

INTERNATIONAL AND REGIONAL TRADE LAW:
THE LAW OF THE WORLD TRADE ORGANIZATION



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**Unit X: Sanitary and Phytosanitary Measures
(SPS)**

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

Unit X: Sanitary and Phytosanitary Measures (SPS)

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Supplementary Reading

Peter van den Bossche & Werner Zdouc, The Law and Policy of the World Trade Organization, 3rd ed. 2013, 894-949.

Michael J. Trebilcock, Robert Howse, & Antonia Eliason, The Regulation of International Trade, 4th ed. 2005, 293-308.

John H. Jackson, William J. Davey, Alan O. Sykes, International Economic Relations: Cases, Materials and Text on the National and International Regulation of Transnational Economic Relations, 6th ed. 2013, 703-721.

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 The WTO superseded the GATT as the umbrella organization for international trade.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.

(...)

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...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.

1-2. Legal Text

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:

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

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

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 5.² 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 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.

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.

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 should, 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
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

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 significantly less restrictive to trade.

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.

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
DEFINITIONS⁴

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;
 - (c) 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

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.

- (d) 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 regulations⁵ which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

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

⁵ Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

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 nationals⁶ 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 proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

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.

- (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 PROCEDURES⁷

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

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 (EC—Hormones)

This Section follows several episodes in the longstanding EC—Hormones dispute, between the United States and the European Communities: the initial Panel Report, the Appellate Body Report, and a subsequent Appellate Body Report on a complaint by the EC against the US regarding the latter's refusal to remove retaliatory measures against the EC for its alleged refusal to implement the initial Appellate Body Judgment in Hormones (US—Continued Suspension). As you read through the cases, consider the following questions carefully:

- *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?*
- *Why might the AB have overruled the panel on the procedural requirements for adopting an SPS measure? Work out for yourself what the AB meant by "rational relationship." How might one argue in favour of the panel's approach? And the AB's?*
- *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

2.1. This dispute concerns EC measures, in particular Council Directive 81/602/EEC ("Directive 81/602/EEC"), Council Directive 88/146/EEC ("Directive 88/146/EEC") ...

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-17 β , 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-17 β , progesterone and testosterone (hereafter also referred to as natural hormones). Oestradiol-17 β 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-17 β ; and MGA mimics progesterone.

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

(...)

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 dethylstilboestrol, 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 Lamming Report concluded as follows:

"The Scientific Working Group is of the opinion that the use of oestradiol-17 β , 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[, the EC Scientific Committee for animal Nutrition and the EC Scientific Committee for Food] ... 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 ... [On 12 June 1984, the Commission proposed a Council Directive] which envisaged the controlled use of the three natural hormones for growth promotion purposes and proposed re-examining the ban on the two synthetic hormones after their scientific evaluation had been completed. 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 ... The essential findings of the Pimenta Report were that the prohibition on hormonal substances for non-therapeutic (i.e. growth-promoting) purposes must be maintained and expanded because:

(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."

(...)

VIII. FINDINGS

(...)

D. THE SPS AGREEMENT

(...)

8.43 The United States claims violations of Articles 2, 3 and 5 of the SPS Agreement. Article 2 elaborates on the basic rights and obligations of Members under the SPS Agreement. Article 3 deals, more specifically, with the objective of harmonization of sanitary measures on the basis of international standards, guidelines, and recommendations. Article 5 deals, in turn, with the

obligation of risk assessment and the determination and application by Members of their appropriate level of sanitary protection.

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).

(...)

8.54 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-17 β* , *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, *zeranone* and *trenbolone* (classified by Codex as "veterinary drugs"), the following Codex standards apply: an ADI of 0-0.5 and 0-0.02 $\mu\text{g}/\text{kg}$ body weight, respectively, and an MRL of 2 $\mu\text{g}/\text{kg}$ β -trenbolone in bovine muscle and 10 $\mu\text{g}/\text{kg}$ α -trenbolone in bovine liver.

(...)

(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. ... ([A] maximum level of such residues has not been prescribed; this level is hereafter referred to as an "unlimited residue level"). 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-17 β* , *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-17 β , 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.

(...)

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

8.79 The fact that the EC measures for oestradiol-17 β , 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).

(b) Burden of proof

(...)

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, *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.

(...)

8.100 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

(...)

8.111 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 [in the scientific studies before the Panel], 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.

(...)

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 [further] argues that it has based its ban on the existence of the following categories of risks related to the hormones at issue: ... (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.

(...)

8.143 ... [W]ith 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 ... [W]e 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.

(...)

8.154 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.

(...)

(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).

(...)

8.171 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.

(...)

8.184 We consider the reasoning in both Appellate Body Reports [*Japan—Alcoholic Beverages* and *US—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 the *natural hormones in dispute as opposed to that of the synthetic hormones at issue*. In a third 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-17 β , 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

(...)

8.193 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.

(...)

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 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.

(...)

8.203 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.

(...)

8.205 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-17 β 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-17 β 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.

(...)

8.212 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). ...

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"

(...)

8.216 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.

(...)

8.218 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.

1. *Comparable situations with different levels of sanitary protection*

(...)

8.225 We note that the European Communities allows the use of carbadox as a growth promoter in pigs and has not set any MRL for that substance. The European Communities thus, in principle, accepts an unlimited residue level of these substances in pork meat. ...

8.226 We thus find that the level of protection adopted by the European Communities for the hormones at issue when used for growth promotion purposes as opposed to that adopted for carbadox is different (a "no residue" level as opposed to an unlimited residue level) ...

(...)

3. *Difference which results in “discrimination or a disguised restriction on international trade”*

(...)

8.241 In this case we note, firstly, the significance of the difference in levels of protection for the five hormones at issue when used as growth hormones and carbadox, 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 these five hormones at issue) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for the five hormones at issue when used as growth promoters and carbadox, results in “discrimination or a disguised restriction on international trade” in the sense of Article 5.5.

(...)

8.244 We [further] find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for ... [the hormones at issue] when used as growth promoters and carbadox, in light of the three elements contained 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.

(...)

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.

2-2. *Appellate Body Report, WT/DS26, 48/AB/R, 16 January 1998*

Feliciano, Presiding Member, Ehlermann, Member, Matsushita, Member

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

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

(...)

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 ... [makes] a general, unqualified, interpretative ruling that the *SPS Agreement* allocates the "evidentiary burden" to the Member imposing an SPS measure.

(...)

101. ... [T]he 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)

104. 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.

105. 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.

106. 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).

107. 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.

...

We finally recall our findings reached above on the specific burden of proof under Article 3.3. In particular, we found that the burden of proving that the requirements imposed by Article 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.

(...)

113. The European Communities further urges that ... 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.

114. The first point that must be made in this connection, is that the *SPS Agreement* itself is silent on the matter of an appropriate standard of review for panels deciding upon SPS measures of a Member. ...

115. The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves. ...

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*

157. 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.

158. 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.

159. 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*

160. Article 3.1 provides:

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.

(...)

162. 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.

163. 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*".

168. 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*

169. 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.

170. 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.

171. 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.

172. 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*

(...)

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.

177. 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. (underlining added)

(...)

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.

(...)

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. ...

196. Several of the ... scientific reports [cited by the European Communities, regarding the hormones involved here (except MGA),] appeared to the Panel to meet the minimum requirements of a risk assessment ... At the same time, the Panel finds that the conclusion of these scientific reports is that the use of the hormones at issue ... is "safe". ...

197. Prescinding from the difficulty raised by the Panel's use of the term "identifiable risk", we agree that the scientific reports [cited by the European Communities] 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.

199. The European Communities laid particular emphasis on the 1987 IARC Monographs and the articles and opinions of individual scientists referred to above. The Panel notes, however, that the scientific evidence set out in these Monographs and these articles and opinions relates to the carcinogenic potential of entire *categories* of hormones, or of the hormones at issue *in general*. ... [They] have not evaluated the carcinogenic potential of those hormones when used specifically *for growth promotion purposes* ... The Panel concludes that these Monographs and these articles and opinions are insufficient to support the EC measures at issue in this case.

200. We believe that the above findings of the Panel are justified. 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.

B. *Different Levels of Protection in Different Situations*

216. 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 olaquinox.

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 zootechnical 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 zootechnical 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 zootechnical 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 zootechnical 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. Zootechnical 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 zootechnical 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 olaquinox. Carbadox and olaquinox 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 olaquinox. The Panel responds to these arguments and the European Communities has reiterated its original arguments in its appellant's submission. ...

228. The first argument of the European Communities is that carbadox and olaquinox are not hormones, but rather anti-microbial agents. The Panel responds that the European Communities has not explained why this difference would itself justify a different regulatory treatment in the light of the carcinogenic potential of both kinds of substances.

(...)

234. ... The Panel notes that the European Communities has advised it that the EC Council, by a Decision of 26 February 1996, has already taken action *motu proprio* to review carbadox and olaquinox. To the Panel, the arguments of the European Communities suggest that it acknowledges that the difference in the levels of protection in respect of added hormones and in respect of carbadox and olaquinox may not be justified and should be reviewed.

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 olaquinox, 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)

(...)

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 characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the *SPS Agreement*. 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 olaquinox.

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 olaquinox 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 olaquinox; (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 olaquinox 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 olaquinox 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 olaquinox, 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*;
- (...)

255. The Appellate Body *recommends* that the Dispute Settlement Body request the European Communities to bring the SPS measures found in this Report and in the Panel Reports, as modified by this Report, to be inconsistent with the *SPS Agreement* into conformity with the obligations of the European Communities under that Agreement

2-3. Note on US—Continued Suspension of Obligations in the EC—Hormones Dispute

By Sungjoon Cho, 103 AJIL 299 (2009)

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).¹ The tension climaxed later that year when President Reagan imposed retaliatory tariffs of 100 percent ad valorem, worth about \$100 million, on EC imports.² 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 on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).³ 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.⁴ These directives banned the importation of meat and meat products treated with six specific growth hormones, namely three natural hormones: oestradiol-17 β (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.⁵

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 5.1⁶ 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.⁷

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 imports, such as Bordeaux wines, from the EC countries.⁸ In the meantime, after losing the *EC—Hormones* case

¹ Foreign Agricultural Service, U.S. Department of Agriculture, Chronology of the European Union's Hormone Ban, available at <http://www.fas.usda.gov/itp/policy/chronology.html>.

² *Id.*

³ Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, in WORLD TRADE ORGANIZATION, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 20 (1994), reprinted in 33 ILM 1154 (1994). . . .

⁴ See Panel Report, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R/USA, paras. 2.1–2.5, 8.1, 8.2 (adopted Feb. 13, 1998), modified by Appellate Body Report, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R (adopted Feb. 13, 1998) [hereinafter *EC—Hormones*]. A case report by David A. Wirth on the Appellate Body decision appears at 92 AJIL 755 (1998).

⁵ See Panel Report, *EC—Hormones*, *supra* note 4, paras. 2.8, 2.9.

⁶ 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."

⁷ Appellate Body Report, *EC—Hormones*, *supra* note 4, para. 208 (emphasis added).

⁸ See Arbitrators' Report, Recourse to Arbitration by the European Communities under Article 22.6 of the

in the WTO, the EC commissioned seventeen scientific studies concerning the adverse health risks from hormone-treated beef.⁹ 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-17 β 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.¹⁰ 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-17 β , and provisionally banned the importation of the same products treated with any of the five other hormones.¹¹ 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.¹²

On March 31, 2008, a WTO panel issued its report in *U.S.—Continued Suspension*.¹³ 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 23.¹⁴ As to the EC’s risk assessment on oestradiol-17 β , the panel, after consulting scientific experts, found that the EC had failed to evaluate relevant health risks specifically in terms of those originating from residues in meat as a result of growth hormone treatment.¹⁵ 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 5.7,¹⁶ given that the EC had not demonstrated any “critical mass” of new evidence to justify its provisional ban.¹⁷ 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. ... [*Editors’ Note: the Appellate Body’s Report is reproduced below.*]

DSU, *EC—Hormones*, WT/DS26/ARB, paras. 83, 84 (July 12, 1999).

⁹ See Appellate Body Report, *United States—Continued Suspension of Obligations in the EC—Hormones Dispute*, WT/DS320/AB/R, para. 488 (adopted Nov. 14, 2008), *modifying* Panel Report, *United States—Continued Suspension of Obligations in the EC—Hormones Dispute*, WT/DS320/AB/R, (adopted Nov. 14, 2008) [hereinafter *U.S.—Continued Suspension*].

¹⁰ Appellate Body Report, *U.S.—Continued Suspension*, *supra* note 9, paras. 489–90, 622.

¹¹ *Id.*, para. 493.

¹² Request for consultations by the European Communities, *U.S.—Continued Suspension*, WT/DS320/1 (Nov. 10, 2004).

¹³ Panel Report, *U.S.—Continued Suspension*, *supra* note 9.

¹⁴ *Id.*, para. 7.251.

¹⁵ *Id.*, para. 7.537.

¹⁶ 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.”

¹⁷ Panel Report, *U.S.—Continued Suspension*, *supra* note 9, para. 7.648.

2-4. *US—Continued Suspension of Obligations in the EC—Hormones Dispute, Appellate Body Report, WT/DS320/AB/R, 16 October 2008*

Unterhalter, Presiding Member, Abi-Saab, Member, Bautista, Member

https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm

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

(...)

I. Introduction

1. The European Communities, the United States, and Canada each appeals certain issues of law and legal interpretations developed in the Panel Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (the "Panel Report, *US – Continued Suspension*"), and the Panel Report, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (the "Panel Report, *Canada – Continued Suspension*"). The Panels were established to consider complaints by the European Communities concerning the suspension of concessions or other obligations by the United States and by Canada against the European Communities because of the latter's alleged failure to comply with the recommendations and rulings of the Dispute Settlement Body (the "DSB") stemming from the *EC – Hormones* dispute. The European Communities asserts that the United States and Canada must cease the suspension of concessions because the European Communities adopted Directive 2003/74/EC and notified it to the DSB as a measure taken to comply with the DSB's recommendations and rulings in *EC – Hormones*.

(...)

III. Issues Raised in This Appeal

262. The following issues are raised on appeal by the European Communities:

(...)

- (e) Whether the Panel failed to respect the principle of due process, and therefore failed to comply with its duties under Article 11 of the DSU, in selecting, and relying upon the advice of, two experts who were not "independent and impartial" as required by the *Rules of Conduct*;
- (f) Whether the Panel erred in interpreting and applying Article 5.1 of the *SPS Agreement* in assessing the consistency of the import ban on meat from cattle treated with oestradiol-17 β for growth-promotion purposes, applied pursuant to Directive 2003/74/EC, in particular by:

- (i) adopting a narrow interpretation of "risk assessment" and failing to take into account evidence on misuse and abuse in the administration of hormones;
 - (...)
 - (v) failing to make an objective assessment of the matter before it, as required by Article 11 of the DSU, by articulating and applying an incorrect standard of review.
- (g) Whether the Panel erred in interpreting and applying Article 5.7 of the *SPS Agreement* when assessing the consistency of the provisional import ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and melengestrol acetate ("MGA") for growth-promotion purposes, applied under Directive 2003/74/EC. More specifically, whether the Panel erred in finding that the relevant scientific evidence was insufficient because it:
- (i) incorrectly found that the determination of whether the relevant scientific evidence is insufficient "must be disconnected" from the chosen level of protection;
 - (ii) articulated and applied an incorrect legal test pursuant to which, where international standards exist for a substance, a "critical mass of new scientific evidence" is required to render the relevant scientific evidence "insufficient";
 - (...)
 - (iv) failed to make an objective assessment of the matter before it, as required by Article 11 of DSU.
- (...)

V. Due Process in the Panel's Consultations with the Scientific Experts

415. We now turn to the European Communities' claims that the Panel failed to respect the principle of due process and, consequently, also failed to make an objective assessment of the matter under Article 11 of the DSU, in selecting and relying upon two of the scientific experts consulted by the Panel.

A. *The Panel's Findings*

416. On 25 November 2005, following consultation with the parties, the Panel adopted Working Procedures for Consultations with Scientific and/or Technical Experts (the "Experts Working Procedures"). The Panel decided not to establish an expert review group as had been suggested by the European Communities, but to consult experts on an individual basis. Moreover, the Panel "sought information not only from selected experts but also from three relevant international entities, the Codex Alimentarius Commission (Codex), the Joint FAO/WHO Expert

Committee on Food Additives (JECFA), and the International Agency for Research on Cancer (IARC)."

417. In accordance with paragraph 3 of the Experts Working Procedures, the Panel solicited suggestions for experts from the Secretariats of Codex, JECFA, and the IARC. From these suggestions, the Panel provided to the parties all the information received from the 11 experts that were interested and available, and asked them to indicate any "compelling reasons" why particular experts should not be chosen. The European Communities objected to the inclusion of experts that had participated in JECFA's risk assessment work, explaining that "the scientific controversy over the JECFA reports is at the heart of this case and is the reason why the Panel is now seeking advice from outside experts." The European Communities added that such experts "cannot be considered to be objective and impartial in these circumstances, because this would amount to asking them to review and criticise their proper work".

418. Because the parties' positions with respect to the experts "differed significantly", the Panel sought additional names of experts from the parties pursuant to paragraph 6 of the Experts Working Procedures. Of the 71 experts suggested by the international organizations and the parties, 40 experts indicated that they were available, and 35 responded to the request for their *curriculum vitae* and information regarding potential conflicts of interest. This information was provided to the parties for comments and objections. As the Panel explained:

One party or another submitted objections with regard to all but one of the experts by arguing either that an expert lacked sufficient expertise in the areas of the dispute identified as needing scientific or technical expertise, or was affiliated with the government of a party to this dispute; or was affiliated with JECFA; or had received funding from the pharmaceutical industry; or had been involved in the regulatory approval of any of the six hormones.

419. On 24 March 2006, the Panel informed the parties of the six experts it had selected. The Panel explained its considerations in the selection process as follows:

The Panel excluded experts with close links with governmental authorities directly involved in policy-making regarding the six hormones and experts with close links to pharmaceutical companies or involved in public advocacy activities. The Panel chose not to exclude *a priori* experts who had participated in the preparation and drafting of JECFA's risk assessments because this would deprive the Panel and the parties of the benefit of the contribution of internationally recognized specialists and because the Panel was of the opinion that experts familiar with the JECFA reports would be well-placed to assist the Panel in understanding the work of JECFA extensively referred to by the parties in their submissions, in particular by the European Communities. Moreover, the Panel, who was fully aware of the fields of competence of these experts, considered that they would be competent to answer questions with respect to risk assessment regarding the hormones at issue. The Panel also decided not to exclude *a priori* all experts who were current or past governmental employees unless a potential conflict of interests

could reasonably be assumed from their official functions. In selecting the experts, the Panel also had in mind the need to choose experts with expertise to cover all the fields identified as at issue in the dispute.

420. The European Communities asked the Panel to reconsider its decision with respect to two experts, Dr. Jacques Boisseau and Dr. Alan Boobis, arguing that "these experts had real or perceived conflicts of interests that should disqualify them from assisting the Panel." ... The Panel did not consider that the European Communities' objections were "justified" ...

424. During the Panel proceedings, the experts provided written responses to scientific and technical questions posed by the Panel. The Panel held a meeting with the scientific experts, which included the participation of the parties. At the meeting, the parties and the Panel had the opportunity "to ask questions to the experts and for the experts to clarify points that they had made in their written responses to the questions".

(...)

C. *Did the Panel Infringe the European Communities' Due Process Rights and Fail to Make an Objective Assessment of the Matter in the Consultations with the Scientific Experts*

433. The Appellate Body has previously found that the obligation to afford due process is "inherent in the WTO dispute settlement system" and it has described due process requirements as "fundamental to ensuring a fair and orderly conduct of dispute settlement proceedings". In our view, the protection of due process is an essential feature of a rules-based system of adjudication, such as that established under the DSU. Due process protection guarantees that the proceedings are conducted with fairness and impartiality, and that one party is not unfairly disadvantaged with respect to other parties in a dispute.

434. The Appellate Body has recognized the need for panels to afford due process to the parties with respect to specific procedural issues. For instance, the Appellate Body has recognized due process as requiring that parties to proceedings be afforded an adequate opportunity to respond to claims, arguments, or evidence presented by other parties. It has also referred to the principle of due process in suggesting the need for panels to have standard working procedures, and for panels to have discretion to allow for the enhanced participation by third parties. Moreover, the Appellate Body has found that due process is required by Article 11 of the DSU. In *US – Gambling*, the Appellate Body stated:

[A]s part of their duties, under Article 11 of the DSU, to "make an objective assessment of the matter" before them, panels must ensure that the due process rights of parties to a dispute are respected.

435. These due process considerations are reflected in the *Rules of Conduct*. Section II (Governing Principle) of the *Rules of Conduct* provides that all covered persons, such as panelists and experts advising panels:

... shall be independent and impartial, shall avoid direct or indirect conflicts of interest and shall respect the confidentiality

of proceedings of bodies pursuant to the dispute settlement mechanism, so that through the observance of such standards of conduct the integrity and impartiality of that mechanism are preserved.

436. Scientific experts and the manner in which their opinions are solicited and evaluated can have a significant bearing on a panel's consideration of the evidence and its review of a domestic measure, especially in cases like this one involving highly complex scientific issues. Fairness and impartiality in the decision-making process are fundamental guarantees of due process. Those guarantees would not be respected where the decision-makers appoint and consult experts who are not independent or impartial. Such appointments and consultations compromise a panel's ability to act as an independent adjudicator. For these reasons, we agree with the view of the European Communities that the protection of due process applies to a panel's consultations with experts. This due process protection applies to the process for selecting experts and to the panel's consultations with the experts, and continues throughout the proceedings.

(a) Standard for Selection of Experts

437. The authority to seek information from individuals or to consult experts is provided to panels pursuant to Article 13 of the DSU (Right to Seek Information). Article 13.2 provides:

Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set forth in Appendix 4.

438. Article 11.2 of the *SPS Agreement* specifically addresses the consultation of experts in disputes under that Agreement. It reads:

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.

439. Panels are understood to have "significant investigative authority" under Article 13 of the DSU and Article 11.2 of the *SPS Agreement* and broad discretion in exercising this authority. In *US – Shrimp*, the Appellate Body expounded on the comprehensive authority of panels under Article 13:

The comprehensive nature of the authority of a panel to "seek" information and technical advice from "any individual or body" it may consider appropriate, or from "any relevant source", should be underscored. This authority embraces more than merely the choice and evaluation of the *source* of the information or advice which it may seek. A panel's authority includes the authority to decide *not to seek* such information or

advice at all. We consider that a panel also has the authority to *accept or reject* any information or advice which it may have sought and received, or to *make some other appropriate disposition* thereof. It is particularly within the province and the authority of a panel to determine *the need for information and advice* in a specific case, to ascertain the *acceptability* and *relevancy* of information or advice received, and to decide *what weight to ascribe to that information or advice* or to conclude that no weight at all should be given to what has been received.

(...)

442. As we noted earlier, experts advising panels are specifically covered by the *Rules of Conduct* and, pursuant to Section II (Governing Principle), they "shall be independent and impartial, [and] shall avoid direct or indirect conflicts of interest ... , so that through the observance of such standards of conduct the integrity and impartiality of that mechanism are preserved".

443. Selected experts are also subject to certain self-disclosure and confidentiality obligations set out elsewhere in the *Rules of Conduct*, and procedures exist for the referral of a "material violation" of these obligations to the Chairman of the DSB for appropriate action.

444. The European Communities claims that due process requires that the "experts a court, tribunal or panel hears or consults are *independent and impartial*." It then asserts that the relevant legal test for evaluating whether an expert is independent and impartial is founded on the self-disclosure obligation in Section VI.2 of the *Rules of Conduct*, which requires that experts "disclose any information ... which is likely to affect or give rise to justifiable doubts as to their independence or impartiality". This is a standard the European Communities asserts is "simple and low" and "does not require certainty or high probability".

445. The requirements under Section VI of the *Rules of Conduct* relate, as the title indicates, to the self-disclosure obligation of covered persons, including experts. The *Rules of Conduct* do not provide for automatic exclusion of a covered person upon the disclosure of information pursuant to Section VI and the Illustrative List of Information to be Disclosed, which is attached to the *Rules of Conduct* as Annex 2. However, we fail to see on what basis a panel, presented with information likely to affect or give rise to justifiable doubts as to the independence or impartiality of an expert, could choose to consult such an expert.

446. We do not agree, however, with the European Communities' characterization of Section VI.2 as setting out a "low" standard. On the contrary, we consider the standard set forth in Section VI.2 to be a strict one. Covered persons should be encouraged to disclose any information that may be relevant for purposes of ascertaining whether there may be justifiable doubts as to their independence or impartiality. Disclosure should not lead to automatic exclusion. Whether the disclosed information is likely to affect or give rise to justifiable doubts as to the person's independence or impartiality must be objectively determined and properly substantiated. In the case of an expert, the panel should assess the disclosed information against information submitted by the parties or other information that may be available. It should then determine whether, on the correct facts, there is a likelihood that the expert's independence and impartiality may be affected, or if justifiable doubts arise as to the expert's independence or impartiality. If this is indeed the case, the panel must not appoint such person as an expert.

(...)

(c) Previous Affiliation with JECFA

456. The European Communities claims that the reasons provided by the Panel for declining to exclude Drs. Boisseau and Boobis never addressed the fundamental question of their affiliation with JECFA. In the view of the European Communities, the Panel disregarded its "most important objection" that an expert who has participated in the drafting of JECFA reports cannot be independent and impartial because, in this case, the experts were being asked to evaluate new scientific evidence underlying reports that were directly critical of, or in conflict with, their prior contribution to the JECFA reports. The European Communities argues that as "authors of the JECFA reports", Drs. Boisseau and Boobis "cannot be considered to be independent and impartial in these circumstances, because this would amount to asking them to review and criticise reports that are their own doing".

457. JECFA, which is administered jointly by the FAO and the WHO, is "an international expert scientific committee" that evaluates the safety of food additives, contaminants, naturally-occurring toxicants and residues of veterinary drugs in food. JECFA "performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations". Some countries use information from JECFA in their national food safety control programmes. Requests for scientific advice "are in general channelled through the Codex Alimentarius Commission (Codex)". Codex also adopts international standards based on evaluations performed by JECFA. Codex has adopted international standards for five of the hormones at issue in this case, that is, oestradiol-17 β , testosterone, progesterone, trenbolone acetate, and zeranol, on the basis of evaluation performed by JECFA. In addition, Codex has initiated a standard-setting process for MGA, also on the basis of JECFA's evaluation, but this process has not yet concluded.

458. The risk assessments performed by JECFA in relation to oestradiol-17 β , testosterone, progesterone, trenbolone acetate, and zeranol lie at the centre of the dispute between the participants in this case. In the case of oestradiol-17 β , the European Communities argued that "the Codex approach has serious limitations in non-linear situations, such as with regard to these hormones", and explained that "currently available Codex guidance poorly addresses cases such as this where the risks are embedded in changes in exposure to biologically active molecules which may, with minute differences in their bioavailability, have dramatic effects, such as turning on or off complete developmental programmes of the human genome, or inducing pathological conditions." The European Communities also argued that JECFA's evaluation was based on "outdated" data. As for the four hormones that are subject to the provisional ban and for which there is an international standard, the European Communities asserted that the conclusions reached by JECFA in 1988 and 1999 are "no longer valid". As regards MGA, which is also subject to the provisional ban, the European Communities notes that "nearly all the studies" referred to in the 2000 JECFA report evaluating MGA "date from the 1960s and 1970s". The European Communities considered JECFA's assessment of these hormones to be "insufficient" for purposes of conducting a risk assessment of the type required by the *SPS Agreement*, in light of the fact that the European Communities had decided to adopt a higher level of protection than that underlying JECFA's international standards. In these circumstances, the Panel should have closely scrutinized any institutional links the experts may have had with JECFA and objectively determined whether those links were likely to affect or give rise to justifiable doubts as to the experts' independence or impartiality.

459. Both Drs. Boisseau and Boobis had close institutional links with JECFA. Dr. Boisseau was a member of JECFA from 1987 to 2002. Dr. Boobis was a member from 1997 to 2006.

Membership of JECFA, in our view, reflects international recognition of the expertise of a particular scientist. The Panel observed, in this regard, that JECFA is an "international, independent entity composed of highly qualified experts selected by the WHO or FAO according to strict procedures". We agree with the Panel that Drs. Boisseau and Boobis are highly qualified scientists. We do not see the fact that Drs. Boisseau and Boobis are qualified and knowledgeable—and thus experts—as giving rise to concerns about their impartiality and independence. On the contrary, we would expect a person who is regarded as an expert to hold views, and even very strong views, on his or her particular area of expertise. However, we agree with the European Communities that the qualifications and relevant knowledge of Drs. Boisseau and Boobis are not by themselves sufficient guarantees of their independence and impartiality. An expert could be very qualified and knowledgeable and yet his or her appointment could give rise to concerns about his or her impartiality or independence, because of that expert's institutional affiliation or for other reasons. Similarly, the fact that JECFA may select its experts according to strict procedures does not in itself ensure that these experts are independent and impartial in respect of the issues that may arise in a WTO dispute.

460. Not only did Drs. Boisseau and Boobis participate in JECFA, they were directly involved in JECFA's evaluations of the six hormones at issue. Dr. Boisseau was a member of JECFA in 1987 when the Committee evaluated oestradiol-17 β , progesterone, testosterone, trenbolone acetate, and zeranol. Both Drs. Boisseau and Boobis were members of JECFA in 1999 when it again evaluated oestradiol-17 β , progesterone, and testosterone. During its 1999 session, JECFA adopted recommended Acceptable Daily Intakes ("ADIs") for oestradiol-17 β , testosterone, and progesterone. The report of the 1999 session lists Dr. Boisseau as the Chairman and Dr. Boobis as one of two Joint Rapporteurs. Drs. Boisseau and Boobis also participated in the evaluation of MGA in 2000. On this occasion, the relevant JECFA report lists Dr. Boisseau as Vice-Chairman and Dr. Boobis as a Joint Rapporteur. Thus, Dr. Boisseau was a member of JECFA when it evaluated all six hormones at issue in this dispute, while Dr. Boobis participated in the evaluation of four of the six hormones. As Chairman, Vice-Chairman, and Joint Rapporteur, they would be expected to have played a significant role in the discussions.

461. Rather than being a source of concern, the Panel considered that Drs. Boisseau's and Boobis' participation in JECFA would make them more useful as experts ...

462. The Panel also observed that "since JECFA's risk assessments were used as the reference risk assessments for purposes of the analysis under Article 5.7 of the *SPS Agreement*, it was necessary for the Panel to be able to rely on the advice of experts intimately knowledgeable about the substance of JECFA's risk assessments." We are not persuaded by the Panel's reasoning. It is precisely because JECFA's risk assessments have such a prominent role in this dispute that the Panel should have exercised particular caution before appointing persons with institutional links to JECFA as experts. The Panel gave the experts wide latitude in terms of their examination of the evidence and the advice they provided. Given how the Panel framed its consultations with the experts, it would have been very difficult for it to limit the scope of the advice it received from Drs. Boisseau and Boobis to the "work of JECFA". In fact, our review of the panel record indicates that the Panel did not limit its consultations with Drs. Boisseau and Boobis to the "work of JECFA". For example, as regards the European Communities' permanent ban on meat from cattle treated with oestradiol-17 β , the Panel asked the experts (including Drs. Boisseau and Boobis):

To what extent, in your view, does the [European Communities'] risk assessment identify the potential for adverse effects on human health, including the carcinogenic or genotoxic potential,

of the residues of oestradiol-17 β found in meat derived from cattle to which this hormone had been administered for growth promotion purposes in accordance with good veterinary practice? To what extent does the [European Communities'] risk assessment evaluate the potential occurrence of these adverse effects?

463. This question goes directly to the adequacy of the European Communities' risk assessment and does not concern JECFA's work. Both Drs. Boisseau and Boobis responded to this question and their responses were relied on by the Panel in its analysis:

Dr. Boisseau concluded that the European Communities did not demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth promotion purposes.

Dr. Boobis stated that, in his view, none of the information provided by the European Communities demonstrates the potential for adverse effects in humans of any of the six hormones in meat from cattle in which they are used for growth promotion purposes at the levels to which those consuming such meat would be exposed. The studies on genotoxicity provide no convincing evidence of potential for harm in consumers. The carcinogenic effects observed are entirely consistent with a hormonal mode of action that exhibits a threshold that would be well above the intake arising from consumption of meat from treated cattle.

In their replies, Drs. Boisseau and Boobis directly evaluated the appropriateness of the European Communities' risk assessment.

464. The Panel also asked the experts whether the European Communities' risk assessment examined the risks arising specifically from the consumption of meat from cattle treated with the six hormones at issue:

Do the risk assessment of the European Communities or any other scientific materials referred to by the European Communities demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth-promotion purposes? If yes, why? If not, what kind of evidence would be required to demonstrate such potential adverse effects? Would your response have been different at the time of adoption of the Directive in September 2003?

465. The question concerns the specificity requirement discussed by the Appellate Body in *EC – Hormones*. Drs. Boisseau and Boobis both volunteered responses, and the Panel again relied on both of their replies in its examination of the consistency with the *SPS Agreement* of the European Communities' risk assessment. ...

(...)

469. The European Communities, however, based much of its case before the Panel on the limitations of JECFA's approach. Given that in its own risk assessment the European Communities called into question the validity of JECFA's risk assessments, it was improper for the Panel to have asked Drs. Boisseau and Boobis, who participated directly in JECFA's evaluations, to evaluate the European Communities' risk assessment. The natural inclination of someone placed in that situation would be to compare the risk assessments, rather than to assess whether the science relied upon by the European Communities can support the conclusions it reached, and to favour or defend JECFA's approach. The manner in which the Panel used these experts does not ensure impartiality and cannot be said to ensure fairness in the consultations with the experts. Such a result is not compatible with the due process obligations that are inherent in the WTO dispute settlement system.

(...)

479. Accordingly, we consider that it was improper for the Panel to consult Drs. Boisseau and Boobis. We reiterate that our concerns do not relate to the qualifications of Drs. Boisseau and Boobis, who are highly recognized experts, nor do they relate to the fact that, as experts, they would have been expected to hold views on issues in their area of expertise. Rather, our concerns arise from their direct involvement in the risk assessments performed by JECFA for the hormones at issue in this dispute and from the particular role that JECFA's risk assessments, and the Codex standards adopted on the basis of those risk assessments, had in this case. As we noted earlier, in its case before the Panel, the European Communities argued that there were limitations in JECFA's evaluation of oestradiol-17 β and that the evidence relied upon by JECFA in the evaluation of the other five hormones was outdated. The Panel, for its part, considered that the existence of an international standard established a presumption that the scientific evidence was not "insufficient" to perform a risk assessment within the meaning of Article 5.7 of the *SPS Agreement*.

480. We understand that panels often face practical difficulties in selecting experts who have the required level of expertise and whose selection is not objected to by the parties. We do not wish to make the expert selection process more difficult than it may already be. However, experts consulted by a panel can have a decisive role in a case, especially when it involves highly complex scientific questions such as this one. The Panel in this case said "the role of the experts was to act as an 'interface' between the scientific evidence and the Panel, so as to allow it to perform its task as the trier of fact." Experts appointed by a panel can significantly influence the decision-making process. If a panel does not ensure that the requirements of independence and impartiality are respected in its consultations with the experts, this can compromise the fairness of the proceedings and the impartiality of the decision-making. In these circumstances, the practical difficulties that a panel may encounter in selecting experts cannot displace the need to ensure that the consultations with the experts respect the parties' due process rights.

481. For these reasons, we consider that there was an objective basis to conclude that the institutional affiliation with JECFA of Drs. Boisseau and Boobis, and their participation in JECFA's evaluations of the six hormones at issue, was likely to affect or give rise to justifiable doubts as to their independence or impartiality given that the evaluations conducted by JECFA lie at the heart of the controversy between the parties. The appointment and consultations with Drs. Boisseau and Boobis compromised the adjudicative independence and impartiality of the Panel. Therefore, we find that the Panel infringed the European Communities' due process rights as a result of the Panel having consulted with Drs. Boisseau and Boobis as scientific experts.

482. ... [We] find that the Panel failed to comply with its duties under Article 11 of the DSU, as a result of the appointment and consultations with Drs. Boisseau and Boobis in the circumstances of this case.

(...)

484. Where a panel's ability to act as an independent adjudicator has been compromised, as we have found in this case, this raises serious issues as to whether the panel's findings may be sustained. We recall, moreover, that Drs. Boisseau and Boobis provided responses to the majority of questions posed by the Panel and the Panel relied extensively on their responses in its assessment of the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the *SPS Agreement*. Thus, the Panel's findings on Articles 5.1 and 5.7 of the *SPS Agreement* would be difficult to sustain upon exclusion of the testimony of Drs. Boisseau and Boobis, assuming that disentangling their testimony from the other elements of the Panel's analysis was possible. Although our finding on this issue could, by itself, lead to the invalidation of the Panel's findings under Articles 5.1 and 5.7 of the *SPS Agreement*, we nevertheless proceed to examine the other claims of error raised by the European Communities in respect of the Panel's assessment of the consistency of Directive 2003/74/EC with the *SPS Agreement*. The significance to the Panel's analysis of the testimony of Drs. Boisseau and Boobis will become more evident from our review of the Panel's findings under Articles 5.1 and 5.7 of the *SPS Agreement*.

VI. The Consistency with Article 5.1 of the SPS Agreement of the European Communities' Import Ban on Meat from Cattle Treated with Oestradiol-17 β for Growth-Promotion Purposes

A. Introduction

485. We turn next to the European Communities' appeal of the Panel's finding that the permanent ban on meat and meat products from cattle treated with oestradiol-17 β for growth-promotion purposes provided for in Directive 2003/74/EC does not meet the requirements of Article 5.1 of the *SPS Agreement*. Section B provides a summary of the European Communities' risk assessment in relation to oestradiol-17 β , which the European Communities contends brought it into compliance with the recommendations and rulings of the DSB in *EC – Hormones*. This is followed by a summary of the Panel's findings under Article 5.1 of the *SPS Agreement* in section C and of the claims and arguments raised on appeal in section D. We then analyze in section E the specific issues raised by the European Communities' appeal against the Panel's assessment of Directive 2003/74/EC under Article 5.1 of the *SPS Agreement*. Finally, our conclusions are set out in section F.

(...)

B. The European Communities' Risk Assessment for Meat from Cattle Treated with Oestradiol-17 β

487. We recall that, in *EC – Hormones*, the European Communities' import ban on meat and meat products from cattle treated with six hormones—oestradiol-17 β , testosterone, progesterone, trenbolone acetate, zeranol, and MGA—was found to be inconsistent with Article 5.1 of the *SPS Agreement*. The Appellate Body found that the scientific studies submitted by the European Communities in that dispute were not "sufficiently specific to the case at hand", because they were "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." For this reason, the Appellate Body concluded that "no risk assessment that reasonably support[ed] or warrant[ed] the import prohibition embodied in the [European Communities'] Directives was furnished to the Panel", and accordingly found that the European Communities' import ban, imposed under Directive 96/22/EC, was not "based on" a risk assessment within the meaning of Article 5.1.

488. Following the adoption by the DSB of the Panel and Appellate Body Reports in *EC – Hormones*, the European Commission initiated and funded 17 scientific studies to evaluate the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of oestradiol-17 β , progesterone, testosterone, zeranol, trenbolone acetate, and MGA in cattle for growth-promotion purposes. The results of these studies, as well as other publicly available information and data collected from international organizations such as Codex and JECFA were reviewed by the SCVPH.

489. On 30 April 1999, the SCVPH published an Opinion entitled "Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products" (the "1999 Opinion"). The 1999 Opinion found that "consumption of beef from hormone-treated non-pregnant cattle can result in excess exposure to oestrogens" and that the "toxicological issues of concern" arising from such excess exposure include "endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects."

490. The 1999 Opinion also reached the following conclusions as to the relevant risks to human health posed by the six hormones, and in particular by oestradiol-17 β :

- As concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the [six] hormones in question.
- In the case of oestradiol-17 β , there was a substantial body of recent evidence suggesting that it had to be considered as a complete carcinogen, as it exerted both tumour initiating and tumour promoting effects. The data available did not, however, allow a quantitative estimate of the risk.
- ...
- For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged. Of the various susceptible risk groups, pre-pubertal children was the group of greatest concern. Again the available data did not enable a quantitative estimate of the risk.
- In view of the intrinsic properties of the hormones and in consideration of epidemiological findings, no threshold levels could be defined for any of the six substances.

491. Subsequent to the adoption of the 1999 Opinion, additional scientific information was made available to the European Commission, in the form of a report by the Committee for Veterinary Medicinal Products ("CVMP") of the European Union (a subcommittee of the

European Medicines Agency (EMA)), and a report by the United Kingdom's Veterinary Products Committee sub-group on the 1999 Opinion. At the request of the European Commission, the SCVPH examined this scientific information and, on 3 May 2000, issued a review of its 1999 Opinion in which it declined to alter the conclusions contained therein (the "2000 Opinion"). The SCVPH observed that "particularly in regards to the subject of estrogenic effects during [various stages of] development, there is no compelling evidence suggesting that these effects do not also occur at low doses." The 2000 Opinion concluded that recent scientific information "did not provide convincing data and arguments demanding revision of the conclusions drawn in the [1999 Opinion] on the potential risks to human health from hormone residues in bovine meat and meat products".

492. On 10 April 2002, a second review of the 1999 Opinion was issued by the SCVPH (the "2002 Opinion"), on the basis of scientific data collected since the previous review. The scientific data reviewed by the SCVPH included the final results of all 17 studies that had been commissioned by the European Commission, as well as scientific data from relevant international organizations and other sources. The SCVPH considered that the data from the 17 scientific studies and recent scientific literature confirmed the validity of the 1999 Opinion, as reviewed in 2000, and that no amendments to those Opinions were justified.

493. In light of the conclusions of the 1999, 2000, and 2002 Opinions, the European Communities adopted Directive 2003/74/EC on 22 September 2003, which amended Directive 96/22/EC. Directive 2003/74/EC provides for the *permanent* prohibition on the importation of meat and meat products from animals treated with oestradiol-17 β for growth-promotion purposes, on the basis of the SCVPH assessment that "recent evidence suggests that [oestradiol-17 β] has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of the risk." Directive 2003/74/EC also provides for a *provisional* ban on meat and meat products from cattle treated with progesterone, testosterone, zeranol, trenbolone acetate and MGA for growth-promoting purposes.

494. Before the Panel, the European Communities argued that the 1999, 2000, and 2002 Opinions, supported by the 17 studies conducted between 1998 and 2001, constitute the risk assessment upon which Directive 2003/74/EC is based.

C. *The Panel's Findings*

(...)

509. The Panel concluded:

All of the statements of the experts, and indeed statements from the Opinions, indicate that the European Communities has evaluated the potential for the identified adverse effects to be associated with oestrogens in general, but has not provided analysis of the potential for these effects to arise from consumption of meat and meat products which contain residues of oestradiol-17 β as a result of the cattle they are derived from being treated with the hormone for growth promotion purposes. The Panel, therefore, concludes that although the European Communities has evaluated the association between excess hormones and neurobiological, developmental, reproductive and

immunological effects, as well as immunotoxicity, genotoxicity, and carcinogenicity, it has not satisfied the requirements of the definition of a risk assessment contained in Annex A(4) because it has not evaluated specifically the possibility that these adverse effects come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-17 β as a result of the cattle being treated with the hormone for growth promotion purposes.

510. ... On the basis of the opinions of the experts consulted and its own review of the SCVPH Opinions, the Panel found that the scientific evidence referred to in the SCVPH Opinions did not support the conclusion that the genotoxicity of oestradiol-17 β has been demonstrated and that residues of oestradiol-17 β in meat and meat products lead to increased risk of cancer or adverse immunological and developmental effects.

511. Accordingly, the Panel concluded that the "[SCVPH] Opinions do not constitute a risk assessment because the Opinions do not satisfy the definition of a risk assessment contained in Annex A(4) second sentence and because the scientific evidence referred to in the Opinions does not support the conclusions therein". As a consequence of this finding, the Panel also found that the permanent ban on meat and meat products treated with oestradiol-17 β for growth-promoting purposes is not a measure "based on" a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. Therefore, the Panel concluded that "the [European Communities'] implementing measure on oestradiol-17 β is not compatible with Article 5.1 of the *SPS Agreement*."

(...)

E. *The Panel's Assessment of Directive 2003/74/EC under Article 5.1 of the SPS Agreement*

1. General Disciplines Applicable to the Adoption of an SPS Measure

522. The *SPS Agreement* recognizes the right of WTO Members to take measures necessary to protect human, animal or plant life or health. The right to take a protective measure must be exercised consistently with a series of obligations that are set forth in that Agreement, and that seek to ensure that such measures are properly justified.

523. There are several concepts that are defined in the *SPS Agreement* and that describe aspects of a WTO Member's decision-making process when taking an SPS measure. The "appropriate level of protection" is defined in paragraph 5 of Annex A to the *SPS Agreement* as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." It is the "prerogative" of a WTO Member to determine the level of protection that it deems appropriate. The SPS measure is the "instrument" chosen by the WTO Member to implement its sanitary or phytosanitary objective. Based on the wording of Article 5.6 of the *SPS Agreement*, the Appellate Body has explained that the "determination of the level of protection is an element in the decision-making process which logically precedes and is separate from the establishment or maintenance of the SPS measure". In other words, the appropriate level of protection determines the SPS measure to be introduced or maintained, rather than the appropriate level of protection being determined by the SPS measure. The Appellate Body has also found that "the *SPS Agreement* contains an implicit obligation to determine the appropriate level of protection."

Although it need not be determined in quantitative terms, the level of protection cannot be determined "with such vagueness or equivocation that the application of the relevant provisions of the *SPS Agreement* ... becomes impossible".

524. Another important aspect of the decision-making process is the "risk assessment". Pursuant to Article 5.1 of the *SPS Agreement*, an SPS measure must be "based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health". Under Article 5.7 of the *SPS Agreement*, WTO Members are also allowed to take an SPS measure, on a provisional basis, where certain conditions are fulfilled, including where the relevant scientific evidence is insufficient to perform a risk assessment. We examine Article 5.7 in more detail in section VII.

(...)

527. ... In *EC – Hormones*, the panel described a "risk assessment" as a "scientific process aimed at establishing the scientific basis" for the SPS measure. The Appellate Body understood the panel 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". Science therefore plays a central role in a risk assessment. However, the Appellate Body has cautioned against taking too narrow an approach to a risk assessment:

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.

528. As we noted earlier, Article 5.1 requires that SPS measures be "based on" a risk assessment. This does not mean that the SPS measures have to "conform to" the risk assessment. Instead, "the results of the risk assessment must sufficiently warrant—that is to say, reasonably support—the SPS measure at stake". Put differently, there must be a "rational relationship" between the SPS measure and the risk assessment.

529. Moreover, the risk assessment need not "come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure", nor does the risk assessment have to "embody only the view of a majority of the relevant scientific community." While recognizing that, in most cases, WTO Members "tend to base their legislative and administrative measures on 'mainstream' scientific opinion", the Appellate Body has observed that, "[i]n 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." The Appellate Body added that an approach based on a divergent opinion from a qualified and respected source, "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."

530. An SPS measure need not be based on a risk assessment performed by the WTO Member taking the measure. It can be based on a risk assessment performed by a relevant international organization or by another WTO Member. The risk assessment can be quantitative or qualitative in nature. Nevertheless, the Appellate Body has noted that "theoretical uncertainty" is not the kind

of risk to be assessed under Article 5.1; instead, the risk to be assessed must be an "ascertainable" risk. In addition, the risk assessment must have the requisite degree of specificity. The assessment must be "sufficiently specific" in terms of the harm concerned and the precise agent that may possibly cause the harm.

531. Whilst WTO Members have the right to take SPS measures, they are not required to do so. The risk assessment may conclude that there is no ascertainable risk, in which case no SPS measure can be taken. Alternatively, a WTO Member may conclude that an SPS measure is not necessary in the light of the risks determined in the risk assessment and the acceptable level of protection determined by that WTO Member.

(...)

533. At the oral hearing, we explored the relationship between the appropriate level of protection and the risk assessment. The European Communities considers that the appropriate level of protection can clearly be taken into account in a risk assessment and may, in some cases, be reflected in the mandate and parameters given to the risk assessors. The United States and Canada recognize that the acceptable level of risk may sometimes play a role, albeit a limited one, in respect of the risk assessment. The United States and Canada, however, caution about the need to maintain the objectivity of the risk assessment process and reject the notion that subjective policy choices have a role to play in a risk assessment. In their view, these policy choices may be taken into account by a WTO Member in determining its appropriate level of risk and in selecting the SPS measure, but should not be part of the risk assessment process, which must remain an objective and scientific evaluation.

534. The risk assessment cannot be entirely isolated from the appropriate level of protection. There may be circumstances in which the appropriate level of protection chosen by a Member affects the scope or method of the risk assessment. This may be the case where a WTO Member decides not to adopt an SPS measure based on an international standard because it seeks to achieve a higher level of protection. In such a situation, the 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. However, 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. Likewise, whatever the level of protection a Member chooses does not pre-determine the results of the risk assessment. Otherwise, the purpose of performing the risk assessment would be defeated.

535. We understand that Codex draws a distinction between "risk assessment" and "risk management". It defines "risk management" as "the process, *distinct from risk assessment*, of weighing policy alternatives ... considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options." In *EC – Hormones*, the Appellate Body noted that the *SPS Agreement* does not refer to the concept of "risk management" and it rejected the panel's restrictive interpretation of a "risk assessment" based on that distinction. The Appellate Body has not provided a clear demarcation of the factors that may be considered in a "risk assessment" under the *SPS Agreement*, but it has held that the list of factors provided in Article 5.2 is not a closed list and, in particular, that abuse or misuse and difficulties of control in the administration of hormones may be considered in the context of a risk assessment.

536. Before we proceed to examine the European Communities' claims, we briefly summarize some of the relevant facts of this case. We note that Codex has adopted an international standard for oestradiol-17 β , based on evaluations carried out by JECFA. The European Communities asserts that it has determined a higher level of protection than that which would be achieved under Codex's standard. According to the European Communities, its level of protection is "no (avoidable) risk, that is a level of protection that does not allow any unnecessary addition from exposure to genotoxic chemical substances that are intended to be added deliberately to food." The European Communities also notes that it has performed a risk assessment for meat from cattle treated with oestradiol-17 β for growth-promotion purposes. This risk assessment consists of the 1999, 2000, and 2002 Opinions, as supported by 17 studies conducted between 1998 and 2001. The European Communities further explains that its SPS measure—that is, the import and marketing ban applied pursuant to Directive 2003/74/EC—was taken in the light of the higher level of protection that it determined for itself and is properly based on its risk assessment.

2. The Panel's Interpretation and Application of Articles 5.1 and 5.2 of the SPS Agreement

537. We examine, first, the European Communities' claim that the Panel erred by adopting "an extremely narrow and consequently erroneous interpretation of Article 5.1 and failed to take into account that risk assessment and risk management partly overlap in the *SPS Agreement*". The European Communities argues that the Panel's restrictive interpretation of risk assessment led it to wrongfully exclude from the scope of its analysis under Article 5.1 evidence concerning misuse or abuse and difficulties of control in the administration of hormones to cattle for growth promotion.

538. We begin by reviewing the Panel's understanding of the Appellate Body's interpretation of Article 5.1 in *EC – Hormones* and particularly its discussion of the relevance of risk management factors for the purposes of a risk assessment within the meaning of Annex A and Article 5.1 of the *SPS Agreement*. The Panel in this case interpreted the Appellate Body's ruling in *EC – Hormones* as follows:

Although the Appellate Body disapproved of the original panel's distinction between "risk assessment" and "risk management" because it had no textual basis in the Agreement, this Panel can find no statement by the Appellate Body confirming that what the European Communities describes as risk management is included within the definition of a risk assessment as set forth in Annex A(4) of the *SPS Agreement*. In fact, the Appellate Body stressed that Article 5 and Annex A 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*.

The Panel agrees with the Appellate Body that its role as a treaty interpreter is 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." The Panel takes note of the Appellate Body's finding that a risk assessment can take into account "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly

associated with the physical sciences." However, the Panel finds that neither that finding nor the text of the Agreement includes within the definition of a risk assessment the concepts put forward by the European Communities as "risk management." (footnote omitted)

(...)

541. We find it difficult to reconcile the Panel's understanding of *EC – Hormones* with what the Appellate Body held in that Report. As we noted above, in that case, the Appellate Body rejected the rigid distinction drawn by the panel between "risk assessment" and "risk management", explaining:

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.

Subsequently in the same Report, the Appellate Body reiterated its view that "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*".

542. Therefore, in our view, the Panel's interpretation of "risk assessment" resulted in the same "restrictive notion of risk assessment" that the Appellate Body found to be erroneous in *EC – Hormones*. The Panel sought in this case to rewrite the Appellate Body Report in *EC – Hormones* and to re-establish the rigid distinction between "risk assessment" and "risk management" that the Appellate Body had rejected in that case.

543. We set out above our understanding of the Appellate Body's finding in *EC – Hormones* in so far as the distinction between "risk assessment" and "risk management" is concerned. We now turn to the European Communities' argument that the distinction that the Panel drew between "risk assessment" and "risk management" resulted in the exclusion of certain factors from the Panel's analysis under Article 5.1 of the *SPS Agreement*. In particular, the European Communities asserts that the Panel improperly excluded the evidence concerning misuse or abuse and difficulties of control in the administration of hormones to cattle for growth promotion.

544. The relevance of the risks relating to abuse or misuse in the administration of hormones was also addressed in *EC – Hormones*. In that case, the Appellate Body noted that "[s]ome 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" and that "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 then specifically examined whether risks relating to misuse or abuse in the administration of the hormones could be considered as part of the "risk assessment":

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"... 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. ... (original emphasis; footnote omitted)

545. Thus, the risks arising from the abuse or misuse in the administration of hormones can properly be considered as part of a risk assessment. Where a WTO Member has taken such risks into account, they must be considered by a panel reviewing that Member's risk assessment. Any suggestion that such risks cannot form part of a risk assessment would constitute legal error.

546. At the interim review stage, the Panel dismissed the relevance of the evidence concerning misuse or abuse in the administration of hormones under Article 5.1 for the following reasons:

... the Panel did not deem it necessary to address this question in the section regarding the conformity with Article 5.1 of the definitive ban on oestradiol-17 β , to the extent that the question whether misuse or abuse exists in the administration of hormones did not have an impact on the issues addressed by the Panel under Article 5.1. Indeed, the question of misuse or abuse in the administration of hormones is relevant to the extent that it can lead to higher concentrations of hormone residues in meat and meat products than would occur if good veterinary practices were applied. As stated by the 1999 Opinion, it is an aspect of exposure assessment. In this case, the Panel found that the European Communities had not evaluated specifically the possibility that the adverse effect[s] that it had identified in its risk assessment come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-17 β as a result of the cattle being treated with this hormone for growth promotion purposes. Therefore, whether the concentrations of hormone residues in meat and meat products could be higher as a result of misuse or abuse did not have to be addressed. ...

547. ... Although the Panel does not seem to reject *a priori* the relevance of the potential risks of misuse or abuse, it then states that it was not necessary to address this question in its analysis, to the extent that it did not have an impact on the issues addressed by the Panel under Article 5.1. However, some of the scientific experts consulted by the Panel indicated that risks arising from residues of oestradiol-17 β in bovine meat are likely to increase where good veterinary practices in the administration of this hormone are not followed. Indeed, these experts agreed that their conclusions in relation to the risks posed by oestradiol-17 β were predicated on good veterinary practices being followed. Accordingly, the abuse or misuse in the administration of oestradiol-17 β has a bearing on the particular risks being assessed by the European Communities. The Panel's conclusion was thus premature because the Panel could not have decided whether the European Communities failed to evaluate specifically the possible adverse effects of residues of oestradiol-17 β in meat before considering the evidence on abuse or misuse. The Panel's summary

dismissal of the relevance of the evidence on misuse or abuse at the interim review stage gives the appearance of being an *ex post* rationalization of an earlier decision to exclude such risks from consideration.

548. The risks of abuse or misuse of the hormones at issue were examined by the European Communities as part of its risk assessment. The 1999 Opinion examines the risks arising from misplaced implants and the consumption of meat from implantation sites, off-label use of the hormones (such as in animals for which the implant or feed pre-mix is not approved), possible uses of non-authorized pharmaceutical formulations, and secondary risks for residues of other drugs. The 1999 Opinion concludes:

it has to be noted that misplaced implants and black market drugs comprise the risk that extremely high levels of residues of hormones remain in edible tissues of animals. In addition, it has to be noted that the contemporaneous use of growth promoting hormones and veterinary therapeutics drugs increases the prevalence of undesirable r[e]sidues in edible tissues of bovines.

549. The 2002 Opinion also addresses the risks of abuse or misuse. It refers to a study that simulated the disregard of good veterinary practices and to two studies relating to MGA. The 2002 Opinion concludes:

... these experiments clearly identify a risk for excessive exposure of consumers to residues from misplaced or off-label used implants and incorrect dose regimes. In these cases, levels of oestradiol and its metabolites in muscle, fat, liver and kidney from hormone treated cattle may be 2-fold up to several hundred folds higher as compared to untreated meat. The level of increase depends on the treatment

(...)

552. As noted earlier, the relevance of abuse or misuse in the administration of the hormones at issue was recognized by the Appellate Body in *EC – Hormones*. The Appellate Body observed that, "[w]here 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'."

553. The Panel does not address the evidence on misuse or abuse referred to in the 1999 and 2002 Opinions in its analysis under Article 5.1 of the *SPS Agreement*. ... The European Communities made it clear that the risks of abuse or misuse were a relevant consideration in its risk assessment. This is confirmed in the 1999 and 2002 Opinions. 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. The Panel had a duty to engage with this evidence and with the discussion of this evidence in the SCVPH Opinions. By summarily dismissing the evidence on the misuse or abuse in the administration of the hormones and the consequent conclusions in the SCVPH Opinions in the manner that it did, the Panel incorrectly applied Article 5.1 and the definition of "risk assessment" in Annex A of the *SPS Agreement*, as interpreted by the Appellate Body.

(...)

555. Accordingly, we find that the Panel erred in its interpretation and application of Article 5.1 of the *SPS Agreement* in relation to risks of misuse and abuse in the administration of hormones to cattle for growth-promoting purposes.

(...)

6. The Panel's Articulation and Application of the Standard of Review under Article 5.1 of the SPS Agreement

585. We turn next to the European Communities' claim that the Panel erred in the standard that it applied to review whether Directive 2003/74/EC was based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. The European Communities argues that the Panel sought to determine "what the correct scientific conclusions are" in relation to the hormones at issue. The European Communities adds that, instead of determining whether "there was any reputable support within the relevant scientific community for the determination made by the European Communities in the light of its chosen level of protection", the Panel decided "to become the jury on the correct science ... by picking and choosing between conflicting and contradictory opinions of the experts in an arbitrary manner." As a result, the Panel impermissibly engaged in a *de novo* review of the European Communities' risk assessment, and failed to take into account diverging views among the experts reflecting a "genuine and legitimate scientific controversy" concerning three particular issues: exposure of humans to hormones from multiple endogenous and exogenous sources; genotoxicity of oestradiol-17 β ; and specificity or direct causality.

(...)

587. We discuss our views on the applicable standard of review before turning to our examination of the Panel's assessment of Directive 2003/74/EC. ... We recall that in *EC – Hormones*, the Appellate Body rejected the European Communities' argument that a "deferential 'reasonableness' standard" is applicable under the *SPS Agreement* to "all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants". The Appellate Body cautioned that the applicable standard of review "must reflect the balance established in [the *SPS Agreement*] between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves" and concluded that Article 11 of the DSU "articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels" reviewing the assessment of facts under the *SPS Agreement*.

(...)

589. The Appellate Body has observed that, so far as fact-finding by panels is concerned, the applicable standard is "neither *de novo* review as such, nor 'total deference', but rather the 'objective assessment of facts'". It further explained that, while panels are "poorly suited to engage in [a *de novo*] review", "'total deference to the findings of the national authorities' ... 'could not ensure an "objective assessment" as foreseen by Article 11 of the DSU'."

590. A panel reviewing the consistency of an SPS measure with Article 5.1 must determine whether that SPS measure is "based on" a risk assessment. It is the WTO Member's task to perform the risk assessment. The panel's task is to review that risk assessment. Where a panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own

scientific judgement for that of the risk assessor and making a *de novo* review and, consequently, would exceed its functions under Article 11 of the DSU. Therefore, the review power of a panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.

591. The Appellate Body has observed that a WTO Member may properly base an SPS measure on divergent or minority views, as long as these views are from qualified and respected sources. This must be taken into account in defining a panel's standard of review. Accordingly, a panel reviewing the consistency of an SPS measure with Article 5.1 of the *SPS Agreement* must, first, identify the scientific basis upon which the SPS measure was adopted. This scientific basis need not reflect the majority view within the scientific community but may reflect divergent or minority views. Having identified the scientific basis underlying the SPS measure, the panel must then verify that the scientific basis comes from a respected and qualified source. Although the scientific basis need not represent the majority view within the scientific community, it must nevertheless have the necessary scientific and methodological rigour to be considered reputable science. In other words, while the correctness of the views need not have been accepted by the broader scientific community, the views must be considered to be legitimate science according to the standards of the relevant scientific community. A panel should also assess whether the reasoning articulated on the basis of the scientific evidence is objective and coherent. In other words, a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon. Finally, the panel must determine whether the results of the risk assessment "sufficiently warrant" the SPS measure at issue. Here, again, the scientific basis cited as warranting the SPS measure need not reflect the majority view of the scientific community provided that it comes from a qualified and respected source.

592. A panel may and should rely on the advice of experts in reviewing a WTO Member's SPS measure, in accordance with Article 11.2 of the *SPS Agreement* and Article 13.1 of the DSU. In doing so, however, a panel must respect the due process rights of the parties. Moreover, a panel may not rely on the experts to go beyond its limited mandate of review. The purpose of a panel consulting with experts is not to perform its own risk assessment. The role of the experts must reflect the limited task of a panel. The panel may seek the experts' assistance in order to identify the scientific basis of the SPS measure and to verify that this scientific basis comes from a qualified and respected source, irrespective of whether it represents minority or majority scientific views. It may also rely on the experts to review whether the reasoning articulated on the basis of the scientific evidence is objective and coherent, and whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the evidence. The experts may also be consulted on the relationship between the risk assessment and the SPS measure in order to assist the panel in determining whether the risk assessment "sufficiently warrants" the SPS measure. The consultations with the experts, however, should not seek to test whether the experts would have done a risk assessment in the same way and would have reached the same conclusions as the risk assessor. In other words, the assistance of the experts is constrained by the kind of review that the panel is required to undertake.

593. In this case, the Panel correctly identified Article 11 of the DSU as setting out the standard of review applicable to its examination of the consistency of the European Communities' risk assessment with Article 5.1 of the *SPS Agreement*. The Panel also referred to the guidance provided by the Appellate Body in *EC – Hormones* concerning the standard of review. Moreover, the Panel made reference to the interpretation of Article 5.1 of the *SPS Agreement* developed by

the Appellate Body in *EC – Hormones* and acknowledged that a risk assessment may be based on divergent or minority views.

594. Next, the Panel referred to its consultations with scientific experts, noting that it had consulted six scientific experts individually, and not as an expert review group. The Panel stated that:

Although the Panel is not carrying out its own risk assessment, its situation is similar in that it may benefit from hearing the full spectrum of experts' views and thus obtain a more complete picture both of the mainstream scientific opinion and of any divergent views.

595. The analogy that the Panel draws between its situation and that of a risk assessor is unfortunate, but is not in itself a sufficient indication that the Panel incorrectly understood the applicable standard of review. We do not think that the Panel meant to suggest that it saw its task under Article 5.1 as requiring it to perform a risk assessment. At the beginning of the statement, the Panel expressly recognizes that it "is not carrying out its own risk assessment".

596. The Panel then elaborated on the approach it would take in respect of the testimony of the experts:

We note that, in some circumstances, only one or two experts have expressed their views on an issue. Sometimes these views were similar or complemented each other. In other circumstances, a larger number of experts expressed opinions and, sometimes, they expressed diverging opinions. While, on some occasions, we followed the majority of experts expressing concurrent views, in some others the divergence of views were such that we could not follow that approach and decided to accept the position(s) which appeared, in our view, to be the most specific in relation to the question at issue and to be best supported by arguments and evidence. (footnotes omitted)

597. The European Communities submits that "the majority view is not probative simply because it represents the majority". We agree that automatically giving more weight to the testimony of the majority of experts would be too rigid an approach. The fact that a majority in the spectrum of the scientific experts consulted by the Panel had a particular view is not a proper basis for determining whether a WTO Member's risk assessment complies with the requirements of Article 5.1 and Annex A of the *SPS Agreement*.

598. Looking at the Panel's analysis of whether the European Communities specifically assessed the risks arising from the consumption of meat from cattle treated with oestradiol-17 β , we note that a significant portion of the Panel's reasoning consists of summaries of the responses of the experts. It is only after summarizing the experts' responses that the Panel describes some of the issues discussed in the 1999 Opinion. Given the applicable standard of review and the role of the Panel that is determined by it, the Panel's analysis should have proceeded differently. The Panel should have first looked at the European Communities' risk assessment. It should then have determined whether the scientific basis relied upon in that risk assessment came from a respected and qualified source. The Panel should have sought assistance from the scientific experts in confirming that it had properly identified the scientific basis underlying the European

Communities' risk assessment or to determine whether that scientific basis originated in a respected and qualified source. The Panel should also have sought the experts' assistance in determining whether the reasoning articulated by the European Communities on the basis of the scientific evidence is objective and coherent, so that the conclusions reached in the risk assessment sufficiently warrant the SPS measure. Instead, the Panel seems to have conducted a survey of the advice presented by the scientific experts and based its decisions on whether the majority of the experts, or the opinion that was most thoroughly reasoned or specific to the question at issue, agreed with the conclusion drawn in the European Communities' risk assessment. This approach is not consistent with the applicable standard of review under the *SPS Agreement*.

599. The Panel's flawed approach is evident in its analysis of the genotoxicity of oestradiol-17 β , one of the central issues in the European Communities' risk assessment. The 1999 Opinion refers to several studies that investigated the genotoxicity of oestradiol. It also states that certain metabolites of oestradiol-17 β "have been found to be directly or indirectly genotoxic" and that "[t]his implies that 17- β oestradiol may act as tumor initiator as well as tumor promoter". The 1999 Opinion goes on to state that "[t]his implies that any excess exposure towards 17- β oestradiol and its metabolites resulting from the consumption of meat and meat products presents a potential risk to public health in particular to those groups of the population which have been identified as particularly sensitive such as prepubertal children". Finally, the 1999 Opinion explains that a threshold cannot be established for these genotoxic metabolites. The European Communities explained that a "threshold" is the "level below which intakes from residue should be considered to be safe."

600. The genotoxicity of oestradiol-17 β is also examined in the 2002 Opinion, which concludes:

Convincing data have been published confirming the mutagenic and genotoxic potential of 17 β -oestradiol as a consequence of metabolic activation to reactive quinines. *In vitro* experiments indicated that oestrogenic compounds *might* alter the expression of an array of genes. (original emphasis)

601. Following the approach that we outlined earlier regarding the applicable standard of review, the first step in the Panel's analysis should have been to identify what in the European Communities' risk assessment was the scientific basis for the conclusions on the genotoxicity of oestradiol-17 β ; verify whether this scientific basis came from a respected and qualified source; and determine whether the reasoning articulated on the basis of that scientific evidence is objective and coherent. As a second step, the Panel should have pursued a similar inquiry concerning the conclusion that the genotoxicity of oestradiol-17 β did not permit the establishment of a threshold, as the European Communities submits. In that context, the Panel would have sought the experts' view as to whether the conclusions reached by the European Communities can find support in the scientific evidence relied upon by the European Communities (even if the expert in question was of a different scientific view).

602. Rather than turning first to the European Communities' risk assessment in order to identify the scientific basis for the conclusions on the genotoxicity of oestradiol-17 β , the Panel begins with a survey of the views of the scientific experts on this issue in general. The Panel tries to justify its approach on its inability to evaluate the evidence itself:

The Panel is not in a position to evaluate the scientific data the SCVPH reviewed in drawing its conclusions. For this reason, the Panel consulted a group of scientific experts and asked them to evaluate the [European Communities'] Opinions as well as the underlying science.

However, under the applicable standard of review, neither the Panel nor the experts it consulted were called upon to evaluate the correctness of the European Communities' risk assessment. The Panel's role was more limited and consisted, as we explained earlier, of identifying the scientific basis and evidence relied upon in the risk assessment; verifying that the scientific evidence comes from respected and qualified sources; and determining whether the reasoning articulated by the European Communities on the basis of the scientific evidence is objective and coherent.

603. The summary of the experts' opinions, which constitutes the lengthiest portion of the Panel's reasoning, often appears to be a general discussion as to whether the genotoxicity of oestradiol-17 β is widely accepted by the broader scientific community, rather than a discussion of the evidence relied upon in the European Communities' risk assessment. The Panel concludes that the "scientific evidence referred to in the Opinions does not support the European Communities' conclusion that for oestradiol-17 β genotoxicity had already been demonstrated explicitly." The Panel's conclusion appropriately focuses on the scientific evidence in the SCVPH Opinions. Yet, the Panel's reasoning reveals several flaws. First, some of the experts seemed to accept the European Communities' position on the genotoxicity of oestradiol-17 β . For example, the Panel quotes the following opinion of Dr. Cogliano in its reasoning:

Dr. Cogliano explained that "the [European Communities'] statement that a threshold cannot be identified reflects their view of genotoxic mechanisms, just as the contrary statement that there is a threshold and that this threshold is above the levels found in meat residues reflects how Canada and the [United States] view genotoxic mechanisms. Neither statement has been demonstrated by the scientific evidence, rather, they are different assumptions that each party uses in their interpretation of the available evidence."

604. The Panel also refers to the following testimony of Dr. Cogliano:

Dr. Cogliano stated in his written responses that the identification of oestradiol-17 β as a human carcinogen indicates that there are potential adverse effects on human health when oestradiol-17 β is consumed in meat from cattle treated with hormones for growth promotion purposes. ...

605. The Panel should have addressed whether Dr. Cogliano's statements provided evidence that the European Communities' position on the genotoxicity of oestradiol-17 β had some acceptance in the scientific community, even if it did not constitute the majority view. ...

606. There is no indication in the Panel's reasoning about how to reconcile Dr. Cogliano's statements with the Panel's conclusion that the scientific evidence in the SCVPH Opinions do not support the European Communities' conclusions that "for oestradiol-17 β genotoxicity had already been demonstrated explicitly" or that the "presence of residues of oestradiol-17 β in meat and meat

products as a result of the cattle being treated with the hormone for growth promotion purposes leads to increased cancer risk."

607. The genotoxicity of oestradiol-17 β also comes up in connection with the European Communities' conclusion that a threshold could not be established for oestradiol-17 β . As with genotoxicity, the risk assessment would need to provide a scientific basis for the conclusion that a threshold could not be established for oestradiol-17 β . The Panel does not identify what was the scientific basis for this conclusion, as it should have done. Rather, the Panel's reasoning reproduces the views of the experts on the issue of genotoxicity, with some of them mentioning the distinction between *in vivo* and *in vitro* genotoxicity. The discussion seeks to establish whether the genotoxicity *in vivo* of oestradiol-17 β had been accepted by the general scientific community, rather than whether the European Communities' risk assessment provided scientific evidence of the genotoxicity *in vivo* of oestradiol-17 β and whether this evidence came from a respected and qualified source. ...

(...)

610. We reiterate that the Panel was not called upon to determine whether there is general acceptance that oestradiol-17 β is genotoxic *in vivo* or that it causes cancer by a genotoxic mechanism. Instead, the focus should have been on the evidence relied upon by the European Communities in its risk assessment. As we noted earlier, the 1999 Opinion refers to several studies on the genotoxicity of oestradiol-17 β . Additional studies are discussed in the 2002 Opinion. These studies should have been the focus of the Panel's analysis, yet they are not mentioned in the Panel's analysis. The Panel does not give any reasons why it did not consider them relevant.

611. The European Communities' risk assessment also focused on the endogenous levels of hormones in pre-pubertal children and observed that these levels were lower than previously thought. Dr. Guttenplan seemed to accept the European Communities' position on this issue:

Dr. Guttenplan found that the levels in meat could result in bioavailable oestrogen exceeding the daily production rate of oestradiol in pre-pubertal children. "For pre-pubertal children, even with the low bioavailability of estrogen ... and its low levels in meats, it appears possible that intake levels would be within an order of magnitude of those of the daily production rate. ...

The Panel does not address this statement further nor does the Panel explain how Dr. Guttenplan's conclusion should be reconciled with the Panel's conclusion that the European Communities' risk assessment did not examine the specific risks arising from the consumption of meat from cattle treated with oestradiol-17 β .

612. We have identified above how the Panel approached its task without proper regard to the standard of review and the limitations this places upon the appraisal of expert testimony. Ultimately, the Panel reviewed the scientific experts' opinions and somewhat peremptorily decided what it considered to be the best science, rather than following the more limited exercise that its mandate required. ...

(...)

614. An additional flaw in the Panel's reasoning relates to the following remark at the end of Panel's summary of the experts' responses:

Additionally, in response to direct questioning during the Panel meeting with the experts, Drs. Boobis, Boisseau, and Guttenplan all agreed that there is no appreciable risk of cancer from residues of oestradiol-17 β in meat and meat products from cattle treated with the hormone for growth promotion purposes. While all the experts who responded to the question agreed that a zero risk could not be guaranteed, the actual level of risk was in their view so small as to not be calculable.

It was not the Panel's task, much less that of the experts that the Panel consulted, to determine whether there is an appreciable risk of cancer arising from the consumption of meat from cattle treated with oestradiol-17 β . Instead, the Panel was called upon to review the European Communities' risk assessment.

615. ... We have found that the Panel did not apply the proper standard of review. This is a legal error and does not fall within the authority of the Panel as the trier of facts. Moreover, we have found instances in which the Panel exceeded its authority in the assessment of the testimony of the scientific experts. By merely reproducing testimony of some experts that would appear to be favourable to the European Communities' position, without addressing its significance, the Panel effectively disregarded evidence that was potentially relevant for the European Communities' case. This cannot be reconciled with the Panel's duty to make an "objective assessment of the facts of the case" pursuant to Article 11 of the DSU.

616. For these reasons, we find that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU, in determining whether the European Communities' risk assessment satisfied the requirements of Article 5.1 and Annex A of the *SPS Agreement*.

F. *Conclusion*

617. We recall that we have found above that the Panel erred in its interpretation and application of Article 5.1 in relation to risks of misuse and abuse in the administration of hormones to cattle for growth-promoting purposes. We have also found that the Panel misallocated the burden of proof, and failed to conduct an objective assessment of the facts, in its analysis of whether the European Communities' risk assessment met the requirements of Article 5.1 of the *SPS Agreement*.

618. In addition, we found earlier that the Panel has infringed the European Communities' due process rights by inappropriately relying on the testimony of Drs. Boisseau and Boobis in its evaluation of the consistency with Article 5.1 of the *SPS Agreement* of the European Communities' risk assessment relating to oestradiol-17 β . Thus, the Panel's conclusions rest, to a large extent, on an improper evidentiary basis.

619. Accordingly, we reverse the Panel's finding that the European Communities has not satisfied the requirements of Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement*. As a consequence, we also reverse the Panel's findings that Directive 2003/74/EC was not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement* and that the European Communities' "implementing measure on oestradiol-17 β is not compatible with Article 5.1 of the *SPS Agreement*."

620. Having reversed the Panel, we must now determine whether we can complete the analysis by reviewing ourselves the consistency of the European Communities' risk assessment relating to oestradiol-17 β with Article 5.1 of the *SPS Agreement*. In the past, the Appellate Body has completed the analysis when there were sufficient factual findings by the panel or undisputed facts on the Panel record to enable it to do so. In light of the numerous flaws we have found in the Panel's analysis, and the highly contested nature of the facts, we do not consider it possible to complete the analysis in this case. Thus, we make no findings on the consistency or inconsistency of the European Communities' import ban relating to oestradiol-17 β .

VII. The Consistency with Article 5.7 of the SPS Agreement of the European Communities' Provisional Import Ban on Meat from Cattle Treated with Testosterone, Progesterone, Trenbolone Acetate, Zeranol, and MGA for Growth-Promotion Purposes

A. Introduction

621. We turn finally to the European Communities' appeal of the Panel's finding that the European Communities' provisional ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and MGA failed to meet the requirements of Article 5.7 of the *SPS Agreement* because the relevant scientific evidence was not "insufficient" within the meaning of that provision. ...

B. The European Communities' Evaluation of the Five Hormones Subject to the Provisional Ban

622. As we noted above, following the adoption of the DSB's recommendations and rulings in *EC – Hormones*, the European Communities initiated 17 scientific studies aimed at evaluating, *inter alia*, the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of oestradiol-17 β , testosterone, progesterone, zeranol, trenbolone acetate, and MGA. The results of these studies, as well as other publicly available information, were reviewed by the SCVPH. On 30 April 1999, the SCVPH issued the "1999 Opinion, in which it concluded that "in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones in question." As regards the five hormones, the 1999 Opinion further provided that "in spite of the individual toxicological and epidemiological data described in the report, the current state of knowledge did not allow a quantitative estimate of the risk." The European Communities concluded that "the currently available information for testosterone, progesterone and the synthetic hormones zeranol, trenbolone and particularly MGA has been considered inadequate to complete [a risk] assessment." The 1999 Opinion also states that "no final conclusions can be drawn with respect to the safety" of the five hormones.

623. The SCVPH subsequently reviewed the 1999 Opinion in 2000 and 2002, in the light of additional scientific information it received, but did not find it necessary to amend the conclusions originally reached in the 1999 Opinion. The 2000 Opinion emphasized "the obvious gaps in the present knowledge on target animal metabolism and residue disposition of the hormones under consideration, including the synthetic hormones", and stated that it expected "that the on-going [European Communities'] research programs will provide additional data on

both topics". The 2002 Opinion arrived at the following specific conclusions in relation to potential risks arising from residues of the five hormones in bovine meat:

(e) No new data regarding testosterone and progesterone relevant to bovine meat or meat products were available. However, it was emphasized that these natural hormones were used only in combination with oestradiol-17 β or other oestrogenic compounds in commercial preparations.

(f) Experiments with zeranol and trenbolone acetate suggested a more complex oxidative metabolism than previously assumed. These data needed further clarification as they might influence a risk assessment related to tissue residues of these compounds.

(g) Zeranol and trenbolone acetate had been tested for their mutagenic and genotoxic potential in various systems with different endpoints. Both compounds exhibited only very weak effects.

(h) Data on the genotoxicity of [MGA] indicated only weak effects. However, pro-apoptotic effects were noted in some cell-based assays, which were attributed to the impurities in commercial formulation. Further experiments should clarify the toxicological significance of these impurities.

(i) Model experiments with rabbits treated with zeranol, trenbolone acetate or [MGA], mirroring their use in bovines, were designed to study the consequences of pre- and perinatal exposure to exogenous hormones. All compounds crossed the placental barrier easily and influenced to varying degrees the development of the foetus, at the doses used in the experiments.

...

(k) Several studies were devoted to the potential impact of the extensive use of hormones on the environment. Convincing data were presented indicating the high stability of trenbolone acetate and [MGA] in the environment, whereas preliminary data were provided on the potential detrimental effects of hormonal compounds in surface water.

624. The European Communities enacted Directive 2003/74/EC, which provides for a *provisional* ban on meat and meat products from cattle treated with progesterone, testosterone, zeranol, trenbolone acetate and MGA for growth-promotion purposes. Before the Panel, the European Communities argued that the SCVPH Opinions and supporting studies provided the "available pertinent information" within the meaning of Article 5.7 on the basis of which the provisional ban on the five hormones had been enacted.

C. *The Panel's Findings*

(...)

626. Having identified Article 5.7 as the relevant provision, the Panel referred to the Appellate Body's interpretation of this provision as setting out the following four cumulative requirements that must be satisfied in order to adopt and maintain a provisional measure under the *SPS Agreement*:

- (a) the measure is imposed in respect to a situation where "relevant scientific evidence is insufficient";
- (b) the measure is adopted "on the basis of available pertinent information";
- (c) the WTO Member which adopted the measure must "seek to obtain the additional information necessary for a more objective assessment of risk"; and
- (d) the Member which adopted the measure must "review the ... measure accordingly within a reasonable period of time".

627. Turning to the first requirement, the Panel referred to the Appellate Body's statement in *Japan – Apples* that scientific evidence will be insufficient for purposes of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment. Recalling the approach it had adopted under Articles 5.1 and 5.2, the Panel dismissed the relevance of instances of misuse or abuse and difficulties of control in the administration of the five hormones for the purposes of its determination of whether the relevant scientific evidence on the five hormones was insufficient under Article 5.7. The Panel reasoned that instances of misuse and abuse are not, as such, a scientific issue likely to make a risk assessment impossible ...

628. The Panel then addressed the European Communities' argument that the appropriate level of protection is relevant for the purposes of determining whether the scientific evidence is insufficient. The Panel rejected the European Communities' argument on the basis of the following reasoning:

We note that sufficient scientific evidence is what is needed to make a risk assessment. The assessment whether there is sufficient scientific evidence or not to perform a risk assessment should be an objective process. The level of protection defined by each Member may be relevant to determine the measure to be selected to address the assessed risk, but it should not influence the performance of the risk assessment as such.

(...)

A risk-averse Member may be inclined to take a protective position when considering the measure to be adopted. However, the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.

629. The Panel next observed that the United States and Canada argued that JECFA and several national regulatory bodies have determined that the scientific evidence regarding these hormones is adequate or sufficient to conduct a risk assessment. The Panel, however, agreed with the parties that scientific evidence which was previously deemed to be sufficient could subsequently become insufficient. On this basis, the Panel sought to determine under what circumstances could relevant, previously sufficient, scientific evidence become insufficient within the meaning of Article 5.7.

630. Recalling the Appellate Body's decision in *Japan – Apples*, the Panel reasoned that "Article 5.7 will apply in situations where, in substance, the relevant scientific evidence does not allow the completion of an objective 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." Also referring to the Appellate Body's decision in *Japan – Apples*, the Panel stated that "the existence of scientific uncertainty does not automatically amount to a situation of insufficiency of relevant scientific evidence". The Panel added that, although it agreed that "under certain circumstances what was previously sufficient evidence could become insufficient", it did not "believe that the existence of scientific uncertainty means that previously sufficient evidence has in fact become insufficient nor should it *ipso facto* justify the applicability of Article 5.7 of the *SPS Agreement*".

631. The Panel then turned to examine the relationship between insufficiency of the evidence and the existence of an international standard. According to the Panel, "[t]he presumption of consistency of measures conforming to international standards, guidelines and recommendations with the relevant provisions of the *SPS Agreement* implies that these standards, guidelines or recommendations, particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*." The Panel recognized that "science continuously evolves", and that it "cannot be excluded that new scientific evidence or information calls into question existing evidence" or that "different risk assessments reach different interpretations of the same scientific evidence". For the Panel, the existence of international standards meant "that there was sufficient evidence for JECFA to undertake the appropriate risk assessments". The Panel added:

As a result, we consider that, in order to properly take into account the existence of international standards, guidelines and recommendations in this case, our approach should be to assess whether scientific evidence has become insufficient by determining whether the European Communities has produced any evidence of some sufficient change in the scientific knowledge so that what was once sufficient to perform an adequate risk assessment has now become insufficient (i.e., "deficient in force, quality or amount"). In this respect, suggesting hypothetical correlations or merely arguing that there could be more evidence on one concern or another should not be deemed sufficient to successfully claim that relevant scientific evidence has become *insufficient*. (original emphasis; footnote omitted)

632. The Panel concluded:

... if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that

"relevant scientific evidence is insufficient". Having regard to our reasoning above, particularly with respect to scientific uncertainty and the existence of international standards, we consider that, depending on the existing relevant evidence, 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. In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risks assessments. We therefore need to determine whether this is the case here. (original emphasis; footnote omitted)

(...)

636. With regard to the effects of the hormones on certain categories of the population, the Panel referred to the conclusions in the European Communities' risk assessment that individuals that have the lowest endogenous levels of sex hormones, particularly prepubescent children and post-menopausal women, might be at an increased risk of adverse health effects associated with exposure to exogenous sources of both oestrogens and testosterone. The Panel noted that the European Communities' risk assessment made reference to the development of new detection methods that had identified considerably lower levels of oestradiol endogenously produced by pre-pubertal children than the levels previously identified using traditional detection methods. The Panel also observed the European Communities' statement in the 1999 Opinion that "this is a critical area requiring additional study".

637. The Panel recalled the "critical mass" standard that it had developed to assess the insufficiency of the relevant scientific evidence under Article 5.7, and concluded that its task was to examine "whether the more sensitive detection methods which identified lower hormonal levels in prepubertal children than thought until now are such as to call into question the range of physiological levels of the sex hormones in humans currently believed to exist".

638. The Panel concluded that:

(...)

... we are not convinced that the studies discussed by the experts call into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient in relation to the effect of the five hormones on pre-pubertal children. Particularly, it has not been established that the data regarding the effects of hormones on which the JECFA assessments are based are insufficient in light of new evidence relating to the other five hormones at issue.

(...)

652. At the end of its analysis, the Panel said that it had asked the scientific experts whether the scientific evidence relied upon by the European Communities supported the European Communities' contention that the scientific studies initiated since 1997 had identified new important gaps, insufficiencies and contradictions in the scientific information and knowledge available on these hormones such that more scientific studies are necessary before the risk to human health from the consumption of meat from cattle treated with these hormones for growth-promotion purposes can be assessed. The Panel recalled its test 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 and noted that the experts who expressed themselves in detail on this matter confirmed, both in general and for each of the five hormones subject to a provisional ban, that such critical mass had not been reached.

653. Thus, the Panel found:

For all these reasons, we conclude that it has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, in relation to any of the five hormones with respect to which the European Communities applies a provisional ban.

654. Having made this finding, the Panel recalled that the four requirements outlined by the Appellate Body in *Japan – Agricultural Products II* applied cumulatively. The Panel added that, "[s]ince we found that the first requirement (the measure is imposed in respect to a situation where 'relevant scientific evidence is insufficient') has not been satisfied, we do not find it necessary to address any of the three other requirements." The Panel concluded:

We therefore conclude that the [European Communities'] compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned.

(...)

E. *The Panel's Finding that the Relevant Scientific Evidence in Relation to the Five Hormones Was Not "Insufficient" Within the Meaning of Article 5.7 of the SPS Agreement*

674. Under Article 2.2 of the *SPS Agreement*, WTO Members are required to "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." This requirement is made operative in other provisions of the *SPS Agreement*, including Article 5.1, which requires SPS measures to be "based on" a risk assessment. At the same time, Article 2.2 excludes from its scope of application situations in which the relevant scientific evidence is insufficient. In such situations, the applicable provision is Article 5.7 of the *SPS Agreement*. Thus, the applicability of Articles 2.2 and 5.1, on the one hand, and of Article 5.7, on the other hand, will depend on the sufficiency of the scientific evidence. The Appellate Body has explained that the relevant scientific evidence will be considered "insufficient" for purposes 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*." This means that where the relevant scientific evidence is sufficient to perform a risk assessment, as defined in Annex A of the *SPS Agreement*, a WTO Member may take an SPS measure only if it is "based on" a risk assessment in accordance with Article 5.1 and that SPS measure is also subject to the obligations in Article 2.2. If the relevant scientific evidence is insufficient to perform a risk assessment, a WTO Member may take a provisional SPS measure on the basis provided in Article 5.7, but that Member must meet the obligations set out in that provision.

675. Having discussed the relationship between Articles 2.2, 5.1 and 5.7, we now focus on the conditions for the application of a provisional SPS measure pursuant to the latter provision. 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.

676. The Appellate Body has explained that Article 5.7 sets out four obligations. Two of these obligations set conditions that must be met before a provisional SPS measure is adopted. The other two obligations are conditions for maintaining the provisional SPS measure once it has been taken. These four obligations are:

- (1) [the measure is] imposed in respect of a situation where "relevant scientific information is insufficient";
- (2) [the measure is] adopted "on the basis of available pertinent information";
- (3) [the Member that adopted the measure] "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
- (4) [the Member that adopted the measure] "review[s] the ... measure accordingly within a reasonable period of time."

677. Article 5.7 begins with the requirement that the "relevant scientific evidence" be "insufficient". As explained earlier, the relevant scientific evidence is "insufficient" where "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*." Under Article 5.1, WTO Members are allowed to base SPS measures on divergent or minority views provided they are from a respected and qualified source. Thus the existence of scientific controversy in itself is not enough to conclude that the relevant scientific evidence is "insufficient". It may be possible to perform a risk assessment that meets the requirements of Article 5.1 even when there are divergent views in the scientific community in relation to a particular risk. By contrast, Article 5.7 is concerned with situations where

deficiencies in the body of scientific evidence do not allow a WTO Member to arrive at a sufficiently objective conclusion in relation to risk. When determining whether such deficiencies exist, a Member must not exclude from consideration relevant scientific evidence from any qualified and respected source. Where there is, among other opinions, a qualified and respected scientific view that puts into question the relationship between the relevant scientific evidence and the conclusions in relation to risk, thereby not permitting the performance of a sufficiently objective assessment of risk on the basis of the existing scientific evidence, then a Member may adopt provisional measures under Article 5.7 on the basis of that qualified and respected view.

678. WTO Members' right to take provisional measures in circumstances where the relevant scientific information is "insufficient" is also subject to the requirement that such measures be adopted "on the basis of available pertinent information". Such information may include information from "the relevant international organizations" or deriving from SPS measures applied by other WTO Members. Thus, Article 5.7 contemplates situations where there is some evidentiary basis indicating the possible existence of a risk, but not enough to permit the performance of a risk assessment. Moreover, there must be a rational and objective relationship between the information concerning a certain risk and a Member's provisional SPS measure. In this sense, Article 5.7 provides a "temporary 'safety valve' in situations where some evidence of a risk exists but not enough to complete a full risk assessment, thus making it impossible to meet the more rigorous standards set by Articles 2.2 and 5.1."

679. The second sentence of Article 5.7 requires that the available pertinent information which provides a basis for a Member's provisional SPS measure be supplemented with "the additional information necessary for a more objective assessment of risk" within a "reasonable period of time". As the Appellate Body noted, these two conditions "relate to the *maintenance* of a provisional [SPS] measure and highlight the *provisional* nature of measures adopted pursuant to Article 5.7." The requirement that the WTO Member "shall seek to obtain the additional information necessary for a more objective assessment of risk" implies that, as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiencies in the relevant scientific evidence with additional scientific research or by gathering information from relevant international organizations or other sources. Otherwise, the provisional nature of measures taken pursuant to Article 5.7 would lose meaning. The "insufficiency" of the scientific evidence is not a perennial state, but rather a transitory one, which lasts only until such time as the imposing Member procures the additional scientific evidence which allows the performance of a more objective assessment of risk. The Appellate Body has noted that Article 5.7 does not set out "explicit prerequisites regarding the additional information to be collected or a specific collection procedure". Nevertheless, the WTO Member adopting a provisional SPS measure should be able to identify the insufficiencies in the relevant scientific evidence, and the steps that it intends to take to obtain the additional information that will be necessary to address these deficiencies in order to make a more objective assessment and review the provisional measure within a reasonable period of time. The additional information to be collected must be "germane" to conducting the assessment of the specific risk. A Member is required under Article 5.7 to seek to obtain additional information but is not expected to guarantee specific results. Nor is it expected to predict the actual results of its efforts to collect additional information at the time when it adopts the SPS measure. Finally, the Member taking the provisional SPS measure must review it within a reasonable period of time.

680. These four conditions set out in Article 5.7, however, must be interpreted keeping in mind that the precautionary principle finds reflection in this provision. As the Appellate Body has emphasized:

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 the perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.

In emergency situations, for example, a WTO Member will take a provisional SPS measure on the basis of limited information and the steps it takes to comply with its obligations to seek to obtain additional information and review the measure will be assessed in the light of the exigencies of the emergency.

(...)

1. Insufficiency and the Acceptable Level of Protection

682. The European Communities argues that the Panel failed to take into account that the European Communities had chosen a higher level of protection when determining whether the relevant scientific evidence is "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*. ...

(...)

685. A WTO Member that adopts an SPS measure resulting in a higher level of protection than would be achieved by measures based on international standards must nevertheless ensure that its SPS measure complies with the other requirements of the *SPS Agreement*, in particular Article 5. This includes the requirement to perform a risk assessment. At the same time, we recognize that, in order to perform a risk assessment, a WTO Member may need scientific information that was not examined in the process leading to the adoption of the international standard. We see no basis in Articles 3.3 and 5.1 of the *SPS Agreement* to conclude that WTO Members choosing a higher level of protection than would be achieved by a measure based on an international standard must frame the scope and methods of its risk assessment, including the scientific information to be examined, in the same manner as the international body that performed the risk assessment underlying the international standard. Thus, where the chosen level of protection is higher than would be achieved by a measure based on an international standard, this may have some bearing on the scope or method of the risk assessment. In such a situation, the 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.

686. For these reasons, we disagree with the Panel's finding that "the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection." We emphasize, however, that whatever level of protection a WTO Member chooses does not pre-determine the outcome of its determination of the sufficiency of the relevant scientific evidence. The determination as to whether available scientific evidence is sufficient to perform a risk assessment must remain, in essence, a rigorous and objective process.

687. The European Communities refers to the chosen level of protection to support its argument that the existence of JECFA risk assessments for the five hormones does not necessarily mean that the relevant scientific evidence was sufficient for the European Communities to perform its own risk assessment. Before the Panel, the European Communities explained that "the evidence which served as the basis for the 1988 and 1999-2000 JECFA evaluations is not sufficient 'to perform a definitive risk assessment within the meaning of Article 5.7, in particular by the WTO Members applying a high level of health protection of no risk from exposure to unnecessary additional residues in meat of animals treated with hormones for growth promotion'." We turn to this issue next.

2. Relevance of International Standards under Article 5.7 of the SPS Agreement

688. The European Communities claims that the Panel erred in finding that the existence of international standards demonstrates "sufficiency" of scientific evidence to perform a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*, and thereby precludes adoption of provisional measures under Article 5.7. According to the European Communities, the Panel considered that the existence of international standards established an "irrebuttable presumption" that the relevant scientific evidence in this case is not "insufficient" for the purposes of Article 5.7.

689. After recalling that international standards, guidelines or recommendations existed with respect to progesterone, testosterone, trenbolone acetate, and zeranol, the Panel observed "the important role given" to international standards by the *SPS Agreement*, and recalled that Article 3.2 of the *SPS Agreement* provides that measures which conform to international standards, guidelines or recommendations shall be presumed to be consistent with the relevant provisions of the *SPS Agreement*. On this basis, the Panel concluded that:

The presumption of consistency of measures conforming to international standards, guidelines and recommendations with the relevant provisions of the *SPS Agreement* implies that these standards, guidelines or recommendations, particularly those referred to in this case, are based on risk assessments that meet the requirements of the *SPS Agreement*. This means, therefore, that there was sufficient evidence for JECFA to undertake the appropriate risk assessments.

(...)

693. The relevant "international standards, guidelines or recommendations" that are referred to in Articles 3.1 and 3.2 are those set by the international organizations listed in Annex A, paragraph 3 of the *SPS Agreement*, which includes Codex as the relevant standard-setting organization for matters of food safety. As we noted above, Codex adopts international standards for veterinary drug residues based on evaluations performed by JECFA. In this case, Codex has adopted international standards for testosterone, progesterone, trenbolone acetate, and zeranol, on the basis of evaluation performed by JECFA. In addition, Codex has initiated a standard-setting process for MGA, also on the basis of JECFA's evaluation, but this process has not yet been concluded.

694. It is ... undisputed that JECFA has performed risk assessments for the six hormones at issue and that Codex has adopted international standards for five of these hormones on the basis of JECFA's risk assessments. The fact that JECFA has performed risk assessments for all six hormones means that the relevant scientific evidence was in its estimation sufficient to do so. Article 3.2 provides that SPS measures which conform to international standards shall be deemed necessary to protect human, animal or plant life or health, and shall be presumed to be consistent with the relevant provisions of the *SPS Agreement* and of the GATT 1994. This presumption, however, does not apply where a Member has not adopted a measure that conforms with an international standard. Article 3.2 is inapplicable where a Member chooses a level of protection that is higher than would be achieved by a measure based on an international standard. The presumption in Article 3.2 cannot be interpreted to imply that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher level of protection.

695. This is borne out by Article 5.7, which provides that WTO Members may adopt provisional SPS 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". There is no indication in Article 5.7 that a WTO Member may not take a provisional SPS measure wherever a relevant international organization or another Member has performed a risk assessment. Information from relevant international organizations may not necessarily be considered "sufficient" to perform a risk assessment, as it may be part of the "available pertinent information" which provides the basis for a provisional SPS measure under Article 5.7. Moreover, scientific evidence that may have been relied upon by an international body when performing the risk assessment that led to the adoption of an international standard at a certain point in time may no longer be valid, or may become insufficient in the light of subsequent scientific developments. Therefore, the existence of a risk assessment performed by JECFA does not mean that scientific evidence underlying it must be considered to be sufficient within the meaning of Article 5.7.

696. In our view, it is reasonable for a WTO Member challenging the consistency with Article 5.7 of a provisional SPS measure adopted by another Member to submit JECFA's risk assessments and supporting studies leading to the adoption of international standards as evidence that the scientific evidence is not insufficient to perform a risk assessment. However, such evidence is not dispositive and may be rebutted by the Member taking the provisional SPS measure.

697. ... Thus we find no fault with the Panel to the extent that it treated the evidence underlying JECFA's risk assessment as having probative value for determining whether the relevant scientific evidence was insufficient. In our view, the existence of risk assessments conducted by JECFA in relation to the five hormones at issue has probative value, but is not dispositive, of the question of whether the relevant scientific evidence on those hormones is "insufficient" within the meaning of Article 5.7.

698. The Panel relied on the existence of international standards to adopt a "critical mass" test for determining when scientific information that was previously considered sufficient becomes insufficient for purposes of Article 5.7 of the *SPS Agreement*. The European Communities also challenges this test on appeal. We examine this issue in the section that follows.

3. The Panel's "Critical Mass" Standard for Determining "Insufficiency" under Article 5.7 of the SPS Agreement

699. The European Communities asserts that the Panel's "critical mass" standard imposed an excessively "high quantitative and qualitative threshold" with respect to the new evidence that is required to render "insufficient" scientific evidence that was previously considered sufficient. According to the European Communities, the quality of the scientific evidence is more important than the quantity, and therefore even a single study could be considered *a priori* sufficient to question the sufficiency of previous scientific evidence. The European Communities adds that the Panel's "critical mass" standard effectively precluded the application of the precautionary principle in the interpretation of Articles 5.1 and 5.7, because the scientific evidence would pass immediately from a state of insufficiency under Article 5.7 to a state of sufficiency under Article 5.1.

(...)

701. We agree that scientific progress may lead a WTO Member and international organizations to reconsider the risk assessment underlying an SPS measure. In some cases, new scientific developments will permit a WTO Member to conduct a new risk assessment with the sufficient degree of objectivity. There may be situations, however, where the new scientific developments themselves do not permit the performance of a new risk assessment that is sufficiently objective. Such a situation would fall within the scope of Article 5.7 of the *SPS Agreement*.

702. The Appellate Body has explained 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*." The body of scientific evidence underlying a risk assessment can always be supplemented with additional information. Indeed, the nature of scientific inquiry is such that it is always possible to conduct more research or obtain additional information. The possibility of conducting further research or of analyzing additional information, by itself, should not mean that the relevant scientific evidence is or becomes insufficient.

703. Moreover, as the Panel noted, science continuously evolves. 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.

704. The Panel next discussed its understanding of "insufficiency" in the specific circumstances where international standards exist for the particular substance. It concluded:

We therefore conclude that if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that "relevant scientific evidence is insufficient". Having regard to our reasoning above, particularly with respect

to scientific uncertainty and the existence of international standards, we consider that, depending on the existing relevant evidence, 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. In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risks assessments. (original emphasis; footnote omitted)

705. 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 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.

(...)

708. We earlier observed that the existence of an international standard for which a risk assessment was conducted could be offered as evidence in support of an assertion that the relevant scientific evidence is not insufficient within the meaning of Article 5.7 of the *SPS Agreement*. It is an evidentiary issue in the sense that the scientific information underlying the international standard has probative value as to the sufficiency of the scientific evidence needed for conducting a risk assessment at a discrete point in time. However, 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. Thus, it is incorrect to use JECFA's risk assessments as a legal benchmark for assessing insufficiency as the Panel did in this case.

(...)

711. The particular insufficiencies in the relevant scientific evidence identified by the European Communities had to be evaluated on their own terms. As indicated earlier, the scientific evidence underlying the risk assessments conducted by JECFA has probative value as to the sufficiency of the scientific evidence needed to perform an assessment of risks in relation to the five hormones; however, it was by no means dispositive of that question, in particular where a WTO Member has elected to adopt an SPS measure that does not conform to the international standard.

712. For these reasons, we reverse the Panel's finding that, where international standards exist, "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" within the meaning of Article 5.7.

(...)

5. The Panel's Application of Article 5.7 of the SPS Agreement

719. We turn finally to the European Communities' claim that the Panel incorrectly applied Article 5.7 of the *SPS Agreement*. On appeal, the European Communities asserts that the Panel "systematically downplay[ed]" and ignored "highly relevant scientific evidence" which "go[es] against the evaluations of the JECFA or support the position of the European Communities and that in fact the scientific evidence was indeed insufficient" to perform a risk assessment, particularly in the following areas: (a) effects of hormones on certain population groups; (b) dose response; (c) bioavailability; (d) long latency periods for cancer and confounding factors; and (e) adverse effects on growth and reproduction. ...

(...)

721. As we noted in subsection 3, the Panel's "critical mass" test imposed an excessively high threshold in terms of the change in the scientific evidence that would make previously sufficient evidence insufficient. Rather than requiring that the new evidence call into question the relationship between the body of scientific evidence and the conclusions concerning risk, the Panel's test required a paradigm shift to the extent the evidence needed to call into question the "fundamental precepts of previous knowledge and evidence" on the five hormones. This erroneous threshold led the Panel to fail to attribute significance to evidence that could cast doubt as to whether the relevant scientific evidence still permits of a sufficiently objective assessment of risk. One such example is the Panel's analysis of the European Communities' contention that the relevant scientific evidence concerning the effects of the hormones on certain categories of the population, in particular pre-pubertal children, was "insufficient" within the meaning of Article 5.7 of the *SPS Agreement*.

722. Before the Panel, the European Communities argued that the development of more sensitive detection methods had identified lower endogenous levels of oestradiol in pre-pubertal children than previously assumed by the detection method referred to in JECFA's risk assessments. According to the European Communities, this suggested that individuals that have the lowest endogenous levels of sex hormones, such as pre-pubertal children and post-menopausal women, might be at an increased risk for adverse health effects that might be associated with exposure to exogenous sources of both oestrogens and testosterone.

723. The new detection method was examined in a scientific study conducted by Klein et al. (1994), and was reviewed by the European Communities in the 1999 Opinion. The Panel described the Klein study, and the conclusions the European Communities derived from it, as follows:

The 1999 Opinion specifies that the hormone levels on which it relies were determined by radio-immunoassays (RIA) and that the use of these assays has frequently been associated with production of variable results, particularly when used to detect low levels of endogenous hormones. The 1999 Opinion notes that Klein et al. (1994) developed an ultrasensitive assay (100-fold more sensitive than RIAs) which identified values of oestradiol considerably lower than the range of oestradiol levels found through RIAs for prepubertal children. (footnote omitted)

724. In its analysis, the Panel recalled its earlier finding that, in order to determine that the evidence on the five hormones was "insufficient" within the meaning of Article 5.7, there must be

"a critical mass of new evidence and/or information that calls into question the fundamental precepts of knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient." On this basis the Panel concluded that its task was to examine "whether the more sensitive detection methods which identified lower hormonal levels in prepubertal children than thought until now are such as to call into question the range of physiological levels of the sex hormones in humans currently believed to exist." The Panel referred to Dr. Sippell's testimony, which characterized the development of ultra-sensitive detection methods as a "quantum leap in [oestrogen] assay methodology" The Panel noted Dr. Sippell's statement that "[t]he risk to children arising from hormones that are naturally present in meat as compared to residues of hormonal growth promoters has, to my knowledge, been estimated for [oestradiol-17 β] only". The Panel then observed that the 2000 Opinion stated that such new detection methods had not been validated, and quoted Dr. Boobis' opinion questioning the validity of the new study presented by the European Communities. On this basis, the Panel concluded that:

We note that the evidence presented relates only to oestradiol, but that the claim we are examining with regard to the insufficiencies of the evidence are with respect to the five other hormones at issue, not oestradiol. We note furthermore that the 2002 Opinion concludes that these more sensitive detection methods have not yet been validated.

On the basis of the above, we are not convinced that the studies discussed by the experts call into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient in relation to the effect of the five hormones on pre-pubertal children. Particularly, it has not been established that the data regarding the effects of hormones on which the JECFA assessments are based are insufficient in light of new evidence relating to the other five hormones at issue.

725. In concluding that it is "not convinced" that the ultra-sensitive assay study referred to by the European Communities "call[s] into question the fundamental precepts of previous knowledge" in relation to the effect of the five hormones on pre-pubertal children, the Panel applied an excessively high threshold in relation to the new scientific evidence which is required to render previously sufficient scientific evidence "insufficient" within the meaning of Article 5.7. Irrespective of whether the Panel was itself persuaded by the Klein study, the Panel erred to the extent that it considered that a paradigmatic shift in the scientific knowledge was required in order to render the scientific evidence relied by JECFA now "insufficient" within the meaning of Article 5.7. The "insufficiency" requirement in Article 5.7 does not imply that new scientific evidence must entirely displace the scientific evidence upon which an international standard relies. It suffices that new scientific developments call into question whether the body of scientific evidence still permits of a sufficiently objective assessment of risk.

726. The Panel seemed to rely on two pieces of evidence in coming to the conclusion that the ultra-sensitive detection method discussed in the Klein study had not yet been validated: a statement to that effect in the 2002 Opinion, and the testimony of Dr. Boobis, who questioned the validity of the Klein study. However, the Panel record shows that at least some of the scientific experts considered that the Klein study could possibly cast doubt as to whether the body of scientific evidence relied on by JECFA still permitted of a sufficiently objective assessment of risks posed by the five hormones in relation to pre-pubertal children.

727. Dr. Sippell seemed to agree with the European Communities' position that the relevant scientific evidence on the effects of hormones in pre-pubertal children was not "sufficient" to conduct a risk assessment under Article 5.1. Dr. Sippell observed that "[w]e just don't have yet everywhere where it would be necessary the methodology, the analytical tools to measure as sensitively as we should do it, and therefore I think that the data available are insufficient." ...

728. Dr. De Brabander concurred, stating that "I cannot say that the [JECFA] data are bad ... I just say you don't know that they are good, and you have to check them with modern analytical methods." Dr. Guttenplan espoused a similar view, noting that "more accurate methods of analysis could now be used to measure the effect of eating hormone-treated beef on blood levels of estrogen in children and post-menopausal women." ...

(...)

730. Although the Panel was correct in observing that the Klein study only examined endogenous levels of oestradiol, lower levels of endogenous production of hormones in humans played a key role in the European Communities' conclusion that no safe threshold level or ADI could be established for any of the six hormones assessed. The 1999 Opinion states that, in the light of "uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no ADI can be established for any of the [six] hormones." For this reason, the Panel should have explored further the question of what relevance, if any, the study relied on by the European Communities examining endogenous levels of oestradiol could have in relation to potential adverse health effects relating to the other five hormones. ...

731. In sum, the Panel erred in its interpretation and application of Article 5.7 of the *SPS Agreement* by adopting an incorrect legal test to assess the European Communities' explanations concerning the insufficiencies in the relevant scientific evidence.

(...)

F. *Conclusions*

733. We found above that the Panel drew too rigid a distinction between the chosen level of protection and the "insufficiency" of the relevant scientific evidence under Article 5.7 of the *SPS Agreement*. We also reversed the Panel's finding that, where international standards exist, a "critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence" is required to render the relevant scientific evidence "insufficient" within the meaning of Article 5.7. ... Finally, we found that the Panel incorrectly interpreted and applied Article 5.7 in determining whether the relevant scientific evidence in relation to the five hormones was "insufficient" within the meaning of that provision. In addition, we have found that the Panel's analysis was compromised because its consultations with Drs. Boisseau and Boobis infringed the European Communities' due process rights.

734. In the light of these errors, we reverse the Panel's finding that "it has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, in relation to any of the five hormones with respect to which the European Communities applies a provisional ban." As a consequence of its finding, the Panel also concluded that "the [European Communities'] compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone,

testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned." Because it is premised on the Panel's earlier finding concerning the "insufficiency" of the relevant scientific information, which we have reversed, the Panel's conclusion cannot stand.

735. Given the numerous flaws that we identified in the Panel's analysis, and the highly contested nature of the facts, we do not consider it possible to complete the analysis. Thus, we make no findings on the consistency or inconsistency of the European Communities' provisional SPS measure relating to progesterone, testosterone, zeranol, trenbolone acetate and MGA.

VIII. Findings and Conclusions

736. For the reasons set out in this Report, the Appellate Body:

(...)

(b) As regards the Panel's consultations with the scientific experts, finds that the Panel infringed the European Communities' due process rights, because the institutional affiliation of Drs. Boisseau and Boobis compromised their appointment and thereby the adjudicative independence and impartiality of the Panel. Accordingly, the Panel failed to comply with its duties under Article 11 of the DSU.

(c) As regards the consistency with Article 5.1 of the *SPS Agreement* of the European Communities' import ban on meat from cattle treated with oestradiol-17 β for growth-promotion purposes, which is applied pursuant to Directive 2003/74/EC:

(i) finds that the Panel erred in its interpretation and application of Article 5.1 in relation to risks of misuse and abuse in the administration of hormones to cattle for growth-promotion purposes;

(...)

(v) finds that the Panel applied an incorrect standard of review in examining whether the European Communities' risk assessment satisfied the requirements of Article 5.1 and paragraph 4 of Annex A of the SPS Agreement, and thereby failed to comply with its duties under Article 11 of the DSU; and

(vi) reverses the Panel's finding that the European Communities' import ban relating to oestradiol-17 β is not based on a risk assessment as required by Article 5.1 of the SPS Agreement; however, the Appellate Body is unable to complete the analysis and therefore makes no findings as to the consistency or inconsistency of the import ban relating to oestradiol-17 β with Article 5.1 of the SPS Agreement.

(d) As regards the consistency with Article 5.7 of the *SPS Agreement* of the European Communities' provisional import ban on meat from cattle treated with testosterone, progesterone, trenbolone acetate, zeranol, and MGA, for growth-promotion purposes, which is applied pursuant to Directive 2003/74/EC:

- (i) reverses the Panel's finding that "the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection";
- (ii) reverses the Panel's finding that, where international standards exist, "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";
- (...)
- (iv) finds that the Panel erred in its interpretation and application of Article 5.7 of the SPS Agreement by adopting an incorrect legal test in determining whether the relevant scientific evidence was "insufficient";
- (v) does not find it necessary to address the European Communities' claim that the Panel acted inconsistently with Article 11 of the DSU; and
- (vi) reverses the Panel's finding that the provisional import ban relating to testosterone, progesterone, trenbolone acetate, zeranol, and MGA does not meet the requirements of Article 5.7 of the SPS Agreement; however, the Appellate Body is unable to complete the analysis and therefore makes no findings as to the consistency or inconsistency of the European Communities' provisional import ban with Article 5.7 of the SPS Agreement.

737. Because we have been unable to complete the analysis ... the recommendations and rulings adopted by the DSB in *EC – Hormones* remain operative. ... [W]e recommend that the Dispute Settlement Body request the United States and the European Communities to initiate Article 21.5 proceedings without delay in order to resolve their disagreement as to whether the European Communities has removed the measure found to be inconsistent in *EC – Hormones* and whether the application of the suspension of concessions by the United States remains legally valid.

3. Japan – Measures Affecting the Importation of Apples (2003)

3-1. Appellate Body Report, WT/DS245/AB/R, 26 November 2003

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

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

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 disease¹⁶ 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 infected¹⁷ by fire blight exude bacterial ooze, or inoculum¹⁸, which is

¹⁶ 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)

¹⁷ "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))

¹⁸ 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

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.

9. 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.

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". Japan did not accept the United States' categorization, arguing that "mature" and "symptomless" are subjective terms and that the distinction has no scientific basis. 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.

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*."²⁸ 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. The Panel also noted that it would be "illogical" to accept the United States'

soil, air or water and which by chance results in the natural inoculation of a host." (*Ibid.*, para. 2.14)

²⁸ Panel 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.*)

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.³⁰

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"³³ 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 instruments³⁵, Japan maintains nine prohibitions or requirements imposed with respect to apple fruit imported 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.

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:

³⁰ *Ibid.*, 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.*)

³³ We 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.

³⁵ The 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)

- (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);
- (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. (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.

(...)

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*

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. Thus, the Panel also considered the risk associated with other apples (that is, immature apples, or mature but damaged apples) 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 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;
- The possible presence of endophytic²⁴⁴ 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;

²⁴⁴ The 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))

- The presence of epiphytic²⁴⁶ bacteria in mature, symptomless apples is considered to be very rare;
- It is not contested that immature apple fruit can be infected or infested by *Erwinia amylovora*;
- Infected apples are capable of harbouring populations of bacteria that could survive through the various stages of commercial handling, storage, and transportation;
- 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; 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 blight 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.

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.

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. 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. 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*.

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*.

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

²⁴⁶ The 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))

States" relating to the risk associated with infected apple fruit. 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. 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", 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. 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.

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" be accorded to the importing Member as to the manner it chooses, weighs, and evaluates scientific evidence. 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". 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"—is reasonable as well as scientific because it is derived from "perspectives of prudence and precaution".²⁶⁹ 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.

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*".²⁷¹ 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

²⁶⁹ *Ibid.*, para. 81, quoting Appellate Body Report, *EC – Hormones*, para. 124.

²⁷¹ Appellate Body Report, *EC – Hormones*, para. 98. (emphasis added)

burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency.²⁷²

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*.²⁷³ (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;
- 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.

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" or 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."

²⁷² Appellate Body Report, para. 98.

²⁷³ Appellate Body Report, p. 14, DSR 1997:I, 323, at 335.

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 from, on the other hand, the principle that the party that asserts a fact is responsible for providing proof thereof. In fact, the two principles are distinct. In the present case, the burden of demonstrating a *prima facie* case that Japan's measure is maintained without sufficient scientific evidence, rested on the United States. Japan sought to counter the case put forward by the United States by putting arguments in respect of apples other than mature, symptomless apples being exported to Japan as a result of errors of handling or illegal actions. It was thus for Japan to substantiate those allegations; it was not for the United States to provide proof of the facts asserted by Japan. Thus, we disagree with Japan's assertion that "the shift of the burden of proof to Japan was made prematurely *before* the demonstration of a *prima facie* case by the United States." There was no "shift of the burden of proof" with respect to allegations of fact relating to apples other than mature, symptomless apples, for Japan was solely responsible for providing proof of the facts it had asserted. Moreover, it was only after the United States had established a *prima facie* case that Japan's measure is maintained without sufficient scientific evidence, that the Panel had to turn to Japan's attempts to counter that case.

158. Japan also contends that the Panel did not have the authority to make certain findings of fact 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.²⁸²

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. 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*

²⁸² Appellate Body Report, para. 129; Japan's appellant's submission, paras. 18 and 44.

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."²⁸⁴ 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."²⁸⁵ 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.²⁸⁶ 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.²⁸⁹ Thus, we find no error in the Panel's approach that the 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

²⁸⁴ Appellate Body Report, para. 104.

²⁸⁵ Appellate Body Report, p. 14, DSR 1997:I, 323, at 335.

²⁸⁶ Panel 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)

²⁸⁹ In 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.

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 scientific evidence available." 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".

164. 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.

165. 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.³⁰¹ 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".

166. 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.³⁰² 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 facts³⁰³; they enjoy "a margin of discretion in assessing the value of the evidence, and the weight to be ascribed to that evidence."³⁰⁴ 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*.

³⁰¹ Appellate Body Report, *EC – Hormones*, para. 117.

³⁰² Appellate Body Report, para. 142.

³⁰³ Appellate Body Report, *EC – Bed Linen (Article 21.5 – India)*, paras. 170, 177, and 181; Appellate Body Report, *EC – Sardines*, para. 299; Appellate Body Report, *Korea – Alcoholic Beverages*, paras. 161-162; Appellate Body Report, *EC – Hormones*, para. 132; and Appellate Body Report, *US – Wheat Gluten*, para. 151. See also, Appellate Body Report, *Australia – Salmon*, paras. 262-267; Appellate Body Report, *Japan – Agricultural Products II*, paras. 140-142; and Appellate Body Report, *Korea – Dairy*, paras. 137-138.

³⁰⁴ Appellate Body Report, *EC – Asbestos*, para. 161.

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".

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*.³¹² 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 5.7.³¹⁶

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";
- (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".³¹⁸

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

177. The Panel's findings address exclusively the first requirement, which the Panel found Japan had not met. 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". Hence, Japan submits that the

³¹² We 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)

³¹⁶ The 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.

³¹⁸ Appellate 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.

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." According to Japan, the Panel "erred by interpreting the applicability of [Article 5.7] too narrowly" and too "rigid[ly]".

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".³²⁶ 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 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", 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."

181. Japan also raised specific questions related to endophytic bacteria in mature apple fruit and regarding the completion of contamination pathways. 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. Moreover, Japan did not persuade the Panel that this scientific evidence is not conclusive or has not produced reliable results.

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

³²⁶ The risk assessment referred to in Article 5.1 is defined in Annex A to the *SPS Agreement*.

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"³³² 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" 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.

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", 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.

³³² Annex A to the *SPS Agreement*, para. 4.

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". 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" 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." 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" unless the United States had raised an objection based on "history", something that the United States had not done.

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". This statement was relevant to the debate under Article 5.7 and was based on the evidence before the Panel.³⁴⁶ 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. 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."

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. 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".

³⁴⁶ We 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)

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 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."

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. 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. 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. 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". 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. 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 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 ...³⁶⁰

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*.³⁶¹ (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. 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

³⁶⁰ The 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)

³⁶¹ *Ibid.*, para. 121.

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.³⁶³
(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*.³⁶⁴

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

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*. 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. As the Panel stated in response to Japan's comments during the Interim Review, "Japan evaluated the

³⁶³ Appellate Body Report, *EC – Hormones*, para. 199.

³⁶⁴ *Ibid.*, para. 200.

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."

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. Rather, Japan claims that the Panel's reasoning relates to a "matter of methodology", which lies within the discretion of the importing Member. 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.

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.³⁷² The Appellate Body found the risk 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."³⁷³ 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".³⁷⁴ 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." 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. 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", 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 "evaluat[ion of] the risks associated with all possible hosts taken together" 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.³⁷⁹

³⁷² Indeed, 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.

³⁷³ 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.

³⁷⁴ *Ibid.*, para. 200.

³⁷⁹ 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

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 methodology" not directly addressed by the *SPS Agreement*. 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"³⁸¹, expressly contemplate examining risk in relation to particular pathways.³⁸² 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, 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*.

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.

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*.

³⁸¹ Japan's appellant's submission, para. 128, quoting "Guidelines for Pest Risk Analysis", *International Standard for Phytosanitary Measures*, No.2 (Rome 1996), Food and Agriculture Organization of the United Nations; Exhibit JPN-30, submitted by Japan to the Panel; and "Pest Risk Analysis for Quarantine Pests", *International Standard for Phytosanitary Measures*, No.11 (Rome 2001), Food and Agriculture Organization of the United Nations; Exhibit USA-15, submitted by the United States to the Panel.

³⁸² For 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

...

(...)

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'." 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." Japan acknowledged that it did not consider policies other than the measure already applied. However, according to Japan, this "again relates to the matter of methodology", which is left to the discretion of the importing Member.

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".³⁸⁸ We agree with the Panel that this phrase "refers to the measures *which might* be applied, not merely to the measures which *are being* applied." The phrase "which might be applied" is used in the conditional tense. In this sense, "might" means: "were or would be or have been able to, were or would be or have been allowed to, were or would perhaps".³⁹⁰ We understand this phrase to imply that a risk assessment should not be limited to an examination of the measure already in place or favoured by the importing Member. In other words, the evaluation contemplated in paragraph 4 of Annex A to the *SPS Agreement* should not be distorted by preconceived views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*.

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'."

³⁸⁸ Annex A to the *SPS Agreement*, para. 4.

³⁹⁰ *Shorter Oxford English Dictionary*, 5th ed., W.R. Trumble, A. Stevenson (eds.) (Oxford University Press, 2002), Vol. I, p. 1725.

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.

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*. 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".

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". 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". 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.

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.⁴⁰³ Such evidence could have reasonably formed the basis for the Panel's

⁴⁰³ See, for example, R.G. Roberts *et al.*, "The potential for spread of *Erwinia amylovora* and fire blight via

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 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.⁴⁰⁴

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*.

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.

⁴⁰⁴ Article 3.7 of the DSU.

4. Optional Reading

4-1. Case Law

Editorial Note: Footnotes have been omitted from the following excerpts

4-1-A. Case law concerning SPS Article 5.1: “Risk Assessment”

Appellate Body Report, Australia – Measures Affecting the Importation of Apples from New Zealand, WT/DS367/AB/R (November 29, 2010).

(...)

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. 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.

(...)

4-1-B. Case law concerning SPS Article 5.5: “Different” Situations

Appellate Body Report, Australia-Measures Affecting the Importation of Salmon, WT/DS18/AB/R (Oct. 20, 1998)

(...)

2. ... 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, revised in May 1996 and finalized in December of 1996 (the "1996 Final Report"). The 1996 Final Report concluded that: ... it is recommended that the present quarantine policies for uncooked salmon products remain in place. 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.

(...)

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.

(...)

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.

(...)

152. ... [W]e 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.

(...)

4-1-C. Case law concerning SPS Article 5.7: “where relevant scientific evidence is insufficient”

(From the *WTO Analytical Index*, excerpting portions of *Japan—Apples*
http://www.wto.org/english/res_e/booksp_e/analytic_index_e/sps_02_e.htm#article5B7b)

295. 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.”

296. 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’.”

(...)

4-2. The Hermeneutics of Science in WTO Law

From Control to Communication: Science, Philosophy and World Trade Law (by Sungjoon Cho)
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1583023

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.”¹ 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”² that one can truly understand, and reconcile with, the other. Only in this open-mindedness, which is often compared to “conversation,”³ can one party voluntarily accept some position which may be even *against* itself.⁴ 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.⁵ Only with this dialogue or conversation can different horizons be “fused,” followed by a true understanding of the other.⁶ In

¹ Taylor, *supra* note __, at 127.

² *Id.*, at 132.

³ *Id.*, at 134.

⁴ 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.

⁵ George Warnke, *Law, Hermeneutics, and Public Debate*, 9 YALE J. L. & HUM. 395, 411 (1997).

⁶ TRUTH AND METHOD, *supra* note __, at 306.

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.⁷ In many cases, "a tremendous leap from a tiny amount of data" may still appear to be scientific.⁸ 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.⁹

The essential lesson from the philosophy of hermeneutics – as it is related to risk science in the WTO – is an unyielding interpretive openness¹⁰ through "a lessening of distance"¹¹ between an interpreter and an interpretandum, anchored by a firm acknowledgement of the inevitable finitude of human experience.¹² After all, the truth can emerge only "in a conversation."¹³ Nor does there exist a final, definite answer when it comes to understanding (truth). Truth only exists, or operates, continuously in the "hermeneutical circle"¹⁴ 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."¹⁵

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

⁷ Karl R. Popper, *Philosophy of Science: A Personal Report*, in BRITISH PHILOSOPHY IN MID-CENTURY 155, 157 (C.A. Mace. ed., 1957) (characterizing Marxism and psychoanalysis as "myths").

⁸ Feldman, *supra* note __, at 145.

⁹ 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.").

¹⁰ See Axel Honneth, *On the Destructive Power of the Third: Gadamer and Heidegger's Doctrine of Intersubjectivity*, 29 PHIL. & SOC. CRITICISM, 5, 5 (2003); Dennis J. Schmidt, *Gadamer*, in A COMPANION TO CONTINENTAL PHILOSOPHY 433 (Simon Critchley & William R. Schroeder eds. 1998).

¹¹ Honneth, *supra* note __, at 5.

¹² Schmidt, *supra* note __, at 440.

¹³ *Id.*, at 434

¹⁴ "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.

¹⁵ Schmidt, *supra* note __, at 436; TRUTH AND METHOD, *supra* note __, at 6.

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. $A_0 \rightarrow (B_0 \rightarrow B_1) \rightarrow A_0 \rightarrow (B_1 \rightarrow B_2) \rightarrow \dots$
2. $A_0 \rightarrow B_0 \rightarrow (A_0 \rightarrow A_1) \rightarrow (B_0 \rightarrow B_1) \rightarrow \dots$

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 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 A0. Then, B may want to voluntarily modify its original position (B0→B1) to accommodate A0. This process may continue multiple times until B's policy change truly gets fused with A's original position (A0).

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 (A0→A1 and B0→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 cases¹⁶ 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

¹⁶ See *supra* note __.

review forums (e.g., the Trade Policy Review Mechanism (TPRM)).¹⁷ In this line, the constructive resolution of a recent trade dispute involving genetically modified (GM) products between the EU and Canada was hermeneutically sound, especially given that both parties established an avenue for continuing dialogue.¹⁸

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.¹⁹ 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)]

Sector	Total Number of Concerns Resolved	Regulating (Importing) States	Complaining (Exporting) States
Animal Health	41	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.
Food Safety	20	Australia, China, Czech Rep., EC, Korea, Malaysia, New Zealand, Philippines, Poland, Singapore, Spain, Switzerland,	Argentina, 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.

¹⁷ 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”).

¹⁸ See David Akin, *EU Drops Ban on Genetically Modified Canola from Canada*, Calgary Herald, Jul. 15, 2009; Ian Austen & James Kanter, *Canada Settles a Crop Trade Complaint Against Europe*, NY Times, Jul. 16, 2009.

¹⁹ 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).

(Source: WTO, SPS Committee)²⁰

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.²¹ 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,”²² 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.²³ 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 other courts, certain procedural deficiencies are often linked to substantive violations.²⁴

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.”²⁵ 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.

²⁰ WTO, Committee on Sanitary and Phytosanitary Measures, Specific Trade Concerns: Resolved Issues, G/SPS/GEN/204/Rev.9/Add.3, Feb. 6, 2009.

²¹ Feldman, *supra* note __, at 167.

²² See Jonathan Baert Wiener & John D. Graham, *Resolving Risk Tradeoffs, in RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT* 226, 230 (John D. Graham & Jonathan Baert Wiener eds., 1995).

²³ Cho, *World Trade Court’s Burden*, *supra* note __, at 717-18 (discussing a “Copernican turn” of shifting from “substantive finality” to “procedural legitimacy”).

²⁴ 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).

²⁵ SPS Agreement, *supra* note __, Annex B, ¶5(b).

[Table 5: Matching Procedural Obligations with Substantive Obligations under the SPS Agreement]

Procedural Obligations	Substantive Obligations
Article 3.4 (requiring members to engage in serious dialogue on international standards); Article 5.8 (requiring a member deviating from international standards to answer an exporting country’s inquiries)	Article 3.1 (requiring members to base their SPS measures on relevant international standards)
Article 5.8 (requiring a member deviating from international standards to answer an exporting country’s inquiries); Article 7 (requiring members to notify information on their SPS measures)	Article 5.1 (requiring the existence of a rational relationship between a risk assessment and an SPS measure)
Article 5.8 (requiring a member deviating from international standards to answer an exporting country’s inquiries); Article 7 (requiring members to notify information on their SPS measures)	Article 5.4 (requiring members to take into account the goal of minimizing negative trade effects); Article 5.5 (requiring members to maintain consistency in determining the appropriate level of regulatory protection)
Article 5.7 (the 3rd & 4th Prong) (requiring members to explore additional information for an objective risk assessment when imposing a provisional measure and review the measure within a reasonable period of time)	Article 5.7 (the 1st & 2nd Prong) (requiring members to adopt a provisional measure only when there is insufficient scientific information but on the basis of any pertinent available information)

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.²⁶

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.²⁷

²⁶ 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, *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).

²⁷ WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the WTO Agreement, *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.”).