

WORLD TRADE

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

ORGANIZATION

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(...)

Appellate Body

EC MEASURES CONCERNING MEAT AND MEAT PRODUCTS  
(HORMONES)

AB-1997-4

Report of the Appellate Body

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WORLD TRADE ORGANIZATION  
APPELLATE BODY

EC Measures Concerning Meat and Meat  
Products (Hormones)

European Communities, Appellant/Appellee

United States, Appellant/Appellee  
Canada, Appellant/Appellee

Australia, New Zealand and Norway, Third  
Participants

AB-1997-4

Present:

Feliciano, Presiding Member  
Ehlermann, Member  
Matsushita, Member

I. Introduction: Statement of the Appeal

1. The European Communities, the United States and Canada appeal from certain issues of law and legal interpretations in the Panel Reports, EC Measures Concerning Meat and Meat Products (Hormones).<sup>1</sup> These two Panel Reports, circulated to Members of the World Trade Organization ("WTO") on 18 August 1997, were rendered by two Panels composed of the same three persons.<sup>2</sup> These Panel Reports are similar, but they are not identical in every respect. The Panel in the complaint brought by the United States was established by the Dispute Settlement Body (the "DSB") on 20 May 1996. On 16 October 1996, the DSB established the Panel in the complaint brought by Canada. The European Communities and Canada agreed, on 4 November 1996, that the composition of the latter Panel would be identical to the composition of the Panel established at the request of the United States.

2. The Panel dealt with a complaint against the European Communities relating to an EC prohibition of imports of meat and meat products derived from cattle to which either the natural hormones: oestradiol-17 $\beta$ , progesterone or testosterone, or the synthetic hormones: trenbolone acetate, zeranol or melengestrol acetate ("MGA"), had been administered for growth promotion purposes. This import prohibition was

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<sup>1</sup>Complaint by the United States, WT/DS26/R/USA, (the "US Panel Report") and Complaint by Canada, WT/DS48/R/CAN, (the "Canada Panel Report").

<sup>2</sup>As the composition of both Panels was identical, we will refer to the Panels as "the Panel".

set forth in a series of Directives of the Council of Ministers that were enacted before 1 January 1995.

Those Directives were:

1. Council Directive 81/602/EEC of 31 July 1981 ("Directive 81/602")<sup>3</sup>;
2. Council Directive 88/146/EEC of 7 March 1988 ("Directive 88/146")<sup>4</sup>; and
3. Council Directive 88/299/EEC of 17 May 1988 ("Directive 88/299")<sup>5</sup>.

3. Directive 81/602 prohibited the administration to farm animals of substances having a hormonal action and of substances having a thyrostatic action. It also prohibited the placing on the European market of both domestically produced and imported meat and meat products derived from farm animals to which such substances had been administered. Two exceptions to this prohibition were provided for. One exception covered substances with an oestrogenic, androgenic or gestagenic action when used for therapeutic or zootechnical purposes and administered by a veterinarian or under a veterinarian's responsibility. The other exception related to three natural hormones (oestradiol - 17 $\beta$ , progesterone and testosterone) and two synthetic hormones (trenbolone acetate and zeranol) used for growth promotion purposes if allowed under the regulations of the Member States of the European Economic Community ("EEC"), until a detailed examination of the effects of these substances could be carried out and until the EEC could take a decision on the use of these substances for growth promotion. The sixth hormone involved in this appeal, MGA, was not included in the second exception; it was covered by the general prohibition concerning substances having a hormonal or thyrostatic action.

4. Seven years later<sup>6</sup>, Directive 88/146 was promulgated prohibiting the administration to farm animals of the synthetic hormones: trenbolone acetate and zeranol, for any purposes, as well as the administration of the natural hormones: oestradiol - 17 $\beta$ , progesterone and testosterone, for growth promotion or fattening purposes. This Directive permitted Member States of the EEC to authorize, under specified conditions, the use of the three natural hormones for therapeutic and zootechnical purposes. Directive 88/146 explicitly prohibited both the intra-EEC trade and the importation from third countries of meat and meat products

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<sup>3</sup>Official Journal, No. L 222, 7 August 1981, p. 32.

<sup>4</sup>Official Journal, No. L 70, 16 March 1988, p. 16.

<sup>5</sup>Official Journal, No. L 128, 21 May 1988, p. 36.

<sup>6</sup>It should be noted that on 31 December 1985 the Council of Ministers adopted Directive 85/649/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, Official Journal, No. L 382, 31 December 1985, p. 228. This Directive prohibited the use of all the hormones (except MGA, the use of which had been previously prohibited) for growth promotion purposes and established more detailed provisions concerning authorized therapeutic uses. This Directive was challenged in the Court of Justice of the European Communities, which annulled it on procedural grounds in its Judgment of 23 February 1988, [1988] E.C.R. 855. Shortly afterwards, the European Commission submitted to the Council a proposal for a substantively identical Directive, which the Council adopted on 7 March 1988 as Directive 88/146/EEC.

obtained from animals to which substances having oestrogenic, androgenic, gestagenic or thyrostatic action had been administered. Trade in meat and meat products derived from animals treated with such substances for therapeutic or zootechnical purposes was allowed only under certain conditions. Those conditions were set out in Directive 88/299.

5. Effective as of 1 July 1997, Directives 81/602, 88/146 and 88/299 were repealed and replaced with Council Directive 96/22/EC of 29 April 1996 ("Directive 96/22").<sup>7</sup> This Directive maintains the prohibition of the administration to farm animals of substances having a hormonal or thyrostatic action. As under the previously applicable Directives, it is prohibited to place on the market, or to import from third countries, meat and meat products from animals to which such substances, including the six hormones at issue in this dispute, were administered. This Directive also continues to allow Member States to authorize the administration, for therapeutic and zootechnical purposes, of certain substances having a hormonal or thyrostatic action. Under certain conditions, Directive 96/22 allows the placing on the market, and the importation from third countries, of meat and meat products from animals to which these substances have been administered for therapeutic and zootechnical purposes.

6. The Panel circulated its Reports to the Members of the WTO on 18 August 1997. The US Panel Report and the Canada Panel Report reached the same conclusions in paragraph 9.1:

(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 requirement 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 of Article 3.1 of that Agreement.

In both Reports, the Panel recommended in paragraph 9.2:

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<sup>7</sup>Official Journal, No. L 125, 23 May 1996, p. 3.

... 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.

7. On 24 September 1997, the European Communities notified the DSB of its decision to appeal certain issues of law covered in the Panel Reports and certain legal interpretations developed by the Panel, pursuant to paragraph 4 of Article 16 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (the "DSU"), and filed two notices of appeal<sup>8</sup> with the Appellate Body pursuant to Rule 20 of the Working Procedures for Appellate Review (the "Working Procedures"). Pursuant to Rule 21 of the Working Procedures, the European Communities filed an appellant's submission on 6 October 1997. On 9 October 1997, the United States and Canada filed appellants' submissions pursuant to Rule 23(1) of the Working Procedures. On 20 October 1997, the United States and Canada each filed an appellee's submission pursuant to Rule 22 of the Working Procedures and the European Communities filed its own appellee's submission pursuant to Rule 23(3) of the Working Procedures. On the same day, Australia, New Zealand and Norway filed separate third participants' submissions in accordance with Rule 24 of the Working Procedures.

8. The oral hearing was held on 4 and 5 November 1997. The participants and third participants presented oral arguments and responded to questions put to them by the Members of the Division hearing this appeal. The participants and third participants also gave oral concluding statements.

## II. Arguments of the Participants and Third Participants

### A. Claims of Error by the European Communities - Appellant

#### 1. Burden of Proof

9. The European Communities argues that the Panel erred in its allocation of the burden of proof in this dispute in three respects. In the view of the European Communities, the Panel erred on the issue of burden of proof under the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") in general; in allocating the burden of proof under Article 3.3 of the SPS Agreement; and in allocating the burden of proof under Article 5.1 of the SPS Agreement.

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<sup>8</sup>WT/DS26/9, 25 September 1997, and WT/DS48/7, 25 September 1997.



10. In respect of the issue of burden of proof under the SPS Agreement in general, the European Communities argues that the Panel erred in finding that the burden of proof under the SPS Agreement rests on the Member imposing a measure.<sup>9</sup> According to the European Communities, none of the general considerations invoked by the Panel supports the view that special rules on the burden of proof should be applied in proceedings concerning the SPS Agreement.

11. As to the allocation of the burden of proof under Article 3.3 of the SPS Agreement, the European Communities disagrees with the Panel's finding that Article 3.3 constitutes an exception to the general obligation, contained in Article 3.1, to base measures on international standards, and that the burden of proof under Article 3.3 is therefore on the responding party.<sup>10</sup> The European Communities argues that the SPS Agreement expressly recognizes that a Member has the right to choose an appropriate level of sanitary and phytosanitary protection, and that Article 3.3 lays down specific conditions governing the exercise of that right in those cases where an international standard exists. According to the European Communities, Article 3.1 does not provide a "general obligation" to be read in isolation, but presents one of three options available to a Member when an international standard exists.

12. With regard to the burden of proof under Article 5.1 of the SPS Agreement, the European Communities opposes the Panel's finding that Canada and the United States had met their burden of presenting a prima facie case of inconsistency with Article 5.1, in respect of importation of meat treated with the MGA hormone.<sup>11</sup> The European Communities notes that Canada and the United States stated that they had conducted risk assessments and had authorized MGA for growth promotion, but refused to provide scientific evidence and information, claiming their studies were proprietary and confidential in nature. The European Communities believes that the Panel has fundamentally erred in law by condoning the refusals by Canada and the United States to submit all studies available.

## 2. Standard of Review

13. The European Communities claims that the Panel erred in law<sup>12</sup> by not according deference to the following aspects of the EC measures: first, the decision of the European Communities to set and apply a level of sanitary protection higher than that recommended by the Codex Alimentarius (the "Codex")

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<sup>9</sup>US Panel Report, paras. 8.52-8.54; Canada Panel Report, paras. 8.55-8.57.

<sup>10</sup>US Panel Report, para. 8.86; Canada Panel Report, para. 8.89.

<sup>11</sup>US Panel Report, para. 8.253; Canada Panel Report, para. 8.256.

<sup>12</sup>US Panel Report, paras. 8.124, 8.127, 8.133, 8.134, 8.145, 8.146, 8.194, 8.199, 8.213 and 8.255; Canada Panel Report, paras. 8.127, 8.130, 8.136, 8.137, 8.148, 8.149, 8.197, 8.202, 8.216 and 8.258.

for the risks arising from the use for growth promotion of the hormones in dispute; second, the EC's scientific assessment and management of the risk from the hormones at issue, and third, the EC's adherence to the precautionary principle and its aversion to accepting any increased carcinogenic risk.

14. It is submitted by the European Communities that WTO panels should adopt a deferential "reasonableness" standard when reviewing a Member's decision to adopt a particular science policy or a Member's determination that a particular inference from the available data is scientifically plausible. To the European Communities, the Panel in this case imposed its own assessment of the scientific evidence.

15. The European Communities asserts that GATT 1947 panel reports rejected a de novo standard of review in relation to fact-finding<sup>13</sup>, and that this approach has been maintained by panels established under the DSU.<sup>14</sup> It is contended that the "reasonable deference standard of review" has been given expression in the Marrakesh Agreement Establishing the World Trade Organization<sup>15</sup> (the "WTO Agreement") in Article 17.6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (the "Anti-Dumping Agreement"). The European Communities considers that the principle of reasonable deference is applicable in all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants, and that therefore, the Panel applied an inappropriate standard of review in the present case.

### 3. The Precautionary Principle

16. The European Communities submits that the Panel erred in law in considering that the precautionary principle was only relevant for "provisional measures" under Article 5.7 of the SPS Agreement.<sup>16</sup> The precautionary principle is already, in the view of the European Communities, a general customary rule

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<sup>13</sup>The European Communities refers to: Panel Report, United States - Imposition of Anti-Dumping Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway, adopted 27 April 1994, ADP/87; Panel Report, United States - Imposition of Countervailing Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway, adopted 28 April 1994, SCM/153; Panel Report, Korea - Anti-Dumping Duties on Imports of Polyacetal Resins from the United States, adopted 27 April 1993, BISD 40S/205; Panel Report, United States - Measures Affecting Imports of Softwood Lumber from Canada, adopted 27-28 October 1993, BISD 40S/358, Panel Report, United States - Anti-Dumping Duties on Imports of Stainless Steel Plate from Sweden, ADP/117, 24 February 1994, unadopted; Panel Report, EC - Anti-Dumping Duties on Audio Tapes in Cassettes originating in Japan, ADP/136, 28 April 1995, unadopted; and Panel Report, United States - Imposition of Countervailing Duties on Certain Hot-rolled Lead and Bismuth Carbon Steel Products originating in France, Germany and the United Kingdom, SCM/185, 15 November 1994, unadopted.

<sup>14</sup>The European Communities refers to: Panel Report, United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear ("United States - Underwear"), adopted 25 February 1997, WT/DS24/R; Panel Report, United States - Measure Affecting Imports of Woven Wool Shirts and Blouses ("United States - Shirts and Blouses"), adopted 23 May 1997, WT/DS33/R.

<sup>15</sup>Done at Marrakesh, Morocco, 15 April 1994.

<sup>16</sup>US Panel Report, paras. 8.157 and 8.158; Canada Panel Report, paras. 8.160 and 8.161.

of international law or at least a general principle of law, the essence of which is that it applies not only in the management of a risk, but also in the assessment thereof. It is claimed that the Panel therefore erred in stating that the application of the precautionary principle "would not override the explicit wording in Articles 5.1 and 5.2 [of the SPS Agreement]", and in suggesting that that principle might be in conflict with those Articles. The European Communities asserts that Articles 5.1 and 5.2 and Annex A.4 of the SPS Agreement do not prescribe a particular type of risk assessment, but rather simply identify factors that need to be taken into account. Thus, these provisions do not prevent Members from being cautious when setting health standards in the face of conflicting scientific information and uncertainty.

#### 4. Objective Assessment of the Facts

17. The European Communities argues that the Panel failed to make an objective assessment of the facts and therefore did not comply with its obligations under Article 11 of the DSU. The Panel, it is alleged, disregarded or distorted the evidence with regard to both the MGA and the other five hormones at issue supplied by the Panel's experts, as well as the scientific evidence presented by the European Communities. In support of this contention, the European Communities submits that the Panel has manifestly distorted the views of both Dr. Lucier<sup>17</sup> and Dr. André.<sup>18</sup> According to the European Communities, contrary to what the Panel found, the evidence provided to the Panel by the majority of its own scientific experts indicated that there was a real risk of adverse effects arising from the use of the hormones at issue. It is also claimed that the Panel manifestly distorted the scientific evidence by considering that the 1995 European Communities Scientific Conference on Growth Promotion in Meat Production (the "1995 EC Conference") amounted to a risk assessment in the sense of Articles 5.1 and 5.2. The distinction made by the Panel between general studies on the health risks associated with hormones and specific studies addressing the health risks of residues in food of hormones used for growth promotion purposes was, in the view of the European Communities, devised by the Panel for the sole purpose of enabling it to conclude that the Monographs of the International Agency for Research on Cancer ("IARC")<sup>19</sup> are not relevant as a risk assessment in this case. This, the European Communities asserts, amounts to a distortion of relevant scientific evidence. The European Communities also alleges that the Panel violated Article 11 of the DSU by discarding several articles and opinions of individual scientists invoked by the European Communities.

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<sup>17</sup>See, in particular, US Panel Report, footnote 331; Canada Panel Report, footnote 437.

<sup>18</sup>See, in particular, US Panel Report, footnote 348; Canada Panel Report, footnote 455.

<sup>19</sup>The 1987 Monographs of the IARC on the Evaluation of Carcinogenic Risks to Humans, Supplement 7 (the "1987 IARC Monographs").

18. With regard to the problems relating to the control of the correct use of the hormones, the European Communities contends that it submitted convincing specific evidence to the Panel, but that the Panel either failed to take this evidence into account or failed to summarize it properly in the Panel Report. Finally, the Panel allegedly ignored the arguments made by the European Communities as to why the situations compared by the Panel under Article 5.5 were not comparable. In rejecting the six reasons advanced by the European Communities as to why the distinction in the levels of sanitary protection between carbadox and olaquinox, on the one hand, and the hormones at issue in this dispute, on the other, is not arbitrary or unjustifiable, the European Communities argues that the Panel failed to take into account the evidence before it.

5. Temporal Application of the SPS Agreement

19. The European Communities states that the Panel's conclusion that the SPS Agreement applies to measures that were enacted before the entry into force of the SPS Agreement but that did not cease to exist after that date, is too sweeping.<sup>20</sup> According to the European Communities, the SPS Agreement shows a different intention in some of its provisions, at least if these provisions are interpreted in the way proposed by the Panel. Articles 5.1 to 5.5 require that certain preparatory actions and procedures be followed before a measure is adopted and obligations of this kind are exhausted once the measures under consideration are adopted. The European Communities, therefore, concludes that the SPS Agreement does not apply to the procedure for the elaboration of the EC measures at issue in this dispute.

6. Article 3.1

20. The European Communities submits that the Panel erred in interpreting the term "based on" in stating that Article 3.2 "equates" measures "based on" international standards with measures which "conform to" such standards.<sup>21</sup> The European Communities asserts that these terms differ in their meaning.

21. It is pointed out by the European Communities that Article 3 employs the term "based on" in paragraphs 1 and 3, whereas it uses the term "conform to" in paragraph 2. Also, Article 2 distinguishes between "based on" (paragraph 2) and "conform to" (paragraph 4). This differing language in consecutive paragraphs of different articles cannot be accidental.

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<sup>20</sup>US Panel Report, paras. 8.25 and 8.26; Canada Panel Report, paras. 8.28 and 8.29.

<sup>21</sup>US Panel Report, para. 8.72; Canada Panel Report, para. 8.75.

22. To the European Communities, a measure may deviate -- but not substantially -- from the content of a recommendation of the Codex and still be considered as "based on" that recommendation for the purposes of Article 3.1. However, what constitutes a "substantial" deviation is not defined in the SPS Agreement. The submission of the European Communities is that Article 3 of the SPS Agreement accomplishes its object of furthering international harmonization by allowing Members to choose one of three alternative options. First, a Member may opt to conform its sanitary measures to the Codex recommendations, in accordance with Article 3.2. Second, a Member may wish merely to "base [its] sanitary ... measures on international ... recommendations", in accordance with Article 3.1, instead of conforming to such recommendations. Third, a Member may decide, in accordance with Article 3.3, to establish sanitary measures which provide a "higher level of sanitary protection" than would measures "based on" the Codex recommendations. As noted above<sup>22</sup>, it is firm view of the European Communities that these three options are of equal standing and that Article 3.3 cannot be qualified as an exception to Article 3.1. The European Communities therefore objects to the Panel's interpretation of and conclusions concerning Article 3.1.

7. Article 3.3

23. The European Communities contends that the Panel's finding that whatever the difference might be between the two exceptions in Article 3.3, a sanitary measure can only be justified under this provision if it is consistent with the requirements contained in Article 5<sup>23</sup>, in effect reduces the two alternative conditions in the first sentence of Article 3.3 to "mere surplusage". According to the European Communities, Article 3.3 defines the concept of the first condition ("scientific justification") in the footnote thereto without making a direct reference to Article 5, paragraphs 1 to 8, as it does with respect to the second condition ("as a consequence of choosing a higher level of protection"). The absence in the footnote to Article 3.3 of language referring to Articles 5.1-5.8 is in itself sufficient indication of the intention of the drafters to qualify the application of Article 5 in the case of the first condition. Thus, the European Communities asserts, the plain meaning and structure of Article 3.3 imply that the risk assessment requirements of Article 5 apply only if the second of these two alternative conditions is met.

8. Article 5.1

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<sup>22</sup>Para. 11 of this Report.

<sup>23</sup>US Panel Report, para. 8.83; Canada Panel Report, para. 8.86.

24. The European Communities contests the Panel's finding that Article 5.1 requires a Member imposing an SPS measure to submit evidence that it "took into account" a risk assessment when it enacted or maintained a measure<sup>24</sup>, since neither the ordinary meaning of the words "based on", in context, nor the object and purpose of Article 5, suggest a "minimum procedural requirement" under Article 5.1.

25. The European Communities contends that to require concrete evidence in the preamble of the EC Directives or some other evidence that the European Communities actually considered the scientific studies in enacting or maintaining the measures at issue is unreasonable and arbitrary, and runs counter to the object and purpose of Article 5 and the SPS Agreement. There is no legal authority for the Panel's interpretation that risk assessment cannot be on-going and therefore no reason for restricting risk assessment to "old evidence". The European Communities asserts that there is a legitimate SPS goal of providing an opportunity for potentially affected Members to produce scientific evidence relevant to particular measures, and of ensuring consideration of that evidence by the Member adopting the SPS measure. Therefore, the European Communities submits that all parties and third parties should have the right to present "new" relevant evidence to the Panel.

26. With regard to the Panel's findings on the consistency of the import prohibition with the substantive requirements of Article 5.1, the European Communities claims that the Panel erred in its interpretation of Article 5.1 in six separate respects. First, the Panel was incorrect in distinguishing between studies that specifically address the hormones for growth promotion purposes, such as the 1982 Report of the EC Scientific Veterinary Committee<sup>25</sup> (the "Lamming Report") and the JECFA Reports<sup>26</sup>, and studies which relate to hormones in general, such as the 1987 IARC Monographs and articles and opinions of individual scientists referred to by the European Communities.<sup>27</sup> The Panel's assumption that such a distinction makes a qualitative difference in terms of risk assessment is wrong, and the distinction is arbitrary. The European Communities argues that Articles 5.1 and 5.2 neither prescribe risk assessment techniques nor specify the requirements of a risk assessment.

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<sup>24</sup>US Panel Report, para. 8.113; Canada Panel Report, para. 8.116.

<sup>25</sup>1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production.

<sup>26</sup>Evaluation of certain veterinary drug residues in food: Thirty-second Report of the Joint FAO/WHO Expert Committee on Food Additives, Technical Report Series 763 (World Health Organization, 1988); and the evaluation of certain veterinary drug residues in food: Thirty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives, Technical Report Series 788 (World Health Organization, 1989).

<sup>27</sup>US Panel Report, paras. 8.127 and 8.130; Canada Panel Report, paras. 8.130 and 8.133.

27. Second, the Panel's view of Article 5.1 as imposing a substantive obligation on Members to conform their SPS measures to the conclusions reflected in the JECFA Reports or the reports of other scientific committees is manifestly incorrect. The "scientific basis" of SPS measures cannot be confined to the formalized conclusions of committees called upon to review or analyze the risks a substance may pose. Those conclusions are just one of the elements to be taken into account. The "available scientific evidence", referred to in Article 5.2, includes both generally held or majority scientific views as well as minority, or dissenting, scientific opinion (often first expressed by individual scientists). The European Communities also controverts the Panel's finding that the reports of the European Parliament are "non-scientific"<sup>28</sup>, and contends that this finding is manifestly wrong, certainly as regards the so-called Pimenta Report.<sup>29</sup>

28. Third, the Panel's interpretation that "based on" within the meaning of Article 5.1 means "in conformity with" is mistaken.<sup>30</sup> The European Communities states that reports of scientific committees frequently say practically nothing or very little on some of the factors indicated in Articles 5.1 and 5.2. To the European Communities, Article 5.1 is designed to compel Members to have some plausible scientific rationale as the "basis" for their sanitary measures, but not to conform their measures absolutely to the technical and scientific conclusions of the reports.

29. Fourth, the European Communities contends that the "most fundamental error of interpretation" of the Panel relates to the concept of risk and risk assessment.<sup>31</sup> "Risk" does not mean "harm" or "adverse effect". "Risk", for the purposes of the SPS Agreement, is the "potential" for the harm or adverse effects arising and, therefore, the mere possibility of risk arising suffices for the purposes of Articles 5.1 and 5.2. A risk evaluated to be one in a million is sufficient justification. If there is a potential for adverse effects (no matter how small), then there is, according to the European Communities, a risk. The concept of risk in the SPS Agreement is a qualitative, not a quantitative concept. Any identified increase in cancer (whether quantitative or qualitative) must be sufficient to constitute a risk against which WTO Members are entitled to protect their population.

30. Fifth, the European Communities disputes the Panel's finding that the problem of control is irrelevant to risk assessment<sup>32</sup>, as contrary to common sense and to the express language of Article 5.2

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<sup>28</sup>US Panel Report, para. 8.109; Canada Panel Report, para. 8.112.

<sup>29</sup>European Parliament, Session Documents, Report drawn up on behalf of the Committee of Inquiry into the Problem of Quality in the Meat Sector, Rapporteur: Mr. Carlos Pimenta, Document A2-11/891/PARTS A-B, March 1989 ("Pimenta Report").

<sup>30</sup>US Panel Report, para. 8.117; Canada Panel Report, para. 8.120.

<sup>31</sup>As reflected in para. 8.124 of the US Panel Report and para. 8.127 of the Canada Panel Report.

<sup>32</sup>US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

and Annex C of the SPS Agreement clarifies. The European Communities also points out that the condition "in accordance with good veterinary practice" is part of the content of the Codex recommendation, and that effective control is necessary to ensure that the hormones at issue are administered in accordance with good practice. Evaluation of any potential risk arising from lack of observance of good practice is an inherent part of the risk assessment exercise. Moreover, it was for the European Communities, and not for the Panel, to determine whether the control measures of an exporting Member are adequate to achieve the EC's appropriate level of sanitary protection. The Panel has disregarded the EC's arguments relating to the practical and technical difficulties that are specific to control of the hormones at issue. The European Communities also protests as an error in law the Panel's conclusion that banning the use of a substance does not necessarily offer better protection of human health than other means of merely regulating its use.

31. Finally, the European Communities submits that the Panel was manifestly wrong in finding that a risk assessment must be carried out for each individual substance.<sup>33</sup> Nowhere in the SPS Agreement, and in particular in Articles 5.1 and 5.2, is there language requiring a risk assessment "for each individual substance". In the view of the European Communities, there is nothing to prevent classes or categories of substances from being assessed together if this is scientifically justified.

#### 9. Article 5.5

32. The European Communities argues that the Panel erred in its interpretation of Article 5.5. With respect to the first element, namely, the existence of different levels of protection in different situations, the Panel erroneously interpreted Article 5.5 in holding that situations involving the same health risk or substance are comparable situations for the purposes of Article 5.5.<sup>34</sup> The European Communities submits that it is inappropriate to compare the level of protection relating to hormones used for growth promotion purposes with the level of protection relating to naturally-occurring hormones. Science and the regulatory practices of Members do not treat man-made risks, such as the risks created by hormones used for growth promotion, and naturally-occurring risks, such as those arising from the presence of hormones in meat, milk, cabbage or broccoli, in the same way. The SPS Agreement applies only to man-made risks because the naturally-occurring hormones in meat and other foodstuffs are not "contaminants and toxins" within the meaning of the SPS Agreement. Furthermore, the European Communities submits

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<sup>33</sup>US Panel Report, para. 8.257; Canada Panel Report, para. 8.260.

<sup>34</sup>US Panel Report, para. 8.176; Canada Panel Report, para. 8.179.



that, contrary to what the Panel found<sup>35</sup>, there is no difference, let alone a significant difference, in the EC level of protection against naturally-occurring hormones and its level of protection against added hormones. The EC measures provide for the same level of protection against naturally-occurring hormones and added hormones, namely, the risk determined by nature.

33. In respect of the second element of Article 5.5, namely, the arbitrary or unjustifiable nature of distinctions in levels of protection, the European Communities contends that the Panel has erroneously assumed that the only factors relevant to determining what is an arbitrary or unjustifiable distinction are "scientific" factors. Other factors, such as public perception of what is dangerous and of what level of risk is acceptable, and the benefit, if any, to be gained from shouldering a risk, must also be relevant. Moreover, the European Communities argues that, contrary to what the Panel found<sup>36</sup>, the distinction between the level of protection adopted in respect of the hormones at issue when used for growth promotion and the level of protection adopted with respect to carbadox and olaquinox is not arbitrary or unjustifiable.

34. As to the third element of Article 5.5, namely discrimination or a disguised restriction on international trade resulting from the distinction in the levels of protection, the European Communities objects to the Panel's finding that it was sufficient to demonstrate "the significance of the difference in levels of protection combined with the arbitrariness thereof".<sup>37</sup> Article 5.5 makes a resultant "discrimination or a disguised restriction on international trade" an additional element beyond arbitrary and unjustifiable distinctions in the levels of protection a Member considers appropriate. The European Communities does not consider the approach developed by the Appellate Body in *Japan - Taxes on Alcoholic Beverages*<sup>38</sup> ("*Japan - Alcoholic Beverages*") and invoked by the Panel in this case as appropriate for the very different problem in determining discrimination (between countries) and a disguised restriction of trade in a regulatory regime designed to protect human health.

35. Furthermore, it is argued by the European Communities that Article 5.5 must be interpreted together with Article 2.3 of the SPS Agreement. Accordingly, "discrimination" in Article 5.5 means "discrimination between States where identical or similar conditions prevail". The Panel ignored Article 2.3 and assumed that discrimination can be between substances, risks and levels of protection. This assumption cannot

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<sup>35</sup>US Panel Report, paras. 8.191 and 8.212; Canada Panel Report, paras. 8.194 and 8.215.

<sup>36</sup>US Panel Report, para. 8.238; Canada Panel Report, para. 8.241.

<sup>37</sup>US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.

<sup>38</sup>Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

be correct since otherwise the term "discrimination" would add nothing to "arbitrary and unjustifiable distinctions", in the view of the European Communities.

36. The European Communities stresses that there is no import ban for beef as such and that the restriction applies only to non-conforming products. This is the inevitable consequence of any SPS measure, and cannot be enough to establish a "disguised restriction on international trade". The European Communities continued to import the same amount of meat after the ban as before, and the prohibition of hormones for growth promotion has no effect on the surpluses of beef. The suggestion of the Panel that the reduction of beef surpluses in the European Communities might have been a secondary motive, is, in any event, not sufficient to establish the discrimination or disguised restriction on international trade contemplated in Article 5.5. Finally, the European Communities submits that the fact that 70% of the bovine meat produced in the United States and Canada is from cattle to which hormones have been administered for growth promotion is no indication of a disguised restriction on trade.

#### 10. Procedural Issues

37. The European Communities asserts that a number of procedural decisions taken by the Panel were unfair and require review by the Appellate Body. The European Communities objects to the Panel's view that it need consider the EC's procedural objections only where the European Communities could make a "precise claim" of prejudice.<sup>39</sup> The Panel should have asked itself whether its procedural decisions were consistent with the DSU, not whether the European Communities could make a precise claim of prejudice. It is asserted by the European Communities that the Panel committed a legal procedural error in refusing to accept the scientific assessments of the European Communities, declining to set up an expert review group, and proceeding to decide itself a scientific matter on which the Panel had no expertise. The Panel's decision to receive a range of opinions from individual experts<sup>40</sup> deprived the European Communities of the procedural guarantees provided for expert review groups in the DSU. By following this procedure, the Panel put itself in a position to choose freely between different scientific opinions. The European Communities contends that the selection of scientific experts by the Panel violated Articles 11, 13.2 and Appendix 4 of the DSU as well as Article 13.2 of the SPS Agreement. The European Communities objects to the selection of two experts on the grounds that one of them was a national of a party or third party and had links with the pharmaceutical industry, while the other was a member of the Codex/JECFA group that had produced the report on the use of hormones in animal growth promotion

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<sup>39</sup>US Panel Report, paras. 8.14-8.15; Canada Panel Report, paras. 8.18-8.19.

<sup>40</sup>US Panel Report, para. 8.7; Canada Panel Report, para. 8.7.

and was the "rapporteur" of this study. Further, according to the European Communities, these two experts lacked expertise in the field.

38. The European Communities also alleges that the Panel erred in refusing to request that Canada and the United States provide the studies on which their authorities had based their decisions to authorize the use of MGA for growth promotion. In the view of the European Communities, the Panel had a duty to carry out an objective assessment of the facts, and declining to request the complainants to produce the evidence on which they based their own domestic decisions is not compatible with this duty. Moreover, Article 18.2 of the DSU provides safeguards for the protection of confidential information. Thus, the allegedly confidential nature of the information on MGA should have been no obstacle to its production and use in the proceeding. The European Communities also asserts that the Panel based the main part of its reasoning concerning Article 5.5 of the SPS Agreement on a claim that the complainants had not made, i.e. that there was a difference of treatment between artificially-added, or exogenous, natural and synthetic hormones when used for growth promotion purposes and the naturally-present endogenous hormones in untreated meat and other foods (such as milk, cabbage, broccoli or eggs). In the view of the European Communities, not only is this "claim" wrong in law and in fact, but the Panel also violated the DSU in relying on it especially since the United States expressly protested against the Panel's use of such a "claim". The European Communities asserts that panels are not entitled to make findings going beyond what has been requested by the parties.

39. The European Communities submits further that the Panel took a number of decisions granting "extended third party rights" to Canada and the United States -- and not to other third parties -- that are not justified by Article 9.3, and are contrary to Articles 7.1, 7.2, 18.2 and 10.3 of the DSU as well as the terms of reference of the Panel. These decisions were: first, to give access to all of the information submitted in the United States' proceeding to Canada; second, to give access to all the information submitted in the Canadian proceeding to the United States; third, to hold a joint meeting with the scientific experts; and fourth, to invite the United States to observe and make a statement at the second substantive meeting in the proceeding initiated by Canada.

B. Arguments by the United States - Appellee

1. Burden of Proof

40. With regard to the allocation of the burden of proof under Article 3.3 of the SPS Agreement, the United States refers to the Appellate Body Report in *United States - Shirts and Blouses*<sup>41</sup> and argues that, like Articles XX and XI:2(c)(i) of the GATT 1994, Article 3.3 of the SPS Agreement is not a positive rule establishing an obligation in itself. It is in the nature of an affirmative defence, and the Panel was therefore correct in finding that the burden of proof under Article 3.3 rests on the defending party. As to the burden of proof under Article 5.1 of the SPS Agreement, the United States contends that the European Communities, in complaining that Canada and the United States did not provide their confidential information concerning MGA, misses the point that the Panel had to determine whether the European Communities had based its import ban on a risk assessment.

## 2. Standard of Review

41. The United States submits that the deferential "reasonableness" standard of review advocated by the European Communities is without support in the text of either the DSU or the SPS Agreement. The United States observes that, under Article 5.1, the Panel was called upon to determine if the EC ban was "based on" an assessment, as appropriate to the circumstances, of the risks to human health. Such a determination does not require a panel to conduct its own risk assessment or substitute its own judgement regarding risks, but only to determine if the measure is "based on" a risk assessment. Under Article 2.2, the question for a panel is not whether it would have come to a different conclusion "based on" the evidence, but rather whether the scientific evidence submitted by the Member maintaining the measure is "sufficient" as a basis for that measure. The United States believes that in this sense, the European Communities is correct in asserting that a panel is not to conduct a de novo review of the scientific basis of the measure.

42. The United States argues, however, that nothing in the SPS Agreement or the WTO Agreement requires a Panel to defer to the Member maintaining the SPS measure. In examining measures under the Agreement on Textiles and Clothing (the "ATC"), which, like the SPS Agreement, does not provide for a particular standard of review, two previous panels found that it would not be appropriate either to apply a de novo standard of review or to grant undue deference to the administrative findings of national authorities.<sup>42</sup> The United States cautions that the GATT panel reports cited by the European Communities, involving anti-dumping and countervailing duty disputes, do not support the existence of a deferential

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<sup>41</sup>Adopted 23 May 1997, WT/DS33/AB/R, pp. 14 and 16.

<sup>42</sup>The United States refers to: Panel Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/R; and Panel Report, *United States - Shirts and Blouses*, adopted 23 May 1997, WT/DS33/R.

standard of review in the SPS Agreement. Those GATT panel reports involved situations where national authorities had taken anti-dumping or countervailing duty measures pursuant to detailed national legislation and procedures mandated by the Tokyo Round Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade (the "Tokyo Round Anti-Dumping Code"). According to the United States, the Decision on Review of Article 17.6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 shows that Members have yet to decide if the standard of review set out in Article 17.6 of the Anti-Dumping Agreement is capable of general application. The United States asserts that the European Communities is mistaken in arguing that this standard of review applies to the SPS Agreement.

### 3. The Precautionary Principle

43. In the view of the United States, the claim of the European Communities that there is a generally-accepted principle of international law which may be referred to as the "precautionary principle" is erroneous as a matter of international law. The United States does not consider that the "precautionary principle" represents a principle of customary international law; rather, it may be characterized as an "approach" -- the content of which may vary from context to context. The SPS Agreement does recognize a precautionary approach; indeed, Article 5.7 permits the provisional adoption of SPS measures even where the relevant scientific evidence is insufficient. Thus, the United States believes that there is no need to invoke a "precautionary principle" in order to be risk-averse since the SPS Agreement, by its terms, recognizes the discretion of Members to determine their own level of sanitary protection. The European Communities does not explain how "the precautionary principle" affects the requirements in the SPS Agreement that a measure be "based on" scientific principles and a risk assessment, and not maintained without sufficient scientific evidence. The EC's invocation of a "precautionary principle" cannot create a risk assessment where there is none, nor can a "principle" create "sufficient scientific evidence" where there is none.

### 4. Objective Assessment of the Facts

44. According to the United States, the European Communities improperly requests the Appellate Body to review the Panel's factual findings to determine whether they were either "inadequate" or "not objective", and thus inconsistent with Article 11 of the DSU. The United States submits that, according to Article 17.6 of the DSU, factual findings are clearly beyond review by the Appellate Body. Furthermore, the

United States contends that the European Communities has not shown either improper influence or conflict of interest that might warrant consideration of the objectivity of the Panel.

5. Temporal Application of the SPS Agreement

45. The United States argues that the European Communities, in claiming that Articles 5.1 to 5.5 do not apply to SPS measures adopted before the SPS Agreement entered into force, has misread the SPS Agreement. There is no support for this claim in the text, context or negotiating history of the SPS Agreement. If the position of the European Communities were accepted, this would, in the view of the United States, leave a gaping exception to the disciplines of the SPS Agreement.

6. Article 3.1

46. According to the United States, since the EC measures are not "based on" the Codex standards, even under the broad test of "based on" proposed by the European Communities, there is no need for the Appellate Body to address the alleged difference between measures "based on" international standards and measures that "conform to" international standards. The United States recognizes that Article 3 of the SPS Agreement uses the two different terms in Articles 3.1 and 3.2, but suggests that whether any theoretical difference between those two terms would have any meaning in practice is a question for another case.

7. Article 3.3

47. The United States believes that the European Communities is incorrect in claiming that its ban need not be "based on" a risk assessment under Article 5.1 in order to qualify under Article 3.3 as a measure for which there is a "scientific justification" for departing from an international standard. A risk assessment provides the necessary "examination and evaluation of available scientific information" required in the footnote to Article 3.3. The European Communities provides no explanation why the "relevant provisions" of the SPS Agreement, referred to in that footnote, do not include Article 5.1. The context of the footnote to Article 3.3 includes the definition of "risk assessment" in Annex A of the SPS Agreement. According to the United States, the fact that Articles 5.1 and 5.2 relate to conducting a risk assessment make it clear that these Articles are "relevant provisions" of the SPS Agreement for purposes of the footnote, and that any doubt regarding the applicability of Article 5.1 is removed by the last sentence of Article 3.3.

8. Article 5.1

48. The United States maintains that the Panel's finding that there is a "procedural requirement" inherent in Article 5.1 is simply a common sense reading of Article 5.1. It would be difficult to see how a measure is "based on" a risk assessment if the Member did not even know of the existence of the risk assessment or never considered the risk assessment in enacting or maintaining the measure. Furthermore, the Panel Report should not be read as imposing a rigid requirement to be satisfied only by referring to the risk assessment in the preamble to the measure. Such a reference, the United States contends, is simply one means of demonstrating that a risk assessment was taken into account.

49. The Panel was correct, according to the United States, in finding that in order that a measure may be "based on" a risk assessment, the scientific principles underlying the measure must reflect the scientific conclusions reached by the scientists conducting the risk assessment. The United States submits that the European Communities did not, at any time during the panel proceedings, produce a risk assessment identifying any risk. In the case of the hormone MGA, it is even more obvious that the EC ban is not "based on" a risk assessment.

50. With regard to the problems of control of correct use of the hormones, the United States submits that the Panel correctly characterized the argument of the European Communities as being a general statement that there is no guarantee of 100 percent compliance with any system of laws. Such a generalized concern is not an adequate basis for the EC ban. Furthermore, there is no evidence that the control of the hormones at issue is more difficult than the control of other veterinary drugs (the use of which is allowed), or that control is more difficult under a regime where hormones are allowed for growth promotion under specific conditions than under a current regime where they are banned. During the oral hearing, the United States observed that the scientific studies indicated that the hormones are safe when used in accordance with good practice. According to the United States, these studies do not address the question of whether the hormones at issue are unsafe when not used in accordance with good practice.

51. As to whether a separate risk assessment is necessary for each particular substance, the United States submits that under Article 5.1, the European Communities must base its ban with respect to MGA on an "evaluation, as appropriate to the circumstances, of the potential for adverse effects on human health arising from the presence of residues of MGA in meat ...". The European Communities provided no such evaluation of MGA. The scientific studies that the European Communities referred to deal with a general class of compounds, and do not deal specifically with MGA.

9. Article 5.5

52. The United States supports the finding that the situation involving carbadox and the situation involving the six hormones at issue are different situations which can nonetheless be compared for the purposes of Article 5.5. To the United States, the Panel was correct in finding that the EC distinction in the levels of protection involving carbadox and the level of protection involving the hormones at issue was arbitrary and resulted in a disguised restriction on international trade. In coming to that conclusion, the Panel found that the hormones at issue, banned in the European Communities, were used for growth promotion purpose in the bovine meat sector where the European Communities wanted to limit supplies and was arguably less concerned with international competitiveness while carbadox, allowed in the European Communities, is used for growth promotion purposes in the pork meat sector where the European Communities has no domestic surpluses and where international competitiveness is a high priority. The United States claims that this issue relates to factual findings that are not reviewable by the Appellate Body.

10. Procedural Issues

53. The United States asks the Appellate Body to dismiss each of the procedural claims raised by the European Communities. The appeal by the European Communities on these issues, the United States claims, raises a threshold question as to whether, and if so, under what circumstances, the procedures employed by the Panel during the proceeding could be considered to be issues of law covered in the Panel Report or legal interpretations developed by the Panel within the meaning of Article 17.6 of the DSU. The United States asserts that the European Communities has not pointed to any textual basis for its arguments, nor to any past practice under the GATT 1947 or the WTO Agreement. The United States submits that, to sustain a claim that a panel's handling of procedural issues was inconsistent with the DSU, a party to a dispute must have raised objections in a timely manner during the panel proceeding, if feasible. In the view of the United States, any other response to procedural objections will weaken the authority of panels and destabilize the dispute settlement system. It would also be fundamentally unfair to permit a party to wait and see what the outcome of a panel proceeding is and make its procedural objections only when it is too late for the panel to address them. The United States urges that the objections raised by the European Communities should be rejected to the extent that they were not first made to the Panel.

54. With respect to the EC's objection concerning the Panel's selection of experts, the United States observes that during the panel proceeding, the European Communities did not object to the participation



of two experts who are not only nationals of the Member States of the European Union, but are also employed by institutions of such Member States. As to the EC's objection to the alleged links of one of the experts to the pharmaceutical industry, the United States asserts that the European Communities did not question these links at the time this expert's name was raised by the Panel, even though the European Communities expressed similar concerns at that time with regard to two other scientists proposed by the Panel.

55. Turning to the issue of whether a procedural objection should be based on a "precise claim" of prejudice, the United States believes that while a Panel clearly has the duty of following the relevant rules of the DSU and the covered agreements, a party seeking the reversal or a modification of a procedural ruling should assume the responsibility of providing concrete reasons and legal arguments justifying its objection. Otherwise, every procedural ruling of a Panel could be subject to objections posed for unspecified reasons.

56. The United States asserts that the Panel's decision to consult individual experts, instead of convening an expert review group, was consistent with the DSU and the SPS Agreement. The European Communities itself concedes that Article 13 of the DSU and Article 11.2 of the SPS Agreement are permissive, and not mandatory, provisions. The United States contends that the Panel was not required to convene an expert review group, either under the terms of Article 13 of the DSU or Article 11.2 of the SPS Agreement. If the Panel had convened an expert review group, the rules and procedures of Appendix 4 of the DSU would have been applicable. Since the Panel did not convene such a group, the Panel's decision not to follow the rules and procedures of Appendix 4 was completely consistent with the DSU and was within the discretion accorded to panels in their procedural decisions.

57. The United States contends that the Panel's harmonization of the two panel proceedings did not impair the rights of defence of the European Communities. The use of the same panelists for both proceedings accorded a procedural advantage to the European Communities. According to the United States, rather than having two meetings with each of the two separate Panels, the European Communities was able to have four sessions with the same Panel. The European Communities willingly agreed to have the same panelists in both proceedings.

58. With respect to the issue of extended third party rights, the United States submits that the European Communities failed to make to the Panel the detailed objections it made for the first time in its appellant's submission. There is no reason why, if one panel may grant such rights in one dispute, another panel

may not also grant such rights in another dispute.<sup>43</sup> The United States believes that there were strong reasons to provide it with extended third party rights in the Canadian panel proceeding. The United States asserts that the European Communities is mistaken in asserting that the Panel's grant of extended third party rights gave the complainants access to documents. Both the United States and the European Communities made public their submissions and statements to the Panel in the United States' panel proceeding, and therefore Canada already had access to all these documents.

C. Arguments by Canada - Appellee

1. Burden of Proof

59. On the matter of allocation of the burden of proof under the SPS Agreement in general, Canada contends that the Panel adopted the reasoning provided by the Appellate Body in *United States - Shirts and Blouses*.<sup>44</sup> As to the allocation of the burden of proof under Article 3.3 of the SPS Agreement, Canada insists that the Panel's findings are correct, although it would be more accurate to hold that "... the burden of proof under Article 3.1 shifts to the defending party to show either that the measure in dispute is consistent with the obligation in Article 3.1, or to invoke the exception under 3.1 and show that it meets the conditions of that exception".<sup>45</sup> Should the Appellate Body reverse or modify the Panel's findings on the burden of proof, Canada submits that in any event, Canada has established a *prima facie* case of violation. With regard to the burden of proof under Article 5.1 of the SPS Agreement, Canada believes that it had provided sufficient evidence concerning the import ban on meat treated with MGA to establish a *prima facie* case.

2. The Precautionary Principle

60. The Panel did not take a position on whether the "precautionary principle" constituted part of the body of international law. Rather, in Canada's view, the Panel acknowledged that the "precautionary principle" was reflected in Article 5.7 of the SPS Agreement, and correctly held that the "precautionary principle" could not override Articles 5.1 and 5.2, or any other provision of the SPS Agreement. Canada also regards the issue of whether the "precautionary principle" is "built into" other provisions of the SPS

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<sup>43</sup>The United States refers to Panel Report, *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, adopted 25 September 1997, WT/DS27/R/USA ("European Communities - Bananas").

<sup>44</sup>Adopted 23 May 1997, WT/DS33/AB/R.

<sup>45</sup>Canada's appellee's submission, para. 59.

Agreement as irrelevant in this appeal. Moreover, the European Communities has not explained what is meant by the "precautionary principle" having been "built into" other provisions of the SPS Agreement, and how this could in any way affect the conclusions of the Panel. The "precautionary principle" should be characterized as the "precautionary approach" because it has not yet become part of public international law. Canada considers the precautionary approach or concept as an emerging principle of international law, which may in the future crystallize into one of the "general principles of law recognized by civilized nations", within the meaning of Article 38(1)(c) of the Statute of the International Court of Justice.

3. Objective Assessment of the Facts

61. Canada submits that many of the claims made by the European Communities in its appellant's submission purport to be claims relating to errors of law but are in reality claims alleging errors of fact. The Appellate Body made it clear in its Report in *European Communities - Bananas*<sup>46</sup>, that factual findings are, pursuant to Article 17.6 of the DSU, beyond review by the Appellate Body.

4. Temporal Application of the SPS Agreement

62. Canada argues that the distinction drawn by the European Communities between provisions of the SPS Agreement that include the terms "maintain" or "apply", and others that do not, is not sustainable. This dichotomy presented by the European Communities would mean that measures in existence on 1 January 1995 are indefinitely exempt from the disciplines of Articles 5.1 and 5.5, but it is hardly credible that the Members intended to exempt them. Other covered agreements contain specific provisions dealing with temporal issues, therefore, non-application of provisions of the SPS Agreement, such as Articles 5.1 and 5.5, would have been dealt with expressly in the text of the SPS Agreement. In any event, the EC measures at issue in this dispute include EC Directives 96/22/EC and 96/23/EC, which were adopted after the WTO Agreement entered into force.

5. Article 3.1

63. Canada maintains that the EC's argument that Article 3.1 does not constitute a "general obligation", but is one of three options available to Members when Codex recommendations exist, is incorrect. Article 3.1 sets out a positive obligation for Members to base their SPS measures on international standards,

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<sup>46</sup>Adopted 25 September 1997, WT/DS27/AB/R.

guidelines or recommendations. The words of Article 3.1 do not describe three "options". If the drafters of the agreement had intended such a meaning, they would have said so. Canada supports the Panel's conclusion that the terms "conform to" and "based on" are "co-extensive". Even if the Appellate Body accepts the view that "conforms to" is narrower in scope than "based on", Article 3.1 does not present a second "option", as argued by the European Communities. A measure that "conforms to" an international standard would also be "based on" that standard.

6. Article 3.3

64. The key element of the footnote to Article 3.3 is that it requires an examination and evaluation of available scientific information. Since the SPS Agreement defines a risk assessment as: "the evaluation of the potential for adverse effects on human ... health ...", the "examination and evaluation of scientific information" in the footnote to Article 3.3 refers to a risk assessment. A Member cannot, in Canada's view, determine that the relevant international standards are not sufficient to achieve its appropriate level of sanitary protection unless the Member does an evaluation of that risk (i.e. a risk assessment), taking into account available scientific evidence.

7. Article 5.1

65. Canada considers that the Panel's interpretation of Article 5.1 accords with the ordinary meaning of the words in their context. If a measure is "founded on" a risk assessment then there must be some evidence that the measure was built upon that foundation. Such a requirement would not amount to "freezing the scientific record", since the Panel made clear that it was looking for evidence that a risk assessment was taken into account when the EC measures were established or at any later point in time. In Canada's view, the Panel's reading of Article 5.1 is sound, and accords with the basic obligations set out in Article 2.2 that a measure must not be maintained without sufficient scientific evidence. If the scientific conclusions reflected in the EC measures do not conform with any of those reached in the risk assessments, then the scientific foundation for the measure clearly does not come from those risk assessments.

66. Canada submits that in defining what is a risk assessment, the European Communities focuses on the word "potential" to the exclusion of "evaluation". In doing so, the European Communities has stopped the process at identifying an adverse effect without carrying out the evaluation of the risk, i.e. performing a risk assessment.

67. At the oral hearing, when asked about the need for a separate risk assessment of each individual substance, Canada opined that one can use characteristics of chemical families as a starting point for exploring whether something might pose a hazard, but it is then necessary to go on and do a full evaluation of that chemical in order to determine whether it in fact poses a hazard.

8. Article 5.5

68. According to Canada, the scope of "different situations" referred to in Article 5.5 is at least as broad as the Panel found. The limited scope suggested by the European Communities conflicts with the ordinary meaning of "different situations". Canada also submits that in the light of the object and purpose of the SPS Agreement and the context of Article 5.5, there is no reason to limit the scope of comparison between levels of protection for human health. In Canada's view, the Panel correctly found that the European Communities had not justified the distinctions in its purported levels of protection. The Panel did not "confine" the range of factors to be taken into consideration; the Panel considered all the arguments the European Communities had provided, but found them wanting. Canada contests the argument of the European Communities that the significance of the difference in levels of protection is no guide to the significance of trade effects. No measure could be more trade restrictive than an import ban.

9. Procedural Issues

69. Canada submits that all of the procedural rulings made by the Panel were fair to all the parties, did not result in any prejudice or injustice, and were within the Panel's jurisdiction and discretion. In particular, Canada believes that the Panel acted within its jurisdiction in making comparisons and findings with respect to the levels of protection for endogenous natural hormones, even if those precise arguments on Article 5.5 of the SPS Agreement were not made by Canada or the United States. Article 11 of the DSU does not limit the mandate of the Panel by compelling it to use only the arguments made by the parties. A panel is not prevented from making an objective finding that does not correspond to either party's argument.

70. Concerning the Panel's decision to consult experts in their individual capacities, rather than as an expert review group, Canada submits that the process chosen by the Panel ensured that all the views of the experts advising the Panel were brought to the Panel's attention. Far from prejudicing the European Communities, this process gave the European Communities an opportunity to elicit evidence to support

its arguments from any of the Panel's experts. While Article 11.2 of the SPS Agreement provides that in disputes involving scientific or technical issues, a Panel should seek advice from experts chosen by the Panel in consultation with the parties to the dispute, this provision does not require the Panel to accept all expert advice without scrutiny. Canada submits that, to the contrary, the Panel had no authority to delegate its fact-finding duty to the experts in such a manner.

71. It is also submitted by Canada that the objection of the European Communities to the nationality of the experts selected to assist the Panel is without merit. Canada is unaware that the European Communities raised any such objection during the Panel's selection of experts. In Canada's view, by suggesting an expert who was a national of one of its Member States, the European Communities waived its right to object to the other scientists on the basis of their nationality. The Panel's decisions on "extended third party rights" were proper exercises of the Panel's discretion, and are not inconsistent with the DSU. The European Communities made references to materials that it had placed before the US Panel, but did not provide those materials in the Canada Panel proceeding. Thus, according to Canada, rather than prejudice the EC case, the Panel allowed all the submissions by the European Communities before the US Panel to be considered by the Canada Panel. Canada maintains that the decision of the Panel to convene a joint meeting of the experts was also within the discretion of the Panel. The European Communities has failed to demonstrate that it suffered any substantive prejudice as a result of this decision. In Canada's view, pursuant to Article 11 of the SPS Agreement, the Panel was entitled to seek advice from experts chosen by the Panel in consultation with the parties, but was under no obligation to convene a meeting with the experts, either severally or jointly.

#### D. Claims of Error by the United States - Appellant

##### 1. Article 2.2

72. In its capacity as appellant, the United States submits that the Panel erred because, having made all of the findings necessary to find that the EC measure was inconsistent with Article 2.2, it did not take the final step and declare the import ban to be inconsistent with Article 2.2.<sup>47</sup> Article 2.2 requires the European Communities to have sufficient scientific evidence to support its measure. Since the Panel methodically listed and reviewed all of the scientific evidence presented by the European Communities, and in respect of each piece of evidence made a factual finding that the evidence did not support the EC measure, the United States submits that the Panel should have come to the legal conclusion that the EC

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<sup>47</sup>US Panel Report, para. 8.271.

import prohibition is maintained without sufficient scientific evidence. In the view of the United States, there was no need for the Panel to determine exactly how much scientific evidence is "sufficient" for purposes of Article 2.2. The Panel found that the European Communities had presented no evidence to support its ban; "no evidence" cannot be considered to meet the threshold of "sufficient evidence".

73. In justifying why it made no finding under Article 2.2, the Panel stated that Articles 3 and 5 provide for more specific obligations than the "basic rights and obligations" set out in Article 2. According to the United States, Articles 3 and 5 of the SPS Agreement do not necessarily provide for more specific rights and obligations than all of the "basic rights and obligations" set out in Article 2. Neither Article 3 nor Article 5 says how much evidence is necessary to support an SPS measure. Article 2.2 establishes that quantum of evidence in requiring that measures not be maintained "without sufficient scientific evidence". The United States submits, therefore, that nothing in the text of Articles 2, 3 or 5 indicate that all of the obligations in Article 2 are subsumed under the provisions of Articles 3 and 5.

## 2. Article 5.6

74. It is urged by the United States that the Panel erred<sup>48</sup> in failing to make a finding under Article 5.6 of the SPS Agreement, and that the Panel's findings on Article 5.5 are sufficient to establish that the EC ban is inconsistent with Article 5.6 of the SPS Agreement. The United States notes that the European Communities prohibits the use of the natural hormones to promote growth, while having no limits on the residues of these exact same substances either naturally-present or used for therapeutic or zootechnical purposes. Since the European Communities accepts the residues of these naturally-occurring hormones in meat as safe, then the EC ban is, in the view of the United States, more trade restrictive than required.

75. The United States also notes that the European Communities prohibits the use of the three synthetic hormones at issue, while permitting the use of similar hormones (the three natural hormones) for therapeutic and zootechnical purposes as well as the use of carbadox, another synthetic compound, for growth promotion purposes. In the view of the United States, the European Communities has, in each instance, chosen the most trade restrictive approach (a ban on trade) with respect to the six hormones for growth promotion purposes. The United States argues that the European Communities could permit residues of these hormones used for growth promotion purposes at the same levels that it permits for other purposes and still achieve its level of protection. The fact that the European Communities permits these levels for these other purposes demonstrates that similarly treating residues from growth promotion would be

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<sup>48</sup>US Panel Report, para. 8.247.

reasonably available to the European Communities and would be technically and economically feasible. Permitting these levels for growth promotion purposes would also be significantly less trade restrictive than the current EC ban.

76. The Panel found that "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."<sup>49</sup> In the view of the United States, this finding is sufficient in itself to establish that the EC ban is inconsistent with Article 5.6. If there is no identifiable risk from the use of these hormones for growth promotion in accordance with good practice, then the EC ban cannot be necessary to achieve a level of protection from an identified risk. The ban is then, by definition, more trade restrictive than required to achieve the appropriate level of sanitary protection by the European Communities.

E. Claims of Error by Canada - Appellant

1. Article 5.6

77. Canada states that its appeal is designed to safeguard its right to rely on its arguments presented to the Panel with respect to Article 5.6, in the event that the Appellate Body decides to modify or reverse the Panel's findings with respect to Articles 3.1, 5.1 or 5.5 of the SPS Agreement. Canada asserts that the EC measures are inconsistent with Article 5.6 of the SPS Agreement. Canada submits that according to the wording of paragraph 5 of Annex A, Article 5.5 and the object and purpose of the SPS Agreement, if there is no scientific evidence of an identifiable risk, there is no basis on which to adopt a measure to achieve a level of sanitary protection under the SPS Agreement, except as provided in Article 5.7.

78. In Canada's view, if a Member could adopt a level of protection and implement a sanitary measure even if it did not provide scientific evidence of an identifiable risk, no effect could be given to the obligation contained in Article 5 to base measures on an assessment of risks. This approach would undermine the wording and object and purpose of the SPS Agreement. Canada notes that the Panel found that the European Communities had not provided any scientific evidence of an identifiable risk related to the hormones at issue when used for growth promotion purposes in accordance with good practice.<sup>50</sup> If there is no scientific evidence of an identifiable risk, and therefore no basis on which to adopt a measure to achieve a level of sanitary protection under the SPS Agreement, except for Article 5.7, then by definition,

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<sup>49</sup>US Panel Report, para. 8.134.

<sup>50</sup>Canada Panel Report, paras. 8.165 and 8.264.



no SPS measure could be adopted that would not be more trade restrictive than required. In Canada's conclusion, applying the Panel's findings with respect to the six hormones at issue to the requirements of Article 5.6, the EC measures are more trade restrictive than required, and inconsistent with Article 5.6.

F. Arguments by the European Communities - Appellee

1. Article 2.2

79. The European Communities questions whether the statement of the Panel regarding Article 2.2 amounts to an issue of law covered in the Panel Report or a legal interpretation developed by the Panel in the sense of Article 17.6 of the DSU. Although the Panel declined to rule on Article 2.2 because of a legal interpretation reached by the Panel regarding the relationship between Articles 2 and 5 of the SPS Agreement, the refusal by the Panel to rule on Article 2.2 places this statement outside the scope of appellate review. The Panel did not address the substantive requirements of Article 2.2, and has not made the necessary findings on whether the scientific evidence submitted by the European Communities is sufficient. The European Communities agrees with the United States that nothing in the text of Articles 2, 3 and 5 of the SPS Agreement indicates that all of the obligations set out in Article 2 are subsumed under the provisions of Articles 3 and 5. From the factual, procedural and substantive points of view, the questions that need to be considered under Article 2.2 are different from those examined by the Panel under Articles 3.1, 5.1, 5.2 and 5.5 of the SPS Agreement. It appears to the European Communities that there is no "sufficient basis" in the Panel Report for the Appellate Body to rule on the claims of the United States in respect of Article 2.2. Moreover, the United States bases its claims on certain paragraphs of the Panel Report that are founded on a manifest misunderstanding or clear distortion of the facts, or inadequate reasoning by the Panel, as explained by the European Communities in its own appeal.

80. The European Communities submits that, should the Appellate Body examine the applicability of Article 2.2 of the SPS Agreement, it should also examine the applicability of Article 5.7, which is expressly referred to in Article 2.2. The European Communities believes that its measures are consistent with Article 2.2 of the SPS Agreement.

81. The European Communities observes that in its appeal, the United States does not discuss what constitutes "sufficient" scientific evidence. Since the concepts of "risk" and "risk assessment" in the SPS Agreement are not quantitative, but qualitative concepts, the word "sufficient" also cannot be taken to

refer to the quantitative, but rather to the qualitative, aspects of the scientific evidence used by the regulatory authorities of a Member. The use of the words "scientific principles" in the same Article reinforces the view that Article 2.2 and the SPS Agreement in general do not require sanitary measures to be "based on" the "best" scientific evidence or the "weight" of available scientific evidence. The European Communities submits, therefore, that the real question is not whether the sanitary measure is "based on" the "best" science or the "preponderance" of science or whether there is conflicting science. Rather, the question is only whether the government maintaining a measure has a scientific basis for that measure.

2. Article 5.6

82. The European Communities also questions whether the statements of the Panel regarding Article 5.6 amount to an issue of law covered in the Panel Report or a legal interpretation developed by the Panel, for purposes of Article 17.6 of the DSU. Although the Panel's refusal to rule on Article 5.6 rests on a certain view of the Panel regarding the relationship between Articles 2 and 5 of the SPS Agreement, such a refusal places the matter outside the scope of appellate review. The European Communities submits that the Panel did not apply the substantive requirements of Article 5.6, and did not make the necessary factual findings that: first, the EC measures are more trade restrictive than required to achieve the EC's level of protection; secondly, there is another measure reasonably available taking into account technical and economic feasibility; and thirdly, this other measure both achieves the EC's level of sanitary protection and is significantly less trade restrictive. Finally, the European Communities argues that Canada and the United States base their claims on certain paragraphs of the Panel Report that are founded on a manifest misunderstanding or clear distortion of the facts or inadequate reasoning by the Panel, as the European Communities has explained in its appeal.

83. The European Communities is convinced that the EC measures are consistent with Article 5.6 of the SPS Agreement. According to the European Communities, the objective is to ensure that consumers are not exposed to any residues of hormones used for growth promotion purposes. The European Communities acknowledges that some hormones are present naturally and cannot be avoided. It also acknowledges that some hormones are administered to cattle for therapeutic and zootechnical purposes, purposes which are unavoidable and beneficial. However, the European Communities has decided that the exposure of its population to hormones above this level should be avoided, and that in particular, there should be a zero level of tolerance for hormones used for growth promotion purposes.

84. The European Communities has considered some possible alternatives to the prohibition of imports of bovine meat containing residues of hormones administered for growth promotion: first, the application of Maximum Residue Limits ("MRLs") to such meat; second, the application of some kind of control to all imports of meat to determine whether hormones had been administered for growth promotion purposes; and third, reliance on the exporters labelling their meat to indicate whether hormones had been administered for growth promotion purposes. According to the European Communities, however, none of the above alternative measures would achieve the specified level of protection.

G. Arguments by the Third Participants

1. Australia

85. Australia considers that the Panel erred in law in its general interpretations concerning the burden of proof under the SPS Agreement<sup>51</sup>, and supports the arguments put forward by the European Communities. However, it is also contended by Australia that paragraphs 8.54 and 8.58 of the Canada Panel Report and paragraphs 8.51 and 8.55 of the US Panel Report present correct interpretations of the burden of proof and that the Panel has, in general, followed these correct interpretations in its legal reasoning and findings.

86. The conclusion reached by the Panel with regard to the temporal application of the SPS Agreement is also supported by Australia. However, Australia also recognizes the concerns raised by the European Communities and agrees that there is nothing in the SPS Agreement that could be interpreted to mean that measures already in place at the time the SPS Agreement came into force are necessarily inconsistent simply because the "preparatory and procedural obligations" provided in Article 5 may not have been met. On the other hand, Australia admits that nothing in the SPS Agreement suggests that such measures can escape application of key provisions, such as Articles 5.1 and 5.2.

87. The Panel's interpretation that the SPS Agreement "equates" the terms "conform to" and "based on" ignores, in Australia's view, the ordinary meaning of these terms in their context and fails to give effect to all the terms of the SPS Agreement. The Panel has ignored the significant fact that the SPS Agreement uses the expression "conform to" in both Article 3.2 and Article 2.4, i.e. in the two situations where rebuttable presumptions are established that certain measures are consistent with the SPS Agreement and/or the GATT 1994. Australia believes that the issue of whether a particular measure is "based on"

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<sup>51</sup>US Panel Report, paras. 8.52-8.54; Canada Panel Report, paras. 8.55-8.57.

an international standard, or "conforms to" such a standard, is something which can only be determined on a case-by-case basis.

88. The Panel failed to give effect to all the terms of the SPS Agreement by its treatment of the two options provided in Article 3.3. According to Australia, the Panel has ignored the differences in the wording of the two options, and their explicit identification as alternatives by the use of the word "or" in Article 3.3. This interpretation has resulted in the Panel concluding that both alternatives mean that a measure can only be justified under Article 3.3 if it meets the requirements of Article 5. In Australia's view, while a Member's determination under the first of these options must be "based on" an examination and evaluation of available scientific information "in conformity with" the relevant provisions of the SPS Agreement, there remains an important distinction between the two options which the Panel failed to recognize.

89. Australia also considers as erroneous the Panel's interpretation of "risk", specifically its use of the term "identifiable risk", which has no basis in the text of the SPS Agreement. What the Panel is required to examine under Articles 5.1 and 5.2 is whether the EC measure is "based on" a risk assessment, and not whether there was an "identifiable risk".

90. In discussing whether there is a need for a separate risk assessment for each individual substance, Australia draws particular attention to the wording of Article 5.1 providing for a risk assessment "as appropriate to the circumstances". This wording expressly recognizes that what constitutes an appropriate risk assessment may differ from case to case. In the view of Australia, the determination of whether a risk assessment is required for a particular individual substance should therefore be made on a case-by-case basis. The Panel recognized that in order to find an SPS measure inconsistent with Article 5.5 all elements of this provision need to be present<sup>52</sup> but the Panel, nevertheless, gave undue weight, in the view of Australia, to the significance of the distinction in the levels of protection. The Panel's reference to the Appellate Body Report in Japan - Alcoholic Beverages<sup>53</sup> concerning the requirements of Article III:2 of the GATT 1994 was misleading and inappropriate.

91. Although Australia supports the view of the United States that the EC measures are inconsistent with Article 2.2 of the SPS Agreement, Australia does not believe there was any need for the Panel to make such a finding.

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<sup>52</sup>US Panel Report, para. 8.174; Canada Panel Report, para. 8.177.

<sup>53</sup>Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

2. New Zealand

92. New Zealand refers to its third party submission to the Panel relating to Articles 2.2 and 5.6. New Zealand submits that since the Panel found that there was no scientific evidence that indicated that an identifiable risk arises from the use of any of the hormones at issue when used for growth promotion purposes in accordance with good practice, the Appellate Body should consider the applicability of Articles 2.2 and 5.6 of the SPS Agreement to the import ban.

3. Norway

93. Norway stresses that the SPS Agreement does not contain obligations to harmonize different levels of protection. The right of every Member to set its own level of protection is, according to Norway, an inherent right that has always been accepted by the GATT and now by the WTO Agreement. In the view of Norway, Members have a variety of options when deciding on their appropriate level of protection. They may decide to adopt a more lenient approach or a more stringent approach. Member A may decide to have a (close to) zero tolerance for deaths related to the usage of certain substances, while Member B accepts one death per million per year. This is entirely for Member A and Member B to decide. When, thereafter, each Member chooses the measure necessary to achieve its level of protection, that measure must comply with the basic obligations of Articles 2, 3 and 5 of the SPS Agreement. As long as the existence of a risk is established, the WTO is only concerned with the justification of the measure the Member chooses to apply to achieve the level of protection it has deemed appropriate. According to Norway, there is no requirement on that Member to come to the same conclusions concerning the evaluation of the available scientific evidence that other Members or international organizations may have reached.

94. On the issue of burden of proof, Norway argues that the Panel erred when it described Article 3.1 as the general rule, thus imposing an obligation on Members to harmonize their SPS measures. Article 3.1 clearly states that harmonization is merely an objective or option, by using the words "... on as wide a basis as possible". The "exceptions" to this objective are not limited to situations covered by Article 3.3. There are others, as can be seen from the words "... except as otherwise provided for in this Agreement, and in particular in paragraph 3". Norway submits that instead of designating one paragraph of Article 3 as a general rule and others as exceptions, the Panel should have read Article 3 within the context of Articles 2.2 and 2.3. In the view of Norway, where the SPS measure is identical for domestic and imported products, the general rule -- as with all obligations -- is that the complainant must present a prima facie case of violation. The requirement in Article 2.2 that measures be "necessary" does not alter the above.

SPS measures are not exceptional measures, and the burden of proving that a measure is not necessary rests in the first instance with the complainant.

95. In respect of Article 5.5, Norway submits that it is the level of protection that is at issue, rather than the measure, which must "conform to" other parts of the SPS Agreement. It is for the complainant to prove that a decision on different levels of protection violates Article 5.5.

### 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;
- (d) Whether the provisions of the SPS Agreement apply to measures enacted before the date of entry into force of the WTO Agreement;
- (e) Whether the Panel made an objective assessment of the facts pursuant to Article 11 of the DSU;
- (f) Whether the Panel acted within the scope of its authority in its selection and use of experts, in granting additional third party rights to the United States and Canada and in making findings based on arguments not made by the parties;
- (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;  
and
- (j) Whether the Panel appropriately exercised "judicial economy" in not making findings on the consistency of the EC measures with Article 2.2 and Article 5.6 of the SPS Agreement.

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

97. The first general issue that we must address relates to the allocation of the burden of proof in proceedings under the SPS Agreement. The Panel appropriately describes this issue as one "of particular importance"<sup>54</sup>, in view of the nature of disputes under that Agreement. Such disputes may raise multiple and complex issues of fact.

98. The Panel begins its analysis by setting out the general allocation of the burden of proof between the contending parties in any proceedings under the SPS Agreement. The initial burden lies on the complaining party, which must establish a prima facie case of inconsistency with a particular provision of the SPS Agreement on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that prima facie case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency. This seems straightforward enough and is in conformity with our ruling in *United States - Shirts and Blouses*<sup>55</sup>, which the Panel invokes and which embodies a rule applicable in any adversarial proceedings.

99. The Panel, however, proceeds to make a general, unqualified, interpretative ruling that the SPS Agreement allocates the "evidentiary burden" to the Member imposing an SPS measure. To support this general statement, which renders the Panel's reference to our own ruling in *United States - Shirts and Blouses* little more than lip-service, the Panel first points to:

... the wording of many of the provisions contained in [the SPS] Agreement and in particular the first three words thereof: "Members

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<sup>54</sup>US Panel Report, para. 8.48; Canada Panel Report, para. 8.51.

<sup>55</sup>Adopted 23 May 1997, WT/DS33/AB/R, p. 14.

shall ensure that ..." (e.g. Articles 2.2, 2.3, 5.1 and 5.6 of the SPS Agreement).<sup>56</sup>

100. The Panel next quotes Article 5.8 of the SPS Agreement, while parenthetically noting that this Article "relates more to transparency than to any requirement of legal justification".<sup>57</sup> Article 5.8 provides:

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

101. Lastly, the Panel seeks support for its general interpretative ruling in Article 3.2 of the SPS Agreement, which establishes a presumption of consistency with relevant provisions of that Agreement and of the GATT 1994 for measures that conform to international standards, guidelines and recommendations. From this presumption, the Panel extracts a reverse inference that if a measure does not conform to international standards, the Member imposing such a measure must bear the burden of proof in any complaint of inconsistency with a provision of the SPS Agreement.<sup>58</sup>

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 ..."<sup>59</sup>, 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

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<sup>56</sup>US Panel Report, para. 8.52; Canada Panel Report, para. 8.55.

<sup>57</sup>US Panel Report, para. 8.53; Canada Panel Report, para. 8.56.

<sup>58</sup>US Panel Report, para. 8.54; Canada Panel Report, para. 8.57.

<sup>59</sup>SPS Agreement, Article 2.2.



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.<sup>60</sup> (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)<sup>61</sup> 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.<sup>62</sup> It appears to us that the Panel has misconceived the

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<sup>60</sup>US Panel Report, paras. 8.86 and 8.87; Canada Panel Report, paras. 8.89 and 8.90.

<sup>61</sup>US Panel Report, para. 8.86; Canada Panel Report, para. 8.89.

<sup>62</sup>US Panel Report, footnote 288; Canada Panel Report, footnote 393.

relationship between Articles 3.1, 3.2 and 3.3, a relationship discussed below<sup>63</sup>, 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.<sup>64</sup>

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.<sup>65</sup>

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).<sup>66</sup>

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:

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<sup>63</sup>Paras. 169-172 of this Report.

<sup>64</sup>Appellate Body Report, United States - Shirts and Blouses, adopted 23 May 1997, WT/DS33/AB/R, p. 14.

<sup>65</sup>Para. 102 of this Report.

<sup>66</sup>See para. 103 of this Report.

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.<sup>67</sup>

...

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.<sup>68</sup>

108. To the extent that the Panel<sup>69</sup> 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*<sup>70</sup>, 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

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<sup>67</sup>US Panel Report, para. 8.151; Canada Panel Report, para. 8.154.

<sup>68</sup>US Panel Report, para. 8.165; Canada Panel Report, para. 8.168.

<sup>69</sup>US Panel Report, paras. 8.151 and 8.165; Canada Panel Report, paras. 8.154 and 8.168.

<sup>70</sup>Adopted 23 May 1997, WT/DS33/AB/R, pp. 14-16.

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.<sup>71</sup>

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

110. The European Communities appeals from certain findings of the Panel<sup>72</sup> upon the ground that the Panel failed to apply an appropriate standard of review in assessing certain acts of, and scientific evidentiary material submitted by, the European Communities.<sup>73</sup> The European Communities claimed, more specifically, that:

... the panel erred in law in not according deference to the following elements of the EC measures:

- the EC's decision to set and apply a level of sanitary protection higher than that recommended by Codex Alimentarius for the risks arising from the use of these hormones for growth promotion;
- the EC's scientific assessment and management of the risk from the hormones at issue; and
- the EC's adherence to the precautionary principle and its aversion to accepting any increased carcinogenic risk.

The panel also erred in law because it:

- assigned a high probative value to the scientific views presented by some of the five scientific experts chosen by it (and to the views of the technical expert appointed by Codex Alimentarius);
- disregarded in effect or distorted the scientific evidence presented by the EC and its scientific advisors, and systematically considered the scientific views of the panel-appointed experts or even a minority of those experts, of higher probative value than the scientific evidence presented by the EC scientists;

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<sup>71</sup>Our finding that the Panel erred in allocating the burden of proof generally to the Member imposing the measure, however, does not deal with the quite separate issue of whether the United States and Canada actually made a prima facie case of violation of each of the following Articles of the SPS Agreement: 3.1, 3.3, 5.1 and 5.5. See in this respect, footnote 180 of this Report.

<sup>72</sup>US Panel Report, paras. 8.124, 8.127, 8.133, 8.134, 8.145, 8.146, 8.194, 8.199, 8.213 and 8.255; Canada Panel Report, paras. 8.127, 8.130, 8.136, 8.137, 8.148, 8.149, 8.197, 8.202, 8.216 and 8.258.

<sup>73</sup>EC's appellant's submission, para. 140.

- based its legal interpretations and findings on a number of critical issues on the majority of scientific views presented by its own appointed experts, instead of limiting itself to examining whether the scientific evidence presented by the EC was based on "scientific principles" (as required by Article 2:2 [of the SPS Agreement]).<sup>74</sup>

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".<sup>75</sup> 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.<sup>76</sup>

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

17.6 In examining the matter referred to in paragraph 5:

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

113. The European Communities further urges that the above-quoted standard, which it describes as a "deferential 'reasonableness' standard"<sup>77</sup> is applicable in "all highly complex factual situations,

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<sup>74</sup>EC's appellant's submission, para. 139.

<sup>75</sup>EC's appellant's submission, para. 122.

<sup>76</sup>EC's appellant's submission, para. 123.

<sup>77</sup>EC's appellant's submission, para. 128.

including the assessment of the risks to human health arising from toxins and contaminants"<sup>78</sup>, and should have been applied by the Panel in the present case.

114. The first point that must be made in this connection, is that the SPS Agreement itself is silent on the matter of an appropriate standard of review for panels deciding upon SPS measures of a Member. Nor are there provisions in the DSU or any of the covered agreements (other than the Anti-Dumping Agreement) prescribing a particular standard of review. Only Article 17.6(i) of the Anti-Dumping Agreement has language on the standard of review to be employed by panels engaged in the "assessment of the facts of the matter". We find no indication in the SPS Agreement of an intent on the part of the Members to adopt or incorporate into that Agreement the standard set out in Article 17.6(i) of the Anti-Dumping Agreement. Textually, Article 17.6(i) is specific to the Anti-Dumping Agreement.<sup>79</sup>

115. The standard of review appropriately applicable in proceedings under the SPS Agreement, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves.<sup>80</sup> To adopt a standard of review not clearly rooted in the text of the SPS Agreement itself, may well amount to changing that finely drawn balance; and neither a panel nor the Appellate Body is authorized to do that.

116. We do not mean, however, to suggest that there is at present no standard of review applicable to the determination and assessment of the facts in proceedings under the SPS Agreement or under other covered agreements. In our view, Article 11 of the DSU bears directly on this matter and, in effect,

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<sup>78</sup>EC's appellant's submission, para. 127.

<sup>79</sup>On the other hand, as suggested by the United States, we must note the Decision on the Review of Article 17.6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994, which states:

Ministers,

Decide as follows:

The standard of review in paragraph 6 of Article 17 of the Agreement on Implementation of Article VI of GATT 1994 shall be reviewed after a period of three years with a view to considering the question of whether it is capable of general application. (underlining added)

This Ministerial Decision evidences that the Ministers were aware that Article 17.6 of the Anti-Dumping Agreement was applicable only in respect of that Agreement.

<sup>80</sup>See, for example, S.P. Croley and J.H. Jackson, "WTO Dispute Panel Deference to National Government Decisions, The Misplaced Analogy to the U.S. Chevron Standard-of-Review Doctrine", in E.-U. Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System* (Kluwer, 1997) 185, p. 189; P.A. Akakwam, "The Standard of Review in the 1994 Antidumping Code: Circumscribing the Role of GATT Panels in Reviewing National Antidumping Determinations" (1996), 5:2 *Minnesota Journal of Global Trade* 277, pp. 295-296.

articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements. Article 11 reads thus:

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

117. So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither de novo review as such, nor "total deference", but rather the "objective assessment of the facts". Many panels have in the past refused to undertake de novo review<sup>81</sup>, 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".<sup>82</sup>

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.<sup>83</sup> 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 ...".

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<sup>81</sup>Panel Report, United States - Underwear, adopted 25 February 1997, WT/DS24/R; Panel Report, Korea - Anti-Dumping Duties on Imports of Polyacetal Resins from the United States, adopted 27 April 1993, BISD 40S/205; Panel Report, United States - Imposition of Anti-Dumping Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway, adopted 27 April 1994, ADP/87; and Panel Report, United States - Initiation of a Countervailing Duty Investigation into Softwood Lumber Products from Canada, adopted 3 June 1987, BISD 34S/194.

<sup>82</sup>Panel Report, United States - Underwear, adopted 25 February 1997, WT/DS24/R, para. 7.10

<sup>83</sup>DSU, Article 3.2.

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.<sup>84</sup> 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

120. We are asked by the European Communities to reverse the finding of the Panel relating to the precautionary principle. The Panel's finding and its supporting statements are set out in the Panel Reports in the following terms:

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.

We thus find that the precautionary principle cannot override our findings made above, namely that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones in accordance with good practice, is, from a substantive point of view, not based on a risk assessment.<sup>85</sup> (underlining added)

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<sup>84</sup>Paras. 131-144 of this Report.

<sup>85</sup>US Panel Report, paras. 8.157 and 8.158; Canada Panel Report, paras. 8.160 and 8.161.



121. The basic submission of the European Communities is that the precautionary principle is, or has become, "a general customary rule of international law" or at least "a general principle of law".<sup>86</sup> Referring more specifically to Articles 5.1 and 5.2 of the SPS Agreement, applying the precautionary principle means, in the view of the European Communities, that it is not necessary for all scientists around the world to agree on the "possibility and magnitude" of the risk, nor for all or most of the WTO Members to perceive and evaluate the risk in the same way.<sup>87</sup> It is also stressed that Articles 5.1 and 5.2 do not prescribe a particular type of risk assessment and do not prevent Members from being cautious in their risk assessment exercise.<sup>88</sup> The European Communities goes on to state that its measures here at stake were precautionary in nature and satisfied the requirements of Articles 2.2 and 2.3, as well as of Articles 5.1, 5.2, 5.4, 5.5 and 5.6 of the SPS Agreement.<sup>89</sup>

122. The United States does not consider that the "precautionary principle" represents customary international law and suggests it is more an "approach" than a "principle".<sup>90</sup> Canada, too, takes the view that the precautionary principle has not yet been incorporated into the corpus of public international law; however, it concedes that the "precautionary approach" or "concept" is "an emerging principle of law" which may in the future crystallize into one of the "general principles of law recognized by civilized nations" within the meaning of Article 38(1)(c) of the Statute of the International Court of Justice.<sup>91</sup>

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.<sup>92</sup> We consider, however, that it is unnecessary, and probably imprudent, for the Appellate

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<sup>86</sup>EC's appellant's submission, para. 91.

<sup>87</sup>EC's appellant's submission, para. 88.

<sup>88</sup>EC's appellant's submission, para. 94.

<sup>89</sup>EC's appellant's submission, para. 98.

<sup>90</sup>United States' appellee's submission, para. 92.

<sup>91</sup>Canada's appellee's submission, para. 34.

<sup>92</sup>Authors like P. Sands, J. Cameron and J. Abouchar, while recognizing that the principle is still evolving, submit nevertheless that there is currently sufficient state practice to support the view that the precautionary principle is a principle of customary international law. See, for example, P. Sands, *Principles of International Environmental Law*, Vol. I (Manchester University Press 1995) p. 212; J. Cameron, "The Status of the Precautionary Principle in International Law", in J. Cameron and T. O'Riordan (eds.), *Interpreting the Precautionary Principle* (Cameron May, 1994) 262, p. 283; J. Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law", in D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law* (Kluwer, 1996) 29, p. 52. Other authors argue that the precautionary principle has not yet reached the status of a principle of international law, or at least, consider such status doubtful, among other reasons, due to the fact that the principle is still subject to a great variety of interpretations. See, for example, P. Birnie and A. Boyle, *International Law and the Environment* (Clarendon Press, 1992), p. 98; L. Gündling, "The Status in International Law of the Precautionary Principle" (1990), 5:1,2,3

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.<sup>93</sup>

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.

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International Journal of Estuarine and Coastal Law 25, p. 30; A. deMestral (et. al), *International Law Chiefly as Interpreted and Applied in Canada*, 5th ed. (Emond Montgomery, 1993), p. 765; D. Bodansky, in *Proceedings of the 85th Annual Meeting of the American Society of International Law (ASIL)*, 1991, p. 415.

<sup>93</sup>In *Case Concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia)*, the International Court of Justice recognized that in the field of environmental protection "... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight ...". However, we note that the Court did not identify the precautionary principle as one of those recently developed norms. It also declined to declare that such principle could override the obligations of the Treaty between Czechoslovakia and Hungary of 16 September 1977 concerning the construction and operation of the Gabčíkovo/Nagymaros System of Locks. See, *Case Concerning the Gabčíkovo-Nagymaros Project (Hungary/Slovakia)*, I.C.J. Judgement, 25 September 1997, paras. 140, 111-114. Not yet reported in the I.C.J. Reports but available on internet at <http://www.icj-cij.org/idecis.htm>.

VII. Application of the SPS Agreement to Measures Enacted Before 1 January 1995

126. Although Directives 81/602, 88/148 and 88/299 were enacted before the entry into force of the WTO Agreement on 1 January 1995, the Panel held<sup>94</sup> that, in line with Article 28 of the Vienna Convention on the Law of Treaties (the "Vienna Convention")<sup>95</sup>, the SPS Agreement should apply to the EC measures at issue because they continued to exist after 1 January 1995 and the SPS Agreement does not show any intention to limit its application to measures enacted after the entry into force of the WTO Agreement. The Panel stated that, to the contrary, several provisions of the SPS Agreement, and in particular Articles 2.2, 3.3, 5.6, 5.8 and 14 thereof, confirm the SPS Agreement does indeed apply to SPS measures which were enacted before 1 January 1995 but were maintained thereafter.<sup>96</sup>

127. The European Communities submits that this conclusion of the Panel is "too sweeping"<sup>97</sup> and that the SPS Agreement shows an intention to limit the temporal application of the Agreement, and in particular Articles 5.1 to 5.5 thereof, to measures enacted after the entry into force of the Agreement.

128. We addressed the issue of temporal application in our Report in *Brazil - Measures Affecting Desiccated Coconut* and concluded on the basis of Article 28 of the Vienna Convention that:

Absent a contrary intention, a treaty cannot apply to acts or facts which took place, or situations which ceased to exist, before the date of its entry into force.<sup>98</sup>

We agree with the Panel that the SPS Agreement would apply to situations or measures that did not cease to exist, such as the 1981 and 1988 Directives, unless the SPS Agreement reveals a contrary intention. We also agree with the Panel that the SPS Agreement does not reveal such an intention. The SPS Agreement does not contain any provision limiting the temporal application of the SPS Agreement, or of any provision thereof, to SPS measures adopted after 1 January 1995.<sup>99</sup> In the absence of such a provision, it cannot

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<sup>94</sup>US Panel Report, para. 8.25; Canada Panel Report, para. 8.28.

<sup>95</sup>Done at Vienna, 23 May 1969, 1155 UNTS 331; (1969), 8 International Legal Materials, 679.

<sup>96</sup>US Panel Report, para. 8.26; Canada Panel Report, para. 8.29.

<sup>97</sup>EC's appellant's submission, para. 264.

<sup>98</sup>Adopted 20 March 1997, WT/DS22/AB/R, p. 15.

<sup>99</sup>Note that Article 14 of the SPS Agreement allows the least-developed country Members and other developing country Members to delay implementation of the provisions of that Agreement for a period of five and two years, respectively, following the date of entry into force of the WTO Agreement. Developing country Members may only delay application of the provisions of that Agreement where such application is prevented by lack of technical expertise, technical infrastructure or resources. This right to defer application of the provisions of the SPS Agreement concerns, however, both SPS measures existing before the entry

be assumed that central provisions of the SPS Agreement, such as Articles 5.1 and 5.5, do not apply to measures which were enacted before 1995 but which continue to be in force thereafter. If the negotiators had wanted to exempt the very large group of SPS measures in existence on 1 January 1995 from the disciplines of provisions as important as Articles 5.1 and 5.5, it appears reasonable to us to expect that they would have said so explicitly. Articles 5.1 and 5.5 do not distinguish between SPS measures adopted before 1 January 1995 and measures adopted since; the relevant implication is that they are intended to be applicable to both. Furthermore, other provisions of the SPS Agreement, such as Articles 2.2, 2.3, 3.3 and 5.6, expressly contemplate applicability to SPS measures that already existed on 1 January 1995. Finally, we observe, more generally, that Article XVI.4 of the WTO Agreement stipulates that:

Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.

Unlike the GATT 1947, the WTO Agreement was accepted definitively by Members, and therefore, there are no longer "existing legislation" exceptions (so-called "grandfather rights").<sup>100</sup>

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

130. We therefore affirm the finding of the Panel with regard to the temporal application of the SPS Agreement. We also note that the measure at issue in this appeal is, since 1 July 1997, no longer embodied in the pre-1995 Directives referred to above, but rather in Directive 96/22, which was elaborated and enacted after the entry into force of the WTO Agreement. None of the parties contests that the currently applicable measure is subject to the disciplines of Articles 5.1 and 5.5 of the SPS Agreement.

#### VIII. The Requirement of Objective Assessment of the Facts by a Panel Under Article 11 of the DSU

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into force of the WTO Agreement and SPS measures enacted since.

<sup>100</sup>With the exception of the measures taken by a Member under specific mandatory legislation referred to in paragraph 3(a) of the language incorporating the GATT 1994 into the WTO Agreement.

131. The European Communities claims that the Panel has disregarded or distorted the evidence submitted by the European Communities to the Panel, as well as the opinions and statements made by the scientific experts advising the Panel. It is claimed, in other words, that the Panel has failed to make an objective assessment of the facts as required by Article 11 of the DSU, and the European Communities asks us to reverse the findings so arrived at by the Panel.

132. Under Article 17.6 of the DSU, appellate review is limited to appeals on questions of law covered in a panel report and legal interpretations developed by the panel. Findings of fact, as distinguished from legal interpretations or legal conclusions, by a panel are, in principle, not subject to review by the Appellate Body. The determination of whether or not a certain event did occur in time and space is typically a question of fact; for example, the question of whether or not Codex has adopted an international standard, guideline or recommendation on MGA is a factual question. Determination of the credibility and weight properly to be ascribed to (that is, the appreciation of) a given piece of evidence is part and parcel of the fact finding process and is, in principle, left to the discretion of a panel as the trier of facts. The consistency or inconsistency of a given fact or set of facts with the requirements of a given treaty provision is, however, a legal characterization issue. It is a legal question. Whether or not a panel has made an objective assessment of the facts before it, as required by Article 11 of the DSU, is also a legal question which, if properly raised on appeal, would fall within the scope of appellate review.

133. The question which then arises is this: when may a panel be regarded as having failed to discharge its duty under Article 11 of the DSU to make an objective assessment of the facts before it? Clearly, not every error in the appreciation of the evidence (although it may give rise to a question of law) may be characterized as a failure to make an objective assessment of the facts. In the present appeal, the European Communities repeatedly claims that the Panel disregarded or distorted or misrepresented the evidence submitted by the European Communities and even the opinions expressed by the Panel's own expert advisors. The duty to make an objective assessment of the facts is, among other things, an obligation to consider the evidence presented to a panel and to make factual findings on the basis of that evidence. The deliberate disregard of, or refusal to consider, the evidence submitted to a panel is incompatible with a panel's duty to make an objective assessment of the facts. The wilful distortion or misrepresentation of the evidence put before a panel is similarly inconsistent with an objective assessment of the facts. "Disregard" and "distortion" and "misrepresentation" of the evidence, in their ordinary signification in judicial and quasi-judicial processes, imply not simply an error of judgment in the appreciation of evidence

but rather an egregious error that calls into question the good faith of a panel.<sup>101</sup> A claim that a panel disregarded or distorted the evidence submitted to it is, in effect, a claim that the panel, to a greater or lesser degree, denied the party submitting the evidence fundamental fairness, or what in many jurisdictions is known as due process of law or natural justice.

134. It is, accordingly, incumbent upon us to examine the claims of the European Communities that the Panel here disregarded or distorted at least some of the evidence submitted to it.

A. Evidence with Regard to MGA

135. According to the European Communities, the Panel's finding that the experts advising the Panel have stated on several occasions that they are not aware of any publicly available scientific studies that evaluate the safety of MGA<sup>102</sup> is manifestly not true.<sup>103</sup> The Panel cited only two of its experts (Dr. Ritter and Dr. McLean) and the statements of these two scientists do not entirely support the Panel's conclusion. Furthermore, the Panel did not mention that Dr. André and Dr. Lucier, two other experts advising the Panel, had respectively said that MGA is a "real risk" and that MGA is an "extraordinarily potent progestant", that is "about 30 times more potent than progesterone and orally active".<sup>104</sup> We note that Dr. Ritter clearly stated with regard to MGA that he had "no information other than of a proprietary nature which [he] did not use"<sup>105</sup> and that Dr. McLean stated he had made no comment in his submission about MGA "because there hasn't been a large amount of data package available".<sup>106</sup> These two statements tend to support the Panel's conclusion. It is true that the Panel does not refer to the statements by Dr. Lucier and Dr. André. However, these statements do not contradict the Panel's conclusion that there is no publicly available study on the safety of MGA. Furthermore, while the Panel could have made a reference to and an evaluation of the statements by Dr. André and Dr. Lucier concerning MGA, it is generally within the discretion of the Panel to decide which evidence it chooses to utilize in making findings. We do not think that the Panel's silence on the statements of Dr. André and Dr. Lucier constitutes a distortion or disregard of evidence.

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<sup>101</sup>It might be asked whether the European Communities did not merely intend to use "disregard" and "distortion" as unusually forceful synonyms for "misapprehend" or "misappreciation". It is not, however, clear that the European Communities did so intend, considering among other things the marked frequency with which "disregard" and "distortion" were used.

<sup>102</sup>US Panel Report, para. 8.255; Canada Panel Report, para. 8.258.

<sup>103</sup>EC's appellant's submission, para. 168.

<sup>104</sup>EC's appellant's submission, para. 170, quoting Annex to the US and Canada Panel Reports, para. 852.

<sup>105</sup>Annex to the US and Canada Panel Reports, para. 352.

<sup>106</sup>Annex to the US and Canada Panel Reports, para. 354 .

136. The European Communities argues that the Panel failed to request the submission of data on MGA and contends that this failure constituted a violation of Article 11 of the DSU. However, we see nothing in Article 11 to suggest that there is an obligation on the Panel to gather data relating to MGA and that it was therefore required to request the submission of this data.

137. Furthermore, the European Communities states that the Panel arbitrarily disregarded all the information concerning MGA that the European Communities had supplied to the Panel. The information here referred to are studies and reports of the IARC on hormones, including progestins, a category of substances to which MGA is said to belong. However, we note that the Panel did not simply ignore the IARC studies and reports but rather had indicated it did not consider them to be relevant because it found that a risk assessment needs to be carried out for each individual substance.<sup>107</sup>

#### B. Evidence with Regard to the Five Other Hormones

138. With regard to the five other hormones in dispute, the European Communities contends that the Panel manifestly distorted the scientific evidence presented by the European Communities and eliminated dissenting scientific views of its own experts in an attempt to make the desired result fit the scientific record.<sup>108</sup> First, the European Communities submits<sup>109</sup> that the Panel incorrectly quotes some of the statements of Dr. Lucier and totally ignores other more relevant statements he made.<sup>110</sup> We note that the Panel did indeed quote Dr. Lucier incorrectly. The Panel wrongly interpreted Dr. Lucier's statement in paragraph 819 of the Annex as meaning that the 0 to 1 in a million risk is caused by the total amount of oestrogens in treated meat. It is clear that Dr. Lucier stated that this risk is caused by the small fraction of oestrogens that is added for growth promotion purposes. However, this mistake on the part of the Panel in interpreting Dr. Lucier's statement does not constitute a deliberate disregard of evidence or gross negligence amounting to bad faith. The Panel also failed to refer to certain other statements made by Dr. Lucier. It seems to us that these statements either merely clarify the statement discussed above or are of a general nature. The Panel cannot realistically refer to all statements made by the experts advising it and should be allowed a substantial margin of discretion as to which statements are useful to refer to

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<sup>107</sup>US Panel Report, para. 8.257; Canada Panel Report, para. 8.260. The Panel pointed out that with respect to the five other hormones in dispute, JECFA, Codex and the European Communities itself have conducted or invoked risk assessments for each individual substance. Furthermore, the Panel referred to the paper presented at the 1995 EC Scientific Conference by J. Bridges and O. Bridges on "Hazards of Growth Promoting Agents and Strategies of Risk Assessment" (Conference Proceedings, p. 250). US Panel Report, para. 8.260; Canada Panel Report, para. 8.263.

<sup>108</sup>EC's appellant's submission, para. 350.

<sup>109</sup>EC's appellant's submission, para. 347.

<sup>110</sup>See, in particular, footnote 331 of the US Panel Report and footnote 437 of the Canada Panel Report.

explicitly. The same thing may be said with regard to the claim by the European Communities that the Panel failed to quote certain statements by Dr. Ritter and Dr. McLean.<sup>111</sup>

139. Second, it is claimed that the Panel manifestly distorted the views of Dr. André when it said that he did not contest the statements made by the other Panel experts on the safety of the hormones in dispute.<sup>112</sup> To the contrary, according to the European Communities, the views expressed by Dr. André support the scientific opinions presented by the EC scientists.<sup>113</sup> Whether or not the views of Dr. André support the statements made by the other Panel experts or the opinions expressed by the EC scientists may be an issue of fact; it does require some technical expertise to deal with it. However, even if the Panel has interpreted the views of Dr. André incorrectly, we see no reason, and no reason was advanced, to consider this mistake as a deliberate disregard or distortion of evidence.

140. Third, it is claimed that the Panel manifestly distorted the scientific evidence by considering that the 1995 EC Scientific Conference amounted to a risk assessment in the sense of Articles 5.1-5.2. However, we note that the Panel does not state that the 1995 EC Conference amounted to a risk assessment. The Panel includes this Conference in the listing of scientific evidence concerning the hormones at issue referred to by the European Communities.<sup>114</sup> With regard to the reports mentioned in this list, the Panel states that several of these reports appear to meet the minimum requirements of a risk assessment, referring to the Lamming Report and the 1988 and 1989 JECFA Reports.<sup>115</sup> The Panel does not, however, refer to the 1995 EC Conference. The Panel discusses the scientific conclusions to be drawn from the 1995 EC Scientific Conference but this does not amount to designating the Conference as a risk assessment.<sup>116</sup>

141. Fourth, the European Communities contends that the distinction made by the Panel between studies that generally relate to the hormones in dispute and studies that specifically address residues in food of these hormones when used for growth promotion purposes is a distinction devised by the Panel for the sole purpose of rejecting the relevance of the 1987 IARC Monographs in this case and amounts to a

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<sup>111</sup>See the statements of Dr. Ritter in paras. 322, 743 and 782, and the statement of Dr. McLean in para. 824, of the Annex to the US and Canada Panel Reports.

<sup>112</sup>See footnote 348 of the US Panel Report and footnote 455 of the Canada Panel Report.

<sup>113</sup>See, in particular, paras. 6.99 to 6.101 of the US Panel Report and paras. 6.98 to 6.100 of the Canada Panel Report.

<sup>114</sup>US Panel Report, para. 8.108; Canada Panel Report, para. 8.111. The 1995 EC Conference Proceedings were submitted by the European Communities itself as annexes to its first submission to the Panel in both the US and Canada proceedings.

<sup>115</sup>US Panel Report, para. 8.111; Canada Panel Report, para. 8.114.

<sup>116</sup>US Panel Report, para. 8.123; Canada Panel Report, para. 8.126.



distortion of relevant scientific evidence.<sup>117</sup> We note, however, that the Panel did consider the 1987 IARC Monographs but held that they could not be regarded as part of a risk assessment for the hormones at issue because the Monographs do not address the carcinogenic potential of these hormones when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use<sup>118</sup>, or the potential for adverse effects arising from the presence in food of residues of the hormones in dispute or from residue levels comparable to those present in food. The Panel's distinction between general and specific studies and its treatment of the 1987 IARC Monographs does not, therefore, appear arbitrary. Furthermore, we note that the Panel concluded, in the alternative, that the Monographs have been taken into account in, and do not contradict, the other studies referred to by the European Communities, in particular the 1988 and 1989 JECFA Reports.<sup>119</sup> We believe that the Panel's treatment of the 1987 IARC Monographs does not amount to a distortion of evidence.

142. Fifth, the European Communities submits that the Panel made no attempt whatsoever to discuss "the scientific views and evidence presented by the other EC scientists" and therefore violated Article 11 of the DSU.<sup>120</sup> It is our understanding that the European Communities refers here to the articles and opinions of individual scientists that are included in the Panel's list of scientific evidence referred to by the European Communities.<sup>121</sup> We note that, contrary to what the European Communities claims, the Panel does discuss these articles and opinions of individual scientists. The Panel Report included a summary discussion of these articles and opinions.<sup>122</sup> However, as the Panel explains, the scientific evidence included in these articles and opinions relates to the carcinogenic or genotoxic potential of entire categories of hormones or the hormones at issue in general; not when used specifically for growth promotion purposes or with respect to residue levels comparable to those present in meat after such use. In our opinion, the Panel's treatment of the articles and opinions of individual scientists, like its treatment of the 1987 IARC Monographs, does not amount to a distortion of evidence.

### C. Evidence with Regard to the Issue of Control

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<sup>117</sup>EC's appellant's submission, para. 368.

<sup>118</sup>US Panel Report, para. 8.127; Canada Panel Report, para. 8.130.

<sup>119</sup>US Panel Report, para. 8.129; Canada Panel Report, para. 8.132.

<sup>120</sup>EC's appellant's submission, para. 380.

<sup>121</sup>US Panel Report, para. 8.108; Canada Panel Report, para. 8.111.

<sup>122</sup>US Panel Report, para. 8.130; Canada Panel Report, para. 8.133. The Panel itself refers to some of the articles and opinions in paras. 4.131-4.136 and 4.180 of the US Panel Report, and paras. 4.154-4.166 of the Canada Panel Report.

143. With regard to the issue of control, the European Communities contends that the Panel failed to take into account the evidence submitted by the European Communities<sup>123</sup> and ignored statements made by some of its own experts.<sup>124</sup> We observe that the Panel did indeed not explicitly refer to all the evidence regarding the issue of control before it. The Panel had found that the risks related to the general problems of control should not be taken into account in risk assessment<sup>125</sup> and accordingly did not refer extensively to the evidence regarding the issue of control. Furthermore, we note that the Panel, subsequently and in the alternative, concluded that even if the issue of control, and the evidence relating to that issue, could be taken into account, the European Communities had not supplied convincing evidence. The Panel, it appears, excluded that evidence on the legal ground of non-relevancy; as will be seen later, the Panel erred in law in holding the evidence non-relevant. Nevertheless, it did examine the evidence.<sup>126</sup>

144. The European Communities also claims that the Panel incorrectly quoted the statements of its experts.<sup>127</sup> Referring to a number of specific statements<sup>128</sup>, the Panel stated that the experts advising the Panel made clear that the potential for abuse under a regime where the hormones in dispute are allowed under specified conditions and under the current regime where they are banned, would be comparable. The European Communities submits that in the statements referred to by the Panel, the experts either explicitly stated they were speculating or added strong reservations to their opinions. After reading these statements carefully, we come to the conclusion that the Panel did not in fact represent the opinions of its experts accurately. However, this mistake does not amount to the egregious disregarding or distorting of evidence before the Panel.

#### D. Evidence on Article 5.5

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<sup>123</sup>The European Communities contends that it submitted convincing specific evidence to the Panel that control would be more difficult under a regime where the hormones in dispute were allowed (under specific conditions of use) than under the current EC regime where the hormones in dispute are banned. It also contends that it submitted clear evidence to the Panel, specifying the risks for human health that the inadequate control of these hormones can pose and that in the United States and Canada there were instances in which the MRL's were not respected. Finally the European Communities submitted evidence relating the practical and technical difficulties that are specific to control of hormones. EC's appellant's submission, paras. 403-433.

<sup>124</sup>EC's appellant's submission, para. 416. The European Communities submits that, for example, Dr. André's reference to misuse in France (see para. 168 of the Annex to the US and Canada Panel Reports) and Dr. McLean's statement on the difficulty of controlling treatment of animals (see para. 474 of the Annex to the US and Canada Panel Reports) were not taken into account by the Panel.

<sup>125</sup>US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

<sup>126</sup>US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

<sup>127</sup>EC's appellant's submission, para. 419.

<sup>128</sup>US Panel Report, footnote 362; Canada Panel Report, footnote 469.

145. The European Communities claims that in finding that the difference in its levels of protection in respect of five of the hormones at issue and in respect of carbadox and olaquinox is arbitrary or unjustifiable<sup>129</sup>, the Panel did not take into account the evidence before it.<sup>130</sup> We note that the Panel considered in detail each of the arguments and related evidence referred to by the European Communities on this particular point.<sup>131</sup> Although the Panel did not agree with the arguments advanced by the European Communities, we do not believe that in doing so, the Panel arbitrarily ignored or manifestly distorted the evidence before it. We deal with these arguments below in some detail.<sup>132</sup>

## IX. Certain Procedures Adopted by the Panel

### A. The Selection and Use of Experts

146. The European Communities considers that in its selection and use of experts, the Panel has violated Article 11.2 of the SPS Agreement and Articles 11, 13.2 and Appendix 4 of the DSU.<sup>133</sup> We note that the Panel decided to request the opinion of experts on certain scientific and other technical matters raised by the parties to the dispute, and rather than establishing an experts review group, the Panel considered it more useful to leave open the possibility of receiving a range of opinions from the experts in their individual capacity. The Panel stresses, among other things, that:

We considered, however, that neither Article 11.2 of the SPS Agreement nor Article 13.2 of the DSU limits our right to seek information from individual experts as provided for in Article 11.2, first sentence, of the SPS Agreement and Articles 13.1 and 13.2, first sentence, of the DSU.<sup>134</sup>

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<sup>129</sup>US Panel Report, para. 8.238; Canada Panel Report, para. 8.241.

<sup>130</sup>The European Communities argues that it had advanced six reasons why this distinction is not arbitrary or unjustifiable but the Panel rejected all these reasons, and in doing so, it failed to take into account the evidence before it. The reasons advanced by the European Communities were the following: first, that carbadox and olaquinox are not hormones and have a different mode of action; second, that carbadox and olaquinox act as growth promoters by combating the development of bacteria; third, that carbadox and olaquinox are only available in prepared feedstuffs in predetermined dosages; fourth, that there are no alternatives to carbadox and olaquinox; fifth, that carbadox cannot be abused; and sixth, that carbadox is used in very small quantities and is hardly absorbed. EC's appellant's submission, paras. 529-548.

<sup>131</sup>US Panel Report, paras. 8.231-8.238; Canada Panel Report, paras. 8.234-8.240.

<sup>132</sup>See paras. 227-235 of this Report.

<sup>133</sup>EC's appellant's submission, para. 587.

<sup>134</sup>US Panel Report, para. 8.7; Canada Panel Report, para. 8.7.

147. We agree with the Panel. Both Article 11.2 of the SPS Agreement and Article 13 of the DSU enable panels to seek information and advice as they deem appropriate in a particular case. Article 11.2 of the SPS Agreement states:

In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group. (underlining added)

Article 13 of the DSU provides, in relevant part:

1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate ...
2. Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to the dispute, a panel may request an advisory report in writing from an experts review group ... (underlining added)

We find that in disputes involving scientific or technical issues, neither Article 11.2 of the SPS Agreement, nor Article 13 of the DSU prevents panels from consulting with individual experts. Rather, both the SPS Agreement and the DSU leave to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate.

148. Both Article 11.2 of the SPS Agreement and Article 13.2 of the DSU require panels to consult with the parties to the dispute during the selection of the experts. However, it is not claimed by any of the participants in this appeal that the Panel did not consult with them when appointing the experts. Moreover, it is uncontested that the experts have been selected in accordance with procedures on which all the participants have previously agreed.<sup>135</sup> It is similarly uncontested that, among the experts consulted by the Panel, there are nationals from each of the parties to the dispute. The rules and procedures set forth in Appendix 4 of the DSU apply in situations in which expert review groups have been established. However, this is not the situation in this particular case. Consequently, once the panel has decided to request the opinion of individual scientific experts, there is no legal obstacle to the panel drawing up, in consultation with the parties to the dispute, ad hoc rules for those particular proceedings.

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<sup>135</sup>US Panel Report, paras. 6.1-6.10; Canada Panel Report, paras. 6.1-6.9.

149. We conclude, therefore, that in its selection and use of experts, the Panel has not acted inconsistently with Articles 11, 13.2 and Appendix 4 of the DSU and Article 11.2 of the SPS Agreement.

B. Additional Third Party Rights to the United States and Canada

150. The European Communities contends that, notwithstanding its protest that these decisions affected its rights of defence, the Panel took a number of decisions granting additional third party rights to Canada and the United States which are not justified by Article 9.3 of the DSU, are inconsistent with Articles 7.1, 7.2, 18.2 and 10.3 thereof, and were not granted to the other third parties.<sup>136</sup> We recall that the European Communities refers to the following decisions of the Panel: first, to hold a joint meeting with scientific experts; second, to give access to all of the information submitted in the United States' proceeding to Canada; third, to give access to all of the information submitted in the Canadian proceeding to the United States; and fourth, to invite the United States to observe and make a statement at the second substantive meeting in the proceeding initiated by Canada.

151. Article 9.3 of the DSU reads as follows:

If more than one panel is established to examine the complaints related to the same matter, to the greatest extent possible the same persons shall serve as panelists on each of the separate panels and the timetable for the panel process in such disputes shall be harmonized.

After examining the procedural course of the two disputes, we consider that four aspects should be underlined. First, both proceedings dealt with the same matter. Second, all the parties to both disputes agreed that the same panelists would serve on both proceedings. Third, although the proceeding initiated by Canada started several months after the proceeding started by the United States, the Panel managed to finish the Panel Reports at the same time. Fourth, given the fact that the same panelists were conducting two proceedings dealing with the same matter, neither Canada nor the United States were ordinary third parties in each other's complaint.

152. With respect to the decision of the Panel to hold a joint meeting with scientific experts, the Panel explains as follows:

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<sup>136</sup>EC's appellant's submission, paras. 605 and 612.

Prior to our meeting with scientific experts, we decided to hold that meeting jointly for both this Panel, requested by Canada, and the parallel panel requested by the United States. This decision stemmed from the similarities of the two cases (the same EC measures are at issue and both cases are dealt with by the same panel members), our decision to use the same scientific experts in both cases and the fact that we had already decided to invite Canada and the United States to participate in the meeting with scientific experts in each of the two cases. In addition, we considered that, from a practical perspective, there was a need to avoid repetition of arguments and/or questions at our meetings with the scientific experts. The European Communities objected to this decision arguing that one joint meeting with experts, instead of two separate meetings, was likely to affect its procedural rights of defence. Where it made precise claims of prejudice to its rights of defence, we took corrective action.<sup>137</sup>

We consider the explanation of the Panel quite reasonable, and its decision to hold a joint meeting with the scientific experts consistent with the letter and spirit of Article 9.3 of the DSU. Clearly, it would be an uneconomical use of time and resources to force the Panel to hold two successive but separate meetings gathering the same group of experts twice, expressing their views twice regarding the same scientific and technical matters related to the same contested EC measures. We do not believe that the Panel has erred by addressing the EC procedural objections only where the European Communities could make a precise claim of prejudice. It is evident to us that a procedural objection raised by a party to a dispute should be sufficiently specific to enable the panel to address it.<sup>138</sup>

153. The decision of the Panel to use and provide all information to the parties in both disputes was taken in view of its previous decision to hold a joint meeting with the experts.<sup>139</sup> The European Communities asserts that it cannot see how providing information in one of the proceedings to a party in the other helps to harmonize timetables.<sup>140</sup> We can see a relation between timetable harmonization within the meaning of Article 9.3 of the DSU and economy of effort. In disputes where the evaluation of scientific data and opinions plays a significant role, the panel that is established later can benefit from the information gathered in the context of the proceedings of the panel established earlier. Having access to a common pool of information enables the panel and the parties to save time by avoiding duplication

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<sup>137</sup>Canada Panel Report, para. 8.18. See also US Panel Report, para. 8.14.

<sup>138</sup>Furthermore, the DSU, and in particular its Appendix 3, leave panels a margin of discretion to deal, always in accordance with due process, with specific situations that may arise in a particular case and that are not explicitly regulated. Within this context, an appellant requesting the Appellate Body to reverse a panel's ruling on matters of procedure must demonstrate the prejudice generated by such legal ruling.

<sup>139</sup>US Panel Report, para. 8.15; Canada Panel Report, para. 8.19.

<sup>140</sup>EC's appellant's submission, para. 610.

of the compilation and analysis of information already presented in the other proceeding.<sup>141</sup> Article 3.3 of the DSU recognizes the importance of avoiding unnecessary delays in the dispute settlement process and states that the prompt settlement of a dispute is essential to the effective functioning of the WTO. In this particular case, the Panel tried to avoid unnecessary delays, making an effort to comply with the letter and spirit of Article 9.3 of the DSU. Indeed, as noted earlier, despite the fact that the Canadian proceeding was initiated several months later than that of the United States, the Panel managed to finish both Panel Reports at the same time.

154. Regarding the participation of the United States in the second substantive meeting of the Panel requested by Canada, the Panel states:

This decision was, *inter alia*, based on the fact that our second meeting was held the day after our joint meeting with the scientific experts and that the parties to this dispute would, therefore, most likely comment on, and draw conclusions from, the evidence submitted by these experts to be considered in both cases. Since in the panel requested by the United States the second meeting was held before the joint meeting with scientific experts, we considered it appropriate, in order to safeguard the rights of the United States in the proceeding it requested, to grant the United States the opportunity to observe our second meeting in this case and to make a brief statement at the end of that meeting.<sup>142</sup>

The explanation of the Panel appears reasonable to us. If the Panel had not given the United States an opportunity to participate in the second substantive meeting of the proceedings initiated by Canada, the United States would not have had the same degree of opportunity to comment on the views expressed by the scientific experts that the European Communities and Canada enjoyed. Although Article 12.1 and Appendix 3 of the DSU do not specifically require the Panel to grant this opportunity to the United States, we believe that this decision falls within the sound discretion and authority of the Panel, particularly if the Panel considers it necessary for ensuring to all parties due process of law. In this regard, we note that in *European Communities - Bananas*<sup>143</sup>, the panel considered that particular circumstances justified the grant to third parties of rights somewhat broader than those explicitly envisaged in Article 10 and Appendix 3 of the DSU. We conclude that, in the case before us, circumstances justified the Panel's

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<sup>141</sup>Moreover, in the proceeding initiated by Canada, the European Communities made references to materials that it had previously submitted in the proceeding initiated by the United States. Canada's appellee's submission, para. 216.

<sup>142</sup>Canada Panel Report, para. 8.20.

<sup>143</sup>Adopted 25 September 1997, WT/DS27/AB/R.

decision to allow the United States to participate in the second substantive meeting of the proceedings initiated by Canada.

C. The Difference Between Legal Claims and Arguments

155. Arguing that panels are not entitled to make findings beyond what has been requested by the parties, the European Communities asserts that the Panel has erred by basing the main part of its reasoning on Article 5.5 of the SPS Agreement on a claim that the complainants had not made.<sup>144</sup> According to the European Communities, the complainants did not complain of a supposed difference of treatment between artificially added or exogenous natural and synthetic hormones when used for growth promotion purposes compared with the naturally present endogenous hormones in untreated meat and other foods (such as milk, cabbage, broccoli or eggs). The European Communities states that nowhere in the sections of the Panel Reports summarising the arguments on Article 5.5 is there any mention of such an argument.

156. Considering that in the request for the establishment of a panel in the proceeding initiated by the United States<sup>145</sup>, as well as in the proceeding started by Canada<sup>146</sup>, both complainants have included a claim that the EC ban is inconsistent with Article 5 of the SPS Agreement, we believe that the objection of the European Communities overlooks the distinction between legal claims made by the complainant and arguments used by that complainant to sustain its legal claims. In *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* we said:

We stated ... in *Brazil - Desiccated Coconut* that all claims must be included in the request for establishment of a panel in order to come within the panel's terms of reference, based on the practice of panels under the GATT 1947 and the Tokyo Round Codes. That past practice required that a claim had to be included in the documents referred to, or contained in, in the terms of reference in order to form part of the "matter" referred to a panel for consideration. Following both this past practice and the provisions of the DSU, in *European Communities - Bananas*, we observed that there is a significant difference between the claims identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the arguments supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal

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<sup>144</sup>EC's appellant's submission, paras. 495 and 594.

<sup>145</sup>WT/DS26/6, 25 April 1996.

<sup>146</sup>WT/DS48/5, 17 September 1996.



submissions and the first and second panel meetings with the parties as a case proceeds.<sup>147</sup> (footnotes omitted)

Panels are inhibited from addressing legal claims falling outside their terms of reference. However, nothing in the DSU limits the faculty of a panel freely to use arguments submitted by any of the parties -- or to develop its own legal reasoning -- to support its own findings and conclusions on the matter under its consideration. A panel might well be unable to carry out an objective assessment of the matter, as mandated by Article 11 of the DSU, if in its reasoning it had to restrict itself solely to arguments presented by the parties to the dispute. Given that in this particular case both complainants claimed that the EC measures were inconsistent with Article 5.5 of the SPS Agreement, we conclude that the Panel did not make any legal finding beyond those requested by the parties.

#### 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.<sup>148</sup>

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

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<sup>147</sup>Adopted 16 January 1998, WT/DS50/AB/R, para. 88.

<sup>148</sup>See paras. 104 and 106 of this Report.

legal interpretations, which have all been appealed by the European Communities and which need to be addressed: the first relates to the meaning of "based on" as used in Article 3.1; the second is concerned with the relationship between Articles 3.1, 3.2 and 3.3 of the SPS Agreement; and the third relates to the requirements of Article 3.3 of the SPS Agreement. As may be expected, the Panel's three interpretations are intertwined.

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

160. Article 3.1 provides:

To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

161. Addressing the meaning of "based on", the Panel constructs the following interpretations:

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.

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.<sup>149</sup> (underlining added)

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.<sup>150</sup> 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".<sup>151</sup> 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.<sup>152</sup> Canada has suggested

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<sup>149</sup>US Panel Report, paras. 8.72 and 8.73; Canada Panel Report, paras. 8.75 and 8.76.

<sup>150</sup>L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles* (Clarendon Press), Vol. I, p. 187.

<sup>151</sup>L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles* (Clarendon Press), Vol. I, p. 477.

<sup>152</sup>Appellate Body Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/AB/R, p. 17.

the use of different terms was "accidental" in this case, but has offered no convincing argument to support its suggestion. We do not believe this suggestion has overturned the inference of deliberate choice.

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<sup>153</sup>) 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.<sup>154</sup> To sustain such an assumption and to warrant such a far-reaching interpretation,

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<sup>153</sup>US Panel Report, para. 8.59; Canada Panel Report, para. 8.62.

<sup>154</sup>The interpretative principle of *in dubio mitius*, widely recognized in international law as a "supplementary means of interpretation", has been expressed in the following terms:

"The principle of *in dubio mitius* applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties."

R. Jennings and A. Watts (eds.), *Oppenheim's International Law*, 9th ed., Vol. I (Longman, 1992), p. 1278. The relevant case law includes: *Nuclear Tests Case (Australia v. France)*, (1974), I.C.J. Reports, p. 267 (International Court of Justice); *Access of Polish War Vessels to the Port of Danzig* (1931) PCIJ Rep., Series A/B, No.43, p. 142 (Permanent Court of International Justice); *USA-France Air Transport Services Arbitration* (1963), 38 International Law Reports 243 (Arbitral Tribunal); *De Pascale Claim* (1961), 40 International Law Reports 250 (Italian - United States Conciliation Commission). See also: I. Brownlie, *Principles of Public International Law*, 4th ed. (Clarendon Press, 1990), p. 631; C. Rousseau, *Droit International Public*, Vol. I (1990), p. 273; D. Carreau, *Droit International*, 4th ed. (Editions A. Pedone, 1994), p. 142; M. Díez de Velasco, *Instituciones de Derecho Internacional Público*, 9th ed., Vol. I (Editorial Tecnos, 1991), pp. 163-164; and B. Conforti, *Diritto Internazionale*, 3rd ed. (Editoriale Scientifica, 1987), pp. 99-100.

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<sup>155</sup>, 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".<sup>156</sup>

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.

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<sup>155</sup>US Panel Report, para. 8.72; Canada Panel Report, para. 8.75.

<sup>156</sup>US Panel Report, para. 8.73; Canada Panel Report, para. 8.76.

170. Under Article 3.2 of the SPS Agreement, a Member may decide to promulgate an SPS measure that conforms to an international standard. Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard. Such a measure enjoys the benefit of a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the SPS Agreement and of the GATT 1994.

171. Under Article 3.1 of the SPS Agreement, a Member may choose to establish an SPS measure that is based on the existing relevant international standard, guideline or recommendation. Such a measure may adopt some, not necessarily all, of the elements of the international standard. The Member imposing this measure does not benefit from the presumption of consistency set up in Article 3.2; but, as earlier observed, the Member is not penalized by exemption of a complaining Member from the normal burden of showing a prima facie case of inconsistency with Article 3.1 or any other relevant article of the SPS Agreement or of the GATT 1994.

172. Under Article 3.3 of the SPS Agreement, a Member may decide to set for itself a level of protection different from that implicit in the international standard, and to implement or embody that level of protection in a measure not "based on" the international standard. The Member's appropriate level of protection may be higher than that implied in the international standard. The right of a Member to determine its own appropriate level of sanitary protection is an important right. This is made clear in the sixth preambular paragraph of the SPS Agreement:

Members,

...

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

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

C. The Requirements of Article 3.3 of the SPS Agreement

173. The right of a Member to define its appropriate level of protection is not, however, an absolute or unqualified right. Article 3.3 also makes this clear:

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.<sup>2</sup> 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.

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<sup>2</sup>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.

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.<sup>157</sup> 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".<sup>158</sup> 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.<sup>159</sup>

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

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<sup>157</sup>EC's appellant's submission, paras. 240-244.

<sup>158</sup>SPS Agreement, Article 3.3.

<sup>159</sup>EC's appellee's submission, para. 88.

- (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

178. We turn to the appeal of European Communities from the Panel's conclusion that, by maintaining SPS measures which are not based on a risk assessment, the European Communities acted inconsistently with the requirements contained in Article 5.1 of the SPS Agreement.

179. Article 5.1 of the SPS Agreement provides:

Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. (underlining added)

A. The Interpretation of "Risk Assessment"

180. At the outset, two preliminary considerations need to be brought out. The first is that the Panel considered that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement<sup>160</sup>, 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.

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<sup>160</sup>US Panel Report, para. 8.93; Canada Panel Report, para. 8.96.

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.<sup>161</sup> The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment".<sup>162</sup> 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".<sup>163</sup>

184. The European Communities appeals from the above interpretation as involving an erroneous notion of risk and risk assessment. Although the utility of a two-step analysis may be debated, it does not appear to us to be substantially wrong. What needs to be pointed out at this stage is that the Panel's use of "probability" as an alternative term for "potential" creates a significant concern. The ordinary

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<sup>161</sup>US Panel Report, para. 8.94; Canada Panel Report, para. 8.97.

<sup>162</sup>US Panel Report, para. 8.95; Canada Panel Report, para. 8.98.

<sup>163</sup>US Panel Report, para. 8.98; Canada Panel Report, para. 8.101.

meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability".<sup>164</sup> "Probability" implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk.

185. In its discussion on a statement made by Dr. Lucier at the joint meeting with the experts in February 1997<sup>165</sup>, the Panel states the risk referred to by this expert is an estimate which "... only represents a statistical range of 0 to 1 in a million, not a scientifically identified risk".<sup>166</sup> The European Communities protests vigorously that, by doing so, the Panel is in effect requiring a Member carrying out a risk assessment to quantify the potential for adverse effects on human health.<sup>167</sup>

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"<sup>168</sup>, 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.<sup>169</sup> 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.<sup>170</sup> 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

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<sup>164</sup>The dictionary meaning of "potential" is "that which is possible as opposed to actual; a possibility"; L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles*, Vol. 2, p. 2310 (Clarendon Press, 1993). In contrast, "probability" refers to "degrees of likelihood; the appearance of truth, or likelihood of being realized", and "a thing judged likely to be true, to exist, or to happen"; *Id.*, p. 2362.

<sup>165</sup>Para. 819 of the Annex to the US and Canada Panel Reports.

<sup>166</sup>US Panel Report, footnote 331; Canada Panel Report, footnote 437.

<sup>167</sup>EC's appellant's submission, paras. 392-397.

<sup>168</sup>US Panel Report, paras. 8.124, 8.134, 8.136, 8.151, 8.153, 8.161, 8.162; Canada Panel Report, paras. 8.127, 8.137, 8.139, 8.154, 8.156, 8.164, 8.165.

<sup>169</sup>US Panel Report, paras. 8.152-8.153; Canada Panel Report, paras. 8.155-8.156

<sup>170</sup>US Panel Report, footnote 331; Canada Panel Report, footnote 437.

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".<sup>171</sup> 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.<sup>172</sup> 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

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<sup>171</sup>US Panel Report, para. 8.107; Canada Panel Report, para. 8.110.

<sup>172</sup>"The ordinary meaning of 'scientific', as provided by dictionary definitions, includes 'of, relating to, or used in science', 'broadly, having or appearing to have an exact, objective, factual, systematic or methodological basis', 'of, relating to, or exhibiting the methods or principles of science' and 'of, pertaining to, using, or based on the methodology of science'. Dictionary definitions of 'science' include 'the observation, identification, description, experimental investigation, and theoretical explanation of natural phenomena', 'any methodological activity, discipline, or study', and 'knowledge attained through study or practice'. (footnotes omitted) United States' Statement of Administrative Action, Uruguay Round Agreements Act, 203d Congress, 2d Session, House Document 103-316, Vol. 1, 27 September 1994, p. 90.

controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.

B. The Interpretation of "Based On"

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

188. Although it expressly recognizes that Article 5.1 does not contain any specific procedural requirements for a Member to base its sanitary measures on a risk assessment, the Panel nevertheless proceeds to declare that "there is a minimum procedural requirement contained in Article 5.1". That requirement is that "the Member imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment".<sup>173</sup> The Panel goes on to state that the European Communities did not provide any evidence that the studies it referred to or the scientific conclusions reached therein "have actually been taken into account by the competent EC institutions either when it enacted those measures (in 1981 and 1988) or at any later point in time".<sup>174</sup> (emphasis added) Thereupon, the Panel holds that such studies could not be considered as part of a risk assessment on which the European Communities based its measures in dispute. Concluding that the European Communities had not met its burden of proving that it had satisfied the "minimum procedural requirement" it had found in Article 5.1, the Panel holds the EC measures as inconsistent with the requirements of Article 5.1.

189. We are bound to note that, as the Panel itself acknowledges, no textual basis exists in Article 5 of the SPS Agreement for such a "minimum procedural requirement". The term "based on", when applied as a "minimum procedural requirement" by the Panel, may be seen to refer to a human action, such as particular human individuals "taking into account" a document described as a risk assessment. Thus, "take into account" is apparently used by the Panel to refer to some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals. We believe that "based on" is appropriately taken to refer to a certain objective relationship between two elements, that is to say, to an objective situation that persists and is observable between an SPS measure and a risk assessment. Such a reference is certainly embraced in the ordinary meaning of the words "based on" and, when considered in context and in the light of the object and purpose of Article 5.1 of the SPS

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<sup>173</sup>US Panel Report, para. 8.113; Canada Panel Report, para. 8.116.

<sup>174</sup>US Panel Report, para. 8.114; Canada Panel Report, para. 8.117.

Agreement, may be seen to be more appropriate than "taking into account". We do not share the Panel's interpretative construction and believe it is unnecessary and an error of law as well.

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

191. In the course of demanding evidence that EC authorities actually "took into account" certain scientific studies, the Panel refers to the preambles of the EC Directives here involved. The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the panel proceedings. Preambles of legislative or quasi-legislative acts and administrative regulations commonly fulfil requirements of the internal legal orders of WTO Members. Such preambles are certainly not required by the SPS Agreement; they are not normally used to demonstrate that a Member has complied with its obligations under international agreements. The absence of any mention of scientific studies in the preliminary sections of the EC Directives does not, therefore, prove anything so far as the present case is concerned.

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

192. Having posited a "minimum procedural requirement" of Article 5.1, the Panel turns to the "substantive requirements" of Article 5.1 to determine whether the EC measures at issue are "based on" a risk assessment. In the Panel's view, those "substantive requirements" involve two kinds of operations: first, identifying the scientific conclusions reached in the risk assessment and the scientific conclusions implicit in the SPS measures; and secondly, examining those scientific conclusions to determine whether or not one set of conclusions matches, i.e. conforms with, the second set of conclusions.<sup>175</sup> Applying the "substantive requirements" it finds in Article 5.1, the Panel holds that the scientific conclusions implicit

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<sup>175</sup>US Panel Report, para. 8.117; Canada Panel Report, para. 8.120.

in the EC measures do not conform with any of the scientific conclusions reached in the scientific studies the European Communities had submitted as evidence.<sup>176</sup>

193. We consider that, in principle, the Panel's approach of examining the scientific conclusions implicit in the SPS measure under consideration and the scientific conclusion yielded by a risk assessment is a useful approach. The relationship between those two sets of conclusions is certainly relevant; they cannot, however, be assigned relevance to the exclusion of everything else. We believe that Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the SPS Agreement, requires that the results of the risk assessment must sufficiently warrant -- that is to say, reasonably support -- the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment.

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

195. We turn now to the application by the Panel of the substantive requirements of Article 5.1 to the EC measures at stake in the present case. The Panel lists the following scientific material to which the European Communities referred in respect of the hormones here involved (except MGA):

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<sup>176</sup>US Panel Report, para. 8.137; Canada Panel Report, para. 8.140.

- the 1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production ("Lamming Report");
- the 1983 Symposium on Anabolics in Animal Production of the Office international des epizooties ("OIE") ("1983 OIE Symposium");
- the 1987 Monographs of the International Agency for Research on Cancer ("IARC") on the Evaluation of Carcinogenic Risks to Humans, Supplement 7 ("1987 IARC Monographs");
- the 1988 and 1989 JECFA Reports;
- the 1995 European Communities Scientific Conference on Growth Promotion in Meat Production ("1995 EC Scientific Conference");
- articles and opinions by individual scientists relevant to the use of hormones (three articles in the journal *Science*, one article in the *International Journal of Health Service*, one report in *The Veterinary Record* and separate scientific opinions of Dr. H. Adlercreutz, Dr. E. Cavalieri, Dr. S.S. Epstein, Dr. J.G. Liehr, Dr. M. Metzler, Dr. Perez-Comas and Dr. A. Pinter, all of whom were part of the EC delegation at [the] joint meeting with experts).<sup>177</sup>

196. Several of the above scientific reports appeared to the Panel to meet the minimum requirements of a risk assessment, in particular, the Lamming Report and the 1988 and 1989 JECFA Reports. The Panel assumes accordingly that the European Communities had demonstrated the existence of a risk assessment carried out in accordance with Article 5 of the SPS Agreement.<sup>178</sup> At the same time, the Panel finds that the conclusion of these scientific reports is that the use of the hormones at issue (except MGA) for growth promotion purposes is "safe". The Panel states:

... 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)

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<sup>177</sup>US Panel Report, para. 8.108; Canada Panel Report, para. 8.111.

<sup>178</sup>US Panel Report, para. 8.111; Canada Panel Report, para. 8.114.



for growth promotion purposes is safe; most of these studies adding that this conclusion assumes that good practice is followed.<sup>179</sup>

197. Prescinding from the difficulty raised by the Panel's use of the term "identifiable risk", we agree that the scientific reports listed above do not rationally support the EC import prohibition.<sup>180</sup>

198. With regard to the scientific opinion expressed by Dr. Lucier at the joint meeting with the experts, and as set out in paragraph 819 of the Annex to the US and Canada Panel Reports<sup>181</sup>, we should note that this opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones.<sup>182</sup> Accordingly, it appears that the single divergent opinion expressed by Dr. Lucier is not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities that related specifically to residues of the hormones in meat from cattle to which hormones had been administered for growth promotion.

199. The European Communities laid particular emphasis on the 1987 IARC Monographs and the articles and opinions of individual scientists referred to above.<sup>183</sup> The Panel notes, however, that the scientific evidence set out in these Monographs and these articles and opinions relates to the carcinogenic potential of entire categories of hormones, or of the hormones at issue in general. The Monographs and the articles and opinions are, in other words, in the nature of general studies of or statements on the carcinogenic potential of the named hormones. The Monographs and the articles and opinions of individual

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<sup>179</sup>US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

<sup>180</sup>In paras. 97-109 of this Report, we conclude that the Panel mistakenly required that the European Communities take on the burden of proof that its measures related to the hormones involved here, except MGA, are based on a risk assessment. We determine that the United States and Canada have to make a prima facie case that these measures are not based on a risk assessment. However, after careful consideration of the panel record, we are satisfied that the United States and Canada, although not required to do so by the Panel, did, in fact, make this prima facie case that the SPS measures related to the hormones involved here, except MGA, are not based on a risk assessment.

<sup>181</sup>This paragraph reads in relevant part:

For every million women alive in the United States, Canada, Europe today, about a 110,000 of those women will get breast cancer. This is obviously a tremendous public health issue. Of those 110,000 women get breast cancer, maybe several thousand of them are related to the total intake of exogenous oestrogens from every source, including eggs, meat, phyto-oestrogens, fungal oestrogens, the whole body burden of exogenous oestrogens. And by my estimates one of those 110,000 would come from eating meat containing oestrogens as a growth promoter, if used as prescribed.

<sup>182</sup>Assuming that Dr. Lucier's estimate is realistic, it is noteworthy that there could be up to 371 persons who, under the conditions identified by Dr. Lucier, would get cancer in the Member States of the European Union. The total population of the Member States of the European Union in 1995 was 371 million.

<sup>183</sup>Para. 195 of this Report.

scientists have not evaluated the carcinogenic potential of those hormones when used specifically for growth promotion purposes. Moreover, they do not evaluate the specific potential for carcinogenic effects arising from the presence in "food", more specifically, "meat or meat products" of residues of the hormones in dispute. The Panel also notes that, according to the scientific experts advising the Panel, the data and studies set out in these 1987 Monographs have been taken into account in the 1988 and 1989 JECFA Reports and that the conclusions reached by the 1987 IARC Monographs are complementary to, rather than contradictory of, the conclusions of the JECFA Reports.<sup>184</sup> The Panel concludes that these Monographs and these articles and opinions are insufficient to support the EC measures at issue in this case.

200. We believe that the above findings of the Panel are justified. The 1987 IARC Monographs and the articles and opinions of individual scientists submitted by the European Communities constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake - the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes -- as is required by paragraph 4 of Annex A of the SPS Agreement. Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand.

201. With regard to risk assessment concerning MGA, the European Communities referred to the 1987 IARC Monographs. These Monographs deal with, inter alia, the category of progestins of which the hormone progesterone is a member. The European Communities argues that because MGA is an anabolic agent which mimics the action of progesterone, the scientific studies and experiments relied on by the 1987 IARC Monographs were highly relevant.<sup>185</sup> However, the Monographs and the articles and opinions of the individual scientists did not include any study that demonstrated how closely related MGA is chemically and pharmacologically to other progestins and what effects MGA residues would actually have on human beings when such residues are ingested along with meat from cattle to which MGA has been administered for growth promotion purposes. It must be recalled in this connection that none of the other scientific material submitted by the European Communities referred to MGA, and that no international standard, guideline or recommendation has been developed by Codex relating specifically to MGA. The United States and Canada declined to submit any assessment of MGA upon the ground that the material they were aware of was proprietary and confidential in nature. In other words, there

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<sup>184</sup>US Panel Report, para. 8.129; Canada Panel Report, para. 8.132.

<sup>185</sup>EC's appellant's submission, para. 179 ff.

was an almost complete absence of evidence on MGA in the panel proceedings. We therefore uphold the Panel's finding that there was no risk assessment with regard to MGA.

202. The evidence referred to above by the European Communities related to the biochemical risk arising from the ingestion by human beings of residues of the five hormones here involved in treated meat, where such hormones had been administered to the cattle in accordance with good veterinary practice.<sup>186</sup> The European Communities also referred to distinguishable but closely related risks - risks arising from failure to observe the requirements of good veterinary practice, in combination with multiple problems relating to detection and control of such abusive failure, in the administration of hormones to cattle for growth promotion.

203. The Panel considers this type of risk and examines the arguments made by the European Communities but finds no assessment of such kind of risk. Ultimately, the Panel rejects those arguments principally on a priori grounds. First, to the Panel, the provisions of Article 5.2 relating to "relevant inspection, sampling and testing methods":

... do not seem to cover the general problem of control (such as the problem of ensuring the observance of good practice) which can exist for any substance. The risks related to the general problem of control do not seem to be specific to the substance at issue but to the economic or social incidence related to a substance or its particular use (such as economic incentives for abuse). These non-scientific factors should, therefore not be taken into account in a risk assessment but in risk management.<sup>187</sup> (underlining added)

Moreover, the Panel finds that, assuming these factors could be taken into account in a risk assessment, the European Communities has not provided convincing evidence that the control or prevention of abuse of the hormones here involved is more difficult than the control of other veterinary drugs, the use of which is allowed in the European Communities. Further, the European Communities has not provided evidence that control would be more difficult under a regime where the use of the hormones in dispute is allowed

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<sup>186</sup>Although the term used in the Codex Standards for the three natural hormones is good animal husbandry practice (Section I, MRLs, Codex Alimentarius, Vol. 3, pp. 7, 12 and 14), the Glossary of Terms and Definitions of the Codex Alimentarius does not contain this term. Instead, it defines the concept:

"Good Practice in the Use of Veterinary Drugs (GPVD): Is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions".

We will therefore use the term good veterinary practice as a shorthand expression of the concept defined in the Codex Alimentarius.

<sup>187</sup>US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

under specific conditions than under the current EC regime of total prohibition both domestically and in respect of imported meat. The Panel concludes by saying that banning the use of a substance does not necessarily offer better protection of human health than other means of regulating its use.<sup>188</sup>

204. The European Communities appeals from these findings of the Panel principally on two grounds: firstly, that the Panel has misinterpreted Article 5.2 of the SPS Agreement; secondly, that the Panel has disregarded and distorted the evidence submitted by the European Communities.<sup>189</sup>

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

206. Most, if not all, of the scientific studies referred to by the European Communities, in respect of the five hormones involved here, concluded that their use for growth promotion purposes is "safe"<sup>190</sup>, if the hormones are administered in accordance with the requirements of good veterinary practice. Where the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is not followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be "safe".<sup>191</sup> The SPS Agreement requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the SPS Agreement justify the examination and evaluation of all

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<sup>188</sup>US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

<sup>189</sup>EC's appellant's submission, para. 399 and 401.

<sup>190</sup>US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

<sup>191</sup>This point was clearly brought out during the oral hearing and both the United States and Canada expressed agreement with this inference. See footnote 186 of this Report concerning the usage of the terms "good veterinary practice" and "good animal husbandry practice".

such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an a priori basis, any such risks from the scope of application of Articles 5.1 and 5.2. We disagree with the Panel's suggestion that exclusion of risks resulting from the combination of potential abuse and difficulties of control is justified by distinguishing between "risk assessment" and "risk management". As earlier noted, the concept of "risk management" is not mentioned in any provision of the SPS Agreement and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the SPS Agreement.

207. The question that arises, therefore, is whether the European Communities did, in fact, submit a risk assessment demonstrating and evaluating the existence and level of risk arising in the present case from abusive use of hormones and the difficulties of control of the administration of hormones for growth promotion purposes, within the United States and Canada as exporting countries, and at the frontiers of the European Communities as an importing country. Here, we must agree with the finding of the Panel that the European Communities in fact restricted itself to pointing out the condition of administration of hormones "in accordance with good practice" "without further providing an assessment of the potential adverse effects related to non compliance with such practice".<sup>192</sup> The record of the panel proceedings shows that the risk arising from abusive use of hormones for growth promotion combined with control problems for the hormones at issue, may have been examined on two occasions in a scientific manner. The first occasion may have occurred at the proceedings before the Committee of Inquiry into the Problem of Quality in the Meat Sector established by the European Parliament, the results of which constituted the basis of the Pimenta Report of 1989. However, none of the original studies and evidence put before the Committee of Inquiry was submitted to the Panel. The second occasion could have been the 1995 EC Scientific Conference on Growth Promotion in Meat Production. One of the three workshops of this Conference examined specifically the problems of "detection and control". However, only one of the studies presented to the workshop discussed systematically some of the problems arising from the combination of potential abuse and problems of control of hormones and other substances.<sup>193</sup> The study

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<sup>192</sup>US Panel Report, para. 8.143; Canada Panel Report, para. 8.146.

<sup>193</sup>B. Jülicher, "Sampling Strategies", in Proceedings of the Scientific Conference on Growth Promotion in Meat Production, Brussels, 29 November to 1 December 1995, pp. 521-540.

presented a theoretical framework for the systematic analysis of such problems, but did not itself investigate and evaluate the actual problems that have arisen at the borders of the European Communities or within the United States, Canada and other countries exporting meat and meat products to the European Communities. At best, this study may represent the beginning of an assessment of such risks.

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

209. Since we have concluded above<sup>194</sup> 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<sup>195</sup> 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.<sup>196</sup>

### A. General Considerations: the Elements of Article 5.5

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<sup>194</sup>See para. 177 of this Report.

<sup>195</sup>EC's appellant's submission, para. 448.

<sup>196</sup>US Panel Report, paras. 8.206, 8.218, 8.244, 8.266 and 8.269; Canada Panel Report, paras. 8.209, 8.221, 8.247, 8.269 and 8.272.

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

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

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

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

When read together with Article 2.3, Article 5.5 may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3.

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

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

215. We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element -- the arbitrary or unjustifiable character of differences in levels of protection considered by a Member as appropriate in differing situations -- may in practical effect operate as a "warning" signal that the implementing measure in its application might be a discriminatory measure or might be a restriction on international trade disguised as an SPS measure for the protection of human life or health. Nevertheless, the measure itself needs to be examined and appraised and, in the context of the differing levels of protection, shown to result in discrimination or a disguised restriction on international trade.

#### B. Different Levels of Protection in Different Situations

216. We examine the first element set out in Article 5.5, namely, that a Member has established different levels of protection which it regards as appropriate for itself in differing situations. The Panel, interpreting the term "different situations", states in effect that situations involving the same substance or the same adverse health effect may be compared to one another.<sup>197</sup> 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.<sup>198</sup>

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<sup>197</sup>US Panel Report, para. 8.176; Canada Panel Report, para. 8.179.

<sup>198</sup>EC's appellant's submission, para. 455.



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<sup>199</sup> and at least one other SPS measure of the European Communities<sup>200</sup>, 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<sup>201</sup>;
- (ii) the level of protection in respect of natural hormones occurring endogenously in meat and other foods<sup>202</sup>;
- (iii) the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes<sup>203</sup>;
- (iv) the level of protection in respect of synthetic hormones (zeranol and trenbolone) when used for growth promotion<sup>204</sup>; and
- (v) the level of protection in respect of carbadox and olaquinox.<sup>205</sup>

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

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<sup>199</sup>See paras. 2-5 of this Report.

<sup>200</sup>Directive du Conseil 70/524/CEE of 23 November 1970, Official Journal No. L 270, 14 December 1970, p. 1, the Annexes of which are replaced by Commission Directive 91/248/EEC of 12 April 1991, Official Journal No. L 124, 18 May 1991, p. 1.

<sup>201</sup>US Panel Report, para. 8.191; Canada Panel Report, para. 8.194; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

<sup>202</sup>US Panel Report, para. 8.191; Canada Panel Report, para. 8.194; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

<sup>203</sup>US Panel Report, para. 8.191; Canada Panel Report, para. 8.194.

<sup>204</sup>US Panel Report, para. 8.212; Canada Panel Report, para. 8.215.

<sup>205</sup>US Panel Report, para. 8.226 (with respect to carbadox only); Canada Panel Report, para. 8.229; and, with regard to MGA, US Panel Report, para. 8.268; Canada Panel Report, para. 8.271.

(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.<sup>206</sup> 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.<sup>207</sup> In contrast, the Panel does not undertake to compare level of protection (iii) with level of protection (i).<sup>208</sup> 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.<sup>209</sup> 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.<sup>210</sup> 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.<sup>211</sup> 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.<sup>212</sup> 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.<sup>213</sup>

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<sup>206</sup>US Panel Report, paras. 8.197 and 8.214; Canada Panel Report, paras. 8.200 and 8.217; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

<sup>207</sup>US Panel Report, para. 8.238; Canada Panel Report, para. 8.241; and, with regard to MGA, US Panel Report, para. 8.268; Canada Panel Report, para. 8.271.

<sup>208</sup>US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.

<sup>209</sup>US Panel Report, para. 8.193; Canada Panel Report, para. 8.196.

<sup>210</sup>US Panel Report, para. 8.194; Canada Panel Report, para. 8.197.

<sup>211</sup>US Panel Report, para. 8.195; Canada Panel Report, para. 8.198.

<sup>212</sup>US Panel Report, para. 8.196; Canada Panel Report, para. 8.199.

<sup>213</sup>US Panel Report, paras. 8.213, 8.264 and 8.265; Canada Panel Report, paras. 8.216, 8.267 and 8.268.

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<sup>214</sup>; 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.<sup>215</sup> 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.<sup>216</sup> 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.<sup>217</sup>

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.<sup>218</sup>

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<sup>214</sup>It may be questioned whether the European Communities has established at all an appropriate level of protection in respect of naturally-occurring hormones in meat and other foods (i.e. which are part of peoples' daily diet). We have accepted arguendo the assumption of the Panel that the European Communities did, for the purposes of this analysis.

<sup>215</sup>US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.

<sup>216</sup>See, for example, US Panel Report, paras. 4.63, 4.64, 4.68, 4.69, 4.71, 4.223, 4.224, 4.225, 4.226 and 4.227, and Canada Panel Report, paras. 4.141, 4.147, 4.217, 4.238 and 4.242.

<sup>217</sup>United States' appellant's submission, paras. 26, 27 and 29.

<sup>218</sup>EC's appellee's submission, paras. 82-84.

Therapeutic use is occasional as opposed to regular and continuous use that characterizes growth promotion.<sup>219</sup> Therapeutic use is selective as it concerns only individual sick or diseased animals; growth promotion involves the administration of hormones to all herds and all the members of a herd of cattle. Thus, therapeutic use takes place on a small scale and normally involves cattle intended for breeding and not for slaughter; in contrast, the use of these hormones for growth promotion occurs on a much larger scale and is much more difficult and costly to control.<sup>220</sup> Zootechnical use may relate to entire herds but would occur only once a year<sup>221</sup>; it is thus clearly distinguishable from the use of hormones continuously and over long periods of time (apparently most of the lifespan of the animals involved). This difference has been stressed in particular by Dr. André, one of the experts advising the Panel.<sup>222</sup>

224. The second difference concerns the mode of administration of hormones. In order to prevent abuse<sup>223</sup>, the European Communities has regulated in substantial detail the conditions under which the administration of natural hormones may be authorized by the Member States of the European Union for therapeutic and zootechnical purposes. The hormones must, in the first place, be administered by a veterinarian or under the responsibility of a veterinarian.<sup>224</sup> In addition, Directive 96/22/EC specifies detailed conditions, such as, for example: strict withdrawal periods; administration by injection or, in case of varying disfunctions, by vaginal spirals, but not by implants; clear identification of the individual animal so treated; and recording of the details of treatment by the responsible veterinarian (e.g. type of treatment, type of veterinary drug used or authorized, date of treatment, identity of the animals treated).<sup>225</sup>

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".

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<sup>219</sup>US Panel Report, para. 4.71; Canada Panel Report, para. 4.242.

<sup>220</sup>US Panel Report, para. 8.198; Canada Panel Report, para. 8.201.

<sup>221</sup>US Panel Report, para. 8.199; Canada Panel Report, para. 8.202.

<sup>222</sup>US Panel Report, paras. 6.183, 6.184 and 6.189; Canada Panel Report, paras. 6.182, 6.183 and 6.188.

<sup>223</sup>See the ninth paragraph of the Preamble of Directive 96/22/EC, dated 29 April 1996, which states:

Whereas the prohibition on the use of hormonal substances for fattening purposes should continue to apply; whereas the use of certain substances for therapeutic or zootechnical purposes may be authorized but must be strictly controlled in order to prevent any misuse; (underlining added)

<sup>224</sup>US Panel Report, para. 4.69; Canada Panel Report, para. 4.192.

<sup>225</sup>US Panel Report, para. 4.69; Canada Panel Report, para. 4.238.

226. We turn to the Panel's comparison between the levels of protection set by the European Communities in respect of natural and synthetic hormones for growth promotion and with respect to carbadox and olaquinox.<sup>226</sup> Carbadox and olaquinox are anti-microbial agents or compounds which are mixed with the feed given to piglets (maximum age of four months). According to a report of JECFA<sup>227</sup>, 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.<sup>228</sup> The experts advising the Panel confirmed that carbadox was genotoxic in character.

227. In the panel proceedings, the European Communities sought to justify the difference in the levels of protection in respect of the natural and synthetic hormones (except MGA) and in respect of carbadox and olaquinox.<sup>229</sup> The Panel responds to these arguments and the European Communities has reiterated its original arguments in its appellant's submission.<sup>230</sup> We canvass the arguments of the European Communities and the Panel's responses, which are set out below in very summary form.

228. The first argument of the European Communities is that carbadox and olaquinox are not hormones, but rather anti-microbial agents. The Panel responds that the European Communities has not explained why this difference would itself justify a different regulatory treatment in the light of the carcinogenic potential of both kinds of substances.<sup>231</sup>

229. The second argument of the European Communities is that carbadox and olaquinox only indirectly act as growth promoters by suppressing the development of bacteria and aiding the intestinal flora of piglets, thereby also exerting preventive therapeutic effects; hormones, it is said, have no preventive therapeutic action when used as growth promoters. However, the Panel considers that both the hormones in dispute and carbadox and olaquinox may have therapeutic effects.<sup>232</sup>

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<sup>226</sup>EC Directive 70/524/CEE of 23 November 1970 governs the use of additives to animal feed. This Directive allows Member States to permit the use of certain additives listed in Annex I of the Directive, under the conditions there specified. On 12 April 1991, EC Directive 91/248/EEC replaced Annexes I and II of the 1970 Directive with new Annexes. The new Annex I includes the following under the subheading "growth promoters": carbadox and olaquinox.

<sup>227</sup>Evaluation of Certain Veterinary Drug Residues in Food: Thirty-sixth Report of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), Technical Report Series 799 (World Health Organization, 1990), pp. 45-50.

<sup>228</sup>US Panel Report, para. 4.220.

<sup>229</sup>US Panel Report, para. 8.229 (with respect to carbadox only); Canada Panel Report, para. 8.232.

<sup>230</sup>EC's appellant's submission, paras. 528-548.

<sup>231</sup>US Panel Report, para. 8.231 (with respect to carbadox only); Canada Panel Report, para. 8.234.

<sup>232</sup>US Panel Report, para. 8.232 (with respect to carbadox only); Canada Panel Report, para. 8.235.

230. The European Communities' third argument is that carbadox and olaquinox are only commercially available in prepared feedstuffs (not as injections or implants) in predetermined dosages and, therefore, are less open to abuse. The Panel observes that, according to experts advising it, products containing any of the five hormones at issue for implantation or injection are also packaged in predetermined dosages. The experts add that carbadox as an additive in feedstuffs poses additional risks since it may harm the persons handling the feedstuff.<sup>233</sup>

231. The fourth argument of the European Communities is that there are no alternatives to carbadox or olaquinox available that have the same therapeutic action. The Panel notes that, according to one of the experts, there are readily available alternatives such as oxytetracycline. According to Canada, oxytetracycline has been the subject of a risk assessment by JECFA and Codex has adopted the Acceptable Daily Intakes (ADI) and MRLs recommended by JECFA.<sup>234</sup>

232. The European Communities' fifth argument is that carbadox cannot be abused since it has growth promotion effects only in piglets up to four months old and a fixed withdrawal period of at least 28 days is set in the relevant Directive. In turn, the Panel notes that, according to its expert advisors, there is no assurance that the piglets treated with carbadox would not be slaughtered and that residues of carbadox would not thereby enter the food chain of human beings. The Panel adds that the use of the hormones at issue as growth promoters could similarly be subjected to strict conditions.<sup>235</sup>

233. The sixth argument the European Communities made is that carbadox is used in very small quantities and is hardly absorbed in the piglet's gut with the result that it leaves practically no residues at all in pork meat destined for human consumption. The Panel replies that, according to the experts advising it, once a substance has been administered to an animal, there will always be some residue of this substance or a metabolite left, albeit a very small amount, in the meat of that animal.<sup>236</sup> In this connection, Canada volunteered the comment that, according to a 1991 study commissioned by the European Communities and provided to the Panel, metabolites of carbadox and olaquinox are "nearly completely absorbed in the gut" and that "in using carbadox, a mutagenic or carcinogenic risk for the consumer seems negligible if the withdrawal time is closely respected".<sup>237</sup>

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<sup>233</sup>US Panel Report, para. 8.233 (with respect to carbadox only); Canada Panel Report, para. 8.236.

<sup>234</sup>US Panel Report, para. 8.234 (with respect to carbadox only); Canada Panel Report, para. 8.237.

<sup>235</sup>US Panel Report, para. 8.235; Canada Panel Report, para. 8.238.

<sup>236</sup>US Panel Report, para. 8.236; Canada Panel Report, para. 8.239.

<sup>237</sup>CEAS Consultants (Wye) Ltd. (et.al.), *The Impact on Animal Husbandry in the European Community of the Use of Growth Promoters*, Final Report, Vol. I (1991), cited in Canada's appellee's submission, paras. 180-181.

234. The European Communities made a seventh argument which was not repeated in its appeal: the complaining parties limit their claim to one or two substances out of 10,000 to 15,000 veterinary medicinal substances the use of which the European Communities authorizes, which indicates "a remarkable degree of consistency in its levels of sanitary protection".<sup>238</sup> The Panel notes that the European Communities has advised it that the EC Council, by a Decision of 26 February 1996, has already taken action *motu proprio* to review carbadox and olaquinox. To the Panel, the arguments of the European Communities suggest that it acknowledges that the difference in the levels of protection in respect of added hormones and in respect of carbadox and olaquinox may not be justified and should be reviewed.<sup>239</sup>

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

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

236. In interpreting this last element or requirement of Article 5.5, the Panel recalls the conclusion of the Appellate Body in *United States - Standards for Reformulated and Conventional Gasoline*<sup>240</sup> ("*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.<sup>241</sup> The Panel also recalls our statement in *Japan - Alcoholic Beverages*<sup>242</sup>, 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".<sup>243</sup> The Panel then renders its interpretation of the last requirement of Article 5.5 of the SPS Agreement as follows:

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<sup>238</sup>US Panel Report, para. 8.237; Canada Panel Report, para. 8.240.

<sup>239</sup>US Panel Report, para. 8.237 (with respect to carbadox only); Canada Panel Report, para. 8.240.

<sup>240</sup>Adopted 20 May 1996, WT/DS2/AB/R.

<sup>241</sup>US Panel Report, paras. 8.182 and 8.240; Canada Panel Report, paras. 8.185 and 8.243.

<sup>242</sup>Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

<sup>243</sup>US Panel Report, para. 8.183; Canada Panel Report, para. 8.186.

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.<sup>244</sup>

(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.<sup>245</sup> 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.<sup>246</sup> 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.<sup>247</sup>

238. We agree with the Panel's view that "all three elements [of Article 5.5] need to be distinguished and addressed separately".<sup>248</sup> 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)<sup>249</sup>

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<sup>244</sup>US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.

<sup>245</sup>EC's appellant's submission, paras. 471-477.

<sup>246</sup>EC's appellant's submission, para. 486.

<sup>247</sup>EC's appellant's submission, para. 491.

<sup>248</sup>US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.

<sup>249</sup>See para. 212 of this Report.



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*<sup>250</sup> 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".<sup>251</sup>

240. In our view, the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. Thus, we do not think that the difference between a "no residues" level and "unlimited residues" level is, together with a finding of an arbitrary or unjustifiable difference, sufficient to demonstrate that the third, and most important, requirement of Article 5.5 has been met. It is well to bear in mind that, after all, the difference in levels of protection that is characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the SPS Agreement. Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case.

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

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<sup>250</sup>Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

<sup>251</sup>The differential involved in *Japan - Alcoholic Beverages* was a tax differential, which is very different from a differential in levels of protection. Unlike a differential in levels of protection, a tax differential is always expressed in quantitative terms and a significant tax differential in favour of domestic products will inevitably affect the competitiveness of imported products and thus afford protection to domestic products. There is a clear and linear relationship between a tax differential and the protection afforded to domestic products. There is, however, no such relationship between a differential in levels of human health protection and discrimination or disguised restriction on trade.

242. According to the Panel, the "significance" of the "arbitrary or unjustifiable" distinction in the level of protection concerning the hormones in dispute as compared with the level of protection in respect of carbadox and olaquinox results in discrimination or a disguised restriction on international trade. It bases this finding on: (i) the great difference in the levels of protection, namely, the difference between a "no residue" level for the five hormones at issue when used as growth promoters, as opposed to an "unlimited residue" level for carbadox and olaquinox; (ii) the absence of any plausible justification put forward by the European Communities for this significant difference; and (iii) the nature of the EC measure, i.e., the prohibition of imports, which necessarily restricts international trade.<sup>252</sup>

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<sup>253</sup>; (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<sup>254</sup>; and (vi) that the hormones at issue are used for growth promotion in the bovine sector "where the European Communities seemingly wants to limit supplies and is arguably less concerned with international competitiveness", whereas carbadox and olaquinox are used for growth promotion in the pork meat sectors "where the European Communities has no domestic surpluses and where international competitiveness is a higher priority".<sup>255</sup>

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.<sup>256</sup> It is also emphasized that the predominant motivation for both the prohibition

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<sup>252</sup>US Panel Report, para. 8.241; Canada Panel Report, para. 8.244.

<sup>253</sup>US Panel Report, para. 8.242; Canada Panel Report, para. 8.245.

<sup>254</sup>US Panel Report, para. 8.242; Canada Panel Report, para. 8.245.

<sup>255</sup>US Panel Report, para. 8.243 (with respect to carbadox only); Canada Panel Report, para. 8.246.

<sup>256</sup>EC's appellant's submission, para. 552.

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.<sup>257</sup> 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

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<sup>257</sup>See, for example: Opinion of the Economic and Social Committee of 13 December 1984 on the proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, Official Journal, No. C 44, 15 February 1985, p. 14; Resolution of the European Parliament of 11 October 1985 on the proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, Official Journal No. C 288, 11 November 1985, p. 158; Resolution of the European Parliament of 16 September 1988 on the use of hormones in meat production, Official Journal, No. C 262, 10 October 1988, p. 167; and Resolution of the European Parliament of 14 April 1989 on the USA's refusal to comply with Community legislation on slaughterhouses and hormones, and the consequences of this refusal, Official Journal, No. C 120, 16 May 1989, p. 356. The latter Resolution was based on, inter alia, the Pimenta Report, Parts A and B.

of the European Communities' mandate to establish a common (internal) market in beef.<sup>258</sup> Reduction of any beef surplus through an increase in the consumption of beef within the European Communities, is not only in the interests of EC farmers, but also of non-hormone using farmers in exporting countries. We are unable to share the inference that the Panel apparently draws that the import ban on treated meat and the Community-wide prohibition of the use of the hormones here in dispute for growth promotion purposes in the beef sector were not really designed to protect its population from the risk of cancer, but rather to keep out US and Canadian hormone-treated beef and thereby to protect the domestic beef producers in the European Communities.

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

### XIII. Appeals by the United States and Canada: Articles 2.2 and Article 5.6 of the SPS Agreement

247. The Panel refrained from making findings under Articles 2.2 and 5.6 of the SPS Agreement. In respect of Article 2.2, the Panel, having found that the EC measures are inconsistent with Articles 3.1, 5.1 and 5.5, did not believe there was any necessity for making a finding on the consistency of the same EC measures with Article 2.2. The Panel, in so concluding, also considered that Articles 3 and 5 provide for more specific rights and obligations than the "basic rights and obligations" set out in Article 2.<sup>259</sup>

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<sup>258</sup>Article 7a of the Treaty Establishing the European Community stipulates:

The Community shall adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992 ...  
The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty.

<sup>259</sup>US Panel Report, para 8.271; Canada Panel Report, para. 8.274.

248. In respect of Article 5.6, the Panel held that since it had already found the EC level of protection reflected in the EC measure in dispute was adopted in violation of Article 5.5, there was no need to examine whether that same measure is also more trade restrictive than necessary to achieve that level in the sense of Article 5.6.<sup>260</sup>

249. The United States, qua appellant, believes the Panel has made all the findings necessary for the purpose and should have declared the EC import prohibition inconsistent with Article 2.2.<sup>261</sup> It is also submitted by the United States that the text of Articles 2, 3 and 5 does not indicate that all of the obligations in Article 2.2 are subsumed under Articles 3 and 5.<sup>262</sup> In respect of Article 5.6, it is similarly urged by the United States that the Panel's findings on Article 5.5 are sufficient to establish that the EC import prohibition is also inconsistent with Article 5.6.<sup>263</sup> Similar submissions are made by Canada as appellant.<sup>264</sup>

250. We agree with the Panel's application of the notion of judicial economy. We have affirmed the Panel's conclusion that the EC measures are inconsistent with Article 5.1 in view of the failure of the European Communities to provide a risk assessment that reasonably supports such measures. Under the circumstances, the necessity or propriety of proceeding to determine whether Article 2.2 of the SPS Agreement has also been violated is not at all clear to us. Had we reversed the Panel's conclusion in respect of the inconsistency of the EC measures with Article 5.1, it would have been logically necessary to inquire whether Article 2.2 might nevertheless have been violated. We are, of course, surprised by the fact that the Panel did not begin its analysis of this whole case by focusing on Article 2 that is captioned "Basic Rights and Obligations", an approach that appears logically attractive. We recall the reading that we have given above to Articles 2 and 5 -- that Article 2.2 informs Article 5.1, and that similarly Article 2.3 informs Article 5.5 -- but believe that further analysis of their relationship should await another case.

251. We have, at the same time, reversed the Panel's conclusion under Article 5.5 of the SPS Agreement that the levels of protection set by the European Communities in respect of the use of hormones for growth promotion result in discrimination or a disguised restriction on international trade. However, it cannot be assumed that all the findings of fact necessary to proceed to a determination of consistency or inconsistency of the EC measures with the requirements of Article 5.6 have been made by the Panel,

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<sup>260</sup>US Panel Report, para 8.247; Canada Panel Report, para. 8.250.

<sup>261</sup>United States' appellant's submission, para. 4.

<sup>262</sup>United States' appellant's submission, para. 18.

<sup>263</sup>United States' appellant's submission, para. 20.

<sup>264</sup>Canada's appellant's submission, paras. 19-22.

which Article also provides that "technical and economic feasibility" should be taken into account. There appears all the more reason for refraining from an examination of the legality of the measures under Article 5.6 and for adhering to the prudential dictates of the principle of judicial economy.

252. We consider, therefore, and so hold, that the Panel did not err in refraining from making findings on Articles 2.2 and 5.6 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;
- (d) upholds the Panel's conclusion that the SPS Agreement, and in particular Articles 5.1 and 5.5 thereof, applies to measures that were enacted before the entry into force of the WTO Agreement, but that remain in force thereafter;
- (e) concludes that the Panel, although it sometimes misinterpreted some of the evidence before it, complied with its obligation under Article 11 of the DSU to make an objective assessment of the facts of the case;

- (f) concludes that the procedures followed by the Panel in both proceedings -- in the selection and use of experts, in granting additional third party rights to the United States and Canada and in making findings based on arguments not made by the parties -- are consistent with the DSU and 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; and
- (n) concludes that the Panel exercised appropriate judicial economy in not making findings on Articles 2.2 and 5.6 of the SPS Agreement.

254. The foregoing legal findings and conclusions uphold, modify and reverse the findings and conclusions of the Panel in Parts VIII and IX of the Panel Reports, but leave intact the findings and conclusions of the Panel that were not the subject of this appeal.

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



Signed in the original at Geneva this 5th day of January 1998 by:

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Florentino Feliciano  
Presiding Member

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Claus-Dieter Ehlermann  
Member

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Mitsuo Matsushita  
Member