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.[2] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
>
> [2]For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

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.[157] 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".[158] 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.[159]

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

(a) "if there is a scientific justification"; or

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

It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that "all measures which result in a [higher] level of ... protection", that is to say, measures falling within situation (a) as well as those falling within situation (b), be "not inconsistent with any other provision of [the SPS]

[157]EC's appellant's submission, paras. 240-244.

[158]*SPS Agreement*, Article 3.3.

[159]EC's appellee's submission, para. 88.

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*[160], which reads as follows:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. (underlining added)

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

181. The second preliminary consideration relates to the Panel's effort to distinguish between "risk assessment" and "risk management". The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a "scientific" examination of data and factual studies; it is

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[160]US Panel Report, para. 8.93; Canada Panel Report, para. 8.96.

not, in the view of the Panel, a "policy" exercise involving social value judgments made by political bodies.[161] The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment".[162] 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".[163]

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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[161]US Panel Report, para. 8.94; Canada Panel Report, para. 8.97.

[162]US Panel Report, para. 8.95; Canada Panel Report, para. 8.98.

[163]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".[164] "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[165], 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".[166] 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.[167]

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"[168], 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.[169] 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.[170] 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"

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[164]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.

[165]Para. 819 of the Annex to the US and Canada Panel Reports.

[166]US Panel Report, footnote 331; Canada Panel Report, footnote 437.

[167]EC's appellant's submission, paras. 392-397.

[168]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.

[169]US Panel Report, paras. 8.152-8.153; Canada Panel Report, paras. 8.155-8.156

[170]US Panel Report, footnote 331; Canada Panel Report, footnote 437.

a risk assessment. As will be elaborated below, this means that a panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment.

2. Factors to be Considered in Carrying Out a Risk Assessment

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

> In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

The listing in Article 5.2 begins with "available scientific evidence"; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is "a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take".[171] 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.[172] 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

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[171]US Panel Report, para. 8.107; Canada Panel Report, para. 8.110.

[172]"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.

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

B. *The Interpretation of "Based On"*

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

188. Although it expressly recognizes that Article 5.1 does *not* contain any specific procedural requirements for a Member to base its sanitary measures on a risk assessment, the Panel nevertheless proceeds to declare that "there is a minimum procedural requirement contained in Article 5.1". That requirement is that "the Member imposing a sanitary measure needs to submit evidence that at least it actually *took into account* a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as *based on* a risk assessment".[173] 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*".[174] (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

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[173]US Panel Report, para. 8.113; Canada Panel Report, para. 8.116.

[174]US Panel Report, para. 8.114; Canada Panel Report, para. 8.117.

an SPS measure and a risk assessment. Such a reference is certainly embraced in the ordinary meaning of the words "based on" and, when considered in context and in the light of the object and purpose of Article 5.1 of the *SPS Agreement*, may be seen to be more appropriate than "taking into account". We do not share the Panel's interpretative construction and believe it is unnecessary and an error of law as well.

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

191. In the course of demanding evidence that EC authorities actually "took into account" certain scientific studies, the Panel refers to the preambles of the EC Directives here involved. The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the panel proceedings. 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.[175] Applying the "substantive requirements" it finds in Article 5.1, the Panel holds that the scientific conclusions implicit in the EC measures do not conform with any of the scientific conclusions reached in the scientific studies the European Communities had submitted as evidence.[176]

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

[175]US Panel Report, para. 8.117; Canada Panel Report, para. 8.120.

[176]US Panel Report, para. 8.137; Canada Panel Report, para. 8.140.

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):

> - 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");
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> - 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");
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> - the 1988 and 1989 JECFA Reports;
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> - 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).[177]

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*.[178] At the same time, the

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[177]US Panel Report, para. 8.108; Canada Panel Report, para. 8.111.

[178]US Panel Report, para. 8.111; Canada Panel Report, para. 8.114.

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) for growth promotion purposes is safe; most of these studies adding that this conclusion assumes that good practice is followed.[179]

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.[180]

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[181], 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.[182] Accordingly, it appears that the single divergent opinion expressed by Dr. Lucier

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[179]US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

[180]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.

[181]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.

[182]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.

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.[183] 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 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.[184] 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.

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[183]Para. 195 of this Report.

[184]US Panel Report, para. 8.129; Canada Panel Report, para. 8.132.

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.[185] 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 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.[186] 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

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[185]EC's appellant's submission, para. 179 *ff*.

[186]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*.

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*.[187] (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 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.[188]

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.[189]

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

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[187]US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

[188]US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

[189]EC's appellant's submission, para. 399 and 401.

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"[190], 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".[191] The *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2. We disagree with the Panel's suggestion that exclusion of risks resulting from the combination of potential abuse and difficulties of control is justified by distinguishing between "risk assessment" and "risk management". As earlier noted, the concept of "risk management" is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*.

207. The question that arises, therefore, is whether the European Communities did, in fact, submit a risk assessment demonstrating and evaluating the existence and level of risk arising in the present

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[190]US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

[191]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".

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".[192] 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.[193] The study presented a theoretical framework for the systematic analysis of such problems, but did not itself investigate and evaluate the actual problems that have arisen at the borders of the European Communities or within the United States, Canada and other countries exporting meat and meat products to the European Communities. At best, this study may represent the beginning of an assessment of such risks.

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

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[192]US Panel Report, para. 8.143; Canada Panel Report, para. 8.146.

[193]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.

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[194] 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[195] 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*.[196]

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

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

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

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[194]See para. 177 of this Report.

[195]EC's appellant's submission, para. 448.

[196]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.

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.[197] 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.[198]

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.

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[197]US Panel Report, para. 8.176; Canada Panel Report, para. 8.179.

[198]EC's appellant's submission, para. 455.

218. In examining the EC measures here involved[199] and at least one other SPS measure of the European Communities[200], 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[201];

(ii) the level of protection in respect of natural hormones occurring endogenously in meat and other foods[202];

(iii) the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes[203];

(iv) the level of protection in respect of synthetic hormones (zeranol and trenbolone) when used for growth promotion[204]; and

(v) the level of protection in respect of carbadox and olaquindox.[205]

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

219. The Panel then proceeds to compare level of protection (i) with, firstly, level of protection (ii) and, secondly, with level of protection (iii). Thereafter, the Panel compares levels of protection (i) and (iv) with level of protection (v). The Panel holds that the differences between levels of protection (i) and (iv) on the one hand, and level of protection (ii) on the other, are arbitrary and unjustifiable.[206] It further held that the differences in levels of protection (i) and (iv) on the one hand, and level (v)

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[199]See paras. 2-5 of this Report.

[200]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.

[201]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.

[202]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.

[203]US Panel Report, para. 8.191; Canada Panel Report, para. 8.194.

[204]US Panel Report, para. 8.212; Canada Panel Report, para. 8.215.

[205]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.

[206]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.

on the other, are also arbitrary and unjustifiable.[207] In contrast, the Panel does not undertake to compare level of protection (iii) with level of protection (i).[208] 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.[209] 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.[210] 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.[211] 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.[212] 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.[213]

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

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[207]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.

[208]US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.

[209]US Panel Report, para. 8.193; Canada Panel Report, para. 8.196.

[210]US Panel Report, para. 8.194; Canada Panel Report, para. 8.197.

[211]US Panel Report, para. 8.195; Canada Panel Report, para. 8.198.

[212]US Panel Report, para. 8.196; Canada Panel Report, para. 8.199.

[213]US Panel Report, paras. 8.213, 8.264 and 8.265; Canada Panel Report, paras. 8.216, 8.267 and 8.268.

foods. In respect of the latter, the European Communities simply takes no regulatory action[214]; 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.[215] 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.[216] 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.[217]

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.[218] Therapeutic use is occasional as opposed to regular and continuous use that characterizes growth

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[214]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.

[215]US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.

[216]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.

[217]United States' appellant's submission, paras. 26, 27 and 29.

[218]EC's appellee's submission, paras. 82-84.

promotion.[219] 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.[220] Zootechnical use may relate to entire herds but would occur only once a year[221]; 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.[222]

224. The second difference concerns the mode of administration of hormones. In order to prevent abuse[223], 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.[224] In addition, Directive 96/22/EC specifies detailed conditions, such as, for example: strict withdrawal periods; administration by injection or, in case of varying disfunctions, by vaginal spirals, but not by implants; clear identification of the individual animal so treated; and recording of the details of treatment by the responsible veterinarian (e.g. type of treatment, type of veterinary drug used or authorized, date of treatment, identity of the animals treated).[225]

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,

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[219]US Panel Report, para. 4.71; Canada Panel Report, para. 4.242.

[220]US Panel Report, para. 8.198; Canada Panel Report, para. 8.201.

[221]US Panel Report, para. 8.199; Canada Panel Report, para. 8.202.

[222]US Panel Report, paras. 6.183, 6.184 and 6.189; Canada Panel Report, paras. 6.182, 6.183 and 6.188.

[223]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)

[224]US Panel Report, para. 4.69; Canada Panel Report, para. 4.192.

[225]US Panel Report, para. 4.69; Canada Panel Report, para. 4.238.

on the one hand, and concerning hormones used for therapeutic and zootechnical purposes, on the other, is not, in itself, "arbitrary or unjustifiable".

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

227. In the panel proceedings, the European Communities sought to justify the difference in the levels of protection in respect of the natural and synthetic hormones (except MGA) and in respect of carbadox and olaquindox.[229] The Panel responds to these arguments and the European Communities has reiterated its original arguments in its appellant's submission.[230] 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 olaquindox 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.[231]

229. The second argument of the European Communities is that carbadox and olaquindox 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

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[226]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 olaquindox.

[227]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.

[228]US Panel Report, para. 4.220.

[229]US Panel Report, para. 8.229 (with respect to carbadox only); Canada Panel Report, para. 8.232.

[230]EC's appellant's submission, paras. 528-548.

[231]US Panel Report, para. 8.231 (with respect to carbadox only); Canada Panel Report, para. 8.234.

preventive therapeutic action when used as growth promoters. However, the Panel considers that both the hormones in dispute and carbadox and olaquindox may have therapeutic effects.[232]

230. The European Communities' third argument is that carbadox and olaquindox 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.[233]

231. The fourth argument of the European Communities is that there are no alternatives to carbadox or olaquindox 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.[234]

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.[235]

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.[236] In this connection, Canada volunteered the comment that, according to a 1991 study commissioned by

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[232]US Panel Report, para. 8.232 (with respect to carbadox only); Canada Panel Report, para. 8.235.

[233]US Panel Report, para. 8.233 (with respect to carbadox only); Canada Panel Report, para. 8.236.

[234]US Panel Report, para. 8.234 (with respect to carbadox only); Canada Panel Report, para. 8.237.

[235]US Panel Report, para. 8.235; Canada Panel Report, para. 8.238.

[236]US Panel Report, para. 8.236; Canada Panel Report, para. 8.239.

the European Communities and provided to the Panel, metabolites of carbadox and olaquindox 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".[237]

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".[238] 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 olaquindox. 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 olaquindox may not be justified and should be reviewed.[239]

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

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

236. In interpreting this last element or requirement of Article 5.5, the Panel recalls the conclusion of the Appellate Body in *United States - Standards for Reformulated and Conventional Gasoline*[240] ("*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.[241] The Panel also recalls our statement in *Japan - Alcoholic Beverages*[242], and in particular the requirement in Article III:2, second sentence,

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[237]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.

[238]US Panel Report, para. 8.237; Canada Panel Report, para. 8.240.

[239]US Panel Report, para. 8.237 (with respect to carbadox only); Canada Panel Report, para. 8.240.

[240]Adopted 20 May 1996, WT/DS2/AB/R.

[241]US Panel Report, paras. 8.182 and 8.240; Canada Panel Report, paras. 8.185 and 8.243.

[242]Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

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".[243] The Panel then renders its interpretation of the last requirement of Article 5.5 of the *SPS Agreement* as follows:

> We consider the reasoning in both Appellate Body Reports to be equally relevant to the relationship between the three elements contained in Article 5.5. All three elements impart meaning to one another. Nevertheless, in order to give effect to all three elements contained in Article 5.5 and giving full meaning to the text and context of this provision, we consider that all three elements need to be distinguished and addressed separately. However, we also agree that in some cases where a Member enacts, for comparable situations, sanitary measures which reflect different levels of protection, the significance of the difference in levels of protection combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection "result[s] in discrimination or a disguised restriction on international trade" in the sense of Article 5.5 (in line with the argument that the magnitude of the very differential of a dissimilar taxation may be enough to conclude that a dissimilar taxation is applied so as to afford protection, as provided for in the second sentence of Article III:2 of GATT.[244] (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.[245] 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.[246] 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.[247]

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[243]US Panel Report, para. 8.183; Canada Panel Report, para. 8.186.

[244]US Panel Report, para 8.184; Canada Panel Report, para. 8.187.

[245]EC's appellant's submission, paras. 471-477.

[246]EC's appellant's submission, para. 486.

[247]EC's appellant's submission, para. 491.

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

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*[250] 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".[251]

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

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[248]US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.

[249]See para. 212 of this Report.

[250]Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

[251]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.

by the basic obligations set out in Article 2.3 of the *SPS Agreement*. Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case.

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

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

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[253]; (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[254]; and (vi) that the hormones at

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[252]US Panel Report, para. 8.241; Canada Panel Report, para. 8.244.

[253]US Panel Report, para 8.242; Canada Panel Report, para. 8.245.

[254]US Panel Report, para 8.242; Canada Panel Report, para. 8.245.

issue are used for growth promotion in the bovine sector "where the European Communities seemingly wants to limit supplies and is arguably less concerned with international competitiveness", whereas carbadox and olaquindox are used for growth promotion in the pork meat sectors "where the European Communities has no domestic surpluses and where international competitiveness is a higher priority".[255]

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

245. We do not attribute the same importance as the Panel to the supposed multiple objectives of the European Communities in enacting the EC Directives that set forth the EC measures at issue. The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes clear the depth and extent of the anxieties experienced within the European Communities concerning the results of the general scientific studies (showing the carcinogenicity of hormones), the dangers of abuse (highlighted by scandals relating to black-marketing and smuggling of prohibited veterinary drugs in the European Communities) of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the meat available in

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[255]US Panel Report, para. 8.243 (with respect to carbadox only); Canada Panel Report, para. 8.246.

[256]EC's appellant's submission, para. 552.

its internal market.[257] A major problem addressed in the legislative process of the European Communities related to the differences in the internal regulations of various Member States of the European Union (four or five of which permitted, while the rest prohibited, the use for growth promotion of certain hormones), the resulting distortions in competitive conditions in and the existence of barriers to intra-community trade. The necessity for harmonizing the internal regulations of its Member States was a consequence of the European Communities' mandate to establish a common (internal) market in beef.[258] Reduction of any beef surplus through an increase in the consumption of beef within the European Communities, is not only in the interests of EC farmers, but also of non-hormone using farmers in exporting countries. We are unable to share the inference that the Panel apparently draws that the import ban on treated meat and the Community-wide prohibition of the use of the hormones here in dispute for growth promotion purposes in the beef sector were not really designed to protect its population from the risk of cancer, but rather to keep out US and Canadian hormone-treated beef and thereby to protect the domestic beef producers in the European Communities.

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

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[257]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.

[258]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.

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.[259]

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.[260]

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.[261] 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.[262] 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.[263] Similar submissions are made by Canada as appellant.[264]

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

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[259]US Panel Report, para 8.271; Canada Panel Report, para. 8.274.

[260]US Panel Report, para 8.247; Canada Panel Report, para. 8.250.

[261]United States' appellant's submission, para. 4.

[262]United States' appellant's submission, para. 18.

[263]United States' appellant's submission, para. 20.

[264]Canada's appellant's submission, paras. 19-22.

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, 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:

Florentino Feliciano
Presiding Member

Claus-Dieter Ehlermann
Member

Mitsuo Matsushita
Member