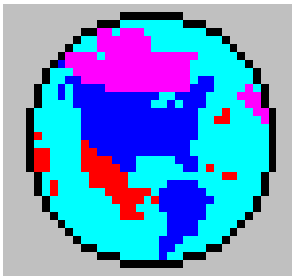
THE LAW OF
REGIONAL ECONOMIC INTEGRATION
IN THE AMERICAN HEMISPHERE



J.H.H. Weiler
University Professor, NYU
Joseph Straus Professor of Law and European Union Jean Monnet Chair,
NYU School of Law

AND

Sungjoon Cho
Assistant Professor of Law,
Chicago-Kent College of Law,
Illinois Institute of Technology

Unit VIII

Sanitary and Phytosanitary Measures (SPS)

Table of Contents

Guiding Questions

Reflect on the following questions while and after reading the material:

1. *Hormones*

   a. *What is the legal relationship between the GATT and the SPS Agreement? Are they parallel obligations; is the SPS Agreement more special; is the SPS Agreement an elaboration of (lex specialis to) Art. XX? Is there a legal conflict allowing the application of the lex specialis rule? See para. 8.273 of the panel report: is the panel's view compelling?*

   b. *SPS Art. 3: what do you think "shall base on" exactly means? Imagine a measure based on, but not conforming to, an international standard.*

   c. *Can you think of why the Appellate Body overruled the panel on the procedural requirements for adopting an SPS measure? Note that the EC attempted to justify its original regulatory stance on the hormone ban by submitting new scientific evidence that would support the ban even after it lost the case.*

   d. *Is the Appellate Body's rejection of the concept of "risk management" plausible? Note that this concept is widely used in the international environmental law.*

   e. *SPS Art. 5.5: Should there be a fundamental distinction between "man-made risks" and "naturally-occurring risks" as expressed in the Appellate Body's ruling? Would such regulatory attitude based on "common sense" or "human face" be still scientific?*

   f. *In interpreting the third element ("arbitrary or unjustifiable differences resulting in discrimination or disguised restriction on international trade"), the Appellate Body rejected the panel's finding that the EC was actually motivated by protectionist intent. Wouldn't the portion of "resulting in discrimination or disguised restriction on international trade" unduly narrow down the operative scope of Art. 5.5? Compare SPS Art. 5.5 with a similar language found in the chapeau of GATT Art. XX.*

   g. *Is the precautionary principle something new and if so, in what sense?*

   h. *The U.S.A. won the case but the EC maintains the ban despite retaliation. Was it wrong to bring the case?*

1. Introduction

1-1. Overview

1-1-1. NAFTA

Chapter 7, Section B: Sanitary and Phytosanitary Measures

http://www.sice.oas.org/summary/nafta/nafta7.asp

This section only applies to SPS measures that may directly or indirectly affect trade between NAFTA countries. All other standards-related measures are dealt with in chapter nine (Article 709). Additionally, Article 301 (national treatment) and Article 309 (import and export restrictions) do not apply to SPS measures because it may be necessary in some situations for SPS measures to treat imported goods less favourably or to restrict or prohibit them in order to protect against the spread of pests or disease. Because these provisions do not apply, the GATT Article XX(b) exception (necessary to protect human, animal or plant life or health) is not required to justify SPS measures (Article 710).

Unlike chapter nine, section B of chapter seven only applies to governments. Article 711, however, requires that each Party ensure that any non-governmental entity on which it relies in applying an SPS measure, e.g., one that administers a control or inspection procedure, acts consistently with section B.

Article 712 confirms the right of each country to establish the level of SPS protection that it considers appropriate and provides that a NAFTA country may achieve the levels of protection through SPS measures that: are based on scientific principles and a risk assessment; are applied only to the extent necessary to provide a country's appropriate level of protection; and do not result in unfair discrimination or disguised restrictions on trade.

Each Party retains the right to establish its own appropriate level of protection, subject to the limitations set out in this section. Each Party, in establishing its appropriate level of protection " ...should take into account the objective of minimizing negative trade effects, ..." with the objective of achieving consistency in such levels, to "... avoid arbitrary or unjustifiable distinctions in such levels in different circumstances, where such distinctions result in arbitrary or unjustifiable discrimination against a good of another Party or constitute a disguised restriction on trade between the Parties." (Article 715)

To avoid creating unnecessary barriers to trade, Article 713 encourages the three countries to use relevant international standards in the development of their SPS measures. When a Party uses a relevant international standard, guideline or recommendation it shall be presumed to have met its basic rights and obligations and cannot be challenged by another Party. However, NAFTA permits each country to adopt more stringent, science-based measures when, and only when necessary, to achieve its

appropriate level of protection. The three countries will promote the development and review of international SPS standards in such international and North American standardizing organizations as the Codex Alimentarius Commission, the International Office of Epizootics, the Tripartite Animal Health Commission, the International Plant Protection Convention and the North American Plant Protection Organization.

Under Article 714, the Parties have agreed to work toward equivalent SPS measures without reducing any country's appropriate level of protection of human, animal or plant life or health. Each Party will accept SPS measures of another Party as equivalent to its own, provided that the exporting country demonstrates that its measures achieve the importing country's appropriate level of protection. In the development of new SPS measures, Parties are required to consider relevant actual and proposed like measures of the other Parties.

Article 715 establishes disciplines on risk assessment. including those for evaluating the likelihood of entry, establishment or spread of pests and diseases. SPS measures must be based on an assessment of risk to human, animal or plant life or health, taking into account risk assessment techniques developed by international or North American standardizing organizations. A Party may grant a phase-in period for compliance by goods from another Party where the phase-in would be consistent with ensuring the importing country's appropriate level of SPS protection. Where there is insufficient scientific evidence or information, a Party may adopt a provisional SPS measure based on available information, including from relevant international standard-setting organizations and from the other Parties. However, the Party is obliged to revise the provisional measure in a timely fashion once sufficient information is available.

Article 716 establishes rules for the adaptation of SPS measures to regional conditions, in particular regarding pest disease-free areas or areas of low pest or disease prevalence. An exporting country must provide objective evidence whenever it claims that goods from its territory originate in a pest- or disease-free area or area of low pest or disease prevalence. This particular provision is important to all three Parties as each country is large geographically and climatic conditions vary greatly within national boundaries. This creates considerable variation in disease and pest prevalence and control conditions. The rules provide conditions-under which product can move on a regional basis when this does not create a risk that cannot be managed by the importing country.

Article 717 establishes rules governing procedures for ensuring the fulfillment of SPS measures. These rules allow for the continued operation of domestic control, inspection and approval procedures, including national systems for approving the use of additives and for establishing tolerances for contaminants in foods, beverages or feedstuffs, subject to such disciplines as national treatment, timeliness and procedural transparency. Where it is necessary to address an urgent problem relating to sanitary or phytosanitary protection and it is not possible to phase in effective dates, each NAFTA country has the responsibility to immediately contact the other countries to provide information about the emergency measures.

Article 718 requires public notice in most cases prior to the adoption or modification of any SPS measures that may affect trade in North America. The notice must identify the goods to be covered, and the objectives of and reasons for the measure. All SPS measures must be published promptly. The Parties will facilitate the provision of technical assistance concerning SPS measures either directly or through appropriate international or North American standardizing organizations (Article 720).

Each country will designate an inquiry point to provide information regarding SPS measures to other Parties and any interested persons including relevant documents regarding any SPS measures, risk assessment procedures, and participation in international standard-setting organizations and systems. As a result, each Party will need to maintain an up-to-date database on the full range of its standards, SPS measures and risk assessment procedures (Article 719). Article 721, however, provides protection for confidential information.

A Committee on Sanitary and Phytosanitary Measures will facilitate the enhancement of food safety and sanitary conditions in the free-trade area, promote the harmonization and equivalence of SPS measures and facilitate technical cooperation and consultations, including consultations regarding disputes involving SPS measures (Article 722). It will oversee the activities of working groups, established as needed to resolve specific issues. The committee will meet on the request of any Party and, unless the Parties otherwise agree, at least once each year. A progress report will be provided to the Commission annually. It shall, to the extent possible, seek the assistance of relevant international and North American standardizing organizations to obtain available scientific and technical advice and minimize duplication of effort.

The Committee will also serve as a forum for technical consultations (Article 723), and may provide technical advice or recommendations on any SPS measure. If these expert consultations fail to resolve a matter in dispute, any consulting Party may request a meeting of the Commission (Article 2007).

1-1-2. WTO

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

INTRODUCTION

The Sanitary and Phytosanitary Measures Agreement

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

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

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

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

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

Key Features

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

Protection or protectionism?

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

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

Justification of measures

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

International standards

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

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

Adapting to conditions

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

Alternative measures

An acceptable level of risk can often be achieved in alternative ways. Among the alternatives — and on the assumption that they are technically and economically feasible and provide the same level of food safety or animal and plant health — governments should select those which are not more trade restrictive than required to meet their health objective. Furthermore, if another country can show that the measures it applies provide the same level of health protection, these should be

accepted as equivalent. This helps ensure that protection is maintained while providing the greatest quantity and variety of safe foodstuffs for consumers, the best availability of safe inputs for producers, and healthy economic competition.

Risk Assessment

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

Transparency

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

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

QUESTIONS AND ANSWERS

What are sanitary and phytosanitary measures? Does the SPS Agreement cover countries' measures to protect the environment? Consumer interests? Animal welfare?

For the purposes of the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

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

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

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

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

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

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

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

What is new in the SPS Agreement?

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

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

to be consistent in their decisions on what is safe food, and in responses to animal and plant health concerns.

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

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

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

whether or not these are technical requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

diseases on animal and plant health. The work of these technical organizations is subject to international scrutiny and review.

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

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

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

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

Three different types of precautions are provided for in the SPS Agreement. First, the process of risk assessment and determination of acceptable levels of risk implies the routine use of safety margins to ensure adequate precautions are taken to protect health. Second, as each country determines its own level of acceptable risk, it can respond to national concerns regarding what are necessary health precautions. Third, the SPS Agreement clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. This also permits immediate measures to be taken in emergency situations.

There are many examples of bans on the production, sale and import of products based on scientific evidence that they pose an unacceptable risk to human, animal or plant health. The SPS Agreement does not affect a government’s ability to ban products under these conditions.

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

It is accepted in the SPS Agreement that food safety and animal and plant health regulations do not necessarily have to be set by the highest governmental authority and that they may not be the same throughout a country. Where such regulations affect international trade, however, they

should meet the same requirements as if they were established by the national government. The national government remains responsible for implementation of the SPS Agreement, and should support its observance by other levels of government. Governments should use the service of non-governmental institutions only if these comply with the SPS Agreement.

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

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

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

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

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

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

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

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

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

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

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

The decision to start the Uruguay Round trade negotiations was made after years of public debate, including debate in national governments. The decision to negotiate an agreement on the application of sanitary and phytosanitary measures was made in 1986 when the Round was launched. The SPS negotiations were open to all of the 124 governments which participated in the Uruguay Round. Many governments were represented by their food safety or animal and plant health protection officials. The negotiators also drew on the expertise of technical international organizations such as the FAO, the Codex and the OIE.
Developing countries participated in all aspects of the Uruguay Round negotiations to an unprecedented extent. In the negotiations on sanitary and phytosanitary measures, developing countries were active participants, often represented by their national food safety or animal and plant health experts. Both before and during the Uruguay Round negotiations, the GATT Secretariat assisted developing countries to establish effective negotiating positions. The SPS Agreement calls for assistance to developing countries to enable them to strengthen their food safety and animal and plant health protection systems. FAO and other international organizations already operate programmes for developing countries in these areas.

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

GATT was an intergovernmental organization and it was governments which participated in GATT trade negotiations; neither private business nor non-governmental organizations participated directly. But as the scope of the Uruguay Round was unprecedented, so was the public debate. Many governments consulted with both their public and private sectors on various aspects of the negotiations, including the SPS Agreement. Some governments established formal

channels for public consultation and debate while others did so on a more ad hoc basis. The GATT Secretariat also had considerable contact with international non-governmental organizations as well as with the public and private sectors of many countries involved in the negotiations. The final Uruguay Round results were subject to national ratification and implementation processes in most GATT member countries.

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

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

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

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

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

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

Consumers in all countries benefit. The SPS Agreement helps ensure, and in many cases enhances, the safety of their food as it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions. More information will increasingly become available to consumers as a result of greater transparency in governmental procedures and on the basis for their food safety, animal and plant health decisions. The

elimination of unnecessary trade barriers allows consumers to benefit from a greater choice of safe foods and from healthy international competition among producers.

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

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

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

Although a number of developing countries have excellent food safety and veterinary and plant health services, others do not. For these, the requirements of the SPS Agreement present a challenge to improve the health situation of their people, livestock and crops which may be difficult for some to meet. Because of this difficulty, the SPS Agreement delayed all requirements, other than those dealing with transparency (notification and the establishment of Enquiry Points), until 1997 for developing countries, and until 2000 for the least developed countries. This means that these countries are not required to provide a scientific justification for their sanitary or phytosanitary requirements before that time. Countries which need longer time periods, for example for the improvement of their veterinary services or for the implementation of specific obligations of the agreement, can request the SPS Committee to grant them further delays.

Many developing countries have already adopted international standards (including those of Codex, OIE and the IPPC) as the basis for their national requirements, thus avoiding the need to devote their scarce resources to duplicate work already done by international experts. The SPS Agreement encourages them to participate as actively as possible in these organizations, in order to contribute to and ensure the development of further international standards which address their needs.

One provision of the SPS Agreement is the commitment by members to facilitate the provision of technical assistance to developing countries, either through the relevant international organizations or bilaterally. FAO, OIE and WHO have considerable programmes to assist developing countries with regard to food safety, animal and plant health concerns. A number of countries also have extensive bilateral programmes with other WTO Members in these areas. The

WTO Secretariat has undertaken a programme of regional seminars to provide developing countries (and those of Central and Eastern Europe) with detailed information regarding their rights and obligations stemming from this agreement. These seminars are provided in cooperation with the Codex, OIE and IPPC, to ensure that governments are fully aware of the role these organizations can play in assisting countries to meet their requirements and fully enjoy the benefits resulting from the SPS Agreement. The seminars are open to participation by interested private business associations and consumer organizations. The WTO Secretariat also provides technical assistance through national workshops and to governments through their representatives in Geneva.

1-2. Legal Text

Read in the Primary Sources:

NAFTA Chapter 7, Arts. 709-723;
Preamble of the SPS Agreement and Arts. 1-5, 11 and Annex A

2. Hormones (1997)

World Trade Organization

WT/DS26/R/USA

18 August 1997

EC Measures Concerning Meat and Meat Products (Hormones)

Complaint by the United States

Report of the Panel

To download the original report, visit http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm

(…)

VIII.FINDINGS

A.CLAIMS OF THE PARTIES

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

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

8.3 The European Communities rejects these claims.

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

(…)

C.GENERAL INTERPRETATIVE ISSUES

(…)

3.Relationship between the SPS Agreement and GATT

(…)

8.38 (…) Many provisions of the SPS Agreement impose "substantive" obligations which go significantly beyond and are additional to the requirements for invocation of Article XX(b). These obligations are, *inter alia,* imposed to "further the use of harmonized sanitary and phytosanitary measures between Members" and to "improve the human health, animal health and phytosanitary situation in all Members". They are not imposed, as is the case of the obligations imposed by Article XX(b) of GATT, to justify a violation of another GATT obligation (such as a violation of the non-discrimination obligations of Articles I or III).

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

(…)

8.41 We therefore find that, in accordance with the ordinary meaning to be given to the terms of the SPS Agreement in their context and in the light of its object and purpose (in conformity with Article 31 of the Vienna Convention), there is no requirement, in any of the provisions of the SPS Agreement, that a prior violation of a GATT provision need be established before the SPS Agreement applies.

8.42 Having reached the conclusion that we are not *per se* required to address GATT claims prior to those raised under the SPS Agreement, we must then decide which of the two agreements we should examine first in this particular dispute. The SPS Agreement specifically addresses the type of measure in dispute. If we were to examine GATT first, we would in any event need to revert to the SPS Agreement: if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement. For these reasons, and in order to conduct our consideration of this dispute in the most efficient manner, we shall first examine the claims raised under the SPS Agreement.

D.THE SPS AGREEMENT

(…)

2. Burden of proof

(…)

8.51 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. (…) 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.

(…)

8.54 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).

(…)

(a) Codex standards

(…)

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. (…).

(…)

8.62 With respect to the three natural hormones in dispute, *oestradiol-17β*, *progesterone* and *testosterone* (classified by Codex as "veterinary drugs"), similar Codex standards apply. For all three hormones, when used for growth promotion purposes, it was considered "unnecessary" to establish an ADI or MRL. For all three hormones the following footnote explained the word "unnecessary": (…)

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

(…)

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

(…)

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

8.69 In considering these EC arguments, we note that Article 3.1 unambiguously prescribes that "... Members shall base their sanitary ... measures on international standards ... *where they exist* ..." (emphasis added). Paragraph 3 of Annex A of the SPS Agreement states equally clearly that the international standards mentioned in Article 3:1 are "for food safety, the standards ... *established by the Codex Alimentarius Commission* relating to ... *veterinary drug ... residues* ..." (emphasis added). No other conditions are imposed in the SPS Agreement on the relevance of international standards for the purposes of Article 3. Therefore, as a panel making a finding on whether or not a Member has an obligation to base its sanitary measure on international standards in accordance with Article 3.1, we only need to determine whether such international standards exist. (…)

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

(b) Sanitary measures *based on* Codex standards

(…)

(i) The meaning of *based on*

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

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

(…)

(ii) Comparison of levels of sanitary protection

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

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

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

(…)

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

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

> "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement".

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

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

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

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

A Note to this paragraph adds the following:

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

(a) Requirements for justification

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

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

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

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

(…)

8.83 We find, therefore, that, whatever the difference might be between the two exceptions, a sanitary measure can only be justified under Article 3.3 if it is consistent with the requirements contained in Article 5. If we were to find that the EC measures in dispute are inconsistent with the requirements imposed by Article 5, these measures cannot be justified under Article 3.3.

However, even if we find that the EC measures at issue are consistent with the requirements imposed by Article 5, this will still not be sufficient for these measures to be justified under Article 3.3 since to reach that conclusion we also need to find that the EC measures in dispute fulfil all provisions of the SPS Agreement other than Articles 3 and 5 (*in casu* Article 2).

(…)

8.89 *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.

(…)

8.95 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

(…)

(ii) The existence of a risk assessment

(…)

8.111We 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

(…)
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. <u>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</u>

(…)

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

2. <u>Scientific conclusions reached in the studies referred to by the European Communities which generally relate to one or more of the hormones in dispute</u>

(…)

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

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

3. Scientific conclusion reflected in the EC measures

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

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

8.137 In our view, the scientific conclusion reflected in the EC measures in dispute, *i.e.*, that the use of the hormones in dispute for growth promotion purposes, even in accordance with good practice, is *not* safe, does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities. (…)

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

5. General categories of risks invoked by the European Communities

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

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

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

(…)

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

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

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

(…)

8.154 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.

(…)

8.159 *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

(…)

(ii) Article 5.5: distinctions in levels of protection

8.167 Article 5.5 provides the following:

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

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

> "Members shall ensure that their sanitary and phytosanitary measures *do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail*, including between their own territory and that of other Members. Sanitary and phytosanitary measures *shall not be applied in a manner which would constitute a disguised restriction on international trade*" (emphasis added).

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

(…)

The three elements contained in Article 5.5

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

> "each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade".

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

8.175 As to the *first element*, the words "different situations" have been interpreted by the parties as follows. The European Communities argues that "different situations" only covers different situations for the *same residue* or for different residues where the *adverse health effect is the same*. (…) The United States argues that the "different situations" referred to in Article 5.5 of necessity must be *comparable* situations. (…)

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

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

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

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

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

(…)

8.184 (…) we 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

(…)

8.187 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.

(…)

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

8.197 We thus find that the European Communities has not met its burden of proving that the distinction it makes in levels of protection for residues of the three natural hormones in dispute when administered *for growth promotion purposes* and residues of the same natural hormones present *endogenously* in meat and other foods is justifiable and that, therefore, this particular

distinction in levels of protection is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

(…)

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

(…)

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

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

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

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

Synthetic hormones for growth promotion compared to natural hormones

(…)

1.Comparable situations with different levels of sanitary protection

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

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

(…)

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

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

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

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

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

(…)

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

8.217 We consider that this finding is further supported by the two additional factors outlined above, which are equally valid for the distinction in levels of protection made by the European Communities for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods.

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

The hormones in dispute compared to carbadox

(…)

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

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

(…)

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

(…)

(b) Articles 5.1 to 5.3: risk assessment

(…)

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

(…)

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

(…)

(c) Article 5.5: distinctions in levels of protection

8.262 Even if we had found that the European Communities met its burden of proving that its measures relating to MGA are based on an assessment of risks in accordance with Articles 5.1 and 5.2 and even if, for that reason, the European Communities could have adopted an appropriate level of protection against these risks, there would still be a need to examine whether the determination and application of this level of protection is consistent with Article 5.5. (…)

(…)

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

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

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

evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

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

(ii) MGA for growth promotion compared to carbadox

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

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

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

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

(…)

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.

World Trade

Organization

WT/DS26/AB/R
WT/DS48/AB/R
16 January 1998

EC MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

AB-1997-4

Report of the Appellate Body

To download the original report, visit http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm

(…)

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*

(…)

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.

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

> 17.6 In examining the matter referred to in paragraph 5:
>
> (i) in its assessment of the facts of the matter, the panel shall determine whether the authorities' establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned;

(…)

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*

(…)

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*(…)

As noted earlier, this right of a Member to establish its own level of sanitary protection under Article 3.3 of the *SPS Agreement* is an autonomous right and *not* an "exception" from a "general obligation" under Article 3.1.

C. *The Requirements of Article 3.3 of the SPS Agreement*

(…)

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

175. Article 3.3 is evidently not a model of clarity in drafting and communication. The use of the disjunctive "or" does indicate that two situations are intended to be covered. These are the introduction or maintenance of SPS measures which result in a higher level of protection:

(a) "if there is a scientific justification"; or
(b) "as a consequence of the level of ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5".

It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that "all measures which result in a [higher] level of ... protection", that is to say, measures falling within situation (a) as well as those falling within situation (b), be "not inconsistent with any other provision of [the SPS] Agreement". "Any other provision of this Agreement" textually includes Article 5. Secondly, the footnote to Article 3.3, while attached to the end of the first sentence, defines "scientific justification" as an "examination and evaluation of available scientific information in conformity with relevant provisions of this Agreement ...". This examination and evaluation would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the *SPS Agreement*.

176. On balance, we agree with the Panel's finding that although the European Communities has established for itself a level of protection higher, or more exacting, than the level of protection implied in the relevant Codex standards, guidelines or recommendations, the European Communities was bound to comply with the requirements established in Article 5.1. We are not unaware that this finding tends to suggest that the distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real. Its involved and layered language actually leaves us with no choice.

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

(…)

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".
(…)
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?.

(…)

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. (…)

191. In the course of demanding evidence that EC authorities actually "took into account" certain scientific studies, the Panel refers to the preambles of the EC Directives here involved.

The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the panel proceedings

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

(…)

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 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. (…)

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. (…)

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". (…) 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.*

(…)

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 olaquindox.

C. *Arbitrary or Unjustifiable Differences in Levels of Protection*

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

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

reasons are deployed by the Panel in comparing the levels of protection in respect of synthetic hormones used for growth promotion and in respect of natural hormones endogenously occurring in meat and other foods.

221. We do not share the Panel's conclusions that the above differences in levels of protection in respect of added hormones in treated meat and in respect of naturally-occurring hormones in food, are merely arbitrary and unjustifiable. To the contrary, we consider there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods. In respect of the latter, the European Communities simply takes no regulatory action; to require it to prohibit totally the production and consumption of such foods or to limit the residues of naturally-occurring hormones in food, entails such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people as to reduce the comparison itself to an absurdity. The other considerations cited by the Panel, whether taken separately or grouped together, do not justify the Panel's finding of arbitrariness in the difference in the level of protection between added hormones for growth promotion and naturally-occurring hormones in meat and other foods.

222. Because the Panel finds that the difference in the level of protection in respect of the three natural hormones, when used for growth promotion purposes, and the level of protection in respect of natural hormones present endogenously in meat and other foods is unjustifiable, the Panel regards it as unnecessary to decide whether the difference in the levels of protection set by the European Communities in respect of natural hormones used as growth promoters and in respect of the same hormones when used for therapeutic or 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. (…)

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.(…)

225. The conclusion we come to, after consideration of the foregoing factors, is that, on balance, the difference in the levels of protection concerning hormones used for growth promotion purposes, on the one hand, and concerning hormones used for therapeutic and zootechnical purposes, on the other, is not, in itself, "arbitrary or unjustifiable".

226. We turn to the Panel's comparison between the levels of protection set by the European Communities in respect of natural and synthetic hormones for growth promotion and with respect to carbadox and olaquindox. Carbadox and olaquindox are anti-microbial agents or compounds

which are mixed with the feed given to piglets (maximum age of four months). According to a report of JECFA, submitted to the Panel by the United States, carbadox is a feed additive that is a known genotoxic carcinogen, that is, carbadox *induces* and does not merely promote cancer. The experts advising the Panel confirmed that carbadox was genotoxic in character.

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

(…)

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

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

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

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

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

238. We agree with the Panel's view that "all three elements [of Article 5.5] need to be distinguished and addressed separately". We also recall our interpretation that Article 5.5 and, in particular, the terms "discrimination or a disguised restriction on international trade", have to be read in the context of the basic obligations contained in Article 2.3, which requires that "sanitary ... *measures* shall not be *applied in a manner which would constitute a disguised restriction on international trade*". (emphasis added)

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

240. In our view, the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. Thus, we do not think that the difference between a "no residues" level and "unlimited residues" level is, together with a finding of an arbitrary or unjustifiable difference, sufficient to demonstrate that the third, and most important, requirement of Article 5.5 has been met. It is well to bear in mind that, after all, the difference in levels of protection that is 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 olaquindox.

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

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

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

245. We do not attribute the same importance as the Panel to the supposed multiple objectives of the European Communities in enacting the EC Directives that set forth the EC measures at issue. The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes

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

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

(…)

XIV. Findings and Conclusions

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

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

(b) concludes that the Panel applied the appropriate standard of review under the *SPS Agreement*;

(c) upholds the Panel's conclusions that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2, and that the precautionary principle has been incorporated in, *inter alia*, Article 5.7 of the *SPS Agreement*;(…)

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

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

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

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

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

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

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

3. Aftermath of the Hormones Decision

http://www.ustr.gov/enforcement/dispute.shtml

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99 - 58

For Immediate Release Contact: Helaine Klasky

July 12, 1999 Amy Stilwell

(202) 395-3230

WTO FINDS U.S. TRADE DAMAGED BY EU BEEF IMPORT BAN

WTO arbitrators found today that the European Union's ban on U.S. beef and beef products has resulted in lost annual U.S. exports of beef to the EU in the amount of 116.8 million. The EU's ban, which covers beef and beef products from animals treated with growth hormones, was previously found to be unjustified under WTO rules. Decades of scientific research -- by both U.S. food safety regulators and international bodies such as the World Health Organization -- have proven the safety of the growth hormones used in U.S. beef production.

"The arbitrator's decision today confirms that under WTO rules, the EU must pay a price for failing to comply with its WTO obligations," said United States Trade Representative Charlene Barshefsky. "The EU's WTO-inconsistent ban on U.S. beef is harming U.S. farmers and processors, and is denying EU consumers access to the world's highest quality beef. The EU must understand that as a result of its failure to comply with its WTO obligations, the United States will act firmly and swiftly under its WTO rights to sharply raise tariffs on imports from the EU in an amount equivalent to the trade damage. Despite taking this action, the United States remains willing -- as it always has been -- to negotiate a resolution of the issue with the EU."

Ambassador Barshefsky further stated that "This is the second time in the last few months that we have had to exercise our WTO rights to raise tariffs on EU goods. First in the bananas case, and now in the beef hormones case, the EU has refused to comply with its WTO obligations, even after WTO dispute settlement resulted in formal findings that EU actions were WTO-inconsistent. I would urge the EU to reconsider its damaging actions and to demonstrate a real commitment to the rules-based multilateral trading system."

Pursuant to the arbitrators' decision, the United States will exercise its WTO rights by imposing 100 percent tariffs on a list of EU products with an annual trade value of 116.8 million. The list of products and other details regarding the tariff increases will be announced in the near future.

Background

This trade dispute over the EU's beef policies dates back to the 1980s. In December 1985, the EU adopted a directive on livestock production restricting the use of natural hormones to therapeutic purposes, banning the use of synthetic hormones, and prohibiting imports of animals, and meat from animals, to which hormones had been administered. The EU adopted this policy even though the safety of consuming beef from cattle treated with certain hormones has been thoroughly researched since the 1950s. On all occasions of FDA testing, the six hormones subject to this trade dispute have always been found to be safe. The clear international scientific consensus is that these approved and licensed products are safe when used in accordance with good veterinary practices. Even the EU's own scientists have agreed with these findings. At present, U.S. beef is shipped to 138 countries.

That EU's 1985 directive was later declared invalid by the European Court of Justice on procedural grounds and had to be re-adopted by the Council, unchanged, in 1988 ("the Hormone Directive"). These measures became effective January 1, 1989, notwithstanding U.S. attempts to resolve this issue bilaterally and multilaterally, including through dispute settlement under the General Agreement on Tariffs and Trade (GATT).

On December 24, 1987, the President of the United States announced an increase in duties on selected European products in response to the Hormone Directive and related measures, but immediately suspended this action to promote a negotiated solution of the issue. The USTR enacted the increase in duties in January 1989 when the EU began implementing the hormone ban against imports from the United States. The USTR subsequently modified the application of increased duties on a number of occasions. During the early 1990s, the United States continued to encourage resolution of this dispute and worked in the FAO/WHO Codex Alimentarius to develop principles that reenforce the pre-eminent role of science in establishing high food safety standards.

Following entry into force of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") on January 1, 1995, the United States and, later, Canada, proceeded with formal WTO dispute settlement procedures against the hormone ban. On May 20, 1996, the WTO's Dispute Settlement Body ("DSB") established a dispute settlement panel ("the WTO panel") to examine the consistency of the EU's hormone ban with the its WTO obligations. (Prior to the establishment of the WTO panel, the EU replaced the Hormone Directive with another directive that re-codified and expanded the hormone ban.)

On August 18, 1997, the WTO panel issued its report, finding that the hormone ban is not based on scientific evidence, a risk assessment, or relevant international standards in contravention of the EU's obligations under the SPS Agreement. The Appellate Body issued its report on January 16, 1998 affirming that the hormone ban is not consistent with the EU's obligations under the SPS Agreement. On February 13, 1998 meeting, the DSB adopted the Panel and Appellate Body reports on hormones.

The EU subsequently requested four years to implement the DSB recommendations and rulings. An Arbitrator determined that the reasonable period of time for implementation was fifteen months, and would expire on May 13, 1999.

The EU took no actions to implement the DSB recommendations and rulings by the May 13, 1999 deadline. Accordingly, on May 17, 1999, the United States exercised its WTO rights by requesting authorization to suspend tariff concessions on EU goods with an annual trade value equivalent to annual lost exports of U.S. beef, estimated by the United States as equal to $202 million. The EU requested arbitration over the amount of lost U.S. beef exports, arguing that the arbitrators should accept the EU's estimate of $53 million.

The arbitrators issued their report within the time provided under WTO rules, which is 60 days after the May 13, 1999 end of the implementation period.

In addition to determining the level of annual lost U.S. exports of beef to the EU, the arbitrators addressed a procedural claim made by the EU. The EU had argued that the arbitration procedure should include an additional, second stage, in which the arbitrator would evaluate the U.S. list of products subject to higher tariffs. The United States pointed out that such a procedure would be inconsistent with WTO rules and would improperly delay the completion of the arbitration. The arbitrators rejected the EU's procedural argument.

Optional Reading

Committee on Sanitary and Phytosanitary Measures

On Diseases

From the WTO Official Website
http://www.wto.org/english/news_e/news01_e/sps_nov2001_e.htm

WTO NEWS: 2001 NEWS ITEMS

SANITARY AND PHYTOSANITARY MEASURES COMMITTEE 31 OCTOBER–1 NOVEMBER 2001

Committee looks at equivalence, transparency, diseases and GMOs

(...)

Foot and mouth, BSE, GMOs and other issues

As in previous meetings, there were detailed discussions of foot-and mouth disease and BSE, and of trade restrictions imposed in response to recent disease outbreaks.

The EU, Japan and Argentina provided updates of their disease-situations, and asked their trading partners to adapt their measures accordingly. Peru and Chile again raised concerns that their fishmeal exports were being unfairly affected by EU measures on BSE.

Other trade concerns raised included Japan's measures on fruit imports from the US related to fire blight, Australia's restrictions on fruit and prawn imports, and EU aflatoxin levels.

Several members reported solutions to trade problems raised at previous meetings, including the Slovak Republic's restrictions on apples, pears and quinces, emergency EU measures on citrus pulp and on gelatin, and Australia's restrictions on sauces containing benzoic acid.

In considering notifications for the first time in the SPS Committee, the US and Canada enquired about the EU's restrictions on genetically modified organisms (GMOs). They complained that the EU had failed to notify its latest directives on traceability and labelling under SPS, even though these indicate that health protection is one of the objectives. The EU delegate said that any comments on this notification should be sent to its authority handling technical barriers to trade issues.

Under "other business", the US also complained about the lack of scientific justification for the EU's continued de facto moratorium on approval of GMO products, and Canada said the latest EC measures discriminate against products produced by GM technology, even where no trace remains in the final products.
(…)

On Transparency

WORLD TRADE ORGANIZATION

G/SPS/7/Rev.2
2 April 2002

(02-1650)

Committee on Sanitary and Phytosanitary Measures

RECOMMENDED PROCEDURES FOR IMPLEMENTING THE TRANSPARENCY OBLIGATIONS OF THE SPS AGREEMENT (ARTICLE 7)

Revision

1.Transparency in the context of the World Trade Organization (WTO) is used to signify one of the fundamental principles of its agreements: the aim is to achieve a greater degree of clarity, predictability and information about trade policies, rules and regulations of Members. In implementing this concept Members use notifications. Under the SPS Agreement, notifications are used to inform other Members about new or changed regulations that may significantly affect their trading partners1. Transparency under the SPS Agreement also includes answering reasonable questions, and publishing regulations.

2.These procedures have been developed to assist Members fulfil their transparency obligations under Article 7 and Annex B of the SPS Agreement regarding the notification of SPS regulations, answering information requests under the national enquiry point system and publishing regulations.

(…)

Revisions

33.Revisions replace an existing notification. Revisions should be submitted, for example, *when the scope of application of a notified regulation is extended, either in terms of Members affected or products covered*, or if a notification contained a large number of errors which necessitated issuing a revision. A Member should provide a further period for comments on the revised notification, normally 60 days. (*emphasis added*)

(…)

1 The SPS Agreement uses the terms 'measures' and 'regulations' somewhat interchangeably when referring to any sanitary or phytosanitary measure such as laws, decrees, or ordinances applied to protect human, animal or plant life or health as defined under paragraph 1 of Annex A to the SPS Agreement.

On Equivalence

From the WTO Official Website
http://www.wto.org/english/news_e/news01_e/sps_oct2001_e.htm

WTO NEWS: 2001 NEWS ITEMS

SANITARY AND PHYTOSANITARY MEASURES 24 OCTOBER 2001

Food safety and health implementation: 'equivalence' decision OK'd

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

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

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

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

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

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

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

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

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

The SPS Committee discussed equivalence under an instruction from the WTO General Council in October 2000.

The WTO's SPS Committee deals with food safety and animal and plant health, but does not set international standards. These are handled by other organizations, in particular the "three sisters" (Codex Alimentarius, Office International des Epizooties or World Organization for Animal Health, and the International Plant Protection Convention).

Case Note (Australian Salmon)

Joel Trachtman

http://www.ejil.org/journal/Vol10/No1/sr3.html

Abstract

This decision evaluated the obligations of Australia under the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") in respect of a quarantine on imports of salmon. The Appellate Body reversed the panel's finding that the measure at issue was a requirement that certain imported salmon be heat-treated, holding that the appropriate measure to evaluate was an import prohibition on fresh, chilled and frozen salmon. The Appellate Body therefore reversed the panel's finding that the measure examined by the panel was inconsistent with art. 5.1, and by implication, art. 2.2, of the SPS Agreement. Having thrown out the panel's decision, the Appellate Body, on the basis of factual findings made by the panel, however, found that the Australian measure was not based on a proper risk assessment, violating art. 5.1, and, by implication, art. 2.2, of the SPS Agreement.

The Appellate Body also upheld the panel's finding that the Australian measure violated art. 5.5, and by implication, art. 2.3, of the SPS Agreement. The Appellate Body did so on the basis of differential treatment of imports of certain other types of fish that presented similar or greater risks.

The Appellate Body was not able to come to a conclusion with respect to art. 5.6 of the SPS Agreement, because of the paucity of the factual record developed by the panel. This strengthens the argument for giving the Appellate Body the right of remand.

Case Note (Japanese Agricultural Products)

Oliver Landwehr

http://www.ejil.org/journal/Vol10/No2/sr2.html

Abstract

In this third case under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Dispute Settlement Body (DSB) found that Japan had acted inconsistently with the SPS Agreement by imposing certain quarantine measures concerning agricultural products. The Appellate Body upheld the Panel's finding that Japanese testing requirements as they applied to apples, cherries, nectarines and walnuts were inconsistent with Articles 2.2, 5.7 and 7 of the Agreement. It reversed the finding of inconsistency under Article 5.6 - not because it thought the Panel's conclusion that there was a less trade-restrictive measure was wrong, but because this finding was reached in a manner inconsistent with the rules on the burden of proof. Having criticized the Panel for not making findings under Article 5.1 with regard to a number of products, the Appellate Body, on the basis of the factual findings of the Panel, concluded that a Pest Risk Assessment produced by Japan was no proper risk assessment in the sense of Article 5.1.

For the first time, the Appellate Body dealt with the requirements of Article 5.7, which it had described in EC - Hormones as the embodiment of the precautionary approach in the SPS Agreement. The Appellate Body noted that Article 5.7 contained four requirements which had to be met cumulatively.