export orchard must be free of plants infected with fire blight and free of host plants of fire blight (other than apples), whether or not infected;

(c) the fire blight-free orchard must be surrounded by a 500-meter buffer zone. Detection of a blighted tree or plant in this zone will disqualify the export orchard;

(d) the fire blight-free orchard and surrounding buffer zone must be inspected at least three times annually. US officials will visually inspect twice, at the blossom and the fruitlet stages, the export area and the buffer zone for any symptom of fire blight. Japanese and US officials will jointly conduct visual inspection of these sites at harvest time. Additional inspections are required following any strong storm (such as a hail storm);

(g) post-harvest separation of apples for export to Japan from fruits destined to other markets;

(h) certification by US plant protection officials that fruits are free of fire blight and have been treated post harvest with chlorine; and

(i) confirmation by Japanese officials of the US officials' certification and inspection by Japanese officials of disinfection and packaging facilities.

(Panell Report, para. 8.5(a)-(i) (footnote omitted))

59 The two requirements claimed to be "procedural" are items (h) and (i), *supra* footnote 58.

60 Panel Report, para. 8.6. Japan claimed that item (f), *supra* footnote 58, should be regarded as two separate requirements: one for the chlorine treatment of harvesting containers and one for the chlorine treatment of packing facilities.


(e) harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution;

(f) containers for harvesting must be disinfected by a chlorine treatment;

(g) the interior of the packing facility must be disinfected by a chlorine treatment;

(h) fruit destined for Japan must be kept separated post-harvest from other fruit;

(i) US plant protection officials must certify that fruits are free from fire blight and have been treated post harvest with chlorine; and

(j) Japanese officials must confirm the US officials' certification and Japanese officials must inspect packaging facilities. 63 (footnote omitted)

16. At the oral hearing, neither participant disagreed that the measure identified by the Panel as set out in the preceding paragraph, derived from the application of several legal instruments related to quarantine and other restrictions placed by Japan on imported agricultural products, is the measure before us on appeal. 64

(...) 

V. Issues Raised in This Appeal

129. Japan raises the following four claims, namely, that the Panel:

(i) erred in finding that Japan's phytosanitary measure is "maintained without sufficient scientific evidence" and is therefore inconsistent with Japan's obligations under Article 2.2 of the SPS Agreement;

(ii) erred in finding that Japan's phytosanitary measure is not a provisional measure under Article 5.7 because the measure was not imposed in respect of a situation where "relevant scientific evidence is insufficient";

(iii) erred in finding that Japan's phytosanitary measure was not based on a risk assessment, as defined in Annex A to the SPS Agreement, and as required by Article 5.1 thereof; and

(iv) failed to comply with its duty under Article 11 of the DSU because it did not conduct an "objective assessment of the facts of the case".

(…)

VII. Article 2.2 of the SPS Agreement

63Panel Report, para. 8.25(a)-(j).
64Japan's and the United States' responses to questioning at the oral hearing.
143. We proceed next to Japan's claim that the Panel erred in finding that the measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement.

144. As explained in the previous section of this Report, the Panel decided that it would not limit its analysis to the risk of transmission of fire blight inherent in mature, symptomless apple fruit.65 Thus, the Panel also considered the risk associated with other apples (that is, immature apples, or mature but damaged apples) 66 that might enter Japanese territory as a result of human or technical errors, or of illegal actions.

145. In the course of its analysis as to whether Japan's measure is maintained without sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement, the Panel, on the basis of the information before it, made the following findings of fact:

- Infection 67 of mature, symptomless apples has not been established. Mature apples are unlikely to be infected by fire blight if they do not show any symptoms 68;
- The possible presence of endophytic 69 bacteria in mature, symptomless apples is not generally established. Scientific evidence does not support the conclusion that mature, symptomless apples could harbour endophytic populations of bacteria 70;
- The presence of epiphytic 71 bacteria in mature, symptomless apples is considered to be very rare 72;
- It is not contested that immature apple fruit can be infected or infested 73 by Erwinia amylovora 74;
- Infected apples are capable of harbouring populations of bacteria that could survive through the various stages of commercial handling, storage, and transportation 75;
- Scientific evidence does not support the conclusion that infested or infected cargo crates could operate as a vector for fire blight transmission; rather, the evidence shows that Erwinia amylovora is not likely to survive on crates 76; and
- Even if infected or infested apples were exported to Japan, and populations of bacteria survived through the various stages of commercial handling, storage, and transportation, the introduction of fire blight would require the transmission of fire

65See supra, para. Erreur ! Source du renvoi introuvable. 66Panel Report, paras. 8.122 and 8.174. 67For the Panel's definition of the term "infection", see supra, footnote 39. 68Panel Report, paras. 8.139 and 8.171. 69The Panel defined "endophytic" as follows: "With respect to E. amylovora, the term endophytic is used when the bacterium occurs inside a plant or apple fruit in a non-pathogenic relationship." (Ibid., para. 2.10 (original boldface)) 70Ibid., paras. 8.128 and 8.171. 71The Panel defined "epiphytic" as follows: "With respect to E. amylovora, the term epiphytic is used when the bacterium occurs on the outer surface of a plant or fruit in a non-pathogenic relationship." (Panel Report, para. 2.10 (original boldface)) 72Ibid., paras. 8.142 and 8.171. 73For the Panel's definition of the terms "infection" and "infestation", see supra, footnote 39. 74Panel Report, para. 8.171. 75Ibid., para. 8.157. 76Ibid., para. 8.143.
brial from imported apples to a host plant through an additional sequence of events that is deemed unlikely, and that has not been experimentally established to date. 77

146. On the basis of these findings of fact, the Panel concluded that scientific evidence suggests a negligible risk of possible transmission of fire blight through apple fruit, and that scientific evidence does not support the view that apples are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan. 79

147. For the Panel, a measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement if there is no "rational or objective relationship" between the measure and the relevant scientific evidence. 80 Given the negligible risk identified on the basis of the scientific evidence and the nature of the elements composing the measure, the Panel concluded that Japan's measure is "clearly disproportionate" to that risk. 81 The Panel reasoned that such disproportion implies that a rational or objective relationship does not exist between the measure and the relevant scientific evidence and, therefore, the Panel concluded that Japan's measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement. 82

148. Japan challenges the Panel's conclusion, arguing that a prima facie case that infected apples would not act as a pathway for fire blight was not made by the United States. Japan contends that, in the absence of such a prima facie case, it was not open to the Panel to find a violation of Article 2.2. In addition, Japan argues that the Panel erroneously found that the United States had made a prima facie case in respect of mature, symptomless apples. According to Japan, this error resulted from the Panel's improper approach to Japan's risk evaluation, based on a misinterpretation of Article 2.2 of the SPS Agreement. 83

149. With respect to infected apples, Japan submits that it was for the United States to establish a prima facie case that there was no risk that infected apples could serve as a vector for the introduction of fire blight within Japan. The United States did not do so, because it presented arguments and evidence relating only to mature, symptomless apples, acknowledging explicitly during the Interim Review that "there is no factual claim or evidence submitted by the United States" relating to the risk associated with infected apple fruit. 84 Absent a prima facie case by the United States that there was insufficient scientific evidence on the risk posed by infected apples, the Panel, according to Japan, should have ruled in favour of Japan and found that infected apples could act as a pathway for fire blight. 86 In addition, Japan submits that, by finding that "Japan did not submit sufficient scientific evidence in support of its allegation that the last step of the pathway had been completed or was likely to be completed" 87, the Panel shifted the burden of proof to Japan; and that such a shift constituted an error of law as it was made prematurely, before the demonstration of a prima facie case by the United States. 88

77Ibid., paras. 8.168 and 8.171.
78Ibid., para. 8.169.
79Ibid., para. 8.176.
80Ibid., paras. 8.101-8.103 and 8.180, relying on Appellate Body Report, Japan – Agricultural Products II, paras. 73-74, 82, and 84.
81Panel Report, para. 8.198.
82Ibid., para. 8.199.
83Japan's appellant's submission, para. 71.
84Ibid., para. 22.
85Ibid., para. 23.
86Ibid., paras. 26, quoting Panel Report, paras. 7.31 and 8.154; and para. 27.
88Japan's appellant's submission, para. 33.
Finally, Japan argues that the Panel was not entitled to use its investigative authority to make findings of fact on the risk relating to infected apples because the United States declined to establish a *prima facie* case with respect to this issue. 89

150. Regarding mature, symptomless apples, Japan advances a distinct argument, namely, that the Panel should have interpreted Article 2.2 in such a way that a "certain degree of discretion" 90 be accorded to the importing Member as to the manner it chooses, weighs, and evaluates scientific evidence. 91 Japan argues that the Panel denied such discretion, as it "evaluated the scientific evidence in accordance with the experts' view, despite the contrary view of an importing Member". 92 Japan contends that its own approach to the risk relating to mature, symptomless apples—an approach that reflects "the historical facts of trans-oceanic expansion of the bacteria" and the rapid growth of international trade, and which is premised on "the fact that the pathways of … transmission of the bacteria are still unknown in spite of several efforts to trace them" 93—is reasonable as well as scientific because it is derived from "perspectives of prudence and precaution". 94 Consequently, the Panel should have accorded deference to Japan's approach and should have assessed whether the United States had established a *prima facie* case in the light of it. Japan argues that the United States did not establish a *prima facie* case in respect of mature, symptomless apples that reflected Japan's approach. In particular, Japan submits that the United States failed to prove that both the history of trans-oceanic dissemination of fire blight and, the fact that the cause of trans-oceanic dissemination is unknown, are irrelevant. 95

151. We will examine successively these two arguments of Japan: first, Japan's case relating to apples other than mature, symptomless apples, and secondly, that regarding mature, symptomless apples.

A. *Apples Other Than Mature, Symptomless Apples*

152. It is well settled that, in principle, it rests upon the complaining party to "establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement*". 96 As the Appellate Body said in *EC – Hormones*:

> The initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that *prima facie* case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency. 97

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89Japan's appellant's submission, paras. 18, quoting Appellate Body Report, *Japan – Agricultural Products II*, para. 129; and para. 36.

90Japan's appellant's submission, para. 76.

91Ibid., para. 75.

92Ibid., para. 78.

93Ibid., para. 73.


95Japan's appellant's submission, para. 87.

96Appellate Body Report, *EC – Hormones*, para. 98. (emphasis added)

97Appellate Body Report, para. 98.
153. In this case, the United States seeks a finding that Japan's measure is inconsistent with Article 2.2 of the SPS Agreement. Therefore, the initial burden lies with the United States to establish a *prima facie* case that the measure is inconsistent with Article 2.2. In particular, the United States must establish a *prima facie* case that the measure is "maintained without sufficient scientific evidence" within the meaning of Article 2.2. Following the Appellate Body's ruling in *EC–Hormones*, if this *prima facie* case is made, it would be for Japan to counter or refute the claim that the measure is "maintained without sufficient scientific evidence".

154. That said, the Appellate Body's statement in *EC–Hormones* does not imply that the complaining party is responsible for providing proof of all facts raised in relation to the issue of determining whether a measure is consistent with a given provision of a covered agreement. In other words, although the complaining party bears the burden of proving its case, the responding party must prove the case it seeks to make in response. In *US–Wool Shirts and Blouses*, the Appellate Body stated:

… we find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof. It is, thus, hardly surprising that various international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that *the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof thereof*. 98 (footnote omitted, emphasis added)

155. In this case, the United States made a series of allegations of fact relating to mature, symptomless apples as a possible pathway for fire blight, and sought to substantiate these allegations. Japan sought to counter the case made by the United States, arguing that:

* Japan must protect itself against failures in the control systems of exporting countries that might result in the introduction of apples other than mature, symptomless apples 99;

• it is possible that apples other than mature, symptomless apples (namely, immature apples or mature but damaged apples) could be infected by fire blight; and

• infected apple fruit has the capacity to serve as a pathway for fire blight. 100

156. Japan was thus responsible for providing proof of the allegations of fact it advanced in relation to apples other than mature, symptomless apples being exported to Japan as a result of errors of handling or illegal actions. We therefore disagree with Japan's contention that the Panel erred because it "shifted the burden of proof to Japan in respect of a factual point that the complainant explicitly declined to prove" 101 or that "the shift of the burden of proof to Japan

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100Ibid., para. 8.154.
101Japan's appellant's submission, para. 31.
was made prematurely before the demonstration of a *prima facie* case by the United States." 102

157. 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 103 from, on the other hand, the principle that the party that asserts a fact is responsible for providing proof thereof. 104 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." 105 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.

158. Japan also contends that the Panel did not have the authority to make certain findings of fact 106 and, in support of this contention, refers to the Appellate Body's statement in *Japan – Agricultural Products II*:

> Article 13 of the DSU and Article 11.2 of the *SPS Agreement* suggest that panels have a significant investigative authority. However, this authority cannot be used by a panel to rule in favour of a complaining party which has not established a *prima facie* case of inconsistency based on specific legal claims asserted by it. 107

We disagree with Japan. We note first that we are not persuaded that the findings of the Panel, identified by Japan in relation to this argument, relate specifically to, or address apples other than mature, symptomless apples, as Japan seems to assume. Also, the Appellate Body's finding in *Japan – Agricultural Products II* does not support Japan's argument that the Panel was barred from making findings of fact in connection with apples other than mature, symptomless apples.

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102 Ibid., para. 33. (original italics)
103 Appellate Body Report, *EC – Hormones*, para. 98.
105 Japan's appellant's submission, para. 33. (original italics)
106 Japan refers to the following findings of the Panel:

> [W]e are of the opinion that the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard is not supported by sufficient scientific evidence; [and]

> [W]e are of the opinion that the requirement that export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight is not supported by sufficient scientific evidence.

(footnotes omitted)

(Japan's appellant's submission, para. 35, quoting Panel Report, paras. 8.185 and 8.195)
107 Appellate Body Report, para. 129; Japan's appellant's submission, paras. 18 and 44.

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Those findings were relevant to the claim pursued by the United States under Article 2.2 of the SPS Agreement, and were responsive to relevant allegations of fact advanced by Japan in the context of its rebuttal of the United States' claim. The Panel acted within the limits of its investigative authority because it did nothing more than assess relevant allegations of fact asserted by Japan, in the light of the evidence submitted by the parties and the opinions of the experts.

159. Japan also submits that, "in order to establish a prima facie case of insufficient scientific evidence under Article 2.2 of the SPS Agreement, the complaining party must establish that there is not sufficient scientific evidence for any of the perceived risks underlying the measure". According to Japan, the Panel should not have concluded that this prima facie case had been established unless the United States had first addressed all the possible hypotheses—including those for which the likelihood of occurrence is low or rests upon theoretical reasonings—and had shown for each of them that the risk of transmission of fire blight is negligible. We find no basis for the approach advocated by Japan. As the Appellate Body stated in EC – Hormones, "a prima facie case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favour of the complaining party presenting the prima facie case." In US – Wool Shirts and Blouses, the Appellate Body stated 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." In the present case, the Panel appears to have concluded that in order to demonstrate a prima facie case that Japan's measure is maintained without sufficient scientific evidence, it sufficed for the United States to address only the question of whether mature, symptomless apples could serve as a pathway for fire blight.

160. The Panel's conclusion seems appropriate to us for the following reasons. First, the claim pursued by the United States was that Japan's measure is maintained without sufficient scientific evidence to the extent that it applies to mature, symptomless apples exported from the United States to Japan. What is required to demonstrate a prima facie case is necessarily influenced by the nature and the scope of the claim pursued by the complainant. A complainant should not be required to prove a claim it does not seek to make. Secondly, the Panel found that mature, symptomless apple fruit is the commodity "normally exported" by the United States to Japan. The Panel indicated that the risk that apple fruit other than mature, symptomless apples may actually be imported into Japan would seem to arise primarily as a result of human or technical error, or illegal actions, and noted that the experts characterized errors of handling and illegal actions as "small" or "debatable" risks. Given the characterization of these risks, in our opinion it was legitimate for the Panel to consider that the United States could demonstrate a prima facie case of inconsistency with Article 2.2 of the SPS Agreement through argument based solely on mature, symptomless apples. Thirdly, the record contains no evidence to suggest that apples other than mature, symptomless ones have ever been exported to Japan from the United States as a result of errors of handling or illegal actions. Thus, we find no error in the Panel's approach that the

108Japan's appellee's submission, para. 9. (original italics)
109Appellate Body Report, para. 104.
111Panel Report, para. 8.141. The Panel also found that "the importation of immature, infected apples may only occur as a result of a handling error or an illegal action". (Ibid., footnote 275 to para. 8.121)
112Ibid., para. 8.174.
113Ibid., para. 8.161.
114In response to questioning at the oral hearing, Japan indicated that the only evidence relating to the export control procedures of the United States that it submitted to the Panel related to a case of codling moth larvae found in apples shipped from the United States to the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu. In our view, there was no reason for the Panel to infer from this that apples other than mature, symptomless ones have ever been exported from the United States to Japan.
United States could establish a *prima facie* case of inconsistency with Article 2.2 of the *SPS Agreement* in relation to apples exported from the United States to Japan, even though the United States confined its arguments to mature, symptomless apples.

**B. Mature, Symptomless Apples**

161. We turn now to Japan's arguments in respect of mature, symptomless apples. As we indicated above, Japan contends that the Panel erred in interpreting Article 2.2 of the *SPS Agreement* because the Panel failed to accord a "certain degree of discretion" to the importing Member in the manner in which it chooses, weighs, and evaluates scientific evidence. Japan submitted that, had the Panel accorded such discretion to Japan as the importing Member, the Panel would not have focused on the experts' views. Rather, the Panel would have evaluated the scientific evidence in the light of Japan's approach, which reflects "the historical facts of trans-oceanic expansion of the bacteria" and the rapid growth of international trade, and which is premised on "the fact that the pathways of ... transmission of the bacteria are still unknown in spite of several efforts to trace them." Japan thus argues that the Panel erred in the application of Article 2.2 of the *SPS Agreement*, as it should have assessed whether the United States had established a *prima facie* case regarding the sufficiency of scientific evidence, not from the perspective of the experts' views, but, rather, in the light of Japan's approach to scientific evidence. According to Japan, had the Panel made such an assessment, it would have been bound to conclude that the United States had not established a *prima facie* case that Japan's measure is maintained without sufficient scientific evidence.

162. We disagree with Japan. As the Panel correctly noted, the Appellate Body addressed, in *Japan – Agricultural Products II*, the meaning of the term "sufficient", in the context of the expression "sufficient scientific evidence" as found in Article 2.2. The Panel stated that the term "sufficient" implies a "rational or objective relationship" and referred to the Appellate Body's statement there that:

> 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.

The Panel did not err in relying on this interpretation of Article 2.2 and in conducting its assessment of the scientific evidence on this basis.

163. As we see it, the Panel examined the evidence adduced by the parties and considered the opinions of the experts. It concluded as a matter of fact that it is not likely that apple fruit would serve as a pathway for the entry, establishment or spread of fire blight in Japan. The Panel then contrasted the extent of the risk and the nature of the elements composing the measure, and concluded that the measure was "clearly disproportionate to the risk identified on the basis of the

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115Japan's appellant's submission, para. 76.
116Ibid., paras. 75-76.
117Ibid., para. 73.
119Ibid., paras. 8.103 and 8.180.
120Ibid., para. 8.103, quoting Appellate Body Report, *Japan – Agricultural Products II*, para. 84.
121Panel Report, para. 8.176.
For the Panel, such "clear disproportion" implies that a "rational or objective relationship" does not exist between the measure and the relevant scientific evidence, and, therefore, the Panel concluded that the measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the *SPS Agreement*. We note that the "clear disproportion" to which the Panel refers, relates to the application in this case of the requirement of a "rational or objective relationship between an SPS measure and the scientific evidence".

We emphasize, following the Appellate Body's statement in *Japan – Agricultural Products II*, that whether a given approach or methodology is appropriate in order to assess whether a measure is maintained "without sufficient scientific evidence", within the meaning of Article 2.2, depends on the "particular circumstances of the case", and must be "determined on a case-by-case basis". Thus, the approach followed by the Panel in this case—disassembling the sequence of events to identify the risk and comparing it with the measure—does not exhaust the range of methodologies available to determine whether a measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2. Approaches different from that followed by the Panel in this case could also prove appropriate to evaluate whether a measure is maintained without sufficient scientific evidence within the meaning of Article 2.2. Whether or not a particular approach is appropriate will depend on the "particular circumstances of the case". The methodology adopted by the Panel was appropriate to the particular circumstances of the case before it and, therefore, we see no error in the Panel's reliance on it.

Regarding Japan's contention that the Panel should have made its assessment under Article 2.2 in the light of Japan's approach to risk and scientific evidence, we recall that, in *EC – Hormones*, the Appellate Body addressed the question of the standard of review that a panel should apply in the assessment of scientific evidence submitted in proceedings under the *SPS Agreement*. It stated that Article 11 of the DSU sets out the applicable standard, requiring panels to make an "objective assessment of the facts". It added that, as regards fact-finding by panels and the appreciation of scientific evidence, total deference to the findings of the national authorities would not ensure an objective assessment as required by Article 11 of the DSU. In our view, Japan's submission that the Panel was obliged to favour Japan's approach to risk and scientific evidence over the views of the experts conflicts with the Appellate Body's articulation of the standard of "objective assessment of the facts".

In order to assess whether the United States had established a *prima facie* case, the Panel was entitled to take into account the views of the experts. Indeed, in *India – Quantitative Restrictions*, the Appellate Body indicated that it may be useful for a panel to consider the views of the experts it consults in order to determine whether a *prima facie* case has been made. Moreover, on several occasions, including disputes involving the evaluation of scientific evidence, the Appellate Body has stated that panels enjoy discretion as the trier of facts; they enjoy "a margin of discretion in assessing the value of the evidence, and the weight to be ascribed

\[122\text{Ibid., para. 8.198.}\]
\[123\text{Ibid., para. 8.199.}\]
\[124\text{Appellate Body Report, para. 84.}\]
\[125\text{Ibid.}\]
\[126\text{Appellate Body Report, *EC – Hormones*, para. 117.}\]
\[127\text{Appellate Body Report, para. 142.}\]
to that evidence.” Requiring panels, in their assessment of the evidence before them, to give precedence to the importing Member's evaluation of scientific evidence and risk is not compatible with this well-established principle.

167. For these reasons, we reject the contention that, under Article 2.2, a panel is obliged to give precedence to the importing Member's approach to scientific evidence and risk when analyzing and assessing scientific evidence. Consequently, we disagree with Japan that the Panel erred in assessing whether the United States had established a prima facie case when it did so from a perspective different from that inherent in Japan's approach to scientific evidence and risk. Thus, we are not persuaded that we should revisit the Panel's conclusion that the United States established a prima facie case that Japan's measure is maintained without sufficient scientific evidence.

168. In the light of these considerations, we uphold the Panel's findings, in paragraphs 8.199 and 9.1(a) of the Panel Report, that Japan's phytosanitary measure at issue is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement.

VIII. Article 5.7 of the SPS Agreement

169. We turn to the issue whether the Panel erred in finding that Japan's phytosanitary measure was not imposed in respect of a situation where "relevant scientific evidence is insufficient" within the meaning of Article 5.7 of the SPS Agreement.

170. Article 2.2 of the SPS Agreement stipulates that Members shall not maintain sanitary or phytosanitary measures without sufficient scientific evidence "except as provided for in paragraph 7 of Article 5". Before the Panel, Japan contested that its phytosanitary measure is "maintained without sufficient scientific evidence" within the meaning of Article 2.2. Japan claimed, in the alternative, that its measure is a provisional measure consistent with Article 5.7.

171. Article 5.7 of the SPS Agreement reads as follows:

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

... 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.

172. The Panel found that Japan's measure is not a provisional measure justified under Article 5.7 of the SPS Agreement because the measure was not imposed in respect of a situation where "relevant scientific evidence is insufficient". 130

173. The Panel identified the "phytosanitary question at issue" as the risk of transmission of fire blight through apple fruit. It observed that "scientific studies as well as practical experience have accumulated for the past 200 years" on this question and that, in the course of its analysis under Article 2.2, it had come across an "important amount of relevant evidence". The Panel observed that a large quantity of high quality scientific evidence on the risk of transmission of fire blight through apple fruit had been produced over the years, and noted that the experts had expressed strong and increasing confidence in this evidence. Stating that Article 5.7 was "designed to be invoked in situations where little, or no, reliable evidence was available on the subject matter at issue", the Panel concluded that the measure was not imposed in respect of a situation where relevant scientific evidence is insufficient. The Panel added that, even if the term "relevant scientific evidence" in Article 5.7 referred to a specific aspect of a phytosanitary problem, as Japan claimed, its conclusion would remain the same. The Panel justified its view on the basis of the experts' indication that, not only is there a large volume of general evidence, but there is also a large volume of relevant scientific evidence on the specific scientific questions raised by Japan.

174. Japan challenges the Panel's finding that the measure is not imposed in respect of a situation where "relevant scientific evidence is insufficient" within the meaning of Article 5.7 of the SPS Agreement. Moreover, Japan submits that its measure meets all the other requirements of Article 5.7. Accordingly, Japan requests us to reverse the Panel's finding and to complete the analysis regarding the consistency of its measure with the other requirements set out in Article 5.7.

A. The Insufficiency of Relevant Scientific Evidence

175. As noted above, Japan's claim under Article 5.7 was argued before the Panel in the alternative. Japan relied on Article 5.7 only in the event that the Panel rejected Japan's view that "sufficient scientific evidence" exists to maintain the measure within the meaning of Article 2.2. It is in this particular context that the Panel assigned the burden of proof to Japan to make a prima facie case in support of its position under Article 5.7.

176. In Japan – Agricultural Products II, the Appellate Body stated that Article 5.7 sets out four requirements that must be satisfied in order to adopt and maintain a provisional phytosanitary measure. These requirements are:

   (i) the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient";

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130Panel Report, paras. 8.221-8.222.
131Ibid., para. 8.218.
132Ibid., para. 8.219.
133Ibid., para. 8.216.
135Ibid.
136Ibid., para. 8.220.
137We note that Japan does not challenge the Panel's conclusion that in order to assess whether the measure was imposed in respect of a situation where "relevant scientific evidence is insufficient", the Panel had to consider "not only evidence supporting Japan's position, but also evidence supporting other views." (Ibid., para. 8.216)
138Japan's appellant's submission, paras. 117-120.
139Ibid., paras. 120-121.
141The Panel's assignment of the burden of proof to Japan to make a prima facie case of consistency with Article 5.7 is not challenged on appeal.
142Appellate Body Report, para. 89.

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(ii) the measure is adopted "on the basis of available pertinent information";

(iii) the Member which adopted the measure "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

(iv) the Member which adopted the measure "review[s] the … measure accordingly within a reasonable period of time". 143

These four requirements are "clearly cumulative in nature" 144; as the Appellate Body said in Japan – Agricultural Products II, "[w]henever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7." 145

177. The Panel's findings address exclusively the first requirement, which the Panel found Japan had not met. 146 The requirements being cumulative, the Panel found it unnecessary to address the other requirements to find an inconsistency with Article 5.7.

178. Japan's appeal also focuses on the first requirement of Article 5.7. Japan contends that the assessment as to whether relevant scientific evidence is insufficient should not be restricted to evidence "in general" on the phytosanitary question at issue, but should also cover a "particular situation" in relation to a "particular measure" or a "particular risk". 147 Hence, Japan submits that the phrase "[w]here relevant scientific evidence is insufficient", in Article 5.7, "should be interpreted to relate to a particular situation in respect of a particular measure to which Article 2.2 applies (or a particular risk), but not to a particular subject matter in general, which Article 2.2 does not address." 148 According to Japan, the Panel "erred by interpreting the applicability of [Article 5.7] too narrowly" 149 and too "rigid[ly]". 150

179. It seems to us that Japan's reliance on the opposition between evidence "in general" and evidence relating to specific aspects of a particular subject matter is misplaced. The first requirement of Article 5.7 is that there must be insufficient scientific evidence. When a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether "relevant scientific evidence is insufficient". This evaluation must be carried out, not in the abstract, but in the light of a particular inquiry. The notions of "relevance" and "insufficiency" in the introductory phrase of Article 5.7 imply a relationship between the scientific evidence and something else. Reading this introductory phrase in the broader context of Article 5 of the SPS Agreement, which is entitled "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection", is instructive in ascertaining the nature of the relationship to be established. Article 5.1 sets out a key discipline under Article 5, namely that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment … of the risks to human, animal or plant life or health". 151 This discipline informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in

143Appellate Body Report, Japan – Agricultural Products II, para. 89. The third and fourth requirements relate to the maintenance of a provisional phytosanitary measure and highlight the provisional nature of measures adopted pursuant to Article 5.7.

144Appellate Body Report, Japan – Agricultural Products II, para. 89.

145Ibid. (original italics)

146Panel Report, para. 8.222.

147Japan's appellant's submission, para. 102.

148Ibid. (original italics)

149Ibid., para. 96.

150Ibid., paras. 100-101.

151The risk assessment referred to in Article 5.1 is defined in Annex A to the SPS Agreement.
favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific", in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread, of, in this case, fire blight in Japan.

180. The Panel found that, with regard to the risk of transmission of fire blight through apples exported from the United States—"normally" 152, mature, symptomless apples—"not only a large quantity but a high quality of scientific evidence has been produced over the years that describes the risk of transmission of fire blight through apple fruit as negligible", and that "this is evidence in which the experts have expressed strong and increasing confidence." 153

181. Japan also raised specific questions related to endophytic bacteria in mature apple fruit and regarding the completion of contamination pathways. 154 In relation to these specific questions, the Panel made the finding of fact, based on indications of the experts retained by the Panel, that there is a large volume of relevant scientific evidence regarding these questions as well. 155 Moreover, Japan did not persuade the Panel that this scientific evidence is not conclusive or has not produced reliable results. 156

182. These findings of fact by the Panel suggest that the body of available scientific evidence permitted, in quantitative and qualitative terms, the performance of an assessment of risks, as required under Article 5.1 and as defined in Annex A to the SPS Agreement, with respect to the risk of transmission of fire blight through apple fruit exported from the United States to Japan. In particular, according to these findings of fact by the Panel, the body of available scientific evidence would allow "[t]he evaluation of the likelihood of entry, establishment or spread" 157 of fire blight in Japan through apples exported from the United States. Accordingly, in the light of the findings of fact made by the Panel, we conclude that, with respect to the risk of transmission of fire blight through apple fruit exported from the United States to Japan ("normally", mature, symptomless apples), the "relevant scientific evidence" is not "insufficient" within the meaning of Article 5.7.

B. Japan's Argument on "Scientific Uncertainty"

183. Japan challenges the Panel's statement that Article 5.7 is intended to address only "situations where little, or no, reliable evidence was available on the subject matter at issue" 158 because this does not provide for situations of "unresolved uncertainty". Japan draws a

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152Panel Report, paras. 8.87 and 8.141.
153Ibid., para. 8.219.
155Ibid., para. 7.9. See also the Panel's findings of fact in paragraphs 8.128, 8.168, and 8.171 of the Panel Report, made in the context of the Panel's analysis under Article 2.2 of the SPS Agreement.
157Annex A to the SPS Agreement, para. 4.
distinction between "new uncertainty" and "unresolved uncertainty" 159, arguing that both fall within Article 5.7. According to Japan, "new uncertainty" arises when a new risk is identified; Japan argues that the Panel's characterization that "little, or no, reliable evidence was available on the subject matter at issue" is relevant to a situation of "new uncertainty". 160 We understand that Japan defines "unresolved uncertainty" as uncertainty that the scientific evidence is not able to resolve, despite accumulated scientific evidence. 161 According to Japan, the risk of transmission of fire blight through apple fruit relates essentially to a situation of "unresolved uncertainty". 162 Thus, Japan maintains that, despite considerable scientific evidence regarding fire blight, there is still uncertainty about certain aspects of transmission of fire blight. Japan contends that the reasoning of the Panel is tantamount to restricting the applicability of Article 5.7 to situations of "new uncertainty" and to excluding situations of "unresolved uncertainty"; and that, by doing so, the Panel erred in law. 163

184. We disagree with Japan. The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient", not to "scientific uncertainty". The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of "scientific uncertainty".

185. We also find no basis for Japan's argument that the Panel's interpretation of Article 5.7 is too narrow for the reason that it excludes cases where the quantity of evidence on a phytosanitary question is "more than little" 164, but the available scientific evidence has not resolved the question. The Panel's statement that Article 5.7 is intended to address "situations where little, or no, reliable evidence was available on the subject matter at issue", refers to the availability of reliable evidence. We do not read the Panel's interpretation as excluding cases where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results. Indeed, the Panel explicitly recognized that such cases fall within the scope of Article 5.7 when it observed, in the Interim Review section of its Report, that under its approach, Article 5.7 would be applicable to a situation where a lot of scientific research has been carried out on a particular issue without yielding reliable evidence. 165

C. The Panel's Reliance on a "History of 200 Years of Studies and Practical Experience"

186. Japan contends that the conclusion of the Panel regarding Article 5.7 is based on its assessment that, as regards fire blight, "scientific studies as well as practical experience have accumulated for the past 200 years". 166 Japan submits that the Panel was not authorized to rule on the basis of a "'history' of 200 year[s] of studies and practical experience" 167 because "the United States did not raise any objection to application of Article 5.7 on the basis of [a] 'history' of 200 year[s] of studies and practical experience." 168 In other words, according to Japan, the Panel was not entitled to draw a conclusion regarding Article 5.7 on the basis of such "history"

159Japan's appellant's submission, para. 101.
160Ibid., footnote 76 to para. 98.
161Ibid., para. 98.
162Japan's appellant's submission, paras. 105-110.
163Ibid., para. 110.
164Panel Report, para. 7.8.
165Ibid., para. 7.9.
166Ibid., para. 8.219; Japan's appellant's submission, paras. 93 and 97.
167Japan's appellant's submission, para. 97.
168Ibid.
unless the United States had raised an objection based on "history", something that the United States had not done. 169

187. In the course of its reasoning, the Panel mentioned that, as regards the risk of transmission of fire blight through apple fruit, "scientific studies as well as practical experience have accumulated for the past 200 years". 170 This statement was relevant to the debate under Article 5.7 and was based on the evidence before the Panel. 171 Accordingly, it was appropriate for the Panel to make such a statement irrespective of whether the United States had explicitly advanced an argument based on "history".

188. In the light of these considerations, we uphold the findings of the Panel, in paragraphs 8.222 and 9.1(b) of the Panel Report, that Japan's phytosanitary measure at issue was not imposed in respect of a situation "where relevant scientific evidence is insufficient", and, therefore, that it is not a provisional measure justified under Article 5.7 of the SPS Agreement. We note that Japan requested us, in the event we were to reverse the Panel's finding on Article 5.7, to complete the analysis in respect of the other requirements set out in Article 5.7 of the SPS Agreement. Given our conclusion, there is no need to do so.

IX. Article 5.1 of the SPS Agreement

189. We turn now to Japan's allegations of error with respect to Article 5.1 of the SPS Agreement. The Panel began its evaluation of the United States' claim under Article 5.1 by noting that both parties effectively identified a document referred to as the "1999 PRA" as the risk assessment to be analyzed in this evaluation. 172 Japan, however, objected to the Panel's consideration of evidence arising subsequent to the 1999 PRA when assessing the 1999 PRA's conformity with the requirements of Article 5.1. Despite this objection, the Panel concluded that it would "consider principally the 1999 PRA as the relevant risk assessment in this case, but we do not exclude that other elements, including subsequent information, could also be of relevance." 173

190. On the substance of the claim, the Panel noted first that the United States did not contest the fact that the 1999 PRA properly identified fire blight as the disease of concern. 174 The focus of the United States' claim was that (i) the risk assessment did not sufficiently evaluate the likelihood of entry, establishment or spread of fire blight, and (ii) this evaluation was not performed "according to the SPS measures which might be applied". 175

191. As to the first element of the claim, the Panel said that a risk assessment must be sufficiently specific to the risk at issue. In this regard, the Panel observed that the 1999 PRA studied several possible hosts of fire blight, including apple fruit. Recognizing that the risk of

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169Japan's appellant's submission, para. 97.
171We note that Dr. Chris Hale, one of the experts consulted by the Panel, referred to a historical perspective when he stated that "fire blight had taken 220 years to spread from New York State, USA in 1780, to its latest geographic locations". (Ibid., para. 6.28)
172Ibid., para. 8.247. In response to questioning at the oral hearing, both participants reaffirmed the focus of the Panel's Article 5.1 analysis to be the 1999 PRA.
175Ibid., para. 8.253.
transmission of fire blight could vary significantly from plant to plant, the Panel found that the risk assessment was not "sufficiently specific" because "the conclusion of the [1999] PRA [did] not purport to relate exclusively to the introduction of the disease through apple fruit, but rather more generally, apparently, through any susceptible host/vector." 176

192. The Panel similarly found the discussion of possible pathways to have "intertwined" the risk of entry through apple fruit with that of other possible vectors, including vectors considered more likely to be potential sources of contamination than apple fruit. 177 The Panel also determined that those parts of the 1999 PRA that specifically addressed apple fruit, although noting the possibility of entry, establishment or spread of fire blight through this vector, did not properly evaluate the probability of the occurrence of such events. Finally, the Panel recalled the testimony of certain experts, identifying several steps in the evaluation of the probability of entry that had been "overlooked" by the 1999 PRA. 178 In the light of these shortcomings, the Panel concluded that Japan's risk assessment did not properly evaluate the likelihood of entry, establishment or spread of fire blight through apple fruit.

193. With respect to the second element of the United States' claim, the Panel observed that a risk assessment, according to Annex A to the SPS Agreement, requires an evaluation "according to the sanitary or phytosanitary measures which might be applied". From this language, the Panel determined that a risk assessment must not only consider the particular measure already in place, but also other measures that "might" be applied. 179 Because the 1999 PRA did not consider other risk-mitigating measures, the Panel found the risk assessment inadequate for purposes of Article 5.1.

194. Reviewing Japan's evaluation of the measure that was already in place, the Panel acknowledged that the 1999 PRA could be considered to have provided "some" evaluation of the likelihood of entry of the disease and possible mitigation through the existing measure. The Panel noted, however, that, in Australia – Salmon, the Appellate Body found that "some" evaluation was insufficient for purposes of Article 5.1 and that a comparison between Japan's evaluation and that of the importing Member in that case reveals the 1999 PRA to be "considerably less substantial". 180 The Panel also noted that the 1999 PRA assumes that the individual components of Japan's measure would be applied cumulatively, without consideration as to their individual effectiveness. The Panel found that the required consideration of alternative measures included an obligation to evaluate whether the independent elements needed to be applied cumulatively and to provide an explanation therefor. 181 As a result, the Panel concluded that, in the 1999 PRA, Japan did not sufficiently conduct its evaluation "according to the sanitary or phytosanitary measures which might be applied".

195. Japan challenges three specific aspects of the Panel's analysis of the 1999 PRA under Article 5.1. First, Japan contests the Panel's finding that the 1999 PRA is inconsistent with the requirements of Article 5.1 because it did not focus its analysis on the risk of fire blight entering through apple fruit, in particular. Japan contends that the Panel misinterpreted Article 5.1 and misunderstood the Appellate Body's decision in EC – Hormones with respect to the requirement

176Ibid., para. 8.271.
177Ibid., para. 8.278.
178Ibid., para. 8.279.
179Ibid., para. 8.283. (original italics)
180Panel Report, para. 8.287.
181Ibid., para. 8.288.
of "specificity" of a risk assessment. Secondly, Japan argues that Article 5.1, contrary to the Panel's interpretation, does not require a consideration of "alternative measures other than [the] existing measures." Finally, Japan claims that its risk assessment should be assessed in the light of evidence available at the time of the assessment, not against evidence that has become available subsequently.

196. We begin our analysis with the text of the relevant provision at issue, Article 5.1 of the *SPS Agreement*:

> 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.

The first clause of paragraph 4 of Annex A to the *SPS Agreement* defines the "risk assessment" for a measure designed to protect plant life or health from risks arising from the entry, establishment or spread of diseases as follows:

> **Risk assessment** - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences …

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182Japan's appellant's submission, paras. 127-129.
184Japan's appellant's submission, paras. 135-138.
185The second clause in paragraph 4 of Annex A to the *SPS Agreement* addresses risk assessments evaluating 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." As such, the second clause does not define the type of risk assessment relevant to this dispute involving the possibility of transmission of fire blight to plants in Japan. (See Appellate Body Report, *Australia – Salmon*, footnote 67 to para. 120)
Based on this definition, the Appellate Body determined in *Australia – Salmon* that:

… a risk assessment within the meaning of Article 5.1 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;

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**.

186 (original italics)

197. As the Panel noted, the United States does not claim that Japan's risk assessment failed to meet the first of these conditions. 187 The Panel therefore limited its analysis of Japan's risk assessment to the second and third conditions. The Panel found that the 1999 PRA did not constitute a "risk assessment", as that term is defined in the *SPS Agreement*, because it did not satisfy either of those conditions. Japan challenges aspects of the Panel's analysis with respect to both of these conditions. We consider each of these conditions before turning to Japan's argument regarding the evidence that may be relied upon by a panel when evaluating a risk assessment.

A. **Evaluating the Likelihood of Entry, Establishment or Spread of Fire Blight**

198. Japan challenges first the Panel's finding that the 1999 PRA was not sufficiently specific to constitute a risk assessment under the *SPS Agreement* because it did not evaluate the risk in relation to apple fruit, in particular. In *EC – Hormones*, in the context of evaluating whether a measure was "based on" a risk assessment, the Appellate Body examined the specificity of the risk assessment relied upon by the importing Member. In that case, the importing Member had referred to certain scientific studies and articles as the risk assessment underlying its measures. In its Report, the Appellate Body described the panel's finding that these materials:

… relate[d] to the carcinogenic potential of entire categories of hormones, or of the hormones at issue in general. ... [They did] not evaluate[] the carcinogenic potential of those hormones when used specifically for growth promotion purposes. Moreover, they [did] not evaluate the specific potential for carcinogenic effects arising from the presence in "food", more specifically, "meat or meat products" of residues of the hormones in dispute. 188 (original italics)

199. The panel in *EC – Hormones* concluded, as a result, that the studies cited by the importing Member were insufficient to support the measures at issue. The Appellate Body upheld these findings, stating that, although the studies cited by the importing Member:

> … [did] indeed show the existence of a general risk of cancer … they [did] not focus on and [did] not address the particular kind of risk [t]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*.189

The Appellate Body therefore concluded that the risk assessment was not "sufficiently specific to the case at hand."190

200. In this case, the Panel, relying on the Appellate Body's finding in *EC – Hormones*, concluded that the 1999 PRA was not sufficiently specific to constitute a "risk assessment" in accordance with the *SPS Agreement*.191 The Panel based this conclusion on its finding that, although the 1999 PRA makes determinations as to the entry, establishment and spread of fire blight through a collection of various hosts (including apple fruit), it failed to evaluate the entry, establishment or spread of fire blight through apple fruit as a separate and distinct vector.192 As the Panel stated in response to Japan's comments during the Interim Review, "Japan evaluated the risks associated with all possible hosts taken together, not sufficiently considering the risks specifically associated with the commodity at issue: US apple fruit exported to Japan."193

201. Japan does not contest the Panel's characterization of the risk assessment as one that did not analyze the risks of apple fruit separately from risks posed by other hosts.194 Rather, Japan claims that the Panel's reasoning relates to a "matter of methodology", which lies within the discretion of the importing Member.195 Japan contends that the requirement of "specificity" explained in *EC – Hormones* refers to the specificity of the risk and not to the methodology of the risk assessment.196

202. We disagree with Japan. Under the *SPS Agreement*, the obligation to conduct an assessment of "risk" is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of a phytosanitary measure.197 The Appellate Body found the risk assessment...

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189Ibid., para. 200.
190Ibid.
192Ibid., paras. 8.268-8.271.
194Japan's appellant's submission, para. 128; Japan's response to questioning at the oral hearing.
195Japan's appellant's submission, para. 127.
196Ibid., para. 129.
197Indeed, we are of the view that, as a general matter, "risk" cannot usually be understood only in terms of the disease or adverse effects that may result. Rather, an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause. For example, the abstract reference to the "risk of cancer" has no significance, in and of itself, under the *SPS Agreement*; but when one refers to the "risk of cancer from smoking cigarettes", the particular risk is given content.
assessment at issue in  

EC – Hormones

not to be "sufficiently specific" even though the scientific articles cited by the importing Member had evaluated the "carcinogenic potential of entire categories of hormones, or of the hormones at issue in general." 198 In order to constitute a "risk assessment" as defined in the  

SPS Agreement, the Appellate Body concluded, the risk assessment should have reviewed the carcinogenic potential, not of the relevant hormones in general, but of "residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes". 199 Therefore, when discussing the risk to be specified in the risk assessment in  

EC – Hormones, the Appellate Body referred in general to the harm concerned (cancer or genetic damage) as well as to the precise agent that may possibly cause the harm (that is, the specific hormones when used in a specific manner and for specific purposes).

203. In this case, the Panel found that the conclusion of the 1999 PRA with respect to fire blight was "based on an overall assessment of possible modes of contamination, where apple fruit is only one of the possible hosts/vectors considered." 200 The Panel further found, on the basis of the scientific evidence, that the risk of entry, establishment or spread of the disease varies significantly depending on the vector, or specific host plant, being evaluated. 201 Given that the measure at issue relates to the risk of transmission of fire blight through apple fruit, in an evaluation of whether the risk assessment is "sufficiently specific to the case at hand" 202, the nature of the risk addressed by the measure at issue is a factor to be taken into account. In the light of these considerations, we are of the view that the Panel properly determined that the 1999 PRA "eva\nuat[ion of] the risks associated with all possible hosts taken together" 203 was not sufficiently specific to qualify as a "risk assessment" under the  

SPS Agreement for the evaluation of the likelihood of entry, establishment or spread of fire blight in Japan through apple fruit. 204

204. Japan contends that the "methodology" of the risk assessment is not directly addressed by the  

SPS Agreement. In particular, Japan suggests that, whether to analyze the risk on the basis of the particular pest or disease, or on the basis of a particular commodity, is a "matter of

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198 Appellate Body Report, para. 199. (original italics) In other words, the risk assessment proffered by the importing Member in  

EC – Hormones considered the relationship between the broad grouping of hormones that were the subject of the measure and cancer.

199 Ibid., para. 200.

200 Panel Report, para. 8.270.

201 Ibid., reads, in relevant part:

The scientific evidence submitted by both parties leaves no doubt that the risk of introduction and spread of the disease varies considerably according to the host plant, with nursery stock and budding material identified as known sources for the spread of fire blight in some cases.

202 Appellate Body Report,  

EC – Hormones, para. 200.


204 We note our understanding that the Panel did not base its finding on, nor make any reference to, whether the  

SPS Agreement requires a risk assessment to analyze the importation of products on a country-specific basis. Neither participant in this appeal has asked us to find that the definition of "risk assessment" in the  

SPS Agreement mandates an analysis of risk specific to each country of exportation. As a result, we make no findings with respect to whether such a country-specific analysis is required in order to satisfy a Member's obligations under Article 5.1 of the  

SPS Agreement.
methodology" not directly addressed by the *SPS Agreement*. 205. We agree. Contrary to Japan's submission, however, the Panel's reading of *EC–Hormones* does not suggest that there is an obligation to follow any particular methodology for conducting a risk assessment. In other words, even though, in a given context, a risk assessment must consider a specific agent or pathway through which contamination might occur, Members are not precluded from organizing their risk assessments along the lines of the disease or pest at issue, or of the commodity to be imported. Thus, Members are free to consider in their risk analysis multiple agents in relation to one disease, provided that the risk assessment attribute a likelihood of entry, establishment or spread of the disease to each agent specifically. Members are also free to follow the other "methodology" identified by Japan and focus on a particular commodity, subject to the same proviso.

205. Indeed, the relevant international standards, which, Japan claims, "adopt both methodologies" 206, expressly contemplate examining risk in relation to particular pathways. 207 Those standards call for that specific examination even when the risk analysis is initiated on the basis of the particular pest or disease at issue 208, as was the 1999 PRA. Therefore, our conclusion that the Panel properly found Japan's risk assessment not to be sufficiently specific, does not limit an importing Member's right to adopt any appropriate "methodology", consistent with the definition of "risk assessment" in paragraph 4 of Annex A to the *SPS Agreement*.

205Japan's appellant's submission, paras. 127-128.
207For example, the *International Standard for Phytosanitary Measures*, No.2, states at page 14:

The final stage of assessment concerns the introduction potential which depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. …

The following is a partial checklist that may be used to estimate the introduction potential divided into those factors which may affect the likelihood of entry and those factors which may affect the likelihood of establishment.

Entry:
- opportunity for contamination of commodities or conveyances by the pest
  …

Establishment:
- number and frequency of consignments of the commodity
  …
- intended use of the commodity
  …

(Exhibit JPN-30, submitted by Japan to the Panel, supra, footnote 206)
Similarly, the *International Standard for Phytosanitary Measures*, No.11, provides at pages 13-14:

All relevant pathways should be considered. … Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a
206. We therefore uphold the Panel's finding, in paragraph 8.271 of the Panel Report, that Japan's 1999 Pest Risk Analysis does not satisfy the definition of "risk assessment" in paragraph 4 of Annex A to the *SPS Agreement*, because it fails to evaluate the likelihood of entry, establishment or spread of fire blight specifically through apple fruit.

*B. Evaluating the Likelihood of Entry, Establishment or Spread of Fire Blight "According to the Sanitary or Phytosanitary Measures Which Might Be Applied"

207. Japan also challenges the Panel's finding that Japan "has not ... properly evaluated the likelihood of entry 'according to the SPS measures that might be applied'." 209 According to the Panel, the terms in the definition of "risk assessment" set out in paragraph 4 of Annex A to the *SPS Agreement*—more specifically, the phrase "according to the sanitary or phytosanitary measures which might be applied"—suggest 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." 210 Japan acknowledged that it did not consider policies other than the measure already applied. 211 However, according to Japan, this "again relates to the matter of methodology", which is left to the discretion of the importing Member. 212

208. The definition of "risk assessment" in the *SPS Agreement* requires that the evaluation of the entry, establishment or spread of a disease be conducted "according to the sanitary or phytosanitary measures which might be applied". 213 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." 214 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". 215 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* requires, to the substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities ... should be considered where appropriate. ...

... Factors to consider are:
- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- whether the imported commodity is to be sent to a few or many destination points in the [pest risk analysis] area
- intended use of the commodity

... (Exhibit USA-15, submitted by the United States to the Panel, *supra*, footnote 206)

208 See *supra*, footnote 207.
211 Japan's response to questioning at the oral hearing.
212 Japan's appellant's submission, para. 133.
213 Annex A to the *SPS Agreement*, para. 4.
214 Panel Report, para. 8.283. (original italics)
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.

209. In this case, the Panel found that the 1999 PRA dealt exclusively with the "plant quarantine measures against E. amylovora concerning US fresh apple fruit", which have been taken by Japan based on the proposal by the US government since 1994. The Panel also found that, in the 1999 PRA, no attempts were made "to assess the 'relative effectiveness' of the various individual requirements applied, [that] the assessment appears to be based on the assumption from the outset that all these measures would apply cumulatively", and that no analysis was made "of their relative effectiveness and whether and why all of them in combination are required in order to reduce or eliminate the possibility of entry, establishment or spread of the disease." Moreover, the Panel referred to "the opinions of Dr Hale and Dr Smith that the 1999 PRA 'appeared to prejudge the outcome of its risk assessment' and that 'it was principally concerned to show that each of the measures already in place was effective in some respect, and concluded that all should therefore be applied'". In our opinion, these findings of fact of the Panel leave no room for doubt that the 1999 PRA was designed and conducted in such a manner that no phytosanitary policy other than the regulatory scheme already in place was considered. Accordingly, we uphold the Panel's finding, in paragraph 8.285 of the Panel Report, that "Japan has not … properly evaluated the likelihood of entry 'according to the SPS measures that might be applied'."

C. Consideration of Scientific Evidence Arising Subsequent to the Risk Assessment at Issue

210. Finally, Japan argues that "Japan’s PRA was consistent with Article 5.1 of the SPS Agreement at the time of the analysis, because conformity of a risk assessment with Article 5.1 should be assessed against the information available at the time of the risk assessment." According to Japan, a risk assessment should be evaluated solely against the evidence available at the time of the risk assessment, such that a Member that fulfils the requirement of a risk assessment when adopting a measure is not held to have acted inconsistently with Article 5.1 upon the discovery of subsequently-published scientific evidence.

211. During the oral hearing, we invited Japan to identify what evidence, arising subsequent to the 1999 PRA, had been relied upon by the Panel in evaluating Japan's risk assessment under Article 5.1. Japan was unable to point to any such evidence. We also asked the participants what the legal consequence would be for the Panel's finding under Article 5.1 if we found, as Japan requests, that the Panel was not permitted to examine evidence post-dating the 1999 PRA. The United States suggested that there would be no consequence for this dispute because the risk assessment was "inadequate" at the time it was completed. Nor did Japan identify any consequence of such a finding on our part.

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216Panel Report, para. 8.284, quoting 1999 PRA, § 3-1. Japan confirmed, in response to questioning at the oral hearing, that the 1999 PRA considered no phytosanitary measure other than the one in place.
218Ibid.
219Ibid., para. 8.289. (footnotes omitted)
220Japan's appellant's submission, para. 135. (original italics)
221Ibid., para. 135.
222The United States' response to questioning at the oral hearing.
212. The Panel concluded that Japan's measure could not be "based on" a risk assessment, as required by Article 5.1, because the 1999 PRA did not satisfy the definition of "risk assessment" set out in paragraph 4 of Annex A to the SPS Agreement.223 The Panel determined that the definition of "risk assessment" was not satisfied because the 1999 PRA failed to meet the two elements discussed above, namely, that a risk assessment (i) "evaluate the likelihood of entry, establishment or spread of" the plant disease at issue, and (ii) conduct such evaluation "according to the SPS measures which might be applied".224

213. As we see it, Japan was unable to identify any scientific evidence relied upon by the Panel, but published after the issuance of the 1999 risk assessment, because the Panel did not, in fact, base its finding on such evidence. The Panel's analysis focused almost exclusively on the risk assessment itself to determine whether the 1999 PRA satisfied the legal requirements the Panel found in the SPS Agreement. The Panel identified those requirements as the need to assess a risk with a certain degree of "specificity", to evaluate probability rather than possibilities, and to evaluate the likelihood of entry "according to the sanitary or phytosanitary measures which might be applied".225 Beyond the text of the 1999 PRA, the only scientific information relied upon by the Panel relates to its finding on "specificity": on this point, the Panel determined that "scientific evidence submitted by both parties leaves no doubt that the risk of introduction and spread of the disease varies considerably according to the host plant".226 From this finding of fact, the Panel concluded that Japan's risk assessment was not "sufficiently specific to the matter at issue" because it did not examine the risk in relation to apple fruit in particular.227

214. In stating that its finding of fact was based on "scientific evidence submitted by both parties", the Panel did not cite those studies or provide any indication of whether those studies dated from before or after Japan's risk assessment. Japan does not assert that this scientific evidence, or any other scientific evidence underlying the Panel's conclusion with respect to Article 5.1, was not available to Japan at the time of the risk assessment. We also note that the Panel record includes relevant scientific evidence adduced by both parties that arose before Japan's risk assessment.228 Such evidence could have reasonably formed the basis for the Panel's conclusion that the risk from fire blight varies according to the host plant. Under these circumstances, we are not persuaded that, when analyzing the conformity of the 1999 PRA with Japan's obligations under Article 5.1, the Panel relied on scientific evidence that was not available to Japan at the time it conducted its risk assessment.

215. As Japan failed to establish that the Panel utilized subsequent scientific evidence in evaluating the risk assessment at issue, it is not necessary for us to express views on the question

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224Ibid., paras. 8.280, 8.285, and 8.288.
225See, for example, ibid., paras. 8.268, 8.270-8.271, 8.274-8.278, 8.284, and 8.287-8.288.
226Ibid., para. 8.271.
227Ibid.
228See, for example, R.G. Roberts et al., "The potential for spread of Erwinia amylovora and fire blight via commercial apple fruit; a critical review and risk assessment", Crop Protection (1998), Vol. 17, No. 1, pp. 19-28, at p. 24; Exhibit JPN-5, submitted by Japan to the Panel and Exhibit USA-4, submitted by the United States to the Panel; T. van der Zwet et al., "Population of Erwinia amylovora on External and Internal Apple Fruit Tissues", Plant Disease (1990), Vol. 74, No. 9, pp. 711-716, at p. 711; Exhibit JPN-7, submitted by Japan to the Panel; and S.V. Thomson, "Fire blight of apple and pear", Diseases of Fruit Crops (J. Kumar et al., eds.), Vol. 3, pp. 32-65, § 2-1 at p. 32 and § 2-9-2 at p. 49; Exhibit USA-44, submitted by the United States to the Panel.
whether the conformity of a risk assessment with Article 5.1 should be evaluated solely against the scientific evidence available at the time of the risk assessment, to the exclusion of subsequent information. Resolution of such hypothetical claims would not serve "to secure a positive solution" to this dispute. 229

216. Accordingly, we uphold the Panel's finding, in paragraph 8.290 of the Panel Report, that Japan's 1999 Pest Risk Analysis does not satisfy the definition of "risk assessment" set out in paragraph 4 of Annex A to the SPS Agreement because it (i) fails to "evaluate the likelihood of entry, establishment or spread of" the plant disease at issue, and (ii) fails to conduct such an evaluation "according to the SPS measures which might be applied". Furthermore, as the 1999 PRA is not a "risk assessment" within the meaning of the SPS Agreement, it follows, as the Panel found, in paragraphs 8.291 and 9.1(c) of the Panel Report, that Japan's phytosanitary measure at issue is not "based on" a risk assessment, as required by Article 5.1 of the SPS Agreement.

229Article 3.7 of the DSU.
4. On Equivalence

From the WTO Official Website

WTO NEWS: 2001 NEWS ITEMS
SANITARY AND PHYTOSANITARY MEASURES 24 OCTOBER 2001
Food safety and health implementation: ‘equivalence’ decision OK’d

WTO members have settled one “implementation” issue by approving a decision on recognizing the equivalence of different food safety and animal and plant health measures.

The decision was approved by the WTO’s Committee on Sanitary and Phytosanitary Measures (SPS) on 24 October.

It outlines steps designed to make it easier for all WTO members to make use of the “equivalence” provisions of the SPS Agreement, i.e. Article 4. This involves governments accepting different measures which provide the same level of health protection for food, animals and plants.

One objective is to help developing countries that use less sophisticated health and safety technologies than those required by importing countries to prove that their products are equally safe.

The issue has been raised by developing countries as a problem they face in implementing the current WTO agreements. It has been discussed in the WTO General Council in its preparations for the Doha Ministerial Conference.

Information that members have supplied on their experience with equivalence makes it clear that formal equivalence agreements covering countries’ entire health and safety systems are rare even between developed countries. This is because the formal agreements are very complicated technically, time-consuming to negotiate, and the improved market access that results is too modest to make the effort worthwhile.

On the other hand, it is more common for governments to recognize each other’s measures as applied to specific products. This can benefit trade.

The decision identifies the kind of information that importing and exporting countries should provide and some factors that importing countries should take into account — e.g. historical trade and the need to avoid hindering existing trade. It also addresses needs for technical assistance, encourages the relevant standard-setting bodies to accelerate their related work, and reinforces procedures to make measures transparent.

A number of developing countries submitted comments on an earlier draft. They include India, Jamaica, Trinidad and Tobago, Botswana, Oman, South Africa, Thailand, Chile and Argentina.

The SPS Committee discussed equivalence under an instruction from the WTO General Council in October 2000.
The WTO’s SPS Committee deals with food safety and animal and plant health, but does not set international standards. These are handled by other organizations, in particular the “three sisters” (Codex Alimentarius, Office International des Epizooties or World Organization for Animal Health, and the International Plant Protection Convention).
Optional Reading

Case Law

Article 5.1: “Risk Assessment”


215. Thus, in its discussion of the standard of review that applies to a panel reviewing a risk assessment under Article 5.1 of the SPS Agreement, the Appellate Body identified two aspects of a panel’s scrutiny of a risk assessment, namely, scrutiny of the underlying scientific basis and scrutiny of the reasoning of the risk assessor based upon such underlying science. With respect to the first aspect, the Appellate Body saw the panel’s role as limited to reviewing whether the scientific basis constitutes "legitimate science according to the standards of the relevant scientific community". The Appellate Body perceived the second aspect of a panel’s review as involving an assessment of whether the reasoning of the risk assessor is objective and coherent, that is, whether the conclusions find sufficient support in the scientific evidence relied upon. Having done so, the panel must determine whether the results of the risk assessment sufficiently warrant the challenged SPS measures.230 We consider that this reasoning of the Appellate Body is consistent with the overarching requirement in Article 2.2 and reflected in Articles 5.1 and 5.2 of the SPS Agreement that there be a "rational or objective relationship" between the SPS measures and the scientific evidence.

Article 5.5: “Different” Situations


(...) QP86A "prohibit[s] the importation into Australia of dead fish of the sub-order Salmonidae, or any parts (other than semen or ova) of fish of that sub-order, in any form unless: [...] prior to importation into Australia the fish or parts of fish have been subject to such treatment as in the opinion of the Director of Quarantine is likely to prevent the introduction of any infectious or contagious disease, or disease or pest affecting persons, animals or plants". (...) Canada requested access to the Australian market for fresh, chilled or frozen, i.e., uncooked, salmon. Australia conducted an import risk analysis for uncooked, wild, adult, ocean-caught Pacific salmonid product ("ocean-caught Pacific salmon"). (...) The risk analysis on ocean-caught Pacific salmon was first set forth in the

1995 Draft Report\textsuperscript{231}, revised in May 1996\textsuperscript{232} and finalized in December of 1996 (the "1996 Final Report").\textsuperscript{233} The 1996 Final Report concluded that:... it is recommended that the present quarantine policies for uncooked salmon products remain in place.\textsuperscript{234} The Director of Quarantine, on the basis of the 1996 Final Report, decided on 13 December 1996 that: ... having regard to Australian Government policy on quarantine and after taking account of Australia's international obligations, importation of uncooked, wild, adult, ocean-caught Pacific salmonid product from the Pacific rim of North America should not be permitted on quarantine grounds.\textsuperscript{235}

(...)

144. (...) [T]he Panel determined that the import prohibition on fresh, chilled or frozen salmon for human consumption and the admission of imports of (i) uncooked Pacific herring, cod, haddock, Japanese eel and plaice for human consumption; (ii) uncooked Pacific herring, Atlantic and Pacific cod, haddock, European and Japanese eel and Dover sole for human consumption; (iii) herring in whole, frozen form used as bait ("herring used as bait"); and (iv) live ornamental finfish, are "different" situations which can be compared under Article 5.5 of the SPS Agreement.\textsuperscript{236}

(...)  

150. Australia (...) contends that the Panel erred in determining that its examination on the comparability of different situations must be limited solely to those disease agents positively detected. According to Australia, the Panel diminished Australia's right to a cautious approach to determine its own appropriate level of protection. Australia argues that the Panel failed to interpret the provisions of Article 5.5 in their context and in the light of the object and purpose of the SPS Agreement. According to Australia, the terms "likelihood" and "potential" in regard to the definition of "risk assessment" contained in paragraph 4 of Annex A, and the terms "scientific principles" and "sufficient scientific evidence" contained in Article 2.2, make it clear that the basic SPS right set out in Article 2.1 to take SPS measures necessary for the protection of animal life or health, is not contingent on positive scientific evidence of disease detection.\textsuperscript{237}

(...)  

\textsuperscript{231} AQIS, \textit{Import Risk Analysis, Disease risks associated with the importation of uncooked, wild, ocean-caught Pacific salmon product from the USA and Canada}, Draft, May 1995.

\textsuperscript{232} AQIS, \textit{An assessment by the Australian Government of quarantine controls on uncooked, wild, ocean-caught Pacific salmonid product sourced from the United States of America and Canada}, Revised Draft, May 1996.


\textsuperscript{234} 1996 Final Report, page 70.

\textsuperscript{235} AQIS, File Note by Paul Hickey, Executive Director, 13 December 1996 (the "1996 Decision").

\textsuperscript{236} Panel Report, para. 8.121. Hereafter, we refer to these groups of imports as "other fish and fish products".

\textsuperscript{237} Australia's appellant's submission, para. 181.
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. Therefore, even if the Panel had excluded from its examination some diseases of concern not positively detected in fresh, chilled or frozen ocean-caught Pacific salmon, this would not invalidate its finding in paragraph 8.121 on comparable situations under Article 5.5.


The United States requested on 7 May 2002 that a panel be established to examine the matter on the basis of "measures" maintained by Japan that "restrict[] the importation of US apples in connection with fire blight or the fire blight disease-causing organism, Erwinia amylovora." 238

In other words, even though a country seeks to export only mature, symptomless apples, there is a risk that apples other than mature, symptomless apples will be exported to Japan, be infected, and transmit fire blight to Japanese host plants.

The Panel indicated that the risk that apple fruit other than mature, symptomless apples may actually be imported into Japan would seem to arise primarily as a result of human or technical error, or illegal actions, and that such apples could serve as a pathway for fire blight. 239 In other words, even though a country seeks to export only mature, symptomless apples, there is a risk that apples other than mature, symptomless apples will be exported to Japan, be infected, and transmit fire blight to Japanese host plants.

The Panel indicated that the risk that apple fruit other than mature, symptomless apples may actually be imported into Japan would seem to arise primarily as a result of human or technical error, or illegal actions, and that such apples could serve as a pathway for fire blight. 240 Given the characterization of these risks, in our opinion it was legitimate for the Panel to consider that the United States could demonstrate a prima facie case of inconsistency with Article 2.2 of the SPS Agreement through argument based solely on mature, symptomless apples.

Article 5.7: “where relevant scientific evidence is insufficient”

(From the WTO Analytical Index, http://www.wto.org/english/res_e/booksp_e/analytic_index_e/sps_02_e.htm#article5B7b)

238Request for the Establishment of a Panel by the United States, WT/DS245/2, 8 May 2002.
239Panel Report, para. 8.28.
240Ibid., para. 8.174.
241Ibid., para. 8.161.
164. Upholding the Panel’s finding that Japan’s phytosanitary measure at issue was not imposed in a situation “where relevant scientific evidence is insufficient”, the Appellate Body on Japan — Apples said that “relevant scientific evidence” will be “insufficient” within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement:

“[J]apan’s reliance on the opposition between evidence ‘in general’ and evidence relating to specific aspects of a particular subject matter is misplaced. The first requirement of Article 5.7 is that there must be insufficient scientific evidence. When a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether ‘relevant scientific evidence is insufficient’. This evaluation must be carried out, not in the abstract, but in the light of a particular inquiry. The notions of ‘relevance’ and ‘insufficiency’ in the introductory phrase of Article 5.7 imply a relationship between the scientific evidence and something else. Reading this introductory phrase in the broader context of Article 5. of the SPS Agreement, which is entitled ‘Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection’, is instructive in ascertaining the nature of the relationship to be established. Article 5.1 sets out a key discipline under Article 5, namely that ‘Members shall ensure that their sanitary or phytosanitary measures are based on an assessment … of the risks to human, animal or plant life or health’. This discipline informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a ‘more objective assessment of risks’. These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: ‘relevant scientific evidence’ will be ‘insufficient’ within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The questions is whether the relevant evidence, be it ‘general’ or ‘specific’, in the Panel’s parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.”

165. The Appellate Body on Japan — Apples also rejected Japan’s interpretation of Article 5.7 through the concept of “scientific uncertainty”, and said that the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence and these two concepts — “insufficiency of scientific evidence” and “scientific uncertainty” — are not interchangeable:

“Japan challenges the Panel’s statement that Article 5.7 is intended to address only ‘situations where little, or no, reliable evidence was available on the subject matter at issue’ because this does not provide for situations of ‘unresolved uncertainty’. Japan draws a distinction between ‘new uncertainty’ and ‘unresolved uncertainty’, arguing
that both fall within Article 5.7. According to Japan, ‘new uncertainty’ arises when a new risk is identified; Japan argues that the Panel’s characterization that ‘little, or no, reliable evidence was available on the subject matter at issue’ is relevant to a situation of ‘new uncertainty’. We understand that Japan defines ‘unresolved uncertainty’ as uncertainty that the scientific evidence is not able to resolve, despite accumulated scientific evidence. According to Japan, the risk of transmission of fire blight through apple fruit relates essentially to a situation of ‘unresolved uncertainty’. Thus, Japan maintains that, despite considerable scientific evidence regarding fire blight, there is still uncertainty about certain aspects of transmission of fire blight. Japan contends that the reasoning of the Panel is tantamount to restricting the applicability of Article 5.7 to situations of ‘new uncertainty’ and to excluding situations of ‘unresolved uncertainty’; and that, by doing so, the Panel erred in law.

We disagree with Japan. The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to ‘cases where relevant scientific evidence is insufficient’, not to ‘scientific uncertainty’. The two concepts are not interchangeable. Therefore, we are unable to endorse Japan’s approach of interpreting Article 5.7 through the prism of ‘scientific uncertainty’.

(...)


(...)

701. [S]cience continuously evolves.\textsuperscript{242} It may be useful to think of the degree of change as a spectrum. On one extreme of this spectrum lies the incremental advance of science. Where these scientific advances are at the margins, they would not support the conclusion that previously sufficient evidence has become insufficient. At the other extreme lie the more radical scientific changes that lead to a paradigm shift. Such radical change is not frequent. Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too inflexible an approach. WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. We are referring to circumstances where new scientific evidence casts doubts as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk.

(...)  

703. The Panel’s statement that "there must be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient" could be understood as requiring that the new scientific evidence lead to a paradigm shift. As we have said, such an approach is too inflexible. Although the new evidence must call into

\textsuperscript{242}Panel Report, US – Continued Suspension, para. 7.645; Panel Report, Canada – Continued Suspension, para. 7.623.
question the relationship between the body of scientific evidence and the conclusions concerning risk, it need not rise to the level of a paradigm shift.
Comment on Japan -- Measures Affecting the Importation of Apples


One Bad Apple?: A Comment on ‘Japan – Measures Affecting the Importation of Apples – Ab-2003-4’

Damien J Neven & JHH Weiler

This chapter briefly sets out the facts of Japan – Measures Affecting the Importation of Apples (‘Japan – Apples’) which concerns phytosanitary measures taken by Japan to target a disease called ‘fire-blight’. It then turns to the objective and rationale of the SPS Agreement. The authors emphasize that the SPS Agreement imposes a discipline on risk-reducing measures, even in the absence of discrimination and protectionism, and thus represents a shift similar to the shift that occurred in the EC with the Dassonville decision of the ECJ.

The chapter further examines how adjudicators can evaluate risk reducing measures according to the SPS Agreement and focuses on two issues: the scope of the mandate of a Panel and the standard of review which Panels should adopt when examining SPS measures. The authors highlight the difficulties which adjudicators face with respect to the question of the necessity of risk-reducing measures. They show that the approach adopted by Panels to address this question often leads them to slip from an evaluation of the necessity of a measure to achieve a given level of risk to a challenge of the level of risk itself (which Members are free to determine for themselves). With regard to the scope of review, the authors submit that a lower standard should be applied when the measure is not discriminatory or protectionist.

The chapter then discusses the methodology of the Panel and the AB in Japan—Apples in light of these observations and considers the requirement imposed by the SPS Agreement that risk-reducing measures have to be consistent across different circumstances as a tool to prevent abusive measures. The authors pay particular attention to the precautionary principle in the context of the SPS Agreement and question the Panel and AB’s unwillingness to apply the precautionary principle in Japan—Apples.

Introduction

This chapter reviews the decision by the Appellate Body regarding measures affecting the importation of apples in Japan. The second section of the chapter presents some background facts. The third section considers the SPS Agreement and emphasises the fact that it imposes a discipline on risk-reducing measures, even in the absence of discrimination or protectionism. The chapter then discusses how the evaluation of risk-reducing measures can be undertaken in the context of the SPS Agreement. The discussion focuses on two issues; namely the scope of the mandate given to the adjudicators and the standard of review that they should apply. The authors emphasise the difficulty that adjudicators face in terms of distinguishing between the level of risk that a country will find it optimal to support (which cannot be challenged), and the question of whether risk-reducing measures are necessary to achieve the chosen level of risk. We further observe that the common methodology used by Panels (that is, of evaluating the existence of risk in the absence of risk-reducing measures) has limited applicability. We also discuss how this approach can be abused and lead the adjudicators to slip from the evaluation of whether the measures are necessary to achieve a given level of risk, to an implicit challenge of the level of risk itself (which should remain the preserve of the Members). Regarding the standard of review, we argue that a lower standard should be applied to measures which do not threaten fundamental principles such as the prohibition of discrimination and protectionism.

The chapter goes on to consider the approach and the findings of the Panel and Appellate Body in light of this discussion. It then discusses the consistency requirement imposed by the SPS Agreement regarding risk-reducing measures across different circumstances and argues that this can be a very effective tool for preventing abusive standards, without compromising states’ autonomy in setting the optimal level of risk that they wish to bear. The chapter also discusses
some of the implications of applying different standards of review to cases which involve
discrimination or protectionism and those which do not. It goes on briefly to consider how the
Panel and Appellate Body handled methods of risk assessment, and highlights the fact that Japan
was held to a very high standard of review. It then discusses the Panel and Appellate Body’s
approach towards the precautionary principle. We consider the precautionary principle in the
context of the SPS Agreement and argue that the agreement fits naturally with the distinction
between risk and ambiguity, and in this context allows for one type of rationale behind the
precautionary principle, while seemingly excluding others. We also observe that there is at least
one issue in which scientific evidence was ambiguous in the case. Accordingly, the Panel and
Appellate Body’s unwillingness to apply the precautionary principle in this case can be
questioned.

Facts relating to the dispute

The disease targeted by Japan's phytosanitary measure in this dispute is called ‘fire blight’, often
referred to by the scientific name for its bacterium, *Erwinia amylovora* or *E. amylovora*. In its
decision, 243 the Appellate Body offers a useful summation of the case, which we employ here.
Fruits infected by fire blight exude bacterial ooze which is transmitted primarily by wind and/or
rain and by insects or birds to open flowers on the same or new host plants. *E. amylovora* bacteria
multiply externally on the stigmas of these open flowers and enter the plant by various openings.
In addition to apple fruit, hosts of fire blight include pears, quince, and loquats, as well as several
garden plants. Scientific evidence establishes, as the Panel found, that the risk of introduction and
spread of fire blight varies considerably according to the host plant.

The uncontested history of fire blight reveals significant trans-oceanic dissemination in
the 200-plus years since its discovery. *E. amylovora*, first reported in New York State in the
United States in 1793, is believed to be native to North America. By the early 1900s, fire blight
had been reported in Canada from Ontario to British Columbia, in northern Mexico, and in the
United States from the East Coast to California and the Pacific Northwest. Fire blight was
reported in New Zealand in 1919, in Great Britain in 1957, and in Egypt in 1964. The disease has
spread across much of Europe, to varying degrees depending on the country, and also through the
Mediterranean region. In 1997, Australia reported the presence of fire blight, but eradication
efforts were successful and no further outbreaks have been reported.

With respect to the incidence of fire blight in Japan, the parties disputed before the Panel
whether fire blight had ever entered Japan; but the United States assumed, for purposes of this
dispute, that Japan was, as it claimed, free of fire blight and fire blight bacteria. It might be added
that Japan wished to remain free of the blight. It should also be noted that Japan’s claim that the
precise pathway of the pathogen across the Pacific was unknown, was neither contested before,
nor found to be wrong by the Panel or Appellate Body. It is probably correct that the trans-
oceanic pathway is still unknown. Nonetheless, that claim was, apparently, assumed to be
irrelevant.

According to the United States, Japan instituted nine measures to preclude contamination:

(a) ‘The prohibition of imported apples from US states other than
apples produced in designated areas in the states of Oregon or
Washington;

(b) the prohibition of imported apples from orchards in which any fire blight is detected on plants or in which host plants of fire blight (other than apple trees) are found, whether or not infected;

(c) the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard;

(d) the requirement that export orchards be inspected three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight for purposes of applying the above-mentioned prohibitions;

(e) a post-harvest surface treatment of apples for export with chlorine;

(f) production requirements, such as chlorine treatment of containers for harvesting and chlorine treatment of the packing facility;

(g) post-harvest separation of apples for export to Japan from fruits destined to other markets;

(h) certification by US plant protection officials that fruits are free of fire blight and have been treated post harvest with chlorine; and

(i) confirmation by Japanese officials of the US officials' certification and inspection by Japanese officials of disinfection and packaging facilities.’

The US claimed that the only products exported from the US to Japan were ‘Mature, symptomless’ apples which had no risk of pathogenic carry and that, hence, in relation to this product, the measures in question violated the SPS, notably Articles 2(2) and 5(1).

The Panel consolidated all Japanese measures into one, but accepted that although officially only mature, symptomless apples were exported, through fraud and error other apples (immature, with symptoms) had to be presumed to be part of the trade and that consequently the Japanese measures would have to be assessed in relation to both groups.

**SPS – objectives and rationale**

This case is not considered doctrinally path breaking or economically problematic. In it, the Appellate Body seemed to consolidate and refine, rather than revise its previous SPS jurisprudence.

It is, thus, a good case for understanding the run-of-the-mill SPS physiognomy. Notable in this case is the fact that, yet again, even a technologically sophisticated country such as Japan was unable to comply with the requirement of risk assessment.

SPS measures existed, of course, before the adoption of the SPS Agreement. Naturally, they would be subject to the traditional GATT disciplines, notably Articles III and XI. 244 In some respects, the interpretative community of the GATT/WTO – governments, adjudicators, lawyers and economists etc – is ‘hard wired’ to the underlying objective and rationale of Article III; that is, separating those state measures which are genuinely put in place to protect against risk

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244 Article XI, of course, also applies to SPS measures; but, as is well known, the combination of the grandfathering provisions of the GATT and the Ad Note to Article III meant that most SPS-type measures would normally be reviewed in the context of Article III.
to humans, animals and plants from those measures which, by design or otherwise, are there to protect domestic production and cannot be justified in full or in part on legitimate SPS grounds.

At the heart of the SPS Agreement, and one of the principle sources of the difficulties which is attached to its interpretation and application, is its apparent addition to the traditional ‘discrimination’ or ‘protectionism’ rationale of GATT disciplines (which SPS still maintains245), a second ‘unjustified obstacle’ rationale which goes beyond Article XI measures.

The principal locus of the new ‘obstacle’ rationale is to be found in Article 2(2) SPS and those provisions which flow from it, notably Article 5.

‘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 or Article 5.’

As stated, the consequence of Article 2(2) is that Members may have in place or institute an SPS measure which has neither the object nor the effect of favouring domestic products – indeed, there might not even be a domestic product to compete with the import in question – and yet have such a measure challenged and found incompatible with SPS discipline because, for example, it places an undue burden on producers in the exporting state. If a state cannot show that its phytosanitary measures are really necessary for safety and health, as defined by science, they simple cannot stand. Further, their established procedures for risk assessment must now themselves comply with a WTO discipline.

In its field of application, the SPS Agreement represents a dramatic shift, similar (though not identical) to that which occurred in the EC with the clarification by the European Court of Justice in 1974 in the Dassonville case, to the effect that the prohibition of measures having an effect equivalent to quantitative restrictions applied to non-discriminatory measures. The rationale for the broad shift in Dassonville and the more limited, but similar shift in the SPS Agreement, is the realisation that in the area of regulatory measures designed to protect against risk, there apparently exist many instances of ‘inappropriate’ state measures which unnecessarily create obstacles to trade without serving the rationale of health or safety, and that these measures may exist without protectionist intent or effect. Note, that even under the pre-SPS GATT regime, it was quite common to find state measures failing the test of proportionality and least-restrictive-measure, that is, found to be excessive for their declared purpose. But they were always so found in the context of a complaint alleging discrimination and protectionism, and as part of the proof of such alleged discrimination and protectionism. Under SPS a complaint may be brought, such as in Japan – Apples, or in Hormones, without the need to allege or prove any degree of protectionism or discrimination.

One can wonder about the type of circumstances in which this discipline may apply. First, in the absence of a protectionist motive, states may have an incentive to apply more stringent standards to products that are imported than those applicable to products that are produced domestically. This arises because the cost of meeting the standards raises the marginal cost of the firms, but the cost increase is typically not fully passed on to consumers (except in the extreme case of perfect competition). Profits also fall. A state will not take foreign profits into account while designing health standards, but will consider domestic profits. Hence, standards which apply to product categories that are imported will be more stringent (more costly at the margin for a given health benefit) than standards which apply to domestic product categories. Standards which apply to product categories which are both imported and produced domestically will fall in between. Overall, states thus have an incentive to impose higher standards when the cost of meeting the standard is partly borne for foreigners. By imposing some consistency in

245 Article 2(3) SPS.
standards across different product categories (Article 5(5)), the SPS Agreement will prevent states from doing this.

Second, the impression is given that states might burden themselves unnecessarily by adopting excessive or ‘inappropriate’ measures because of deficient methodologies of risk assessment. It could be because of limited ability to conduct appropriate risk assessment.

This chapter focuses in particular on the application of the SPS Agreement in a context where neither discrimination nor protectionism are the centre of the enquiry.246 The underlying thesis

246 The following is the preamble to the SPS which articulates its principal objectives:

'Reaffirming' that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;
of the chapter is that the implication of the shift from a ‘discrimination’-type enquiry to an ‘obstacle’-type enquiry has not been fully worked out by Panels and the Appellate Body.

The evaluation of risk and risk-reducing measures

Members are entitled to adopt appropriate SPS measures, which reduce risk. But when may a Panel determine that an SPS measure is ‘inappropriate’? In order to clarify the task of the adjudicators, it is useful to consider a situation involving ‘risk’ as one in which several outcomes could arise in the future. For the purposes of simplicity, we can focus on two outcomes; say a bad outcome (B) and a good outcome (G). Let us also assume that the likelihood that each outcome will prevail can be assessed in terms of probabilities, so that B arises with a probability p and G arises with a probability (1-p). In some circumstances, it may be difficult to formulate these probabilities, for instance, when there are competing theories regarding the development of a disease. We will discuss below how decisions should be made in those circumstances, which involve some ‘ambiguity’ and how the SPS Agreement treats such ambiguity. For the time being, we assume that probabilities can be estimated.

It is also useful to distinguish between the level of risk that will prevail in the absence of any risk-reducing measures and the level of risk that a state will consider desirable. This can be formulated in terms of probabilities; let p be the probability that a bad outcome will arise in the absence of any risk-reducing measures. The level of risk that a state will want to enforce (will consider as optimal) can be denoted p*.

In this context, two questions arise, which feature prominently in the case. First, what is the mandate of the Panel? Second, what is the standard of review that the Panels should adopt?

The mandate of the adjudicator

What is the mandate of the Panel? Is the Panel meant to question the level of risk that the state wishes to enforce (ie p*)? Or is it simply meant to question the measures that have been adopted in order to achieve this level of risk? The Appellate Body has insisted regularly that Members are meant to retain the autonomy to set their own level of acceptable risk which may differ from one Member to another (see, for instance, Australian Salmon and Hormones). Article 4(1) is premised on this primordial understanding:

‘Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.’

Obviously, Article 4(1) contemplates a situation where the levels of SPS protection may differ.

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Desiring therefore 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);’

247 Appellate Body in Australian Salmon, para. 125.
248 Appellate Body in Hormones, para. 124.
Hence, it appears that the mandate of the Panel is limited to the evaluation of whether the disputed measures are necessary in order to achieve the desired level of risk and in particular whether these measures are supported by scientific evidence.

Before discussing how the Panel and Appellate Body approached this mandate, a few remarks on the level of risk absent any measure (p), the optimal (desired) level of risk (p*) and risk-reducing measures (which reduces the probability from p to p*) may be useful:

(1) It is clear that level of risk absent any measure (p) will differ across countries. This arises simply because of differences in local conditions, so that some countries will be less exposed than others (for instance, because of differences in climatic or geographical conditions). Plants and animals belonging to the same family as well as humans may also differ in their susceptibility to certain risk factors in different jurisdictions. It is known, for example, that certain ethnicities are more susceptible to certain diseases than others.

One also expects that the risk-reducing measures that are necessary to achieve a given level of desired risk (p*) will differ across countries for the same reasons. Indeed, Article 2(2) does not, in and of itself, demand or necessarily result in the harmonisation of phytosanitary measures across countries. For example, climatic conditions might be such that measures pertaining to the type of packaging or treatment of foods needed to ensure their sanitary condition when put into the stream of commerce might be perfectly safe for, say, a cold climate and unsafe for a warm climate thus requiring different phytosanitary regimes.

Of course, the evaluation of risk in the absence of measures as well as the measures that are in place to reach the desired level of risk could be subject to dispute, without disputing the standard of safety that the state wishes to afford its population. For instance, what may be contested and will be in dispute is the extent to which the measure a state adopts to ensure that standard of safety is necessary to achieve that standard given the objective conditions affecting the control of the risk in the importing country. It is assumed that both importing and exporting states have a shared understanding of acceptable risk. It is also not disputed, as might be the case, that the phytosanitary regime of the exporting country which covers the exports is appropriate for the conditions in the exporting country. What is claimed is that there are objective circumstances which pertain in the importing country and not in the exporting country which render a product which is safe in the exporting country, unsafe in the importing country.

(2) One can also expect that the desired (optimal) level of risk that states will choose to support will differ. The optimal level of risk will result from a trade-off between the benefits of reducing risks and the cost of risk-reducing measures. The willingness to pay for risk-reducing measures will be determined by preferences, and in particular the degree of risk aversion, and resources (the budget constraint that governments face). Those might differ across countries. For instance, one expects that states which have stringent budget constraints will have a lower willingness to pay for a reduction of risk. Some societies have a greater awareness of, and sensitivity to, ecological concerns than other societies. One notices these differences in mundane policies such as roadside billboard advertising, waste disposal regimes etc. Sometimes, one observes such different sensibilities even in matters of health and safety. Policies towards airbags, seatbelts, or smoking differ from society to society.

There could, of course, be SPS disputes where the importing country challenges the sufficiency of the measure even for the exporting country, or challenges the manner in which the regime in the exporting country is administered.
reflecting a complex set of different values reflective and constitutive of societal identity. One can imagine similar differences in the field of phytosanitary regulation. Certain medicines are banned in some countries and not in others. Certain medicines require a doctor’s prescription and a trained pharmacist dispensing service in some countries, and are sold over the counter in other countries. Local conditions will also affect the cost of risk-reducing measures. Overall, one can thus expect some variance across states in the optimal level of risk that they will choose to support.

(3) As states can freely choose their optimal level of risk, nothing would appear to prevent a state from selecting, in principle, a level of zero risk (in the language of the Appellate Body itself), that is, \( p^* = 0 \). However, it is not clear that one should attach too much attention to this possibility, for at least two reasons. First, as mentioned above, the SPS Agreement imposes a consistency requirement across measures in different circumstances. Since the implementation of zero risk will entail very high costs, which will have to be borne in a range of different circumstances, it is likely to be prohibitively costly. Second, and more importantly, the notion of a ‘zero-risk’ level is an abstraction. It is really a limit case, which may not matter very much in practice. Whatever the protective measure in place, it is likely that there will always be a strictly positive probability that a bad outcome will prevail. From this perspective, referring to a *de minimis* notion of risk may be better than the notion of zero risk. A *de minimis* risk can be seen as a risk which belongs to a small interval close to zero. The upper boundary of this interval could be defined by level of risk which is so small that it cannot be measurably affected by risk-reducing measures.

(4) The task of the adjudicators is delicate; they will be confronted with risk-reducing measures that are challenged. But they need to distinguish between the level of risk that states have chosen (that they cannot challenge) – which is presumably ensured by risk-reducing measures under review and the necessity of the measures to achieve this level of risk. Facts are often untidy. Consider the following situations. Imagine two different regimes under which the same medicine might be permitted for over-the-counter sale in one country and required to be dispensed by an authorised pharmacist in another. This latter measure is being challenged. The adjudicator will need to distinguish between the following hypothesis: first, this may be an instance of differences in preferences which lead to different optimal risks. If so, the measure should be considered as SPS compliant. Second, it may very well be that states have the same optimal level of risk, but that different risk-reducing measures are necessary to achieve that level of risk in the two countries (for instance, because the general public is less well educated in the latter). In this instance, the measure should also be considered as SPS compliant. Third, it may be that states have the same optimal level of risk, and that risk-reducing measures have the same effectiveness in the two countries. In this instance, the stricter measure is not necessary and should not be considered as SPS compliant.

(5) To ascertain the SPS compliance of contested phytosanitary measures requires an examination of whether the measures themselves are necessary to ensure health and are based on, and maintained with due regard to, scientific principles and evidence. If the measures themselves are based on scientific evidence and satisfy all other requirements of the SPS discipline, the only question will become whether they were applied correctly to any given import. But SPS measures are almost invariably contested in the context of a specific dispute where, as stated above, specific products found safe and healthy in one jurisdiction are excluded from another on the basis of a competing set of phytosanitary measures. *De facto* what the Panels
typically end up doing at least in part – and *Japan – Apples* is a good example of this – is to examine whether or not, on the basis of the evidence before them, the products in question are ‘safe’ (e.g. whether the actual apples exported to Japan pose a risk or otherwise).

This approach may be appropriate if considered as a sufficient condition to find that a measure is not SPS compliant. Indeed, if it is found that the level of risk, in the absence of any risk-reducing measure is ‘zero’, or belongs to a *de minimis* interval, then *a fortiori*, risk-reducing measures are not necessary. Any such measure can be deemed as non-SPS compliant.250

However, this approach can easily slip and effectively challenge the level of risk that the state considers as optimal. If we are correct in saying that in applying Article 2 and its derivatives, the adjudicators end up evaluating the compatibility of the measures with the SPS Agreement by trying to assess whether or not the evidence adduced supports the conclusion that the products which do not comply with the measures are safe or unsafe, then it could be readily seen how easy it would be to substitute the risk sensibility of the adjudicator or of the expert witness for that of the importing state as the critical test of safety and consequently of SPS compliance of the measures which contest such safety.

Sometimes the slippage is due a subconscious rejection of the full implications of the regulatory autonomy granted to states to set the level of optimal risk. This subconscious rejection is fed, in part, by a certain ambivalence in the SPS towards the notion of real full autonomy. See, for example, how Article 4 speaks of ‘… appropriate level of sanitary or phytosanitary protection’ (emphasis added). Could this not be read as an invitation to the WTO adjudicator to find that the level of protection itself (rather than the measure put in place to ensure that level) is inappropriate?

Moreover, the vocabulary and at times the structure of scientific risk assessment is often such that the distinction between the objective prediction of probability and the value which one places on such a prediction are conflated. What, the expert witness will be asked, or the scientific evidence will be sifted for, is the risk of the pathogen finding its way into Japanese commerce, and the answer might be: ‘negligible’. Strictly speaking, the scientific evidence should restrict itself so far as possible to the quantification of probability of an occurrence. But typically they will be invited to assess the ‘risk’ – an evaluation which might involve a combination of scientific probability and political determination of acceptable danger. The lexical expression ‘negligible risk’ might, thus, constitute no more than a code for a very low probability which must then be evaluated in the context of the polity which is assessing the risk. But it might also embrace a value judgment: so small, so negligible, that it is not worth bothering about. But that combined judgment is always part of a context which conditions the value judgment element. The risk of contamination of this species of fauna, says the expert from the wildflower rich Switzerland is 1:10,000,000 and hence ‘negligible’ and not worth bothering about. If it was the only species in some other country or of considerable economic or cultural

250 It could also be argued that evaluating whether there is credible scientific evidence to demonstrate a health risk of the apples in question, or the beef in question, or the salmon in question, is the only method of establishing whether in fact and in law the phytosanitary regulations in question are themselves necessary for protection of health and based on scientific principle and, especially, maintained (i.e. applied as in the contested case at hand) with sufficient scientific evidence.
significance, the very same probability, 1:10,000,000 might not seem negligible at all.
Hence, the adjudicators – Panel and Appellate Body – might end up pronouncing on
the reasonableness of the standard of protection of the importing state, rather than on the
extent to which science supports the conclusion that the products might
compromise that standard. Whereas the adjudicator may appropriately question the
good faith of the asserted standard, and whereas the SPS itself stipulates certain
conditions for consistency of risk within regulatory areas, the question of
determining the actual degree of risk aversion is ultimately meant to be left to the
state.
This potential slippage is also important to the extent that it conditions certain
perceptions and positions of both the adjudicators and the parties. As regards the
adjudicators, even though the decision of the Appellate Body is at issue, the
relationship in cases such as this between the Appellate Body and Panel is critical.
This is because the findings as to whether the measures in question are based on
scientific principles and maintained with sufficient scientific evidence are matters of
fact to be established by the Panel, only overturned with difficulty, and on the basis
of which the Appellate Body makes its own findings and issues its Report.

The standard of review

The second issue concerns the standard of review which Panels should adopt when examining
SPS measures. In *Hormones*, the European Communities drew a distinction between a *de novo*
approach and the unhappily termed ‘deference’ approach.

‘In the view of the European Communities, the principal alternative approaches to the
problem of formulating the “proper standard of review” so far as panels are concerned are
two-fold. The first is designated as "de novo review". This standard of review would
allow a panel complete freedom to come to a different view than the competent authority
of the Member whose act or determination is being reviewed. A panel would have to
"verify whether the determination by the national authority was ‘correct’ both factually
and procedurally". The second is described as "deference". Under a "deference" standard,
a panel, in the submission of the European Communities, should not seek to redo the
investigation conducted by the national authority but instead examine whether the
"procedure" required by the relevant WTO rules had been followed.’251

We do not believe that ‘deference’ is a particularly appropriate word; nor do we believe that the
alternative to a *de novo* review is simply a review of procedural propriety. Far more helpful are
the distinctions drawn in many national administrative and constitutional law systems, where the
review turns to the strictness of the scrutiny to be applied to a measure. Typically, in judicial
review of administrative action, the adjudicator does not seek to put himself or herself in the
position of the administrative authority (*de novo* review), but does more than simply review
procedural propriety. The adjudicator will apply some test of reasonableness. An adjudicator will
overturn a measure only if it was unreasonable (or even egregiously unreasonable) for an
administrative authority to decide as it has. By contrast, if the measure in question, threatened a
fundamental value, such as a basic right protected in the constitution, a much stricter scrutiny
would be applied, seeking a compelling reason to adopt the measure in question. The details
differ in different jurisdictions, but the underlying distinctions are commonly found.

251 Appellate Body in *Hormones*, para. 111.
In *Hormones*, the Appellate Body gave a singularly unhelpful response to the European Community’s contention, by stipulating a nebulous standard based on Article 11 of the DSU which requires Panels to base their findings on an ‘objective assessment of the facts’,252 whatever that may mean. The Appellate Body simply avoided the serious issue underlying the EC submission. This response might have served in the context of a predominantly discrimination-oriented regime ex GATT, but it cannot serve in the differentiated WTO which has, running in parallel, discrimination- and obstacle-based disciplines. Article 11 is a catchall phrase which would apply to all disputes and thus does not address what, in our opinion, is the real question. The prohibition against discrimination and protectionism is, arguably, the most fundamental principle underlying WTO trade disciplines. As such, when a state measure is discriminatory and protectionist, one might argue, that it should receive very strict scrutiny with a high burden of justification placed on the state which puts in place such a measure. By contrast, a non-discriminatory SPS measure, one might argue, is more akin to an administrative act, and as such should be subject to a lower burden of justification. The failure of the Appellate Body to deal seriously with this issue in *Hormones*, did not make it go away as will be seen from our analysis of some of the central issues in the case.

Particular concerns also arise when slippage occurs, namely when the adjudicator, by evaluating the level of risk absent any measure, ends up challenging the optimal risk chosen by the state (as discussed above).

Once the enquiry turns to the degree to which there is or is not scientific evidence to impugn the safety of the product (as an indirect method of evaluating SPS compliance of the state measure which would exclude the product as unsafe), it is very easy to substitute one’s own judgment for that of the administrative agency of the importing state. ‘If [the Panel implicitly reasons] it has not been proven to our satisfaction that there is sufficient scientific evidence to establish a real danger, then *ipso jure* the state measure is not SPS compliant’.

The SPS Agreement like the WTO and GATT more generally, is not altogether helpful on the standard of review to be exercised in such cases. Must it all allow the state in question a margin of error? Should the question not be whether a reasonable government which had asserted a certain sanitary standard has reasonably come to the conclusion that measure X is necessary to ensure sanitary and phytosanitary protection? This would mean that only unreasonable (rather than wrong) measures would be struck down. By focusing on the safety of the product as a means for determining the SPS compliance of the measure, there is a risk of upsetting the apple cart and of WTO Panels putting themselves in the business of government, rather than in the business of reviewing governance. They end up applying a test which, in most countries, administrative tribunals in similar situations would consciously seek to avoid.

**Risk assessment in *Japan – Apples***

In *Japan – Apples*, the Panel appears to have followed the very methodology outlined above. Its enquiry on the compatibility of the phytosanitary measures put in place by Japan became, at its core, an assessment of the risk posed to Japan by apples imported from the USA. In relation to each alleged risk, the Panel weighed the scientific evidence presented by the parties as interpreted and augmented by the consulted experts. Once the level of risk was established it was used as a yardstick to measure the compliance of the phytosanitary instruments with the SPS.253

Sometimes their factual conclusions are categorical:

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252 Appellate Body in *Hormones*, para. 117.

253 Panel in *Japan – Apples*, para. 8.177.
‘We therefore conclude … that there is not sufficient scientific evidence to conclude that mature, symptomless apples would harbour endophytic populations of bacteria.’ 254

On other occasions they are more nuanced:

‘We conclude … that, with respect to mature, symptomless apple fruit, the risk that the transmission pathway be completed is ‘negligible.’ Nevertheless, the experts consulted by the Panel, while firmly considering that the transmission by mature apple fruit is unlikely, suggested … that apples from severely blighted orchards … not be exported.’ 255

One notes here the more qualified terms – ‘negligible’ and ‘unlikely’. One also notes how the ‘experts’, and through them the Panel, end up engaging in the business of government, rather than reviewing the reasonableness of governance by government.

‘We therefore conclude that errors of handling or illegal actions are risks that may be, in principle, legitimately considered by Japan. These risks have been acknowledged by the experts, even though they consider them to be “small” or “debatable.”’ 256

There would thus be a small risk that apples containing the fire blight may enter the stream of commerce in Japan, despite all precautions. However, on the all-important issues of an existence of a transmission vector from such apples to Japanese fruit, the Panel concluded that:

‘… the experts considered the completion of the pathway to be unlikely.’ 257

Of course, one should note, ‘unlikely’ does not mean ‘impossible’.

And in the dispositive paragraph, this becomes as follows:

‘We therefore conclude … that it has not been established with sufficient scientific evidence that the last stage of the pathway (ie transmission of the fire blight to a host plant) would likely be completed.’ 258

Ultimately, the claim of Japan fails on these findings. Since the risks are such (that is, unlikely), the measures put in place by Japan can easily be found to have no rational relation to the scientific evidence available. 259

In effect, the Panel did not hold that there was no risk. They held that the risk was so small that it did not justify the measures.

One could interpret the Panel’s finding as suggesting that the risk belonged to a de minimis interval. From this perspective, the Panel’s approach and its conclusion that the measure cannot be SPS compliant would be appropriate.

However, one could certainly question whether the Panel has established that the risk belong to a de minimis interval. In particular, it is odd that the Panel should make a finding.

254 Panel in Japan – Apples, para. 8.128.
255 Panel in Japan – Apples, para. 8.152.
256 Panel in Japan – Apples, para. 8.161.
257 Panel in Japan – Apples, para. 8.166.
258 Panel in Japan – Apples, para. 8.168.
259 Panel in Japan – Apples, para. 8.198.
that apples from the orchards with fire blight should be excluded, even though there is no scientific basis for this.

It is also striking that the Panel never wondered about the optimal level of risk that Japan wanted to enforce. If it has indeed established that the level of risk absent any measure is within a de minimis interval, it does not matter. However, it would seem that it is always the duty of the Panel to inform itself as to what is the optimal level of risk that the state has chosen. This seems essential in order to avoid confusing the risk that the measure implies with the question of whether the measure was necessary to achieve this chosen level of risk.

Once in the hands of the Appellate Body, given the factual nature of the findings, there is not much the Appellate Body is willing or able to do. Thus in recital 163 of the Appellate Body Report we find:

‘As we see it, the Panel examined the evidence adduced by the parties and considered the opinions of the experts. It concluded as a matter of fact that it is not likely that apple fruit would serve as a pathway for the entry, establishment or spread of fire blight in Japan.260 The Panel then contrasted the extent of the risk and the nature of the elements composing the measure, and concluded that the measure was "clearly disproportionate to the risk identified on the basis of the scientific evidence available." 261 For the Panel, such "clear disproportion" implies that a "rational or objective relationship" does not exist between the measure and the relevant scientific evidence, and, therefore, the Panel concluded that the measure is maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement. We note that the "clear disproportion" to which the Panel refers, relates to the application in this case of the requirement of a "rational or objective relationship between an SPS measure and the scientific evidence".’

Further, what is not discussed in the case is the question of standard of review and in particular whether, as a means for testing SPS compliance, one should adopt the approach discussed above: First, you check whether, procedurally and substantively, the sanitary and phytosanitary rule was based on science and maintained with sufficient scientific evidence. You conduct this review in the manner in which, say, the French Constitutional Council reviews ex ante legislation and not in the American case and controversy manner. Then, if necessary, you review in administrative law fashion whether a reasonable state authority applying the rules, which have already been found to be in and of themselves SPS compliant, could have reached the result in the specific case. Japan argued, artlessly, that insufficient deference was given to its ‘approach’ to scientific evidence, a contention which is summarily rejected. Again, implicitly the Appellate Body endorsed the methodology of the Panel, which focused on the evaluation of risk, with all the potential slippage which this methodology entails.

What is never addressed in the legal give and take is the weight to be given to the experts’ assessment of small risk, likely and unlikely risk, and negligible risk and more generally what could be the upper limit of the de minimis interval. There seems to be consensus that there is some risk. The weight to be given to it is a matter which, one would think, should be contextualised. In the assessment of the Panel, one has the impression that, despite the existence of some risk, a uniform regulatory rule would be applicable to all.

**Consistency and discrimination**

260 Panel in *Japan – Apples*, para. 8.176.
261 Panel in *Japan – Apples*, para. 8.198.
If one is to retain the current orthodoxy according to which even under the SPS the Members enjoy autonomy to set their own levels of acceptable risk, it is not, strictly speaking, the task of the Panels and the Appellate Body to review that national policy decision. So long as the Members pursue the various disciplines of the SPS, notably that they engage in an appropriate process of risk assessment and management, and that their determination of the risk and the measures to combat it are based on scientific evidence, the review should stop there. The Panel can review the measures for proportionality and hold those incompatible with the SPS provisions which are ‘more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection’.262 But what is an ‘appropriate level’ remains, according to the doctrine developed by the Appellate Body in *Hormones*,263 and *Australian Salmon*264 a matter for each Member.

The Panels and the Appellate Body may, however, as part of their inherent jurisdiction review the good faith of these determinations by a state. This is a very delicate task – it is never easy for an international tribunal of any kind to base its decision and motivate its decision on the grounds of bad faith – which usually amounts to a finding that it simply does not believe the state party in question. It would seem to us that two interconnected devices may render this task somewhat easier.

In the first place Members in SPS cases should be prodded, by the Panels, to articulate the level of risk against which the measures in question are designed. In fact it is difficult to understand how a Member can engage in the kind of risk assessment which Article 5 SPS requires without such articulation. An inability to articulate the level of risk, even if not in precise quantitative terms, may have significant probative value in indicating that the required risk assessment ex Article 5 was deficient. In addition, it would be the only way for the Panel to do what falls to it, which is to review whether the measures adopted are indeed necessary and scientifically grounded to counter or mitigate the risk level so articulated. In this regard, we respectfully disagree with the ruling of the Appellate Body in *Hormones* in which it held that:

‘[t]o 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.’265

It may not find an explicit basis in the Agreement, but without some indication of the magnitude of risk aimed at, both Panel and Appellate Body risk descending into intuitive approximations.

Members might, of course, put the cart before the horse: examine the measures they have in place and construct from it, retroactively, the level of risk which supposedly informed the choice of the measure in question. This is where the second ‘bad faith’ device may be employed. It is permissible to check the autonomous determination of the level of risk against the requirement of consistency in Article 5(5) of the SPS Agreement:

‘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

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262 SPS Article 5(6).
263 Appellate Body in *Hormones*, paras 124 and 172.
264 Appellate Body in *Australian Salmon*, paras 199 et seq.
265 Appellate Body in *Hormones*, para. 186.
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.

In *Hormones* the Panel gave a rather narrow definition to the meaning of ‘different situations’ – construing the terms to apply to risks resulting from the ‘same substance’ and creating the ‘same adverse health effects’. This would be of limited utility in this dispute, since it is the very absence of fire blight in Japan which informed its measure. Article 5.5 could however be read to apply to situations in, say, a similar sector (in this case safety of plant life) assuming that all other things are more or less equal. If, for example, as in this case, it were found that Japan insisted on a very low tolerance to risk in relation to fire blight, but in other comparable situations was willing to tolerate far higher levels of risk to the health of plant life, one might be justified in drawing the conclusion, absent a convincing justification from Japan, that its measure was a disguised restriction to trade and hence non SPS compliant. The Panel specifically stated in *Hormones* that its ruling there should not be seen as either defining or ‘further limiting’ the meaning of the terms ‘different situation’ in Article 5.5. And the Appellate Body confirmed a broader approach:

‘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.’

It is to be noted, however, that one cannot apply the consistency clause in the manner suggested above in an overly rigid or mechanical manner. One cannot impugn a set level of risk simply and only because one finds that the state is not consistent in related fields. If this were so, state measures affecting imported products would always have to be pitched at the very lowest standard tolerated in the importing state, militating against, for example, a progressive raising of standards. Article 5(5) should not be construed as a mechanism which would relegate the importance of harmonisation. But the language of the provision – each Member shall avoid arbitrary and unjustifiable distinctions – could be comfortably used to reject abusive standards without compromising the regulatory autonomy of the state under the orthodox understanding. If the state could not explain the maintenance of such distinctions, there would be a means of finding them incompatible with SPS without expressly impugning the good faith or otherwise of the state. It should be emphasised that the consistency requirement should not be seen as a device which is necessarily aimed at uncovering crypto-protectionism. Unjustifiable distinctions can eradicate not only the purposively abusive SPS measure, but also the unthinking, careless measures which are detrimental to trade without a real social justification. It is important to notice that according to Article 5.5 arbitrary or unjustified distinctions are impugned if they result not only in discrimination, but also in a disguised restriction on trade. In the context of the SPS Agreement, a disguised restriction to trade need not be in the context of a protectionist scheme.

The principal innovation of the SPS Agreement was the introduction of a legal discipline which was not rooted in protectionism. A state measure may be found to be SPS non-compliant even if, as in Japan – Apples, there is no finding of protectionism and discrimination. As noted by

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266 Panel in *Hormones*, para. 8.176.
267 Appellate Body in *Hormones*, para. 217.
the Appellate Body in *Hormones*, a state measure may be found to be GATT compliant (i.e., not in violation of, say, Articles III and XI) and yet still be non-compliant with SPS. At the same time, a measure which is discriminatory or protectionist is, *ipso jure*, also in violation of the SPS. We have argued in this chapter, that measures which are putatively discriminatory and protectionist merit stricter scrutiny by the adjudicators, and the burden of justification on the state employing them would necessarily be higher than in a situation where the disputed measures are not alleged to be discriminatory or protectionist.

If this were so, this would in the context of SPS produce a certain legal paradox, the implications of which can only be sorted out as the jurisprudence develops. Imagine two states applying identical SPS measures such as those in *Japan – Apples*. In state A, there is very low production of the product in question and, let us stipulate, the economics of the market are such that protectionism is neither the object nor the effect of the measures in question. In state B there are, by contrast, high levels of production of the product in question, and the effect of the SPS measures in place are such as to afford protection and raise suspicion as to the aim of the measures. It would seem that the measures in state B would, and perhaps should, receive stricter scrutiny. Assume further that the measures are ‘truly’ compliant. The result could be that since state A had a lower burden of justification, its SPS measures would be found not to violate the Agreement whereas state B, with the higher burden of justification might find its measures impugned. Hence, the same measures would be SPS compliant in one country, but not the other. This may be a source of concern in the following sense; the measures of state B appear more suspicious because of their protective effect. But at the same time, precisely because state B has high levels of production of the item in question, the consequences of contamination can be much more devastating than in state A; yet it, with the higher level of risk, ends up with the higher burden of justification and the greater risk of having its measure impugned. This anomaly may be used as an argument against the thesis which would differentiate the burden of justification depending on the issue of protectionism and discrimination. But that, in turn, militates against a principle of judicial review found in most jurisdictions according to which there should be higher levels of scrutiny of a public measure which violates a fundamental norm.

**Risk assessment**

 Whilst acknowledging that the Japanese risk-assessment exercise studied several possible hosts of fire blight, including apple fruit, the Panel then found that the risk assessment was not ‘sufficiently specific’ because the conclusion of the assessment did ‘not purport to relate exclusively to the introduction of the disease through apple fruit, but rather more generally, apparently, through any susceptible host/vector.’ As the Appellate Body explains, the Panel also found that the discussion of possible pathways ‘intertwined’ the risk of entry through apple fruit with that of other possible vectors, including vectors considered more likely to be potential sources of contamination than apple fruit and hence more damaging. Finally, although the assessment noted the *possibility* of entry, establishment or spread of fire blight through this vector, it did not properly evaluate the *probability* of the occurrence of such events. The result was to invalidate the risk assessment conducted by Japan.

 For Japan the issue was one of methodology in which the Members should enjoy discretion, provided the risk can be established. The Appellate Body solidly upheld the Panel and insisted, following its ruling in *Hormones*, that the assessment would have to follow the potential

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268 Of course, because of more damaging consequences, country B may wish to select a lower level of optimal risk. Assuming however that both countries have selected a *de minimis* risk, the anomaly will remain.

269 Panel in *Japan – Apples*, para. 8.271.
specific pathogens of the disease and that these would have to be assessed in relation to the contemplated SPS measure in question.

We do not propose to critique this reasoning of the Appellate Body except to note that the pattern which now emerges from several SPS cases suggests that, absent an international standard which a state might follow, it will be rather difficult for all countries and notably developing countries to conduct the kind of risk assessment which would satisfy the stringent methodological requirements stipulated by the Appellate Body.

The legal issue in question here also goes to the standard of review, which is more assumed then discussed. On the one hand the Appellate Body seems to suggest that there is plenty of leeway for alternative methodologies. Thus, in recital 204 we read:

‘Contrary to Japan's submission, however, the Panel's reading of EC–Hormones does not suggest that there is an obligation to follow any particular methodology for conducting a risk assessment. In other words, even though, in a given context, a risk assessment must consider a specific agent or pathway through which contamination might occur, Members are not precluded from organizing their risk assessments along the lines of the disease or pest at issue, or of the commodity to be imported. Thus, Members are free to consider in their risk analysis multiple agents in relation to one disease, provided that the risk assessment attribute a likelihood of entry, establishment or spread of the disease to each agent specifically. Members are also free to follow the other "methodology" identified by Japan and focus on a particular commodity, subject to the same proviso.’

This passage suggests a reasonableness standard, rather than a categorical one. But this seems to be negated by the categorical manner in which Japan is to follow the Australia Salmon test of 5(1).270 We do not want to suggest that the Appellate Body was necessarily wrong from a legal point of view. But it does tip the scales considerably against poorer and less scientifically equipped and sophisticated Members. The powerful Members seem to get at least two bites of this apple, if not three. First, they will have, of course, much greater clout when negotiating international standards which will then be de facto imposed on less powerful Members. Second, it will be difficult to match their scientific apparatus when their regime comes into conflict with another one. And finally, they of course will have more resources to try to extricate themselves from an uncomfortable international standard.

270 ‘… a risk assessment within the meaning of Article 5.1 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;

(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.’

Appellate Body in Australian Salmon, para. 121 (original italics).
The precautionary principle

So far, we have assumed that probabilities can be attached to future events. This arises when the mechanisms through which, for instance, a disease can spread are well understood and because the circumstances which affect the spread of the disease can be observed. Hence, the likelihood of each possible outcome can be estimated with confidence. By contrast, a disease may be poorly understood and there may be competing theories regarding its development with no evidence to support one theory or another. Accordingly, there may be several probability distributions over possible events, depending on which theory is used.271 As indicated above, there is no scientific explanation behind the spread of the fire blight across the ocean. This may be such an instance.

Before examining how the SPS Agreement considers such cases and discussing the approach of the Panel, some insight from decision theory on how to behave under these two sets of circumstances may be useful. In other words, should the uncertainty which surrounds the evaluation of probabilities affect decisions?

Risk and ambiguity

The work of Von Neumann and Morgenstern (1944) has shown that when an objective probability distribution can be defined over a set of outcomes, preferences will be linear in probabilities, at least as long as they respect the ‘independence axiom’. That is also to say that decisions can be formulated as the result of the maximisation of expected utility.

Savage (1956) considered a situation where the decision-maker cannot rely on objective probability distribution. He considered a set of possible events and analysed the choices that an individual would make over alternative gambles which yield different payoffs in these events. He assumed that the individual would always be able to make a choice. He further assumed that the choice between two gambles would not be affected by a modification of the payoffs that accrue when both gambles yield the same payoff (the independence axiom again). For instance, assume that there are two events H and L, which are not exhaustive, so that Non H and Non L can also arise. The first gamble yields a payoff of 1 if H occurs and 0 if L occurs. The second gamble yields 0 if H occurs and 1 if L occurs. Both gambles give a payoff of ‘d’ if neither H, nor L occur. The independence axiom says that a change in ‘d’ should not change the choice between the two gambles. Savage showed that from observation of choices made under these assumptions,272 one could generate a relationship between events which is nothing but a subjective probability relationship (such that the event could be ordered as more or less probable).

This finding has an important consequence. It says that when no underlying probability distribution is available, preferences will be linear in subjective probabilities. Decisions can be formulated as the maximisation of subjective expected utility. This also implies that, faced with alternative probability distributions over a set of events, a decision-maker should pick one and behave as if the resulting probabilities were certain.

To illustrate, consider the following experiment, due to Ellsberg (1961). There are two urns, each with 100 balls, which can be either red or black. In urn 1, the proportion is unknown. For urn 2, it is known that there are 50 red and 50 black balls. An agent is asked to choose between the following bets; bet red, in which case he gets a prize if a red ball is extracted and zero otherwise, or bet black, in which case he gets a prize if a black ball is extracted and zero otherwise. Consider possible bets over urn 2. Agents will naturally be indifferent between betting

271 Taking it for granted that there is no likelihood that can be attached to possible probability distribution. If it were the case, they could be aggregated to yield one distribution.
272 And a couple of additional technical assumptions.
red or black. Asked the same question of urn 1, agents will typically provide the same answer. This can be seen as a situation where there are 101 possible theories about the allocation of balls in the urn. Agents form the subjective assessment that in the absence of any information to distinguish between the theories, they are all equally likely and hence attach a subjective probability of 0.5 that a red (or black) ball will be extracted.

In this framework, there is thus nothing special about scientific uncertainty. Precaution is just like protection: the optimal risk-reduction efforts can be obtained from a standard cost-benefit analysis (see Gollier, 2001 for a discussion), using subjective probabilities.

Some suspicion about the validity of the framework, however, arises if agents in the above example are being asked an additional question, namely whether they prefer to bet red in urn 1 or bet red in urn 2. It turns out that most agents prefer to bet red in urn 2 than bet red in urn 1. This implies that red from urn 2 is perceived as more likely than red from urn 1. But if an agent also prefers to bet black from urn 2 rather than black from urn 1, non-red from urn 2 would appear more probable than non-red from urn 1. This is inconsistent with the notion that the choice of agents reveals probabilities. That is also to say that choices cannot be compared according to their expected utility. As shown by Ellsberg (1961), the problem arises because the axiom of independence is violated.

This experiment indicates that some agents may be ready to pay more for reducing a risk that is more uncertain. Alternative models of decision have also been developed which do not rely on the axiom of independence. For instance, Henry and Henry (2003) describe a model in which agents face different probability distributions over a set of events. Uncertainty is thus described in terms of a family of distributions. In their framework, choices cannot be compared in terms of expected utility (independence is not assumed), but can be compared in terms of a weighted average of the maximum and the minimum of expected utility that obtains across the possible probability distributions. This allows for a representation of preferences in terms of an attitude to risk (the usual risk aversion as depicted by the shape of the utility function) and an attitude towards the uncertainty with respect to the true probability distribution, which is referred to as the degree of aversion towards ambiguity. The latter is represented by the weights that are given respectively to the maximum and the minimum of expected utility.

Finally, it is worth noting that the decisions that agents take in this framework can also be seen as displaying some ‘precaution’. The aversion of the agents towards ambiguity leads to them taking some action in which they give weight to worst theories.

**Risk, ambiguity and precaution in the SPS Agreement**

As discussed above, the Appellate Body confirmed that Japan’s phytosanitary measures were maintained ‘without sufficient scientific evidence’ and hence the measures were not in conformity with Article 2.2 of the SPS Agreement. At the same time, the Appellate Body ruled that the phytosanitary measures imposed by Japan were ‘not imposed in respect of a situation where relevant scientific evidence is insufficient’, so that temporary measures could not be justified under Article 5.7. The Appellate Body noted in particular that the Panel had come across an important amount of relevant evidence and that ‘a large quantity of high quality scientific evidence … had been produced over the years and … that the experts had expressed increasing confidence in this evidence’. Altogether, the Appellate Body thus seems to have considered (1) that there is reliable scientific evidence on the risks involved in the spread of the disease at stake;

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273 Originally developed by Ghirardato et al (2002).
274 For instance, the maximin criteria proposed by Gilboa and Schneider (1990) (such that individuals should behave as if the true theory is the one that yields the lowest expected utility) can be shown to display a strong aversion to ambiguity (see Henry, 2002).
and (2) that the evidence confirmed that the risk of having the disease spread through imported apples was small.

Importantly, the Appellate Body also reiterated the Panel’s observation that Article 5.7 ‘was designed to be invoked in situations where little or reliable evidence was available on the subject matter at issue’.

It is striking that the structure of the SPS Agreement, as well as the interpretation of the agreement which is given by the Appellate Body (and Panel) fit with the distinction between risk and ambiguity. It appears in particular that Article 5(7) can be used when ambiguity is strong.

The ‘sufficiency of scientific evidence’ in Article 2(2) and the ‘(in)sufficiency of relevant scientific evidence’ in Article 5(6) thus also appear to refer to different concepts. The use of similar terms could be confusing and these concepts could be spelt out more clearly. The structure of the test as to whether a measure can be allowed could also be clarified: following the terms of the discussion above, a restrictive measure can be allowed if uncertainty cannot be confidently characterised in terms of a probability distribution. If uncertainty can be confidently characterised in terms of probability distribution, a restrictive measure might still be allowed if it significantly reduces the occurrence of an event which according to this probability distribution is sufficiently likely and sufficiently damaging. Hence, it would appear that any test of whether a measure could be lawful should start with Article 5(7) (and not Article 2(2)) and question the ambiguity of scientific evidence. A precise evaluation of the measure at stake (under Article 2(2)) would be conducted only if it is concluded that scientific evidence is sufficiently ‘unambiguous’.

The question of how ambiguity should be measured in practice in cases where consensus cannot be detected is difficult, however. It would presumably involve a measure of the subset of possible events for which probabilities are (dis-)similar under the range of possible distributions put forward by experts.

The previous discussion indicates that Article 5(7) of the SPS Agreement can be seen as the expression of a precautionary principle. However, it reflects a particular motive for precaution, namely the presence of ambiguity. Yet, as discussed by Gollier (2001), there are other possible justifications for precautionary actions and those are not explicitly mentioned in this provision.

These arise in particular from the dynamic nature of scientific uncertainty. When future risks depend on past consumption (as in the case of climate change), the question arises as to whether preventive efforts should be undertaken today or tomorrow. On the face of it, the expectation that knowledge will improve over time and hence that actions will be more efficient in the future would appear to warn against premature actions. This is the argument which is often advanced to justify the US refusal to sign the Kyoto protocol. It is what Gollier refers to as the ‘learn then act’ principle. However, if knowledge is improved through the observation of the risks themselves, matters may be different. In those circumstances, the observation of damages today should lead to more preventive actions.

Second, it may be that postponing preventive actions may also increase future risks; in those circumstances, the prospect of being poorer in the future may lead to a reduction in the amount of pollution today.

Third, the extent to which current decisions change flexibility in the future may also be a concern. Some risks may be subject to irreversibilities and the lack of preventive measures may reduce options in the future. In other words, there may be an option value in undertaking preventive action, which in principle can be estimated using real option theory.

Hence, the question arises as to whether the SPS Agreement should not reflect those particular circumstances when precautionary actions are particularly appropriate; namely when

275 Gollier (2001) uses the subjective expected utility framework. However, the dynamic effects that he investigates would appear to apply in other frameworks, at least at the level of general principles.
future risks are increased, flexibility is impaired and learning proceeds by observation of current trends.

*Precaution in Japan – Apples?*

As discussed above, the Panel and the Appellate Body ruled that the phytosanitary measures imposed by Japan were 'not imposed in respect of a situation where relevant scientific evidence is insufficient', so that temporary measures could not be justified under Article 5(7). Still, the absence of scientific explanation behind the spread of fire blight across the ocean may be an instance of ambiguity.

*Japan – Apples* is thus a good illustration of the rather narrow nature of Article 5(7) as an expression of a broader notion of precaution. For example, there is, on the one hand, considerable scientific evidence on the mechanisms which explain the potential transmission mechanisms of fire blight. On the other hand, there is no standard and acceptable account which actually can track and explain how fire blight travelled across the oceans to reach Australia or certain Asian countries. A wider notion of precaution might suggest that, pending the discovery of the actual transoceanic pathway, a state may be entitled to invoke Article 5(7).

This raises a question of framing. If you frame the question as to the ‘macro’ pathway in its historical context, one would be driven to the conclusion that there was no scientific evidence. If, by contrast you frame the question as to the specific mechanisms that explain how the pathogen might migrate from a blighted apple to a healthy one, there is evidence. It is not clear why, in this case, the second framework is more appropriate than the first one. Once again, we come back to the all important issue of the standard of review. Had the Panel taken the view that its task was not to establish the risk posed by imported apples, but to establish the reasonableness of the Japanese measure, and the circumstances of its application to the specific imports from the United States, it would also have asked itself, whether it was reasonable for the Japanese Government to look, in the context of Article 5(7) at the first, rather than the second, framework as articulated above. Since the Panel slipped into the business of risk assessment itself, rather than assessment of risk assessment, it could come to its conclusion, which the Appellate Body then followed uncritically.
References


On September 29, 2006, the World Trade Organization (WTO) panel on the EC-Biotech dispute finally issued its official report,[1] three years after the panel had been established. On August 7, 2003 three exporters of agricultural and food products containing genetically modified organisms (GMOs), i.e., the United States (WT/DS291), Canada (WT/DS292), and Argentina (WT/DS293), filed complaints under the WTO dispute settlement mechanism against the EC’s alleged moratorium on the approval of GMOs during the period of October 1998 to August 2003, as well as against some of the EC Member states’ national ban on GMOs and GM foods. On February 8, 2006, the panel issued an interim report in which it produced two main findings.[2]

First, the panel in its interim report recognized the existence of such moratoria – a general one as well as product-specific ones – and held that the moratoria resulted in “undue delay” in the EC’s GMOs approval procedure, violating Article 8 and Annex C of the WTO Agreement on Sanitary and Phytosanitary Measures (SPS). Second, the panel struck down national bans (safeguards) established by certain EC Member states on certain EC-approved GMOs on the ground that these states failed to conduct risk assessments and thus violated SPS Article 5.1. The panel found that the sufficiency of available scientific evidence, such as earlier conclusions rendered by relevant EC scientific committees, precluded these Member states from invoking provisional measures (national bans or safeguards) under SPS Article 5.7 without having conducted a risk assessment under Article 5.1.

The findings in the final panel report unsurprisingly parallel the February interim report, except for a critical change in the panel’s position on remedies (recommendations), which will be discussed below. All in all, the panel report raises many interesting legal questions which have not been fully addressed and thus remain controversial.

Major Legal Issues

The Legal Nature of a General De Facto Moratorium

The panel, siding with the complainants, construed the EC’s suspension of its approval procedure on GMOs from October 1998 to August 2003 as a general “de facto” moratorium, while it did not address the WTO-legality of the EC’s approval legislation itself since this issue was not raised by complainants.[3] Interestingly, however, the panel refused to acknowledge such a moratorium as a “measure” under the SPS Agreement, but nonetheless said that the moratorium “affected the operation and application of the EC approval procedures,” which resulted in “undue delay” under the procedures and therefore violated Article 8 and Annex C of the SPS Agreement.[4]

However, this moratorium might be regarded as just a procedural outcome, or an application, of the relevant EC approval legislation which the panel did deem an SPS measure.[5] In other words, the moratorium might not be fully detached from the relevant EC approval legislation and treated separately. According to this interpretation, the panel could have ruled that the moratorium did constitute an SPS measure. To construe the moratorium as an SPS measure would have led the panel to decide whether the moratorium violated substantive, not merely procedural, obligations under the SPS Agreement, such as Article 5.1 (Risk
Assessment). By finding that the moratorium was not an SPS measure in and of itself, the panel avoided this burdensome task and simply held that the EC has not acted inconsistently as to Article 5.1.\[6\]

**Mootness**

The EC claimed that even if there was a moratorium between June 1999 to August 2003, this case was “moot” if the moratorium “ceased to exist” after the establishment of the panel. The EC submitted that under these circumstances the panel should not rule on the moratorium.\[7\] The panel rejected the EC’s mootness claim. Relying on GATT/WTO jurisprudence, the panel viewed that it “had the authority” to rule on a measure within its terms of reference even if the measure subsequently ceased to exist.\[8\]

Nonetheless, the panel might have ruled that the case was moot. In fact, the panel itself noted that two biotech products were approved in 2004 after the panel was established in August 2003.\[9\] These new developments might have terminated the “across-the-board” moratorium which the complainants claimed existed.\[10\]

**Conditional Remedy**

In the interim report, the panel had originally rendered no recommendation as to the EC’s general moratorium\[11\] in accordance with the WTO jurisprudence under which a panel refrains from making a recommendation regarding a WTO-inconsistent measure if such measure is no longer in force after the establishment of the panel.\[12\] However, in the final report the panel accepted the complainants’ request\[13\] and rendered a “qualified” recommendation that the EC should bring the general moratorium into conformity with relevant WTO obligations “if, and to the extent that” it still exists.\[14\]

The panel justified such a conditional remedy by observing that due to its murky and complex nature the moratorium might be re-imposed in the future; thus, deciding this issue here and now would “secure a positive solution” to this dispute.\[15\] Yet, one might speculate that under this logic, decisions could always be rendered on measures no longer in force, since all violations could potentially be reintroduced in the future.

**Legal Relationship between the WTO Rules and Other Rules of International Law**

The EC attempted to justify some Members states’ national bans on GMOs under the “precautionary principle” provided in the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the “Biosafety Protocol”).\[16\] The United States, however, rejected any application of non-WTO agreements to this WTO dispute.\[17\] The U.S. highlighted that the Biosafety Protocol should not be applied to this dispute since it is not a party to the Protocol.\[18\]

The panel treated this linkage question as an issue of treaty interpretation. It first acknowledged that Article 31.3(c) of the Vienna Convention on the Law of Treaties mandated the panel to “take into account” any relevant rules of international law only if these rules are “applicable” to parties concerned.\[19\] The panel held that the Biosafety Protocol would not be applicable in this case since none of the complainants was a party to the Protocol.\[20\] Therefore, the panel concluded that it was not required to consider the Protocol.\[21\] As to the broad question whether the precautionary principle belongs to general principles of law, the panel noted that it need not address such a “complex” and “unsettled” issue in this specific dispute.\[22\]

**Prospects**

The panel report will be adopted as it stands within 60 days after its circulation, unless a party appeals.\[23\] No party has expressed its intent to appeal, and the losing party, the EC, might not have a strong reason to do so. The EC observed that since it resumed the approval of GMOs in 2004, the panel’s recommendations based on the old situation would have no practical impact to the EU.\[24\]

**Epilogue**
In an unusually harsh tone, the panel problematized the leak of its confidential interim rulings to the public, warning that such leak “could damage the integrity of the WTO dispute settlement system as a whole.”[25] While parties concerned denied any involvement in the breaches of confidentiality and condemned these breaches, the panel emphasized that “these statements cannot easily be reconciled with the fact that these leaks did occur.”[26] The panel also found it “surprising and disturbing” that two non-governmental organizations (the Institute for Agriculture and Trade Policy and Friends of the Earth), whose amicus curiae briefs the panel accepted, disclosed the confidential report on their websites.[27] In response, the Friends of the Earth reportedly stated that it “acted in the public interest.”[28]

Finally, the panel report did not rule on the general safety of GMOs or on the general legality of the EC approval procedure. Its report mainly concerns narrow procedural issues, such as “undue delay.” Yet, the panel spent three years and produced a 1000-page report plus yet another 1000 pages of Annexes. One might question whether using the WTO dispute settlement system over this type of dispute was really “fruitful.”[29]

About the author

Footnotes


[4] Id., para. 8.6

[5] Id.


[8] Id., paras. 7.1306-7.1308.

[9] Id., paras. 7.1303, 7.1305

[10] Id., para. 7.1304.


[12] Id., para. 7.1314.


[14] Id., para. 7.1317.

[15] Id., paras. 7.1310-7.1311

[16] Id., paras. 7.53-7.55.

[17] Id., para. 7.56

[18] Id., para. 7.58

Id., para. 7.75.

Id.

Id., para. 7.89.

WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 16:4.

See WTO Panel Provisionally Rules, supra note 2.

Panel Report, supra note 1, para. 6.185.

Id., para. 6.195.

Id., para. 6.196.


WTO DSU, supra note 23, art. 3.7 (“Before bringing a case, a Member shall exercise its judgement as to whether action under these procedures would be fruitful.”).
1. Abstract

In this third case under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Dispute Settlement Body (DSB) found that Japan had acted inconsistently with the SPS Agreement by imposing certain quarantine measures concerning agricultural products. The Appellate Body upheld the Panel’s finding that Japanese testing requirements as they applied to apples, cherries, nectarines and walnuts were inconsistent with Articles 2.2, 5.7 and 7 of the Agreement. It reversed the finding of inconsistency under Article 5.6 – not because it thought the Panel’s conclusion that there was a less trade-restrictive measure was wrong, but because this finding was reached in a manner inconsistent with the rules on the burden of proof. Having criticized the Panel for not making findings under Article 5.1 with regard to a number of products, the Appellate Body, on the basis of the factual findings of the Panel, concluded that a Pest Risk Assessment produced by Japan was no proper risk assessment in the sense of Article 5.1. For the first time, the Appellate Body dealt with the requirements of Article 5.7, which it had described in EC – Hormones as the embodiment of the precautionary approach in the SPS Agreement. The Appellate Body noted that Article 5.7 contained four requirements which had to be met cumulatively.

2. Facts

Since the early 1970s the United States had tried to export various fruit products to Japan. Under the Plant Protection Law of 1950, Japan prohibits the importation of eight agricultural products (apples, cherries, peaches, walnuts, apricots, pears, plums and quince) on the ground that they are potential hosts of codling moth, a pest of quarantine significance to Japan (because it does not occur in Japan). The import prohibition can be lifted if an exporting country demonstrates that an alternative quarantine treatment achieves the same level of protection. In practice, the alternative quarantine treatment is fumigation with methyl bromide. But Japanese law imposes a requirement to test and confirm the efficacy of the quarantine

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treatment for each variety of the product (‘the varietal testing requirement’). So despite the development of effective quarantine treatments for fruits, the procedure to gain access to the Japanese market for different varieties of these products can take several years. For this reason a number of varieties’ applications filed more than a decade ago are still pending. The US claims that due to Japan's burdensome testing requirements, exports to Japan of these products represent only a small part of US exports worldwide.

3. Analysis of the Panel and Appellate Body Reports

After dealing with the issue of food safety in the *Hormones* case and animal disease control in the *Salmon* case, the Appellate Body now had to make findings in a case where the measures at issue were related to plant pest control.

a. General Issues

Before dealing with the issues of substantive law, the Appellate Body had to address two general questions. As in the two prior SPS cases, the allocation of the burden of proof by the Panel was questioned on appeal. In the context of Article 5.6, the Panel had to examine whether alternative measures existed which were less trade restrictive than the varietal testing requirement. It concluded that one of the alternative measures suggested by the scientific experts advising the Panel (the determination of sorption levels) was equally effective and less burdensome. The Panel thus held that Japan was in breach of Article 5.6. Japan appealed the finding because the US had not even argued that the determination of sorption levels was an alternative measure which met the three elements under Article 5.6. On the contrary, the Panel had explicitly stated that the US, as complaining party, had ‘not specifically addressed’ the alternative measure proposed by the experts.278 But it went on to say that the US had ‘given views which were consistent with’ the argument that this was an alternative method in the sense of Article 5.6. In Japan's view, the Panel, by finding facts neither argued nor proven by the parties, exempted the US from making a *prima facie* case in accordance with the established rules on the burden of proof.279 The Appellate Body agreed. It recalled its statements in *US – Shirts and Blouses* and *EC – Hormones*, according to which the initial burden lies on the complaining party. Although Article 13 DSU allowed a panel to seek information from any relevant source and Article 11.2 SPS explicitly instructed panels to seek advice from experts, these rights could not be used by a panel to rule in favour of a complaining party which had not established a *prima facie* case of inconsistency.280 In the present case the US had not established this presumption because it had not even claimed that the determination of sorption levels was a valid alternative. The Appellate Body thus reversed the Panel's finding.281

On appeal Japan also claimed that the Panel had failed to discharge its duty under Article 11 DSU to make an objective assessment of the matter before it. Japan contended that there was a lack of proper examination of evidence by the Panel, that the Panel cited the views of the experts in an arbitrary manner and that the Panel’s evaluation of the evidence was contradictory.282 The Appellate Body recalled its statements in *EC – Hormones* that bear on the question of what may be characterized as a failure to make an objective assessment of the facts. In its view, however, the Panel had not failed to do so in the present case.283

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278 Panel Report, footnotes 328, 332 and 333.
279 Appellate Body Report, para. 120.
280 Para. 129.
281 Para. 131.
282 Para. 140.
283 Para. 142.
b. The SPS Agreement

Unlike the Panel in Australia – Salmon, the Panel started by examining the rights and obligations under Article 2.2, rather than the more specific obligations under Article 5.1. This was because the alleged risk assessment did not address the measure at all. Under Article 2.2 the question was whether the varietal testing requirement was maintained without ‘sufficient scientific evidence’ in the sense of Article 2.2. The Panel recalled the Appellate Body's statement in EC – Hormones that Article 2.2 had to be read together with Article 5.1 and that the requirement of SPS measures being ‘based on’ a risk assessment referred to a certain objective and rational relationship between an SPS measure and a risk assessment. The Panel stressed that its task was to determine whether Japan to date was in breach of its obligation, not whether in the future scientific evidence could be produced which could allow Japan to comply with its obligation. In order to make this determination, the Panel examined the statements given by the experts advising the Panel. It concluded that it had not been sufficiently demonstrated that there was a rational or objective relationship between the varietal testing requirement with respect to apples, cherries, nectarines and walnuts, and the scientific evidence submitted to the Panel. Accordingly the Panel found that Japan maintained the measure without sufficient scientific evidence in the sense of Article 2.2. But the Panel also noted that Japan had invoked Article 5.7, which is explicitly mentioned in Article 2.2 as an exception to the science-based disciplines of the SPS Agreement.

Under Article 5.7 a Member can impose provisional measures. The Panel therefore had to address the conditions for an invocation of Article 5.7. According to the Panel there were four elements, all of which had to be met: (i) the measure is imposed in respect of a situation where ‘relevant scientific information is insufficient’; (ii) the measure is adopted ‘on the basis of available pertinent information’; (iii) the Member must ‘seek to obtain the additional information necessary for a more objective assessment of risk’; and (iv) it must ‘review the … phytosanitary measure accordingly within a reasonable period of time’. The Panel went on to say that even if it were to assume that Japan had met the first two elements, there would still be the obligation to seek new information and to review the import ban, which was introduced almost 30 years ago. But there was no evidence before the Panel that Japan had done so. As a consequence, Japan could not invoke Article 5.7 and had thus acted inconsistently with its obligations under Article 2.2. The Appellate Body fully agreed with the reasoning of the Panel with respect to Article 2.2. It also rejected Japan's proposition that the reference in Article 2.2 refers only to the first sentence of Article 5.7. To the contrary, all four requirements were said to be cumulative in nature. With respect to the last two requirements the Appellate Body specified that the additional information sought by the Member must be ‘germane to conducting a risk assessment’ and that the reasonable period of time had to be established on a case-by-case basis depending on the special circumstances of each case. In conclusion, it upheld the Panel’s finding that Japan had not fulfilled the requirements contained in the second sentence of Article 5.7.

The Panel had declined to make a finding on Article 5.1 on the grounds that it had already found a violation of Article 2.2. But the Appellate Body noted that the finding of inconsistency with Article 2.2 only concerned the measures applied to apples, cherries, nectarines and walnuts. By not making a finding...
under Article 5.1 with regard to the other products, the Panel improperly applied the principle of judicial economy.

The Appellate Body then recalled the three-step test for a risk assessment under Article 5.1 as set out in Australia – Salmon. Japan had argued that its varietal testing requirement was based on the 1996 Pest Risk Assessment of Codling Moth. But the Appellate Body noted that this paper did not discuss or even refer to the varietal testing requirement. It concluded that the varietal testing requirement as it applied to apricots, pears, plums and quince was inconsistent with Article 5.1 SPS.

Article 5.6 demands that SPS measures be not more trade restrictive than required to achieve their appropriate level of protection. In the Panel's view the footnote to Article 5.6 states that this is the case unless there is another SPS measure which (i) is reasonably available, taking into account technical and economic feasibility; (ii) achieves Japan's appropriate level of sanitary protection; and (iii) is significantly less restrictive to trade than the sanitary measure contested. The Panel therefore considered the alternative measures proposed by the US and the experts advising the Panel. The US suggested testing product-by-product instead of variety-by-variety. But the Panel was not convinced that there was sufficient evidence to find that testing by product would achieve Japan's appropriate level of protection. The scientific experts concluded that if there were differences between varieties, these would be related to different levels of sorption of the fumigant by different varieties (in the fumigation chamber). Accordingly, the determination of sorption levels could be an alternative measure that was less trade restrictive. The US appealed the finding of the Panel that testing by product was not an alternative under Article 5.6. This appeal was rejected by the Appellate Body because, in essence, it challenged the Panel's consideration and weighing of the evidence, which fell outside the scope of appellate review.

The Appellate Body agreed with Japan's appellant's submission that the Panel erred in law by basing its conclusion on facts not argued by the parties and thus relieving the US of its burden to establish a prima facie case.

Article 7 is captioned ‘Transparency’ and, together with Annex B, imposes notification and publication requirements for SPS measures. Since the Japanese varietal testing requirement had not been published, the US claimed that Japan was in breach of Article 7 and Annex B. Japan argued that its measure was no phytosanitary regulation in the sense of para. 1 of Annex B because it was not mandatory (exporting countries could demonstrate quarantine efficiency by other means). The Panel noted, however, that the wording of the provision did not require a measure to be mandatory or legally enforceable. The varietal testing requirement was therefore subject to the publication obligation in para. 1 of Annex B and by not publishing it Japan had acted inconsistently with its obligation. The Appellate Body agreed, adding that the list of covered legal instruments in the footnote to para. 1 of Annex B was not exhaustive, as indicated by the words ‘such as’.

The Panel had declined to make a ruling on Article 8 and para. 1 (c) of Annex C, given that it had already found inconsistency with Articles 2.2, 5.6 and 7.309 The Appellate Body merely noted that the US had not appealed the Panel's failure to make a finding under Article 8 and Annex C. It did not therefore consider it necessary to address this issue.

4. Conclusions

298 Para. 111.
299 Para. 113.
300 Para. 114.
301 Para. 8.72.
302 Paras 8.73, 8.84.
303 Paras 8.74 f., 8.103.
304 Para. 98.
305 Paras 8.110 f.
306 Para. 8.111.
308 Para. 105.
309 Para. 8.117.
310 Para. 117.
*Japan – Varietals* was the third in a series of SPS cases. Since there is no active panel dealing with SPS cases at present, it will also be the last SPS case for some time. With the adoption of this Report, the ‘case law’ of the Appellate Body now covers all three subject matters of the SPS Agreement: human health in *EC – Hormones*, animal health in *Australia – Salmon* and plant health in the present case. By now, the main legal issues have been settled and it is to be expected that in the future the cases will revolve almost exclusively around scientific and technical matters. Already in this case there were few fundamental legal questions left. Nevertheless, *Japan – Varietals* emphasizes once more the strict science-based disciplines of the SPS Agreement. So far, no respondent has ever been able to demonstrate a ‘rational relationship’ between a risk assessment and the SPS measure applied. And very few risk studies would comply with the risk assessment required in Article 5.1.

Unfortunately, the Panel and Appellate Body did not make findings on the question of what is ‘insufficient evidence’ in the sense of Article 5.7 since they had already found a violation of this Article for other reasons. It remains open, therefore, whether the Appellate Body is really prepared to give this Article a meaning that would, to some extent, incorporate the precautionary principle into the SPS Agreement.
Case note on Australia – Measures Affecting Importation of Salmon

Joel P. Trachtman


1. Abstract

This decision evaluated the obligations of Australia under the Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”) in respect of a quarantine on imports of salmon. The Appellate Body reversed the panel’s finding that the measure at issue was a requirement that certain imported salmon be heat-treated, holding that the appropriate measure to evaluate was an import prohibition on fresh, chilled and frozen salmon. The Appellate Body therefore reversed the panel’s finding that the measure examined by the panel was inconsistent with art. 5.1, and by implication, art. 2.2, of the SPS Agreement. Having thrown out the panel’s decision, the Appellate Body, on the basis of factual findings made by the panel, however, found that the Australian measure was not based on a proper risk assessment, violating art. 5.1, and, by implication, art. 2.2, of the SPS Agreement.

The Appellate Body also upheld the panel’s finding that the Australian measure violated art. 5.5, and by implication, art. 2.3, of the SPS Agreement. The Appellate Body did so on the basis of differential treatment of imports of certain other types of fish that presented similar or greater risks. The Appellate Body was not able to come to a conclusion with respect to art. 5.6 of the SPS Agreement, because of the paucity of the factual record developed by the panel. This strengthens the argument for giving the Appellate Body the right of remand.

2. Facts

In this case, Canada was challenging Australia’s prohibition on imports of fresh, chilled and frozen salmon from Canada under Quarantine Proclamation 86A (“QP86A”). Upon Canada’s request, Australia performed a risk analysis with respect to fresh wild salmon the results of which were set forth in a 1996 Final Report (which was preceded by a 1995 Draft Report). Pursuant to the 1996 Final Report, the Australian Director of Quarantine determined to maintain the quarantine. The decision relates to both ocean-caught Pacific salmon, and other Canadian salmon.

3. Analysis of the Appellate Body Report

a. Terms of Reference
The Appellate Body first clarified that the measure it addressed was the import prohibition on fresh, chilled and frozen salmon, and not a separate measure that permits heat treated salmon, such as smoked salmon, to be imported. On this issue, the Appellate Body reversed the panel, which had treated these separate measures as “two sides of the same coin.” This decision affected the terms of reference of the panel, which according to the Appellate Body, should not have included the Australian measures relating to heat treated salmon.

Australia had criticized the panel for referring in a footnote to art. 6 of the SPS Agreement, when Canada’s request for the establishment of a panel did not refer to art. 6. The Appellate Body agreed with Australia that art. 6 was not included in the panel’s terms of reference, but disagreed that the panel had exceeded its terms of reference. Rather, the Appellate Body found that the panel’s incidental reference to art. 6 of the SPS Agreement did not constitute an expansion of its terms of reference. The Appellate Body rejected a number of other relatively minor procedural points raised by Australia.

b. The SPS Agreement

As to Canadian salmon other than ocean-caught Pacific salmon, the panel found that Australia had imposed and maintained its measure without the benefit of any risk assessment, and thereby violated arts. 2.2 and 5.1 of the SPS Agreement. This finding was not appealed. The Appellate Body thus turned to the application of the Australian measures to ocean-caught Pacific salmon.

As noted above, the panel had erred in assuming that the measure at issue was a heat treatment requirement, rather than the import prohibition. Australia argued that this error vitiated the panel’s findings regarding whether the Australian measure was supported by a risk assessment. Here, as in a number of other cases, the Appellate Body runs up against the limitations of art. 17.6 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (the “DSU”). As in certain prior cases (Gasoline, Periodicals, Poultry and

312 Appellate Body Report, para. 105.
313 Appellate Body Report, para. 110.
315 Canada—Certain Measures Concerning Periodicals, adopted 30 July 1997, WT/DS31/AB/R.
the Appellate Body determined, to the extent possible based on the factual findings of the panel and/or undisputed facts in the panel record, to complete the legal analysis and determine whether the import prohibition on fresh, chilled or frozen salmon is based on a risk assessment. The Appellate Body is in this position, of course, because it lacks a right of remand.

The panel did not determine, but merely assumed, that the 1996 Final Report constituted a risk assessment as to ocean-caught Pacific salmon. The Appellate Body examined ab initio whether this assumption was warranted. For these purposes a risk assessment is an “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory . . . and of the associated potential biological and economic consequences . . . .” The Appellate Body disagreed with the panel, holding that this formulation requires a full evaluation of the likelihood of such events, rather than either a statement of the possibility of such events or a finding of some likelihood of such events. However the evaluation may be either quantitative or qualitative. The Appellate Body found that the 1996 Final Report does not, however, fully evaluate the likelihood of the referenced events, and therefore does not meet the requirement of a risk assessment. The Australian measure therefore violated both art. 5.1 (failure to make an appropriate risk assessment) and art. 2.2 (failure to base measure on scientific principles) of the SPS Agreement as to ocean-caught Pacific salmon.

The Appellate Body then turned to consideration of whether Australia’s measures constituted arbitrary or unjustifiable distinctions in levels of protection, resulting in discrimination or a disguised restriction on international trade, in violation of art. 5.5 of the SPS Agreement. The Appellate Body first agreed with the panel that circumstances are comparable if they involve either the risk of entry, establishment or spread of the same or a similar disease, or similar biological or economic consequences. It was therefore able to accept the panel’s comparison of measures relating to other types of fish for purposes of art. 5.5. The panel had found at least as high a risk, if not a higher degree of risk, relating to herring used as bait and ornamental finfish, which were subject to more lenient sanitary measures, and the Appellate Body agreed.

318 SPS Agreement, Annex A, para. 4.
319 Appellate Body Report, para. 124.
321 Appellate Body Report, para. 146.
Finally, the Appellate Body evaluated the panel’s determination that these distinctions result in discrimination or a disguised restriction on international trade. The panel had engaged in a relatively inchoate analysis, identifying “warning signals” as well as several more substantial “additional factors.” The Appellate Body focused on the panel’s finding that the change in recommendations from the 1995 Draft Report to the 1996 Final Report were unexplained, and involved a shift from a recommendation to permit entry of salmon under certain circumstances. The Appellate Body also considered the fact the panel’s surmise that internal controls within Australia did not contain as high a level of protection as the import prohibition at issue here. While this did not carry much weight, the Appellate Body agreed with the panel that it could be considered. The Appellate Body finally affirmed the panel’s conclusion that the distinctions in the levels of protection imposed by Australia result in disguised restriction on international trade, in violation of art. 5.5, and by implication, art. 2.3 of the SPS Agreement.323

Here, it is noteworthy that the Appellate Body did not engage in the same kind of analysis it used in the Shrimp case, seeking the “equilibrium line” in order to make a similar determination under the *chapeau* of art. XX of GATT. The language of art. 5.5 of the SPS Agreement is, of course, based on the *chapeau*. While these are of course distinct provisions in formally separate agreements, the use of similar language would seem to evidence an intent to invoke a similar analysis.324 In the Shrimp decision, the Appellate Body set up a kind of balancing test which varies substantially from the analysis in the present decision.325

The Appellate Body turned next to the question of whether the Australian measure violated art. 5.6 of the SPS Agreement, by virtue of the fact that it is more trade restrictive than required, meaning, pursuant to the footnote to art. 5.6, that there is another measure that is reasonably available, that achieves Australia’s appropriate level of protection and that is significantly less trade restrictive. The panel had referred to the 1996 Final Report for analyses of the various policy options that were available to Australia. The panel had found that all four of the alternatives evaluated in the 1996 Final Report seemed to meet these criteria.

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323 Appellate Body Report, para. 177.
324 As the Appellate Body recognized in paras. 251-255 of its Report. Interestingly, there the Appellate Body found that it could not determine whether the import prohibition constitutes an arbitrary or unjustifiable discrimination within the meaning of art. 2.3.
compared to the measure that the panel considered: heat treatment. However, the Appellate Body had already determined that this was not the correct measure to consider, but that the prohibition on imports was the correct measure. Therefore the Appellate Body rejected the panel’s decision and engaged in its own analysis.

For Australia’s appropriate level of protection, the Appellate Body looked not to the prohibition on imports as the panel had, because that would imply a zero-risk level of protection, whereas Australia had consistently stated that it sought to reduce risk to “very low levels.” Thus, the Appellate Body left it to Australia to define its own level of risk, but took it at its word. The test is then not that applied by the panel, to determine whether alternatives could implement the level of risk currently enjoyed by Australia, but to determine whether the alternatives could implement the level of risk sought to be achieved by Australia: a lower threshold in this case. The Appellate Body found that the SPS Agreement thus contains an implicit obligation to set an appropriate level of protection. While the Appellate Body found that Australia had done so, it found that it could not, based on the 1996 Final Report, verify whether any of the alternative measures would achieve that level. On this basis, the Appellate Body found that it could not come to a conclusion that Australia violated art. 5.6 of the SPS Agreement. The lack of a right of remand results in rough justice indeed. Interestingly, the Appellate Body raised and discarded the possibility that Canada had raised a presumption of violation by Australia. Given the problem of the panel’s failure to develop needed facts, the allocation of the burden of proof becomes critical.

Canada had appealed from the panel’s determination not to make any findings regarding arts. 5.5 and 5.6 with respect to Canadian salmon other than ocean-caught Pacific salmon. The panel’s reasoning brings to mind the joke about the drunk searching for his car keys under a street lamp, because the light is better there, despite the fact that he had lost the keys across the street: the panel stated that most of the reports before it only related to ocean-caught Pacific salmon. The panel justified this method by reference to judicial economy.

The Appellate Body disagreed with the panel, finding this false judicial economy:

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326 Appellate Body Report, paras. 197-199.
328 Appellate Body Report, para. 211.
329 Panel Report, para. 8.60.
In this case, for the Panel to make findings concerning violation of Article 5.1 with respect to other Canadian salmon, without also making findings under Articles 5.5 and 5.6, would not enable the DSB to make sufficiently precise recommendations and rulings so as to allow for compliance by Australia with its obligations under the SPS Agreement, in order to ensure the effective resolution of this dispute with Canada. An SPS Measure which is brought into consistency with Article 5.1 may still be inconsistent with either Article 5.5 or Article 5.6, or with both.  

The Appellate Body continued to apply art. 5.5 to the case of other Canadian salmon. It found that Australia’s statements regarding its appropriate level of protection, seeking to reduce risk to very low levels for ocean-caught salmon, apply to all salmon. It therefore found that the same analysis that applied to ocean-caught salmon under art. 5.5 also applied to other salmon. For similar reasons, the Appellate Body found that its conclusion as to art. 5.6 was the same for other salmon as for ocean-caught salmon.

4. Conclusions

This second case regarding the SPS Agreement, after the celebrated *Hormones* case, continues to work out the degree of discipline to be imposed on states as they engage in sanitary and phytosanitary regulation, including the degree of scientific backing and rationality to be required of states under that agreement.

This division of the Appellate Body avoided using the rather innovative “balancing test” devised by the division that decided the *Shrimp* case to interpret the *chapeau* of art. XX of GATT, despite the similar language in art. 2.3 of the SPS Agreement. It will be instructive to observe how future Appellate Body decisions deal with this problem.

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WORLD TRADE ORGANIZATION
WT/DS26/28

EUROPEAN COMMUNITIES – MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

Joint Communication from the European Communities and the United States

The following communication, dated 25 September 2009, from the delegations of the European Communities and the United States to the Chairperson of the Dispute Settlement Body, is circulated at the request of those delegations.

Please find attached a Memorandum of Understanding regarding the importation of beef from animals not treated with certain growth-promoting hormones and increased duties applied by the United States to certain products of the European Communities, agreed between the United States and the European Communities on 13 May 2009, in relation to the dispute European Communities – Measures Concerning Meat and Meat Products (Hormones) (DS26).

We would be grateful if this Memorandum of Understanding could be circulated to the Dispute Settlement Body.

For the European Communities:

Eckart Guth
Ambassador
Permanent Representative of the European Commission

For the United States:

David Shark
Chargé d'Affaires, a.i.
Permanent Mission of the United States of America
MEMORANDUM OF UNDERSTANDING BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMISSION REGARDING THE IMPORTATION OF BEEF FROM ANIMALS NOT TREATED WITH CERTAIN GROWTH-PROMOTING HORMONES AND INCREASED DUTIES APPLIED BY THE UNITED STATES TO CERTAIN PRODUCTS OF THE EUROPEAN COMMUNITIES

The United States of America ("United States") and the European Commission ("the Commission") have reached an understanding, as documented in this Memorandum of Understanding ("Understanding"), regarding the importation of High Quality Beef into the European Communities ("EC") and the level of increased duties applied by the United States to certain EC products in connection with the World Trade Organization ("WTO") dispute EC – Measures Concerning Meat and Meat Products (Hormones) (DS 26).

The United States and the Commission commit to the terms and obligations set forth in the attached Annex. Following implementation of the obligations set forth in Article II.1 and Article II.3 of the Annex, the United States and the EC will notify this Understanding to the Dispute Settlement Body ("DSB").

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA

FOR THE EUROPEAN COMMISSION
ANNEX

ARTICLE I PURPOSE AND OBJECTIVES

With this Understanding, the United States and the EC intend to achieve the following objectives:

1. To provide, in a first phase ("Phase 1"), for temporary and partial:
   (a) Expansion by the EC of market access for High Quality Beef and
   (b) Reduction in the level of increased duties applied by the United States to certain EC products authorized by the WTO in 1999 (the "increased duties")

in order for the Parties to gain experience in additional trade in High Quality Beef and facilitate a transition to long-term conditions;

2. To provide the opportunity to move to a second phase ("Phase 2"), for:
   (a) Further expansion by the EC of market access for High Quality Beef and
   (b) Reduction to zero of the increased duties

in order for the Parties to gain experience in additional expanded trade in High Quality Beef and facilitate a transition to long-term conditions; and

3. To provide the further opportunity for entering into a third phase ("Phase 3") with regard to the WTO dispute between the Parties, EC – Measures Concerning Meat and Meat Products (Hormones).

ARTICLE II CORE OBLIGATIONS

1. At the beginning of Phase 1, the EC will establish an autonomous tariff rate quota for High Quality Beef of an annual quantity of 20,000 Metric Tonnes product weight, and for which the in-quota tariff rate is zero (0) per cent.

2. The EC will open the autonomous tariff rate quota referred to in paragraph 1 by 3 August 2009.

3. With respect to the increased duties, the United States will not add to scope, change the origin of products subject to increased duties or increase the level of such duties as in force as of 23 March 2009.

4. Should the United States and the EC enter into Phase 2, as described in Article I.2, and negotiated under Article IV.2:
(a) The EC will increase the quantity of the autonomous tariff rate quota referred to in paragraph 1 to 45,000 Metric Tonnes product weight and
(b) The United States will suspend all increased duties imposed in connection with WTO dispute settlement proceedings in EC – Measures Concerning Meat and Meat Products (Hormones).

5. Should the United States and the EC enter into Phase 3, as described in Article I.3, and negotiated under Article IV.3:
(a) The EC will maintain the quantity of the autonomous tariff rate quota referred to in paragraph 1, at the level specified in paragraph 4(a) and
(b) The United States will cease the increased duties imposed in connection with WTO dispute settlement proceedings in EC – Measures Concerning Meat and Meat Products (Hormones).

ARTICLE III
QUOTA MANAGEMENT

1. The Parties agree that the tariff rate quota referred to in Article II will be administered by the Commission in accordance with the rules applied for similar import tariff rate quotas for agricultural products managed by a system of import licenses.
2. The Commission will implement and administer the tariff rate quota set out in this Understanding in accordance with Article XIII of the General Agreement on Tariffs and Trade (GATT) 1994, including its interpretative notes, and the Import Licensing Agreement. The Commission will make every effort to administer the tariff rate quota referred to in Article II in a manner that allows importers to fully utilize it.

ARTICLE IV
MONITORING AND CONSULTATIONS

1. The United States and the EC will:
(a) Monitor and review the operation of this Understanding and,
(b) Upon the request of either Party, conduct additional bilateral consultations regarding the operation of this Understanding, including issues of quota management, not later than thirty (30) days following the receipt of the request in writing for consultations.

2. The United States and the EC will, beginning not later than eighteen (18) months from the date specified in Article II.2, meet to review the operation of Phase 1 with a view to entering into Phase 2.
3. Should the United States and the EC enter into Phase 2, the United States and the EC will, beginning not later than six (6) months from the date on which the EC implements the obligation set out in Article II.4(a), meet to review the operation of Phase 2 with a view to entering into Phase 3. This review will notably cover, inter alia, the following issues:

(a) The duration of Phase 3,
(b) The status and effects of the Understanding relative to the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU),
(c) The consequences of non-compliance with the terms of the Understanding by either Party, and
(d) The status and disposition of any dispute settlement proceeding in EC – Measures Concerning Meat and Meat Products (Hormones), including the continuing non-disclosure of any interim report as referred to in Article VII.2.

4. After concluding the review referred to in paragraph 3, if the Parties agree on conditions for entering into Phase 3, the Parties may, by applying the procedure set out in Article V.5, amend the Understanding in order to reflect the agreed conclusions of that review. Such an amendment will not alter the core obligations as referred to in Article II.5.

ARTICLE V
DURATION, WITHDRAWAL AND AMENDMENT

1. Phase 1 will have a duration of three (3) years from the date specified in Article II.2.
2. Should the Parties enter into Phase 2, Phase 2 will have a duration of one (1) year from the date the Parties enter into Phase 2.
3. If no agreement as referred to in Article IV.4 can be reached by the end of Phase 2, the Understanding will be considered terminated, unless the Parties agree otherwise. During a period of six (6) months following such termination of the Understanding, the core obligations as defined in Article II.4 will be maintained by both Parties.
4. Either the United States or the EC may withdraw from this Understanding by providing written notice to the other Party. Should either Party provide such written notice, this Understanding shall expire six (6) months from the date such notice was provided. Should both Parties provide such written notice, this Agreement shall expire six (6) months from the earliest of the dates on which such notice was provided. During this six (6) month period, the core obligations, as defined in Article II, applicable at the time of the provision of the withdrawal notice, will be maintained by both Parties.
5. The United States and the EC may amend this Understanding by mutual agreement in writing.
ARTICLE VI
DEFINITIONS

For the purposes of this Understanding, "High Quality Beef" means:
"Beef cuts obtained from carcasses of heifers and steers less than 30 months of age which have only been fed a diet, for at least the last 100 days before slaughter, containing not less than 62 percent of concentrates and/or feed grain co-products on a dietary dry matter basis that meet or exceed a metabolisable energy (ME) content greater than 12.26 megajoules (MJ) per one kilogram of dry matter. The heifers and steers fed this diet shall be fed, on average, not less than 1.4 percent of live body weight per day on a dry matter basis.
The carcass from which beef cuts are derived shall be evaluated by an evaluator employed by the national government who bases the evaluation, and a resulting classification of the carcass, on a method approved by the national government. The national government evaluation method, and its classifications, must evaluate expected carcass quality using a combination of carcass maturity and palatability traits of the beef cuts. Such an evaluation method of the carcass shall include, but not be limited to, an evaluation of the maturity characteristics of color and texture of the longissimus dorsi muscle and bone and cartilage ossification, as well as an evaluation of expected palatability traits including a combination of the discrete specifications of intramuscular fat and firmness of the longissimus dorsi muscle.
The cuts shall be labeled in accordance with Article 13 of Regulation (EC) No. 1760/2000. The indication 'High Quality Beef' may be added to the information on the label."

ARTICLE VII
RESERVATION OF RIGHTS

1. Neither Party will request the establishment of a panel under Article 21.5 of the DSU in EC – Measures Concerning Meat and Meat Products (Hormones) before expiry of eighteen (18) months following the date referred to in Article II.2 or the opening of the tariff rate quota referred to in Article II.1, whichever occurs later.
2. If a panel is established under Article 21.5 of the DSU in EC – Measures Concerning Meat and Meat Products (Hormones), the Parties will work together to ensure that:
(a) The interim report is not issued and
(b) The authority of the panel does not lapse due to the expiry of the period referred to in Article 12.12 of the DSU

before the end of Phase 1 if the Parties do not withdraw from Phase 1 before its conclusion, or Phase 2, if the Parties should enter into Phase 2 and do not withdraw from Phase 2 before its conclusion. The Parties agree to take the steps that may be necessary to achieve those objectives.
Without limiting the foregoing, the Parties agree to jointly request the panel to include in its Working Procedures that the
panel will provide notice to the Parties five (5) weeks before issuing the interim report; and the Parties agree that if the date of issuance of the interim report is during Phase 1 or Phase 2, the Parties will request the panel to suspend its proceeding.

1. Neither this Understanding nor the Parties’ taking of any of the steps contemplated by this Understanding prejudices the disagreement between the Parties regarding whether the DSB recommendations and rulings in EC – Measures Concerning Meat and Meat Products (Hormones) have been implemented.

2. Other than as specifically set forth herein, this Understanding is without prejudice to the rights and obligations of the United States and the EC under the WTO agreements.
Non-Adjudicative Solution

From Control to Communication: Science, Philosophy and World Trade Law
(by Sungjoon Cho)

Abstract

Science has recently become increasingly salient in various fields of international law. In particular, the WTO Sanitary and Phytosanitary (SPS) Agreement stipulates that a regulating state must provide scientific justification for its food safety measures. Paradoxically, however, this ostensibly neutral reference to science tends to complicate treaty interpretation. It tends to take treaty interpretation beyond a conventional methodology under the Vienna Convention on the Law of Treaties, which is primarily concerned with clarifying and articulating the treaty text. The two decades old transatlantic trade dispute over hormone-treated beef is a case in point. This article demonstrates that beneath the controversy between the United States and the European Union on the safety of hormone-treated beef lurks a critical hermeneutical divergence on the scope and meaning of relevant risk science, which a conventional model of international adjudication cannot fully fathom. The article is a philosophical retelling of what has been regarded largely as a legal-regulatory controversy. Informed by the philosophical hermeneutics, the article concludes that only a continuing dialogue or communication between disputing parties concerned can narrow down the hermeneutical discrepancy on risk science.

(...) 

IV. Applying Philosophical Insights to International Law of Risk Regulation

A. From Control to Communication

Philosophical insights shed critical light not only on the futility of the judicialization of science but also on the hitherto lack of genuine mutual understanding in the transatlantic dispute over the hormone-treated beef. Note that understanding is “party-dependent.” 331 The U.S. should have realized that the EU’s understanding on risk science is grounded in the EU’s own history or context (“horizon”) as much as the U.S.’ understanding on the same subject is driven by the U.S.’ own horizon. Because a party’s original horizon prevents itself from recognizing the other’s horizon and its undistorted image, it is only through the “patient identification and undoing of those facets of our implicit understanding that distort the reality of the other”332 that one can truly understand, and reconcile with, the other. Only in this open-mindedness, which is often compared to

331 Taylor, supra note __, at 127.
332 Id., at 132.
“conversation,” can one party voluntarily accept some position which may be even against itself. A dialogue partner can question our assumptions which we could not doubt on our own but which we should nonetheless rethink to reach our own understanding. Only with this dialogue or conversation can different horizons be “fused,” followed by a true understanding of the other. In sum, Gadamer’s hermeneutical openness urges an interpreter to endeavor to fuse her own horizon with that of other party’s horizon to extract meanings, namely to “understand.”

Applying this theory of philosophical hermeneutics to risk regulation within the meaning of the WTO, one can embrace two different subjects of understanding: facts and norms. For example, an exporting country may interpret an importing country’s regulation to protect human health, such as a ban on hormone-treated beef. Then, the same member is positioned to interpret relevant WTO texts related to risk regulations, such as the SPS Agreement, in tandem with its previous interpretation on the facts. These two subjects are often enmeshed in practical interpretive situations.

Here, the critical hermeneutical error which the exporting country might commit is its impulsion for “control” over the dogmatic struggle with its trading partner via a manipulative application of scientific methodologies, which might border on “myths,” not science in its true meaning. In many cases, “a tremendous leap from a tiny amount of data” may still appear to be scientific. Blind faith in a particular set of laboratory data when evaluating a trading partner’s risk regulation would not lead to any genuine scientific understanding, especially when scientists fail to agree on critical scientific issues. Likewise, if the WTO court plays a Dworkinian Hercules by subscribing to a certain paradigm of science and imposes it on a losing party, the court tends to disregard that party’s unique regulatory context. Naturally, the losing party is likely to perceive such interpretation as flawed and illegitimate.

The essential lesson from the philosophy of hermeneutics – as it is related to risk science in the WTO – is an unyielding interpretive openness through “a

333 Id., at 134.
334 TRUTH AND METHOD, supra note _, at 361. As in the principle of Socratic dialogue, every conversation (dialogue) should start from the point of the “docta ignorantia” which is to acknowledge the original ignorance as well as fallibility. Van Niekerk, supra note _, at 234.
336 TRUTH AND METHOD, supra note _, at 306.
338 Feldman, supra note _, at 145.
339 Cho, World Trade Court’s Burden, supra note _, at 710 (“[T]he Court’s judicialization of science may become ‘political’. Under these circumstances, the Court’s exercise of its interpretive burden over the BOP tends to erode its legitimacy by inviting more, not less, politics from the parties concerned.”).
340 See Axel Honneth, On the Destructive Power of the Third: Gadamer and
lessening of distance”341 between an interpreter and an interpretandum, anchored by a firm acknowledgement of the inevitable finitude of human experience.342 After all, the truth can emerge only “in a conversation.”343 Nor does there exist a final, definite answer when it comes to understanding (truth). Truth only exists, or operates, continuously in the “hermeneutical circle”344 between the interpreter and the interpretandum. In other words, the interpreter should continue to ask, and refine, questions until he or she is satisfied, that is to say until the interpreter’s horizon is fused with that of the others. This is why American regulators would not understand, in a genuine manner, the European ban on the hormone-treated beef until they actually reach out to their European counterpart and fully appreciate the “phenomenon itself in its unique and historical concreteness.”345

One may locate this hermeneutical circle in a regulatory dialogue within the context of the SPS Agreement. Mutual understanding is possible when such a dialogue changes either party or both parties participating in the dialogue. This dialectic is not about one party forcing the other party to accept the former’s original position. Rather, hermeneutical convergence can occur when a dialogue induces the modification of an original position of either or both parties in the form of mutual understanding. The following table may illustrate this dialectic change under the stylized settings of regulatory dialogue.

[Table 3: Two Possible Hermeneutic Circles for Hermeneutical Convergence]

| 1. A₀ → (B₀ → B₁) → A₀ → (B₁ → B₂) → ... |
| 2. A₀ → B₀ → (A₀ → A₁) → (B₀ → B₁) → ... |

Suppose that A is an exporting country which raises an inquiry on B, an importing (regulating) country, regarding B’s sanitary measure. A₀ is A’s original position on risk science (risk assessment) according to which B’s sanitary measure is without scientific justification. B₀ is B’s original position on risk science according to which its measure is scientifically justified. Under the first

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341 Honneth, supra note —, at 5.
342 Schmidt, supra note —, at 440.
343 Id., at 434
344 “Understanding is (...) a circular movement in which the understanding of the meaning of new chapters of the book proceeds on the basis of the understanding the interpreter has constructed of the meaning and unity of the previous chapters, while at the same time, his or her understanding of the new chapter may require revising the understanding of those previous parts.” Warnke, supra note —, at 409.
345 Schmidt, supra note —, at 436; TRUTH AND METHOD, supra note —, at 6.
scenario, A demands from B scientific justification behind B’s measure. In the course of preparing for answers to A’s inquiry, B may seek to discover the context of A’s inquiry, such as A’s motivation, background, culture and interest. Such discovery tends to make B better understand Ao. Then, B may want to voluntarily modify its original position (Bo→B1) to accommodate Ao. This process may continue multiple times until B’s policy change truly gets fused with A’s original position (Ao).

Under the second scenario, the modification of original positions is reciprocal. In the course of reason-giving and reason-receiving, both parties embrace opportunities to change their original positions (Ao→A1 and Bo→B1). After multiple loops of such regulatory dialogue, both parties may reach mutual understanding with their mutually changed positions. In other words, as the number of loops or interactions (n) increase, their hermeneutical discrepancy (Bn-An) tends to shrink toward zero. Between these two highly simplified yet non-exhausted scenarios, one might reasonably speculate that the second scenario might signify a better chance for mutual understanding in that the probability of closing the hermeneutical gap (Bn-An) appears higher here than the first scenario.

B. Some Policy Suggestions

Philosophical discussions on hermeneutics have important ramifications on the current debate on international trade and risk science. At present, there is little shared understanding among WTO members on the very meaning of science or scientific justification as to the health risks of various food additives or other food modification technologies. Given this situation, any impulsive legal-regulatory attempt in the international level to impose a specific paradigm of science in a specific trade dispute is likely to invite more disputes, rather than resolving them. In this regard, the theory of philosophical hermeneutics tends to offer some practical suggestions.

First, disputing parties should restrain their temptation to jump to WTO litigation over those disputes which involve different paradigms of science. A losing party would find it difficult to tolerate a decision which goes against its socio-cultural fundamental (horizon). Adjudicating these cases is likely to produce wrong cases and only cost the WTO its efficacy and legitimacy. Therefore, parties should engage more in dialogue on the root issues through various institutionalized avenues under the WTO, such as consultations, SPS committee and other peer review forums (e.g., the Trade Policy Review Mechanism (TPRM)). In this line, the constructive resolution of a recent trade dispute involving genetically modified (GM) products between the EU and

346 See supra note _.
347 This dialogue is not limited to regulators. Through a dialogue, scientists may narrow their own epistemic gap in evaluating scientific theories and data. See Douglas Crawford-Brown et al., Environmental Risk, Precaution, and Scientific Rationality in the Context of WTO/NAFTA Trade Rules, 24 Risk Analysis 461, 468 (2004) (observing that risk science should be located in the “dialogue” among scientists regarding “how to judge data and theories, how to weight lines of evidence, and how to balance these considerations in a judgment of epistemic status and in a depiction of the uncertainty in risk estimates”).
Canada was hermeneutically sound, especially given that both parties established an avenue for continuing dialogue.348

Notably, an increasing number of SPS disputes have recently been resolved under the SPS Committee. Nearly thirty percent of “specific trade concerns” reported to the SPS Committee were addressed by discussions and consultations under the Committee process.349 Although those specific trade concerns handled in the SPS Committee may or may not involve controversies related directly to different paradigms of risk science, this extra-judicial peer review mechanism still offers an operable avenue for regulatory dialogue over risk science.

### [Table 4: Specific Trade Concerns: Resolved Issues (1995-2008)]

<table>
<thead>
<tr>
<th>Sector</th>
<th>Total Number of Concerns Resolved</th>
<th>Regulating (Importing) States</th>
<th>Complaining (Exporting) States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Health</td>
<td>41</td>
<td>Argentina, Australia, Austria, Belgium, Bolivia, Brazil, Canada, Chile, China, Columbia, Cuba, Czech Rep., El Salvador, France, Germany, Iceland, Indonesia, Israel, Hungary, Italy, Netherland, Norway, Poland, Romania, Singapore, Slovak Rep., Slovenia, Spain, Taiwan, Turkey, U.S., Venezuela, Argentina, Brazil, Canada, Chile, EC, Hungary, India, Panama, Switzerland, Uruguay, U.S.</td>
<td></td>
</tr>
</tbody>
</table>

Australia, China, Argentina,

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349 WTO Committee on Sanitary and Phytosanitary Measures, Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures, G/SPS/36, Jul. 11, 2005. See also Sungjoon Cho, The WTO’s Gemeinschaft, 56 ALA. L. REV. 483, 537-38 (2004) (noting that an SPS dispute between Canada and Brazil regarding the former’s ban on the latter’s export of beef for the fear of the BSE (Mad Cow diseases) was resolved under the SPS Committee process by adopting a revised “Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7)”; Lang & Scott, supra note __, at 592-95 (introducing several SPS disputes which were addressed under the SPS Committee’s peer review (“Specific Trade Concerns”) process).
| **Food Safety** | 20 | Czech Rep., EC, Korea, Malaysia, New Zealand, Philippines, Poland, Singapore, Spain, Switzerland, | Australia, Bolivia, Brazil, Canada, EC, Gambia, India, Indonesia, Philippines, Senegal, Sri Lanka, Switzerland, Thailand, U.S., |
| **Plant Health** | 24 | Australia, Brazil, China, EC, Honduras, Indonesia, Japan, Korea, Mexico, New Zealand, Panama, Slovak Rep. Switzerland, Taiwan, Turkey, U.S., | Argentina, Brazil, Canada, Chile, EC, Ecuador, Hungary, New Zealand, Poland, Thailand, U.S., |

(Source: WTO, SPS Committee)\(^\text{350}\)

Even if the WTO court eventually adjudicates these kinds of disputes due to the absence of a judiciability doctrine, it should focus on those tasks which the judicial system is well suited to address.\(^\text{351}\) One conceivable option is for the WTO court to adjust its hermeneutical focus to “procedural” obligations, such as reason-giving, transparency and notification, which mandate dialogue and communication between concerned parties. These procedural obligations enable regulating states to reach out to certain “omitted voices,”\(^\text{352}\) such as foreign governments and producers, and get access to the latter’s regulatory context (horizon). In an effort to facilitate this kind of communication between regulating states and those affected by such regulations, the WTO court may accord certain probative value to the regulating state’s undertaking of these procedural obligations. In other words, whether the regulating state discharged the burden of proof as to its “substantive” requirement, such as the existence of a “rational relationship” between a risk assessment and the final regulation, may depend on whether the same state performed those procedural obligations.\(^\text{353}\) The underlying logic beneath this probative incentive is that any risk regulation adopted without a hermeneutical empathy tends to lack its rational (scientific) basis. Perhaps such flawed regulations may be protectionist or pseudo-scientific measures. In fact, this procedural-substantive nexus is not new. As is seen in

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\(^{350}\) WTO, Committee on Sanitary and Phytosanitary Measures, Specific Trade Concerns: Resolved Issues, G/SPS/GEN/204/Rev.9/Add.3, Feb. 6, 2009.

\(^{351}\) Feldman, *supra* note _, at 167.


\(^{353}\) Cho, *World Trade Court’s Burden, supra* note _, at 717-18 (discussing a “Copernican turn” of shifting from “substantive finality” to “procedural legitimacy”).
other courts, certain procedural deficiencies are often linked to substantive violations.\textsuperscript{354}

For example, under the SPS Agreement an exporting state may ask to an importing (regulating) state about “the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation.”\textsuperscript{355} If the regulating state fails or neglects to respond to the inquirer in this situation, such failure or neglect may generate a plausible suspicion that the regulating state in fact lacks a risk assessment which would scientifically justify the regulation in question. At this juncture, the burden of proving that the regulating state nonetheless complied with the risk assessment requirement (SPS Article 5.1) may be shifted to the defendant (regulating state). Under the SPS Agreement, one might locate several possibilities of such a nexus between procedural and substantive obligations. In each nexus, a regulating state’s failure to fulfil a certain procedural obligation may militate against discharging the burden of proving that the state has complied with a correspondent substantive (material) obligation.

\begin{table}[h]
\centering
\begin{tabular}{|p{7cm}|p{7cm}|}
\hline
\textbf{Procedural Obligations} & \textbf{Substantive Obligations} \\
\hline
\textbf{Article 3.4} (requiring members to engage in serious dialogue on international standards); \textbf{Article 5.8} (requiring a member deviating from international standards to answer an exporting country’s inquiries) & \textbf{Article 3.1} (requiring members to base their SPS measures on relevant international standards) \\
\hline
\textbf{Article 5.8} (requiring a member deviating from international standards to answer an exporting country’s inquiries); \textbf{Article 7} (requiring members to notify information on their SPS measures) & \textbf{Article 5.1} (requiring the existence of a rational relationship between a risk assessment and an SPS measure) \\
\hline
\textbf{Article 5.8} (requiring a member deviating from international standards to answer an exporting country’s inquiries); \textbf{Article 7} (requiring members to notify information on their SPS measures) & \textbf{Article 5.4} (requiring members to take into account the goal of minimizing negative trade effects); \textbf{Article 5.5} (requiring members to maintain consistency in determining the \\
\hline
\end{tabular}
\caption{Matching Procedural Obligations with Substantive Obligations under the SPS Agreement}
\end{table}

\textsuperscript{354} Under some jurisdictions, a procedural failure (such as the absence of notification) may lead to disapplication of an underlying (substantive) measure. See e.g., Case C-194/94, CIA Security International SA v Signalson SA and Securitel SPRL, [1996] ECR I-2201 (ruling that a domestic court should disapply a technical regulation if a Member has failed to notify such regulation to the European Commission under Directive 83/189).

\textsuperscript{355} SPS Agreement, \textit{supra} note _, Annex B, ¶15(b).
Finally, WTO members, in and out of the WTO context, should seriously seek to “educate” the public as to the risk science on specific trade issues. This education and social marketing will raise awareness and literacy among consumers and policymakers on key issues on science and human health, which will in turn facilitate risk communication among the concerned parties. Once regulators, regulatees and affected parties (consumers) are placed in the same hermeneutical circle, we may expect some kind of hermeneutical convergence in which the Gadamerian fusion of horizons transpires. Until then, we might have to get accustomed to the twilight zone of science.\textsuperscript{356}

In conclusion, the WTO court’s interpretive refocusing on procedural disciplines not only enhances the legitimacy of its decision but also helps parties reach mutually acceptable regulatory settlement through continuing regulatory cooperation. As the WTO Dispute Settlement Understanding advises, parties themselves should think hard about whether using the WTO dispute settlement system would be really “fruitful” before they file the complaint.\textsuperscript{357}

\textsuperscript{356} The EU’s new policy on genetically modified (GM) foods, which is coined “technical pluralism,” seems to be based on this position. It permits the “co-existence” of GM and non-GM supply chains. See generally Justo Corti Varela, \textit{The EU “Coexistence” Policy under WTO Law: Problems and Solutions}, Conference Paper presented to the ESIL-ASIL Research Forum (“Changing Futures?: Science and International Law), Oct. 2009 (on file with the author).

\textsuperscript{357} WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the WTO Agreement, \textit{supra} note _, art. 3.7 (“Before bringing a case, a Member shall exercise its judgement as to whether action under these procedures would be fruitful.”).