

Report of the Panel : EC Measures Concerning Meat and Meat Products (Hormones)
Complaint by the United States¹

VIII. FINDINGS

C. GENERAL INTERPRETATIVE ISSUES²

1. Scope of the measures in dispute

8.16 The United States contests the EC ban on imports of meat and meat products from cattle, treated with any of six specific hormones (oestradiol-17 β , testosterone, progesterone, zeranol, trenbolone and MGA) for growth promotion purposes. The United States does not challenge the EC ban on imports of meat and meat products from cattle treated with hormones other than the six specified or treated with any hormones for purposes other than growth promotion.

8.17 At the end of the Panel proceedings, the United States argued that its complaint was not limited to meat and meat products of bovine origin (i.e., originating from cattle) but also extended to, for example, lamb meat. In this regard the United States referred to an Annex to its first submission where it is stated that zeranol is approved in the United States for use in lambs. We note, however, that, although technically within the terms of reference of the Panel, at no point in the Panel proceedings did the United States raise specific arguments or submit factual or scientific evidence against a ban imposed by the European Communities on the use of hormones in farm animals other than cattle. We further note that all scientific studies

¹ ไม่ใช่เอกสารต้นฉบับ (Original) : Panel Report, "EC Measures Concerning Meat and Meat Products (Hormones), WTO, WT/DS26/R/USA " <www.wto.org/wto/dispute/distab/html>, 18 August 1997.

² *Ibid.* p.167-176.

invoked by both the United States and the European Communities relate to risks to human health or cattle from the ingestion or administration of hormones; not risks to any other animals. We find, therefore, that the EC ban in so far as it relates to meat or meat products from farm animals other than cattle falls outside the scope of this dispute.

8.18 At the end of the Panel proceedings, the United States also seemed to argue that its complaint was not limited to meat and meat products but also extended to live animals. However, our terms of reference direct us to examine "the matter referred to the DSB by the United States in [document WT/DS26/6, i.e., the request for the establishment of a panel by the United States]". In that document the United States only claimed that the contested EC measures "adversely affect imports of meat and meat products". We therefore consider that the matter referred to in that document is limited to meat and meat products and thus find that the EC ban on imports of live animals falls outside our terms of reference.

8.19 Finally, we note that the European Communities argues that its import ban on live animals to which any of the six hormones have been administered, is necessary for the protection of both human and animal health. However, the European Communities does not make this argument with respect to its import ban on meat or meat products. Specifically, the European Communities has not argued that its import ban on meat or meat products is necessary for the protection of animal health either inside or outside the EC territory. Since the animal health arguments invoked by the European Communities exclusively relate to its import ban on live animals and considering the finding reached above that the EC ban on imports of live animals treated with hormones does not fall within the scope of this dispute, we find that within the scope of this dispute we need not take into account the arguments made by the European Communities which relate to animal health.

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

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

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

"any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs".

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

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

8.23 Both parties also agree that, according to Article 1.1 of the SPS Agreement, the SPS Agreement is applicable to this dispute. Article 1.1 provides that the SPS Agreement

"applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade".

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

8.24 With respect to the application *ratione temporis* of the SPS Agreement to the EC measures in dispute, we note that the SPS Agreement entered into force on 1 January 1995 (the date of entry into force of the WTO Agreement of which, according to Article II:2 of that Agreement, the SPS Agreement is an integral part). The EC measures in dispute, however, were enacted before 1 January 1995 (namely 31 July 1981 and 7 March 1988), thus raising the issue of whether the SPS Agreement applies to these measures.

8.25 Article 3.2 of the DSU directs us to clarify the provisions of the SPS Agreement "in accordance with customary rules of interpretation of public international law". According to established practice, the fundamental rules of treaty interpretation set out in the Vienna Convention on the Law of Treaties ("Vienna Convention") form part of these customary rules of interpretation. The general principle in international law, as embodied in Article 28 of the Vienna Convention, is that "[u]nless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to ... any situation which ceased to exist before the date of the entry into force of the treaty ..." (emphasis added). The EC measures can, in this context, be considered as continuing "situations" which were enacted before the entry into force of the SPS Agreement but which did not cease to exist after that date (contrary to the situation envisaged in Article 28). In line with Article 28 of the Vienna Convention, the SPS Agreement should, therefore, in principle apply to these EC measures, unless an intention to the contrary can be established.

8.26 An examination of the SPS Agreement reveals no intention to the contrary. Indeed, several provisions of the SPS Agreement confirm the general principle that the SPS Agreement should also apply to sanitary measures which were enacted before its entry into force but which remain in force thereafter. Except for Article 14 which authorizes delays in the application of some or all of the provisions of the SPS Agreement for least-developed and other developing countries, no transition periods are provided for. The fact that Article 14 explicitly provides for a two-year transition period for developing countries with respect to some of their existing sanitary and phytosanitary measures, confirms that the SPS Agreement generally applies to measures enacted before the entry into force of the SPS Agreement but which are maintained in force after that date. This is also confirmed in several provisions of the SPS Agreement which explicitly address situations where Members "maintain" a sanitary or phytosanitary measure, such as Article 2.2 ("Members shall ensure that any sanitary ... measure ... is based on scientific principles and is not maintained without sufficient scientific evidence..."), Article 3.3 ("Members may introduce or maintain sanitary ... measures ... if ..."), Article 5.6 ("... when establishing or maintaining sanitary ... measures ... Members shall ensure that ...") and Article 5.8("... a specific sanitary ... measure introduced or maintained by another Member ...").

8.27 We finally note that according to Article XVI:4 of the WTO Agreement, each Member "shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements [including the SPS Agreement]". This provision confirms that measures which already existed as of the date of entry into force of the SPS Agreement also need to be consistent with the requirements imposed by that Agreement.

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

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

"The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures".

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

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

3. Relationship between the SPS Agreement and GATT

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

8.32 The parties to the dispute present diverging views with respect to whether we should first address GATT or the SPS Agreement. However, neither of the parties claims that the relevant provisions of the SPS Agreement and GATT are in conflict. Therefore, we do not need, as a preliminary matter, to address the General Interpretative Note to the Multilateral Agreements on Trade in Goods which only applies "[i]n the event of conflict between a provision of [GATT] and a provision of another Agreement in Annex 1A [inter alia, the SPS Agreement]".

8.33 The European Communities makes a distinction between the "substantive" and "procedural" provisions of the SPS Agreement. According to the European Communities, the substantive provisions only interpret Article XX(b) of GATT, without adding any new obligations, while the procedural provisions contain requirements

additional to GATT. Therefore, the European Communities concludes, the "substantive" provisions of the SPS Agreement can only be addressed if recourse is made to GATT Article XX(b), i.e., if, and only if, a violation of another provision of GATT is first established. The additional "procedural" provisions, on the other hand, can be examined directly and independently of a prior GATT violation.

8.34 The United States argues that the SPS Agreement is the *lex specialis* for a review of sanitary measures and should, therefore, be addressed first. The United States claims that the application of the SPS Agreement does not require a prior violation of GATT since the SPS Agreement is a "free-standing" agreement which applies to all sanitary measures and imposes requirements additional to those in Article III or the exceptions in Article XX of GATT.

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

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

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

According to Article 1.1 of the SPS Agreement, two requirements need to be fulfilled for the SPS Agreement to apply: (i) the measure in dispute is a sanitary or phytosanitary measure; and (ii) the measure in dispute may, directly or indirectly, affect international trade. There are no additional requirements. The SPS Agreement contains, in particular, no explicit requirement of a prior violation of a provision of GATT which would govern the applicability of the SPS Agreement, as asserted by the European Communities.

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

8.38 Moreover, we find the EC claim that the SPS Agreement does not impose "substantive" obligations additional to those already contained in Article XX(b) of GATT not to be persuasive. It is clear that some provisions of the SPS Agreement elaborate on provisions already contained in GATT, in particular Article XX(b). The final preambular paragraph of the SPS Agreement provides, indeed, that the Members desired "to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Examples of such rules are, arguably, some of the obligations contained in Article 2 of the SPS Agreement. However, on this basis alone we cannot conclude that the SPS Agreement only applies, as Article XX(b) of GATT does, if, and only if, a prior violation of a GATT provision has been established. Many provisions of the SPS Agreement impose "substantive" obligations which go significantly beyond and are additional to the requirements for invocation of Article XX(b). These obligations are, inter alia, imposed to "further the use of harmonized sanitary and phytosanitary measures between Members" and to "improve the human health, animal health and phytosanitary situation in all Members". They are not imposed, as is the case of the obligations imposed by Article XX(b) of GATT, to justify a violation of another GATT obligation (such as a violation of the non-discrimination obligations of Articles I or III).

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

be met in order for a Member to enact or maintain specific types of measures, namely sanitary and phytosanitary measures.

8.40 The conclusion that the SPS Agreement contains obligations which are not already imposed by GATT is confirmed in Article 2.4 of the SPS Agreement which provides that "[s]anitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Indeed, to presume that one set of obligations (in casu GATT) is met because another set of obligations (in casu the SPS Agreement) has been fulfilled, seems to imply that the latter set of obligations imposes at least as many as, and probably more obligations than, the former. Support for this conclusion is also found in Article 3.2 of the SPS Agreement which provides that "[s]anitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994" (emphasis added). While both agreements may apply in a given factual situation, the foregoing provision nonetheless establishes the SPS Agreement as an agreement which imposes obligations which are different from those imposed by GATT.

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

8.42 Having reached the conclusion that we are not per se required to address GATT claims prior to those raised under the SPS Agreement, we must then decide which of the two agreements we should examine first in this particular dispute. The SPS Agreement specifically addresses the type of measure in dispute. If we were to examine GATT first, we would in any event need to revert to the SPS Agreement:

if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement. For these reasons, and in order to conduct our consideration of this dispute in the most efficient manner, we shall first examine the claims raised under the SPS Agreement.

D. THE SPS AGREEMENT

1. Overview of the provisions in dispute

8.43 The United States claims violations of Articles 2, 3 and 5 of the SPS Agreement. Article 2 elaborates on the basic rights and obligations of Members under the SPS Agreement. Article 3 deals, more specifically, with the objective of harmonization of sanitary measures on the basis of international standards, guidelines or recommendations. Article 5 deals, in turn, with the obligation of risk assessment and the determination and application by Members of their appropriate level of sanitary protection.

8.44 Article 3.1 requires Members to base their sanitary measures on international standards, guidelines or recommendations except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3. We note, therefore, that even if international standards may not, in their own right, be binding on Members, Article 3.1 requires Members to base their sanitary measures on these standards.

8.45 According to Article 3.2 sanitary measures which conform to international standards, guidelines or recommendations are presumed to be consistent with both the SPS Agreement and GATT. We shall therefore, as a first step, examine whether there are international standards, guidelines or recommendations with respect to the EC

measures in dispute and, if so, whether the EC measures are based on these standards, guidelines or recommendations in accordance with Article 3.1.

8.46 If there are international standards, guidelines or recommendations and the European Communities has not based its measures thereon, we will need, as a second step, to examine whether the European Communities can justify its measures under Article 3.3 since Article 3.1, which imposes the requirement to base sanitary measures on international standards explicitly refers to Article 3.3 as providing for an exception to this requirement.

8.47 Finally, if there are no international standards, guidelines or recommendations with respect to the EC measures in dispute, or to some of them, there would be no standards, guidelines or recommendations for these measures to be based on in line with Article 3.1. However, even in that case the consistency of the EC measures in dispute with Articles 2 and 5 of the SPS Agreement would still need to be examined.

2. Burden of proof

8.48 Given the nature of disputes under the SPS Agreement, which imposes substantive and procedural requirements raising various, and in this case complex, issues of fact, the allocation of the burden of proof is of particular importance. It involves consideration of the wording, general outline and object and purpose of the SPS Agreement as a whole. We, therefore, first examine this issue in general before addressing the specific burden of proof for each of the provisions in dispute in more detail below.

8.49 In stating its claims under the SPS Agreement, the United States seems to presume that the European Communities bears the burden of proof. The United States argues that the SPS Agreement, inter alia, requires the European Communities to base

its sanitary measures on a risk assessment and prohibits the European Communities from maintaining such measures without scientific evidence. According to the United States, the SPS Agreement does not allow for measures to be maintained without scientific evidence until such time as science proves "beyond doubt" that there is no risk (against which a sanitary measure can protect, for example, consumers). The United States seems, therefore, to conclude that it is up to the European Communities to provide evidence that there is a risk to be protected against and that there has been a risk assessment. It is not up to the United States to prove that there is no risk or that the European Communities did not carry out a risk assessment.

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

8.51 In addressing the burden of proof under the SPS Agreement, we consider that, as is the case in most legal proceedings, the initial burden of proof rests on the complaining party in the sense that it bears the burden of presenting a *prima facie* case of inconsistency with the SPS Agreement. It is, indeed, for the party that initiated the dispute settlement proceedings to put forward factual and legal arguments in order to substantiate its claim that a sanitary measure is inconsistent with the SPS Agreement. In other words, it is for the United States to present factual and legal arguments that, if unrebutted, would demonstrate a violation of the SPS Agreement. Once such a *prima facie* case is made, however, we consider that, at least with respect to the obligations imposed by the SPS Agreement that are relevant to this case, the burden of proof shifts to the responding party.

8.52 In our view, the allocation of evidentiary burden under the SPS Agreement to the Member imposing a sanitary or phytosanitary measure flows directly from the wording of many of the provisions contained in that Agreement and in particular the first three words thereof:

"Members shall ensure that..." (e.g. Articles 2.2, 2.3, 5.1 and 5.6 of the SPS Agreement;

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

"When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or
Page 175 phytosanitary measure may be requested and shall be provided by the Member maintaining the measure" (emphasis added).

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

"Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994".

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

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

3. Article 3.1: sanitary measures based on international standards

8.56 Article 3.1 of the SPS Agreement reads as follows:

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

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

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

(a) Codex standards

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

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

(b) Sanitary measures based on Codex standards³

8.71 The United States argues that the European Communities ignored the five Codex standards outlined above. Rather than establishing an ADI or MRL for any of these hormones, the United States submits, the European Communities has chosen to prohibit the sale of meat from any animal to which these hormones have been administered for growth promotion purposes, whether or not there is any residue of these hormones found in that meat. The European Communities does not submit that its measures are based on the Codex standards, but rather argues that, as discussed

³ *Ibid.*, p. 179 -187.

above, there are no relevant Codex standards on which its measures in dispute need to be based.

(i) The meaning of based on

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

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

8.74 Without limiting the possibilities of how a level of protection may be expressed for a particular substance, we consider that in the specific field of veterinary drugs (including the six hormones at issue), a level of protection can be directly linked to the amount of residues of that drug allowed either to be ingested by humans on a daily basis or to be present in a particular food. A level of protection can thus, inter alia, be expressed by way of setting a maximum amount of residues allowed for daily intake by humans over a lifetime (often defined as acceptable daily intake or ADI) and (or) by way of adopting a maximum amount of residues allowed to be present in a particular food (often defined as maximum residue limit or MRL). However, the fact that an ADI or MRL can reflect a level of protection (without *stricto sensu* itself being a level of protection), does not exclude, as the European Communities has argued, that an ADI or MRL can also be a sanitary measure in the sense of the SPS Agreement.

(ii) Comparison of levels of sanitary protection

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

0.02 g/kg of body weight and an MRL of 2 and 10 g/kg for, respectively, bovine muscle and bovine liver). The EC measures in dispute, in as far as they relate to zeranol and trenbolone, are, therefore, not based on existing international standards as specified in Article 3.1.

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

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

8.78 We next examine whether the EC measures with respect to five of the six hormones in dispute, which are not based on existing international standards, otherwise are consistent with the requirements of the SPS Agreement (sections 4 and 5). We then

address the EC measures which relate to the sixth hormone, MGA, for which no international standard exists (section 6).

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

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

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

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

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

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

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

A Note to this paragraph adds the following:

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

(a) Requirements for justification

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

- there is a "scientific justification" for imposing the measure, i.e., the Member imposing the measure has determined "on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of [the SPS] Agreement, ... that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary ... protection" ("the first exception"); or
- the measure is "a consequence of the level of sanitary ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5" ("the second exception").

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

8.81 We will consider first whether either the first or the second exception outlined above is met. In doing so, we first address the relationship and difference between these two exceptions. The United States argues that both exceptions have the same effect since both refer to a situation where the basis for departing from the relevant

international standard is that the international standard is not sufficient to achieve the Member's appropriate level of protection. The European Communities argues that the first exception is fulfilled when the international standard is inadequate, faulty or obsolete from a scientific point of view and that, according to the second exception, a Member is in any case entitled to introduce or maintain measures which aim at achieving its appropriate level of protection, to be determined in accordance with Article 5 of the SPS Agreement.

8.82 We note that both exceptions explicitly refer to other provisions of the SPS Agreement. The first exception contains the following reference: "... on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of [the SPS] Agreement ..."

(emphasis added). The second exception refers to "... the relevant provisions of paragraphs 1 through 8 of Article 5" (emphasis added). Article 3.3, second sentence, in turn, explicitly states that even if the sanitary measure at issue falls under one of the two exceptions of Article 3.3, first sentence, the sanitary measure in question still needs to be consistent with all provisions of the SPS Agreement other than Article 3.

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

(b) Burden of proof

8.84 We recall the findings made above on the burden of proof under the SPS Agreement, in particular that for the obligations imposed by the SPS Agreement that are

relevant to this case, the party contesting a sanitary measure (in casu the United States) bears the initial burden of proof in that it has to present a prima facie case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the party imposing the measure (in casu the European Communities).

8.85 We consider that this allocation of burden to the party imposing a sanitary measure is, for the reasons set out above, applicable to Article 3.3 and particularly justified under the first sentence

thereof which contains specific requirements to be fulfilled for a Member to justify a sanitary measure which is not based on an international standard.

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

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

8.88 Since in this dispute we have already found that there exist international standards and that the EC measures at issue are not based on these standards, we find

that the burden of justifying the measures in dispute under Article 3.3, and in particular under the first sentence thereof, rests on the European Communities.

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

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

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

(a) Risk assessment and risk management

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

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

8.93 According to Article 5.1, a Member needs to ensure that its sanitary measures are based on an assessment of risks. The obligation to base a sanitary measure on a risk assessment may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement which provides that "Members shall ensure that any sanitary ... measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence ..." (emphasis added). Articles 5.1 to 5.3 sum up factors a Member needs to take into account in making this assessment of risks.

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

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

8.96 Articles 5.4 to 5.6 are particularly relevant to the risk management decision. Article 5.4 establishes the objective of minimizing negative trade effects in the determination by a Member of its appropriate level of protection. Article 5.5 aims at achieving consistency in the application of the concept of appropriate level of protection. Article 5.6, in turn, provides that the sanitary measure which is finally adopted shall not be more trade-restrictive than required to achieve the appropriate level of protection of the Member concerned. Articles 5.4 to 5.6 may be viewed as specific applications of the basic obligations provided for in Article 2.2 which, *inter alia*,

states that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health" (emphasis added) and Article 2.3 which provides that "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail ..." and that "Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade"

(emphasis added).

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

(b) Articles 5.1 to 5.3: risk assessment

8.98 According to Article 5.1:

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

Paragraph 4 of Annex A of the SPS Agreement defines "risk assessment" with respect to contaminants (including residues of the hormones at issue) as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of ... contaminants ... in food, beverages or feedstuffs" (emphasis added).

Guided by the wording of these provisions, we consider that, in this dispute, a risk assessment carried out in accordance with the SPS Agreement should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat or meat products, and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of these effects.

8.99 Article 5.1 provides in general terms, without any limitation in time, that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks ...". It does not prevent that with respect to a sanitary measure enacted before the entry into force of the SPS Agreement, the risk assessment is carried out or invoked after the entry into force of that Agreement (and thus after the enactment of the sanitary measure in question). However, the fact that a sanitary measure may be enacted before the entry into force of the SPS Agreement does not mean that, once the SPS Agreement entered into force, there is no obligation for the Member in question to base that measure on a risk assessment. Moreover, the more general obligation contained in Article 2.2 of the SPS Agreement explicitly provides that "Members shall ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not maintained without sufficient scientific evidence ..." (emphasis added).

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

8.101 In this respect we consider at the outset that it is for the European Communities to submit evidence before the Panel that its measures are based on a risk assessment; it is not for the Panel itself to conduct its own risk assessment on the basis of scientific evidence gathered by the Panel or submitted by the parties during the Panel proceedings.

8.102 " We next examine: (i) the techniques and factors to be taken into account in a risk assessment in accordance with Article 5; (ii) whether the European Communities has demonstrated the existence of such a risk assessment; and (iii) assuming that such

risk assessment exists, whether the European Communities has demonstrated that its measures at issue are based on this risk assessment.”...

6. The precautionary principle⁴

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

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

8.159 In summary, in this section we have found that, even assuming that the European Communities has demonstrated the existence of a risk assessment in accordance with Article 5, it has not fulfilled the minimal procedural requirements contained in Article 5.1 to base its sanitary measures on risk assessment. We have also found that, even if it would have fulfilled these minimal procedural requirements, the European Communities has not met its burden of proving that its measures in

⁴*Ibid* .p.203 – 214.

dispute, in so far as they also ban the import of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes in accordance with good practice, are, from a substantive point of view, based on a risk assessment. The EC measures in dispute, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, inconsistent with the requirements of Article 5.1. The fact that these measures are not based on existing international standards (contrary to Article 3.1) cannot, therefore, be justified under Article 3.3 which includes as one of the requirements for justification, consistency with Article 5.1. The EC measures, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, also inconsistent with the requirements of Article 3.1.

(c) Articles 5.4 to 5.6: risk management

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

8.161 We recall the definition of "appropriate level of sanitary protection", namely:

"The level of protection deemed appropriate by the Member establishing a sanitary ... measure to protect human, animal or plant life or health ..."
(paragraph 5 of Annex A of the SPS Agreement; emphasis added). We also note the wording of Article 5.5, further examined below:

"... in the application of the concept of appropriate level of sanitary ... protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid ..."

Guided by the wording of these provisions and the object and purposes of the SPS Agreement, we consider that if there is no scientific evidence of an identifiable risk, there is no basis on which to adopt a measure to achieve a level of sanitary protection under the SPS Agreement, except as provided in Article 5.7. If this were not the case, i.e., if a Member could adopt a level of protection and implementing sanitary measures even if it did not provide scientific evidence of an identifiable risk, no effect would be given to the obligation contained in Article 5 to base sanitary measures on an assessment of risks. This approach would undermine the wording and object and purpose of the SPS Agreement.

8.162 We have found above that the European Communities has not provided evidence of an identifiable risk related to the presence of five of the six hormones at issue for which international standards exist when these hormones are used for growth promotion purposes in accordance with good practice. Accordingly, the European Communities has not established the existence of any identifiable risk against which the EC measures at issue, in so far as they also ban the use of the five hormones when used as growth promoters in accordance with good practice, can protect human life or health. Since we considered above that the adoption of a sanitary measure presupposes the existence of an identifiable risk (except as provided in Article 5.7), it is not possible for the European Communities to ban the use of these hormones as growth promoters in accordance with good practice.

8.163 However, even if we would have found that the European Communities met its burden of proving that its measures are based on an assessment of risks in accordance with Articles 5.1 and 5.2 and even if, for that reason, the European Communities could have adopted a measure to achieve its appropriate level of protection against these

risks, there would still be a need to examine whether the determination and application of this level of protection is consistent with Articles 5.4 to 5.6. We will, therefore, next examine these provisions.

8.164 The parties to this dispute seem to agree that the establishment of an "appropriate level of sanitary protection" by a Member is a sovereign act, namely, as the definition in paragraph 5 of Annex A of the SPS Agreement provides, the level of protection "deemed appropriate by the Member establishing a sanitary ... measure" (emphasis added). As outlined above, we note, however, that Members have agreed, in exercising their sovereign right to set their appropriate levels of protection, to observe the provisions of the SPS Agreement, in particular Articles 5.4 and 5.5 thereof. Furthermore, in choosing a measure to achieve that appropriate level of protection Members have agreed to observe the provisions of Articles 2, 5.1 to 5.3 and 5.6.

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

(i) Article 5.4: minimizing trade effects

8.166 Article 5.4 provides the following:

"Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects" (emphasis added).

Guided by the wording of Article 5.4, in particular the words "should" (not "shall") and "objective", we consider that this provision of the SPS Agreement does not impose an obligation. However, this objective of minimizing negative trade effects has nonetheless to be taken into account in the interpretation of other provisions of the SPS Agreement.

(ii) Article 5.5: distinctions in levels of protection

8.167 Article 5.5 provides the following:

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

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

"Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of

other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade" (emphasis added).

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

8.169 We consider that the first part of the first sentence of Article 5.5 ("With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health ..."; emphasis added), unlike the second part, does not impose an obligation upon Members. Consistency is not imposed as an obligation but as an objective which nonetheless has to be taken into account in the interpretation of Article 5.5.

8.170 We further note that the Committee on Sanitary and Phytosanitary Measures, established by Article 12 of the SPS Agreement to "provide a regular forum for consultations", has been given a mandate by Article 5.5, second sentence, to "develop guidelines to further the practical implementation of this provision" and, in so doing, needs to "take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves". No such guidelines have to date been developed. However, considering the mandatory wording of the second part of the first sentence of Article 5.5 ("each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations ..."; emphasis added) and the existence of the basic obligations contained in Article 2.3, we find that the lack of guidelines by the Committee in no way limits the legally binding nature of the second part of the first sentence of Article 5.5.

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

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

The three elements contained in Article 5.5

8.173 We next examine the elements that must be assessed to determine if a Member's sanitary measure does not conform to the requirements of the second part of the first sentence of Article 5.5. The relevant part of Article 5.5 reads as follows: "each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade".

8.174 The first element contained in Article 5.5 is that the Member concerned adopts different appropriate levels of sanitary protection in "different situations". The second element is that the distinction in levels of protection for the different situations is "arbitrary or unjustifiable". The third element is that the distinction in levels of protection

results in "discrimination or a disguised restriction on international trade". In order to find a sanitary measure to be inconsistent with Article 5.5 all three elements need to be present.

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

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

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

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

8.179 The third element contained in Article 5.5 is that the distinction in level of protection results in

"discrimination or a disguised restriction on international trade".

8.180 The United States has not presented a claim with respect to the term "discrimination"; only with respect to the term "disguised restriction on international trade". The United States argues that "a disguised restriction on international trade" is present in the context of Article 5.5 where a Member claims a legitimate basis for the difference in the chosen levels of protection being compared, but where instead the differing levels of protection are being employed for commercial reasons to restrict trade.³⁸²

The European Communities argues that the measures in dispute do not result in discrimination and that the fact that sanitary measures affect imports is not a sufficient reason to claim that they restrict trade, or even less, that they discriminate.

8.181 We note, first of all, the relation between this third element of "discrimination or a disguised restriction on international trade" in Article 5.5 and the basic obligations contained in Article 2.3 of the SPS Agreement providing that:

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

We also note the relation between these two provisions and the language of the chapeau of Article XX of GATT which reads as follows:

"Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between the countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:" (emphasis added).

8.182 With respect to the meaning of "discrimination" and "a disguised restriction on international trade" we recall the conclusions reached by the Appellate Body in its Report on "United States - Standards for Reformulated and Conventional Gasoline" where the terms "arbitrary or unjustifiable discrimination" and "a disguised restriction on international trade", contained in the chapeau of Article XX of GATT, were examined as follows: "Arbitrary discrimination", 'unjustifiable discrimination' and 'disguised restriction' on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that 'disguised restriction' includes disguised discrimination in international trade. It is equally clear that concealed or unannounced restriction or discrimination in international trade does not exhaust the meaning of 'disguised restriction'. We consider that 'disguised restriction', whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination', may also be

taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX" (original emphasis).

8.183 We further recall the Appellate Body Report on "Japan - Taxes on Alcoholic Beverages" where the Appellate Body found that for an internal tax measure to be inconsistent with the second sentence of Article III:2 of GATT, three separate issues must be addressed so as to give full meaning to the text and context of this provision: (i) the products need to be "directly competitive or substitutable"; (ii) they need to be "not similarly taxed"; and (iii) the dissimilar taxation needs to be "applied ... so as to afford protection to domestic production". The Appellate Body found that the panel had erred in blurring the distinction between the second and third issue by equating dissimilar taxation (i.e., tax difference above a *de minimis* level) with the separate and distinct requirement of demonstrating that the tax measure "affords protection to domestic production". The Appellate Body then concluded the following:

"As previously stated, a finding that 'directly competitive or substitutable products' are 'not similarly taxed' is necessary to find a violation of Article III:2, second sentence. Yet this is not enough. The dissimilar taxation must be more than *de minimis*. It 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. In this case, the Panel concluded that it was enough. Yet in other cases, there may be other factors that will be just as relevant or more relevant to demonstrating that the dissimilar taxation at issue was applied 'so as to afford protection' ... And, in every case, a careful, objective analysis, must be done of each and all relevant facts and all relevant circumstances to determine 'the existence of protective taxation'. Although the Panel blurred its legal reasoning in this respect, nevertheless we conclude that it reasoned correctly that in this case, the Liquor Tax Law is not in compliance with Article III:2" (emphasis added).

8.184 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).

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

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

1. Comparable situations with different levels of sanitary protection

8.186 This examination involves a comparison of the levels of protection for the same substance, namely, respectively, oestradiol-17 β , testosterone and progesterone, in different situations depending on the origin or use of that substance. Since we have found above that we can compare situations where the same substance is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5387, we find that the treatment of the three natural hormones in dispute when used for growth promotion purposes as opposed to the treatment of these hormones which (i) occur endogenously in meat and other foods and (ii) which have been administered for therapeutic or zootechnical purposes, constitute comparable situations in the sense of Article 5.5.

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

if these hormones would not be totally identical substances, they pose, in any event, the same adverse health effect and can, therefore, according to our finding made above, be considered as comparable situations for the purposes of Article 5.5.

8.188 We next examine whether the European Communities has adopted a different level of protection for these comparable situations.

8.189 With respect to the three natural hormones administered for growth promotion purposes, the European Communities argues that its level of sanitary protection is concerned only with added hormones; in other words, the European Communities does not consider that it is acceptable to expose consumers to any hormones in their food over and above the levels which occur in nature, as any such additional exposure could be a hazard to health.

8.190 The appropriate level of protection set by the European Communities for natural hormones present endogenously in meat and other foods or administered for therapeutic or zootechnical purposes is an unlimited residue level. In other words, the European Communities has not adopted any maximum residue level for these categories of natural hormones. With respect to oestradiol-17 β when used for therapeutic or zootechnical purposes, this unlimited residue level of protection has recently been confirmed by the European Communities when it adopted the conclusions reached in the 1988 JECFA Report and classified this hormone, when used for therapeutic or zootechnical purposes, as a substance for which MRLs are unnecessary. With respect to the two other natural hormones in dispute, progesterone and testosterone, when used for therapeutic or zootechnical purposes, no final decision has as yet been taken by the competent EC authorities.

8.191 We thus find that the level of protection adopted by the European Communities for the three natural hormones in dispute when used for growth promotion and that adopted for the same hormones (i) occurring endogenously in meat and other

foods and (ii) used for therapeutic or zootechnical purposes, is different ("no residue" level as opposed to an unlimited residue level) and that, therefore, distinctions in levels of protection for these comparable situations exist in the sense of the first element of Article 5.5.

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

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

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

8.194 In this respect we further recall the conclusion reached in the 1988 JECFA Report that the total residue level of natural hormones in meat from treated animals (i.e., the combination of natural hormones endogenously present and those added for growth promotion) falls well within the physiological range of levels found in meat from

untreated animals, which levels vary according to the sex and age of the animal. We also note that, according to data submitted to the Panel, the residue level of natural hormones in many natural products (such as eggs and soya oil) is much higher than the level of residues of these hormones administered for growth promotion as well as the total residue level of these hormones in treated meat. In this respect, we further note that Codex has also established MRLs for substances which endogenously occur in natural products.

8.195 With respect to the potential difficulties in detecting the presence of natural hormones used as growth promoters, we refer to our conclusions reached above, namely that only under the current EC regime (a ban) does the problem arise of how to distinguish between endogenous and added natural hormones whereas under a regime where one would allow the use of these hormones (with, for example, an MRL or tolerance level for all natural hormones) there would be no need to distinguish endogenous from added natural hormones. We also note that, in any event, the problem of detection would be the same for both natural hormones used as growth promoters and those occurring endogenously in meat and other foods (since the scientific experts stated that both are qualitatively the same) and can, therefore, not justify a different treatment.

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

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

is justifiable and that, therefore, this particular distinction in levels of protection is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

8.198 Natural hormones used as growth promoters as opposed to those used for therapeutic or zootechnical purposes. The European Communities argues that the use of the natural hormones for therapeutic and zootechnical purposes occurs on a small scale, is subject to very strict conditions (such as administration by a veterinarian and strict withdrawal periods) and normally only involves cattle intended for breeding, not for slaughter; whereas the use of these hormones as growth promoters occurs on a much larger scale and is more difficult and costly to control. These differences in use and control, the European Communities argues, ensure that any risk related to the therapeutic or zootechnical use of these hormones is prevented and that in practice a level of "no residue" is achieved, as is the case for the use of these hormones as growth promoters. For these reasons, the European Communities concludes, the distinction in levels of protection is justified.

8.199 We note that, according to scientific experts advising the Panel, zootechnical use of these hormones can occur on a large scale and at regular intervals, namely each year for oestrus synchronization of entire herds. Moreover, even when these hormones are used for therapeutic or zootechnical purposes, all parties and scientific experts advising the Panel agree that some residue level, albeit a very small one, will always remain in the meat when the treated animal is eventually slaughtered. Therefore, a "no residue" level cannot in practice be achieved when these hormones are used for therapeutic or zootechnical purposes.

8.200 "However, since we have already concluded that the difference in levels of protection imposed in the European Communities for the three natural hormones when used for growth promotion purposes as opposed to those present endogenously in meat and other foods cannot be justified, we consider it unnecessary to decide whether or not the distinction made by the European Communities between natural hormones used as growth promoters and those used for therapeutic or zootechnical purposes is justified."...

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

1. Comparable situations with different levels of sanitary protection⁵

8.220 In this examination we compare different substances. However, both parties in this dispute and the experts advising the Panel agree that the situations thus compared involve the same adverse health effect, namely carcinogenicity.

8.221 Since we have found above that we can compare situations where the same adverse health effect is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5, we find that the treatment of the five hormones at issue when used as growth promoters as opposed to that of carbadox are comparable situations in the sense of the first element of Article 5.5.

8.222 We next examine whether the European Communities has adopted a different level of protection for these comparable situations.

8.223 The United States argues that the EC level of protection for the hormones at issue when used for growth promotion is different from that for carbadox. The United States submits that with respect to the hormones at issue when used for growth promotion purposes the European Communities has suggested that its appropriate level of protection is "zero risk". With respect to carbadox, the United States argues that it is clear from the fact that the European Communities permits the use of carbadox and the sale and consumption of meat from animals to which carbadox has been administered, that the European Communities is choosing an appropriate level of protection that is less stringent than for the hormones involved in this dispute.

⁵ *Ibid.*p.218 – 219.

8.224 With respect to the hormones in dispute when used for growth promotion purposes, the European Communities adopted a "no residue" level as its appropriate level of protection. With respect to carbadox, the European Communities argues that, even though these substances are allowed, strict controls, specific characteristics of these substances and the way they are administered, ensure that no residue levels will remain in treated pigs when slaughtered and that, therefore, in the European Communities in practice the same level of protection applies to carbadox as the level adopted for the hormones in dispute, namely a "no residue" level.

8.225 We note that the European Communities allows the use of carbadox as a growth promoter in pigs and has not set any MRL for that substance. The European Communities thus, in principle, accepts an unlimited residue level of these substances in pork meat. Moreover, we recall that, contrary to what the European Communities argues, a "no residue" level cannot be achieved in practice when use of the substance concerned is allowed (even under strict conditions) since there will always be some residue level of the substance or a metabolite, albeit a very small one, left in the meat, even after a long period of time. We consider, for these reasons, that the European Communities cannot reasonably claim that its level of protection for carbadox is a "no residue" level.

8.226 “ We thus find that the level of protection adopted by the European Communities for the hormones at issue when used for growth promotion purposes as opposed to that adopted for carbadox is different (a "no residue" level as opposed to an unlimited residue level) and that, therefore, a distinction in the levels of protection for these comparable situations exists in the sense of the first element of Article 5.5.”...

3. Difference which results in "discrimination or a disguised restriction on international trade.”⁶

⁶*Ibid.*p.222 – 229.

8.239 The United States submits that the distinction made by the European Communities in levels of protection for the hormones at issue when used as growth promoters and carbadox results in a disguised restriction on international trade in the sense of the third element contained in Article 5.5. According to the United States, the European Communities swine industry (where growth promoters are allowed) is relatively more efficient and market-oriented than the European Communities beef industry (where growth promoters are banned), a sector where efficiency is not that important because of domestic price support measures, import protection and export subsidies. When banning hormones, the United States concludes, the European Communities clearly wanted to reduce beef supplies, a concern not present in the pork sector where the European Communities wanted, on the contrary, to preserve competitiveness and maintain export markets.

8.240 We recall that the three elements contained in Article 5.5 all impart meaning to one another and that in some cases the significance of the difference in levels of sanitary protection for comparable situations combined with the arbitrariness of thereof, may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".

8.241 In this case, we note, firstly, the significance of the difference in levels of protection for the five hormones at issue when used as growth promoters and carbadox, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with any of these five hormones at issue) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for the five hormones at issue when used as growth promoters and carbadox, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.242 We consider that this finding is further supported by the two additional factors outlined above, which are equally valid for the distinction in levels of protection made by the European Communities for the five hormones at issue when used as growth promoters and carbadox.

8.243 We finally note that there is another factor which indicates that the distinction in treatment made by the European Communities for the hormones at issue when used as growth promoters and carbadox results in "discrimination or a disguised restriction on international trade". That is the fact that the hormones at issue, which are banned in the European Communities, are used for growth promotion in the bovine meat sector where the European Communities seemingly wants to limit supplies and is arguably less concerned with international competitiveness, whereas carbadox, which is allowed in the European Communities, is used for growth promotion in the pork meat sector where the European Communities has no domestic surpluses and where international competitiveness is a higher priority.

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

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

(iii) Article 5.6: measures not more trade restrictive than required to achieve the appropriate level of protection

8.246 Article 5.6 reads as follows:

"Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade- restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility".

A footnote to Article 5.6 states the following:

"For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade".

8.247 Since we found above that the EC level of protection reflected in the EC measures in dispute has been adopted in violation of Article 5.5, we do not consider it necessary to further examine whether these measures are also more trade restrictive than required to achieve that level in the sense of Article 5.6.

(d) Article 5.7: provisional sanitary measures

8.248 Article 5.7 reads as follows:

"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other

Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

8.249 We recall our finding reached above on the role of the precautionary principle in the SPS Agreement, in particular that this principle would not override the explicit wording of that Agreement, *inter alia*, because it has been incorporated in a specific form in Article 5.7. In this dispute, the European Communities has explicitly stated that its measures are not provisional measures in the sense of Article 5.7. We do, therefore, not need to further examine this provision.

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

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

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

(a) Burden of proof

8.252 We recall our finding reached above on the general burden of proof under the SPS Agreement, in particular that for the obligations imposed by the SPS

Agreement that are relevant to this case, the party contesting a sanitary measure (in casu the United States) bears the burden of presenting a prima facie case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the party imposing the measure (in casu the European Communities). We consider that, for the reasons mentioned above, this allocation of evidentiary burden is applicable to the obligations imposed on Members under Article 5. We recall, in particular, the wording of Article 5.1, especially the first three words thereof:

"Members shall ensure that their sanitary ... measures are based on an assessment ... of the risks..." (emphasis added)

and the wording of the second part of the first sentence of Article 5.5 : "... each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if ..." (emphasis added).

Therefore, in this dispute the United States has to present a prima facie case that the EC measures in dispute relating to MGA are inconsistent with the requirements of Article 5, after which the burden shifts to the European Communities to prove that it has complied with these requirements.

(b) Articles 5.1 to 5.3: risk assessment

8.253 With respect to Articles 5.1 to 5.3 dealing with the requirement of a risk assessment, the United States argues that the European Communities has not submitted any risk assessment for the hormone MGA and that the European Communities has, therefore, a priori, not based its measures with respect to MGA on any risk assessment as required by Article 5.1. The United States further submits that its Food and Drug Administration has fully evaluated the safety of MGA and concluded that the use of this hormone as a growth promoter does not present a risk to human health. We find that the United States thus meets its burden of presenting a prima facie case of inconsistency with Article 5.1.

8.254 We recall our reasoning outlined above on the requirement of the existence of a risk assessment in accordance with Articles 5.1 to 5.3, in particular that with respect to the five other hormones in dispute we assumed that the European Communities met its burden of demonstrating the existence of a risk assessment since

it referred to several scientific reports which appear to meet the minimum requirements of a risk assessment.

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

8.256 The European Communities argues that the EC measures in dispute regulate hormones on the basis of their physiological action, not on the basis of individual substances and that the administration of any substance having an oestrogenic, androgenic or gestagenic action is covered by the EC ban, including MGA which has a gestagenic action.

8.257 We note, however, that with respect to all five other hormones in dispute, JECFA, Codex and the European Communities itself have conducted or invoked risk assessments for each individual substance. We further note that one of the basic principles of a risk assessment appears to be that it needs to be carried out for each individual substance. As was stated in the 1995 EC Scientific Conference:

"It must be emphasised that a separate risk assessment must be conducted on each growth promoting substance. It is not appropriate to attempt to produce a detailed generic risk assessment for a class of growth promoters".

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

8.259 We recall, in this respect, that the European Communities has explicitly stated that Article 5.7, which deals with cases where relevant scientific evidence is

insufficient and allows a Member to take provisional sanitary measures, does not apply to the measures in dispute, including those relating to MGA.

8.260 We further recall our reasoning and findings reached above (with respect to the five other hormones in dispute) on the procedural and substantive requirements a Member must satisfy in order to base its sanitary measures on a risk assessment in accordance with Article 5.1. We recall, in particular, that the European Communities has, from a procedural point of view, not provided any evidence that the studies it referred to have actually been taken into account by the competent EC institutions or are reflected in the EC measures in such a way that these measures could be said to be based on these studies. We further recall that the European Communities has not met its burden of proving that its measures in dispute, in so far as they also ban the use of the five hormones at issue for growth promotion purposes in accordance with good practice, are, from a substantive point of view, based on a risk assessment.

8.261 The same reasoning applies a priori to the EC measures with respect to MGA since the European Communities has not submitted any study in which the risks related to MGA are assessed. We thus find that the European Communities has not met its burden of providing evidence to the Panel that its measures in dispute, in so far as they relate to the hormone MGA, are, either from a procedural or a substantial point of view, based on a risk assessment and that, therefore, these measures are inconsistent with the requirements of Article 5.1.

(c) Article 5.5: distinctions in levels of protection

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

argues that the European Communities fails to justify the following differences in regulatory treatment:

(i) a ban on MGA when used for growth promotion purposes as opposed to not setting any limit for residues of the natural hormones present endogenously in untreated meat and other foods (such as milk, cabbage, broccoli or eggs) or used for therapeutic or zootechnical purposes; and (ii) a ban on MGA when used for growth promotion purposes as opposed to allowing the use of carbadox as a growth promoter in swine production. Only with respect to the last mentioned difference in treatment does the United States explicitly invoke Article 5.5.

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

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

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

8.265 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA (the third synthetic hormone in dispute). Firstly, the European Communities has adopted different levels of protection (a "no residue" limit as opposed to an unlimited residue level) for comparable situations, in casu situations posing the same adverse health effect (i.e., carcinogenicity), namely for MGA

used as a growth promoter and the natural hormones in dispute which occur endogenously in meat and other foods in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

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

(ii) MGA for growth promotion compared to carbadox

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

8.268 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA. Firstly, the European Communities has adopted different levels of protection (a "no residue" limit as opposed to an unlimited residue level) for comparable situations, in casu situations posing the same adverse health effect (i.e., carcinogenicity), namely for MGA used as a growth promoter and carbadox

in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted any evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

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

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

7. Article 2: "Basic Rights and Obligations"

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

E. ARTICLES I AND III OF GATT

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

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

F. CONCLUDING REMARKS

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

IX. CONCLUSIONS

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

(i) The European Communities, by maintaining sanitary measures which are not based on a risk assessment, has acted inconsistently with the requirements contained in Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

(ii) The European Communities, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations which result in discrimination or a disguised restriction on international trade, has acted inconsistently with the requirements contained in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

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

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