(b) Summary of the main arguments of the parties[315]

7.2 With reference to the Panel's question whether panels are permitted to open hearings to public observation under Articles 12 (including Appendix 3), 14.1 and 17.10 of the DSU, the **European Communities** argues that a panel may adopt working procedures that foresee open hearings, as Article 12.1 of the DSU provides that panels may depart from the working procedures in Appendix 3 after consulting the parties to the dispute.

7.3 The European Communities also argues that this conclusion is not affected by Article 14.1 of the DSU on confidentiality of panel deliberations. The term "deliberations" does not cover the meetings with the parties, for which a different terminology is used in Appendix 3 of the DSU.

7.4 The European Communities considers that in the present case where all the parties have agreed to open hearings, the Panel should accommodate the parties' request. Article 18.2 of the DSU also supports the position that parties are entitled to "waive" the confidentiality of their positions.

7.5 Regarding the legal implications of open hearings on covered persons under the Rules of Conduct, the European Communities considers that no legal issues arise under the Rules of Conduct. In the European Communities view, the Rules of Conduct are and remain fully binding on all covered persons in this dispute, even if the hearings are opened to the public. The Panel's deliberations will in any event not be affected by the opening and remain confidential, as required by Article 14.1 of the DSU.

7.6 With respect to the systemic and political impact of opening hearings, the European Communities is of the view that there are no implications for WTO Members who are not parties to this dispute, or on the intergovernmental character of the WTO, nor would it impair the chances to reach a mutually agreed solution, as preferred by the DSU (Article 3.7). Also, there are no implications for third parties because the parties have jointly requested that the public be excluded from the third parties' session during the presentation by a third party, unless that third party agreed to make its presentation open for observation by the public.

7.7 Regarding the procedures that may be adopted to protect confidential information in an open hearing, the European Communities indicates that it does not expect that confidential information will be submitted in this dispute. The European Communities does not consider that there is any issue of confidentiality in relation to information submitted by other Members or non-Members (under Article 13 of the DSU), unless the confidentiality requirement of the last sentence of Article 13.1 of the DSU applies, in which case the corresponding portion of any meeting where this information is discussed could be closed.

7.8 With respect to the third-party session, the European Communities considers that each third party should decide whether to open the part of the third-party session dealing with that third-party's statement.

7.9 Regarding the question whether panels are permitted to open hearings under Articles 12 (including Appendix 3), 14.1 and 17.10 of the DSU, the **United States** notes that the parties agreed that the panel meetings in this dispute should be opened to interested Members and the public. In the view of the United States, open panel meetings are permissible under the DSU, including under Appendix 3 thereto.

[315] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report.

7.10 The United States agrees that any deliberations among the three panel members must be confidential. However, Article 14.1 of the DSU does not apply to the meetings of the panel with the parties and does not prohibit opening panel meetings to the public.

7.11 The United States also argues that the Panel has the ability to remove any provision of Appendix 3 that might be perceived as an impediment to accommodating the parties' decision to make their statements public by allowing the public to observe them as they are delivered. Second, Article 18.2 of the DSU, which is echoed in Paragraph 3 of Appendix 3, explicitly provides that "[n]othing in this Understanding shall preclude a party to a dispute from disclosing statements of its own positions to the public." Appendix 3 is part of the DSU and so, per Article 18.2, nothing in Appendix 3 prevents a party from disclosing statements of its own position to the public.

7.12 Concerning the legal implications of open hearings on covered persons under the Rules of Conduct, the United States argues that the provisions in the Rules of Conduct that require panelists to maintain confidentiality apply only to information that is in fact confidential.

7.13 The United States further argues that since the procedural rules of the DSU permit public hearings, the confidentiality provisions of the Rules of Conduct do not prevent the opening of panel meetings to the public.

7.14 Regarding the systemic and political impact of opening hearings, the United States argues that opening the Panel meetings to the public is a natural extension of the discretion provided to the parties in Article 18.2 of the DSU for a party to disclose its statements to the public.

7.15 The United States believes that the third parties should be consulted, but only to determine if they would also choose to open portions of the third-party session with the Panel to the public.

7.16 The United States does not foresee a decision in this dispute to open panel meetings as having a political or systemic impact. For example, the opening of panel meetings in this dispute would not prejudice the ability of parties to other disputes to choose to open, or keep confidential, their respective panel meetings.

7.17 Regarding the procedures to be adopted to protect confidential information in an open hearing, the United States believes that any portions of the Panel meetings dealing with confidential information would not be open to the public. Additional safeguards to provide against the disclosure of confidential information could be included in the working procedures.

7.18 Finally, the United States argues that the third parties would retain their ability to decide whether their submissions and statements are public. Any confidential statements would not be broadcast.

(c) Summary of the arguments of the third parties[316]

7.19 **Australia** contends that when parties agree not to follow the Working Procedures in Appendix 3, or parts thereof, it would be difficult for the Panel to justify a decision that goes against the wishes of the parties. In Australia's view, to do so would undermine a basic principle of dispute settlement whereby parties consult with each other and with the Panel and seek mutual agreement on the conduct of disputes, according to Article 12.1 of the DSU.[317]

[316] A more detailed account of the third parties' arguments can be found in Section V of the descriptive part of this Report.

[317] Replies by Australia to Panel questions concerning open hearings, question 1.

7.20 While not objecting to the opening of the Panel's hearing for public observation, Australia is however concerned about the modalities of organizing the meetings, equity of access and logistic issues and believes that the opening of the Panel's meetings to the public should be subject to the provisions that allow for protection of confidential information.[318]

7.21 **Brazil** questions the specific grounds and the DSU provisions on which the Panel based its decision to accept the parties' request to open the Panel meetings for public observation. According to Brazil, transparency constitutes an important element in the debate carried out by Members in DSB meetings, which will largely benefit from any further clarification by the Panel as to the legal reasons which motivated its decision to open the meetings to the public.[319]

7.22 Brazil argues that a decision on whether or not to open panels' proceedings to the public relies solely on the WTO membership, in particular the DSU review process which is the appropriate *locus* to deal with issues regarding the dispute settlement mechanism. According to Brazil, if panels were to decide on this issue, they would go beyond their mandate, playing a role that is exclusive to the WTO membership.[320]

7.23 Brazil also contends that opening the meetings to the public would represent a reinterpretation of Article 14 of the DSU, signalling that there are cases to which confidentiality is not applied, such as Panel and Appellate Body meetings.[321]

7.24 **China** prefers the Panel to meet the third parties in closed session. It argues that based on Article 18.2 of the DSU, panels do not have the right to unilaterally disclose the third-party submissions and oral presentations.[322]

7.25 **India** submits that the issue of external transparency is being discussed in the ongoing negotiations in the Special Session of the DSB. Until there is a consensus on the opening of panel meetings to public observation and the modalities therefor, India believes that the Panel proceedings have to be in closed session[323], and its deliberations have to remain confidential[324] as provided in the DSU.[325]

7.26 India contends that the possibility of a panel to decide to deviate from the Working Procedures in Appendix 3 has been provided with the view of having panel procedures with sufficient flexibility so as to ensure high-quality panel reports.[326] In India's view, although panels are given some discretion in establishing their own working procedures, they do not have the discretion to modify the substantive provisions of the DSU, such as confidentiality requirements.[327]

7.27 India argues that Article VII of the Rules of Conduct[328] requires each "covered person" to maintain the confidentiality of dispute settlement deliberations and proceedings at all times. India

[318] Replies by Australia to Panel questions concerning open hearings, question 2.
[319] Oral statement of Brazil, para. 2.
[320] Replies by Brazil to Panel questions concerning open hearings, question 1.
[321] Replies by Brazil to Panel questions concerning open hearings, question 1.
[322] Replies by China to Panel questions concerning open hearings, question 1 and 2.
[323] Paragraph 2 of the working procedures in Appendix 3 of the DSU.
[324] Paragraph 3 of the working procedures in Appendix 3 of the DSU.
[325] Replies by India to Panel questions concerning open hearings, question 1.
[326] Article 12.2 of the DSU
[327] Oral statement of India, para. 6.
[328] Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes, adopted by the DSB on 3 December 1996 (WT/DSB/RC/1).

questions how the Panel is going to ensure that these requirements are met after opening the proceedings to the public for observation.[329]

7.28 India submits that the decision of the Panel to open its proceedings to the public necessarily involves some issues on which consultation and decisions with WTO Members, and not just the parties and third parties, would have been necessary. For example, India questions how the Panel, at its own level, addressed issues relating to the implications on the functioning of the WTO Secretariat, budgetary implications and implications relating to the use of the official languages of the WTO, for which rules and practices have been established by other bodies of the WTO. India also questions how the Panel could take a view on the additional costs arising out of the opening up of the proceedings to public without the Budget Committee having considered the matter.[330]

7.29 According to India, the WTO is a Member-driven organization and it is solely for the WTO Members to decide whether or not to change the WTO rules and open up panel proceedings to the public; a Panel cannot take upon itself that function, even at the request of parties to the dispute.[331]

7.30 India posits that the meeting of the Panel with the third parties should be in closed session as required under paragraph 2 of the Working Procedures contained in Appendix 3 of the DSU.[332]

7.31 **Mexico** disagrees with the opening of the Panel meetings to the public on the grounds that panel meetings constitute panel "deliberations" and as such should be confidential, as per Article 14.1 of the DSU. Mexico also argues that transparency is a sensitive issue that is currently under discussion in the negotiations to amend the DSU. Mexico argues that the DSU rules require that the meetings be confidential and, therefore, the decision of the two parties should only prevail to the extent that it does not affect the right of other Members including third parties.[333]

7.32 Mexico emphasizes that public hearings are a cross-cutting issue that should be addressed in general by the WTO, and should not be imposed by a panel at the request of two Members. Mexico regrets that the decision will set a precedent that may affect the outcome of the negotiations and will in all likelihood end up complicating the preparation of working procedures of future panels.[334] Mexico suggests that the third-party session follow the established WTO practice of being held in closed session.[335]

7.33 According to **New Zealand**, there are no legal constraints that would prevent the Panel from opening its hearings to the public. New Zealand quotes Article 12.1 of the DSU which allows panels to follow the working procedures in the DSU unless the panel decides otherwise after consulting the parties. New Zealand argues that while Appendix 3 provides for closed session hearings, the working procedures can be amended with the consent of the Panel and the parties. New Zealand further notes that the reference in Article 14.1 of the DSU to panel deliberations being confidential refers to the internal deliberations of the panel, not the hearings with the parties. New Zealand submits that this is in line with the practice of other international tribunals which have open hearings but whose deliberations are nonetheless confidential. According to New Zealand, Article 18.2 of the DSU

[329] Oral statement of India, para. 7.
[330] Oral statement of India, para. 8.
[331] Oral statement of India, para. 9.
[332] Replies by India to Panel questions concerning open hearings, question 2.
[333] Oral statement of Mexico, para. 2; Mexico replies to Panel questions following the first meeting, paras. 3 and 9.
[334] Oral statement of Mexico, para. 3.
[335] Replies by Mexico to Panel questions concerning open hearings, question 2.

allows parties to waive confidentiality. New Zealand did not object to its third party hearings being public.[336]

7.34 **Norway** considers that Article 12.1 of the DSU gives the Panel the discretion to follow other working procedures than the ones provided in Appendix 3 after consulting the parties. It sees no legal constraints in granting the parties' request to open the hearings to the public. Norway also agrees to having the third party session of the hearing open to the public.[337]

7.35 The **Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu** (Chinese Taipei) argues that, in accordance with the procedures and customary practices developed over more than half a century under GATT, which are reflected in Articles 14.1, 18.2 and Appendix 3 of the DSU, panel proceedings are to be kept confidential. It argues that only Members by consensus can change the rules of confidentiality. According to Chinese Taipei, a panel, even with the consent of the parties does not have the legal authority to open the proceedings to the public.[338]

7.36 Chinese Taipei refers to Article VII of the Rules of Conduct which requires that each covered person shall at all times maintain the confidentiality of the dispute settlement deliberations and proceedings. According to it, the only exception to this confidentiality obligation is Article 18.2 of the DSU. Chinese Taipei is therefore of the opinion that this exception does not extend to the possibility of allowing parties to decide whether to open panel meetings to the public.[339]

7.37 According Chinese Taipei, "panel deliberations" implies more than one form of deliberation, thus including not only internal consideration among panelists, but also the entire process of the panel's consideration of the dispute.[340]

7.38 Chinese Taipei argues that the flexibility arising from Article 12.1 of the DSU to change working procedures in Appendix 3 cannot be extended to cover provisions in the working procedures that directly elaborate on the obligations of the DSU. It further argues that if the drafters had contemplated that the confidentiality requirement could be changed, they would have said so, just like in Article 18.2 of the DSU. In the absence of such language, only an amendment to the DSU by the Members through negotiations can change the requirement of confidential deliberations.[341]

7.39 Chinese Taipei is of the opinion that the third-party sessions should be held in closed session.[342]

(d) Decision of the Panel

7.40 On 1 August 2005, the Panel decided to accept the parties' joint request to open the Panel hearings for public observation. The Panel also decided that the meetings at which the parties are invited to appear, as referred to in paragraph 2 of Appendix 3 to the DSU, would be open for observation by the public through a closed-circuit broadcast, keeping in mind the Panel's obligation to ensure that its Working Procedures are objective, impartial and non-discriminatory, and after careful consideration of the existing provisions of the DSU and its Appendix 3. In addition, since not all third parties had agreed that their session with the Panel be open for observation by the public, the Panel decided that that session would remain closed. As provided in paragraph 3 of the Panel's Working

[336] Replies by New Zealand to Panel questions concerning open hearings, questions 1 and 2.
[337] Replies by Norway to Panel questions concerning open hearings, questions 1 and 2.
[338] Replies by Chinese Taipei to Panel questions concerning open hearing, question 1, paras. 1 and 2.
[339] Replies by Chinese Taipei to Panel questions concerning open hearing, question 1, paras. 4 and 5.
[340] Replies by Chinese Taipei to Panel questions concerning open hearing, question 1, para. 3.
[341] Replies by Chinese Taipei to Panel questions concerning open hearing, question 1, paras. 6 and 7.
[342] Replies by Chinese Taipei to Panel questions concerning open hearing, question 2, para. 12.

Procedures[343], the parties retain the right to request at any time, including during panel meetings at which they are invited to appear, that their specific statements not be broadcast so as to remain confidential. The Panel also reserved its right to decide on its own to suspend broadcasting at any time, including during such meetings.[344] The Panel sent its revised Working Procedures and timetable to the parties and third parties on 1 August 2005.

7.41 The Chairman of the Panel also sent letters to the Chairman of the DSB[345] and the Director-General of the WTO[346], informing them of the Panel decision on this matter and requesting the assistance of the WTO Secretariat in making appropriate logistical arrangements for the open hearings.

7.42 After the Panel decided to consult scientific experts[347], the opinion of the parties was sought on whether they wished that any meeting with the parties and the scientific experts also be open for public observation. The parties replied affirmatively.

7.43 Since this was the first time in GATT/WTO history that a panel has held hearings open for public observation, the Panel deems it appropriate to elaborate further on the reasons why it agreed to open its substantive meetings for public observation.

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[343] The Panel's working procedures are contained in Annex A-2 to this Report.

[344] The letter of the Panel to the Parties of 1 August 2005 is reproduced in Annex A-1 to this Report.

[345] See WT/DS320/8, 2 August 2005.

[346] Letter of the Chairman of the Panel to the Director-General of the WTO of 2 August 2005. The letter reads as follows:

> "On behalf of the Panels in the two cases referred to above, I would like to request your assistance concerning the implementation of a procedural decision taken by the Panels.
>
> Following a common request made by the parties on 13 June 2005, we have decided that the panel meetings to which the parties are invited to appear will be open for observation by the public through a closed-circuit TV broadcast. We informed the parties of our decision on 1 August 2005. The session with the third parties will remain closed as not all the third parties have agreed to have it open for observation by the public. The third parties were advised of our decision on 1 August 2005. Finally, the Chairman of the DSB has also been advised of our decision, with a request that he informs the entire DSB membership of the possibility to observe the hearings.
>
> The Panels appreciate the assistance of the Secretariat on these cases to date and would like to request continued Secretariat assistance with respect to the logistical arrangements needed to implement our decision. In this regard, we would like to ensure transparency and non-discriminatory access by all, in particular by all WTO Members, to the closed-circuit TV broadcast. For that purpose, we would request the Secretariat to guarantee that each WTO Member delegation has <u>at least</u> two seats available in the room where the closed-circuit broadcast will be shown. We would also ask the Secretariat through its website to make all Members and the public aware that they are allowed to attend the closed-circuit broadcast and to provide details on pre-registration and seating arrangements.
>
> We have scheduled the first substantive meeting of the Panels with the parties for 12-15 September 2005 and understand that this meeting could take place in Room W with a closed-circuit TV broadcast of the meeting in the General Council Room.
>
> I would greatly appreciate your assistance in ensuring that the logistical arrangements to which I have referred in this letter can be finalized by the Secretariat."

[347] See Section VII.A.2 below.

7.44 The Panel first wishes to recall that it acted at the joint request of the parties. Some third parties, however, objected to the holding of a hearing that would be observable by the public. As a result, the hearing with third parties was not opened to public observation.

7.45 The Panel considers that the DSU does not expressly contemplate the possibility for meetings of panels to be open for public observation. On the contrary, Paragraph 2 of Appendix 3 to the DSU provides that "the panel shall meet in closed session" and that "The parties to the dispute, and interested parties, shall be present at the meeting only when invited by the panel to appear before it." The Panel understands this to mean that it shall always meet *in camera*, whether or not the parties and/or interested parties have been invited to appear before it. No reference is made in that provision to other Members or to the general public.

7.46 However, Article 12.1 of the DSU provides that "[p]anels shall follow the Working Procedures in Appendix 3 unless the panel decides otherwise after consulting the parties to the dispute." In other words, the Panel has the possibility to depart from any provision of Appendix 3, its only obligation being to consult the parties to the dispute first.

7.47 This discretion, however, applies only to the provisions of the Working Procedures in Appendix 3, not to any other provision of the DSU. The Panel thus is of the view that Article 12.1 entitles it to proceed with any adaptation of the working procedures contained in Appendix 3, as long as such an adaptation is not expressly prohibited by any provision of the DSU. Therefore, we need to examine whether there is any DSU provision that would explicitly prohibit the opening of panel meetings to public observation.

7.48 The Panel notes in this respect the confidentiality requirements contained in Articles 14.1, 18.2 and Appendix 3, paragraph 3 to the DSU. It also recalls the obligations of its members pursuant to the Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes.[348]

7.49 Regarding the requirement in Article 14.1 of the DSU that "[p]anel deliberations shall be confidential", the Panel first notes that one of the ordinary meanings of the word "deliberations" is "careful consideration, weighing up with a view to decision". The term "deliberations" also applies to "[c]onsideration and discussion of a question by a legislative assembly, a committee, etc.; debate".[349] However, the Panel is not of the view that a panel hearing is similar to a consideration by a legislative body or a committee. Even though exchanges of points of view take place in both instances, the nature of the exchange of arguments by parties to a dispute before an adjudicating body remains different from that of an assembly or a committee. This suggests that the term "deliberation" was not intended to cover the exchange of arguments between the parties, but rather the internal discussion of the Panel with a view to reach its conclusions. We note that our interpretation of the term "deliberation" conforms to the use of that term in the statutes of other international judicial bodies.[350]

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[348] WT/DSB/RC/1, 11 December 1996.

[349] *The New Shorter Oxford English Dictionary* (4th ed., 1993), p. 624.

[350] Article 46 of the Statute of International Court of Justice provides that "[t]he hearing in Court shall be public, unless the Court decides otherwise, or unless the parties demand that the public be not admitted". Article 54.3 of the Statute provides that "[t]he deliberations of the Court shall take place in private and remain secret ...". Article 26 of the Statute of the International Tribunal for the Law of the Sea provides that" [t]he hearing shall be public, unless the Tribunal decides otherwise, or unless the parties demand that the public be not admitted". Article 42 of the Rules of the Tribunal provides that "[t]he deliberations of the Tribunal shall take place in private and remain secret ..." Article 20 of the Statute of the International Criminal Tribunal for Former Yugoslavia provides that "[t]he hearing in Court shall be public, unless the Trial Chamber decides to close the proceedings in accordance with its rules of procedure and evidence". Rule 78 of its Rules of Procedure and Evidence provides: "[a]ll proceedings before a Trial Chamber, other than deliberations of the Chamber,

It is also confirmed by the context of Article 14.1. Article 14 deals with confidentiality in the work of panels *stricto sensu* (deliberations, drafting of the panel report, opinions of panelists), whereas the provisions dealing with the conduct of the proceedings with the parties are contained in Article 12. The Panel therefore concludes that Article 14.1 of the DSU does not apply to panel hearings and that opening the Panel's substantive meetings with the parties to public observation does not breach that provision.

7.50 Regarding the requirement contained in Article 18.2 of the DSU that "[w]ritten submissions to the panel ... shall be treated as confidential", we note that, by opening its hearings to public observation, the Panel did not disclose to the public the content of the parties' written submissions. By making statements to which the public could listen, the parties themselves exercised their right under Article 18.2 to "disclos[e] statements of [their] own positions to the public". The Panel is mindful that, by asking questions or seeking clarifications during the hearings with respect to written submissions of the parties, it may have itself "disclosed" the content of such submissions. However, the Panel notes that at all times the parties retained the right to request that specific statements of theirs not be broadcasted so as to remain confidential and that, in this case, the parties had made their written submissions public. The Panel notes also that Article 18.2 provides that "Members shall treat as confidential information submitted by another Member to the Panel or the Appellate Body *which that Member has designated as confidential*."[351] We consider that this sentence clarifies the scope of the confidentiality requirement which applies to the Panel and to Members, and that panels have to keep confidential only the information that has been designated as confidential or which has otherwise not been disclosed to the public. Any other interpretation would imply a double standard, whereby panels would have to treat as confidential information which a WTO Member does not have to treat as confidential. The Panel also notes that, by requesting that the Panel hold hearings open to public observation, the parties to this dispute have implicitly accepted that their arguments be public, with the exception of those they would identify as confidential.

7.51 Finally, the Panel notes that Article VII of the Rules of Conduct for the Understanding on the Rules and Procedures Governing the Settlement of Disputes provides that "[e]ach covered person shall at all times maintain the confidentiality of dispute settlement deliberations and proceedings together with any information identified by a party as confidential." The Panel notes that such confidentiality obligation on the covered persons during the panel proceedings is applicable to the extent not inconsistent with the DSU provisions.[352] In this case, the parties waived their right to confidentiality and requested open hearings. As demonstrated above, the Panel accordingly adapted its working procedures by departing from Appendix 3 in a manner consistent with the DSU provisions. Therefore, the Rules of Conduct should not be construed in a manner that would restrict the rights of Members under the DSU. The Panel concludes that Article VII does not prevent the Panel from holding hearings open to observation by the public.

7.52 The Panel is mindful that the issue of transparency of panel and Appellate Body proceedings is currently under review as part of the negotiations on improvements and clarifications of the DSU. However, the Panel recalls that the dispute settlement system of the WTO serves to preserve the rights and obligations of Members under the covered agreements, which include the DSU, and to clarify the

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shall be held in public, unless otherwise provided." Rule 29 provides that "[t]he deliberations of the Chambers shall take place in private and remain secret."

[351] Emphasis added.

[352] See Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes (WT/DSB/RC/1), Article II.1:

> "These Rules shall in no way modify the rights and obligations of Members under the DSU nor the rules and procedures therein."

existing provisions of those agreements in accordance with customary rules of interpretation of public international law. The Panel considers that its role is not to address transparency in general terms, but to determine whether the DSU as it currently stands permits that, under the circumstances of this particular case, the Panel hearing be open to public observation. When called upon to decide on whether to open hearings to public observation, the Panel concluded that this was the case. However, this finding is limited to this particular case and is without prejudice to any approach to the issue of transparency that the Members may negotiate.

7.53 For the reasons set out in the previous paragraphs, the Panel considers that it is entitled, under the particular circumstances of this case and pursuant to Article 12.1 of the DSU, to open its hearings for public observation. This is why the Panel decided to accept the parties' request to open its meetings with the parties for public observation. The third-party session was, however, not open to public observation, due to the absence of consensus among the third parties on this matter.[353]

7.54 The first substantive hearing with the parties was held on 12, 13 and 15 September 2005. The hearing with third parties took place on 14 September 2005. The hearing with the scientific experts was held on 27-28 September 2006. The second substantive meeting with the parties was held on 2 and 3 October 2006.

2. Panel's decisions relating to the consultation of individual scientific experts and international organizations

(a) Decision to consult scientific experts

7.55 During its first substantive meeting, the **Panel** requested the parties' views as to whether there was a need to consult scientific experts should the Panel deem it necessary to examine the consistency of the EC implementing measure with the *SPS Agreement* as part of its review of this case.[354]

7.56 The **European Communities** replied that it did not believe that it was necessary for this Panel to look into these scientific issues to make findings and rulings within its terms of reference. However, the Panel did not have the expertise to decide on such issues itself, should the Panel decide to review the scientific issues at stake. In such a scenario, the consultation of scientific and technical experts would be absolutely necessary. However, the European Communities considered that this Panel could not consult the experts that were used in the original *EC – Hormones* case. New experts would have to be chosen.[355]

7.57 The **United States** considered that, in view of the clarity of the scientific issues in this dispute, there was technically no need to consult experts in this proceeding. However, the Panel, in a scientific dispute such as this, had discretion to consult with experts on the scientific evidence in developing its analysis and making its findings. This said, a panel could not delegate to experts the panel's central task of interpreting the covered agreements cited in a dispute. Experts may advise only on factual issues, not on the application of the legal standards in the covered agreements to the facts at hand.

7.58 On whether the Panel should consult with the scientific experts from the original *EC – Hormones* proceedings, the United States noted that the process by which the original experts were selected differed from that which had evolved over the course of subsequent disputes and that experts

[353] See WT/DS320/8.
[354] Question 74 of Panel questions after the first substantive meeting.
[355] EC's reply to Panel questions after the first substantive meeting, question 74, Annex B-1.

should be selected pursuant to current practice, which would mean that the three experts selected by the original panel should be consulted.[356]

7.59 After having considered the parties' replies, the **Panel** noted that, from the parties' replies to its questions, it appeared that no party disagreed that, should the Panel proceed with an assessment of the measure taken by the European Communities to comply with the recommendations and rulings of the DSB in the *EC – Hormones* case, advice from technical or scientific experts would be necessary.

7.60 The Panel noted the views expressed by the European Communities regarding the nature of this case and the order in which its claims should be reviewed by the Panel, but it was of the opinion that, at that stage, it was in its interest, as well as in the interest of the parties, to be fully informed of all relevant aspects of the dispute. The Panel thus decided to initiate a process for consultation with experts in relation to the technical or scientific aspects of the compatibility of the EC implementing measure with the relevant provisions of the *SPS Agreement*, without prejudice to the positions held by any party in this respect and without prejudice to the conclusions that the Panel would ultimately reach on the claims raised by the European Communities. The Panel informed the parties accordingly in a letter dated 20 October 2005.[357]

7.61 The Panel does not deem it necessary to add to its reasoning on this issue except to recall that, as specified by the Appellate Body in *US – Shrimp*:

> "... the DSU accords to a panel established by the DSB, and engaged in a dispute settlement proceeding, ample and extensive authority to undertake and to control the process by which it informs itself ... of the relevant facts of the dispute ... That authority, and the breadth thereof, is indispensably necessary to enable a panel to discharge its duty imposed by Article 11 of the DSU to 'make an objective assessment of the matter before it, including an *objective assessment of the facts of the case*.'"[358]

7.62 In this particular case, as explained further in the subsequent sections of this report and in spite of the approach of the European Communities focusing on the breach of certain provisions of the DSU by the defending party, the Panel deemed it important to consult experts in order to "make an objective assessment of the matter before it, including an objective assessment of the facts of the case." In addition, Article 11.2 of the *SPS Agreement* "explicitly instructs"[359] panels to seek expert advice in disputes under the *SPS Agreement* involving scientific and technical issues:

> "In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute."[360]

7.63 The Panel is mindful that this case is not exactly a dispute "under [the SPS] Agreement" since its terms of reference do not refer to the *SPS Agreement*. We nonetheless consider that, since we may have to determine whether the European Communities has complied with its obligations under the *SPS Agreement* if we need to determine whether Article 22.8 of the DSU has been breached, this dispute is, at least indirectly, "under [the SPS] Agreement".

7.64 We therefore conclude that our decision to consult scientific experts is consistent with the requirements of the DSU and the *SPS Agreement*.

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[356] US's reply to Panel questions after the first substantive meeting, question 74, Annex B-3.
[357] Annex A-3 to this Report.
[358] Appellate Body Report on *US – Shrimp*, para. 106 (emphasis original).
[359] See Appellate Body Report on *Japan – Agricultural Products II*, paras. 127-128.
[360] Article 11.2 of the *SPS Agreement*, emphasis added.

(b) EC request for a single expert review group

7.65 Once it decided to consult scientific experts, the **Panel** sought comments from the parties on the proposed Working Procedures for Consultation with Scientific and/or Technical Experts, the technical or scientific aspects on which the Panel should consult experts and on whether the meeting with the experts and parties should be open for observation by the public.

7.66 In a letter dated 3 November 2005, commenting on the draft working procedures for the consultation of experts, the **European Communities** requested that a single expert review group be called upon to assist the Panel, arguing that it was important that the Panel receive consistent advice on the issues and that it would reduce the risk of the Panel having to review and decide between competing scientific views among the experts.

7.67 The **United States** objected to the request of the European Communities in a letter of 8 November 2005, noting that in every sanitary and phytosanitary dispute to date in which experts had been consulted, including the original *EC – Hormones* proceeding, they had been consulted on an individual basis. This method for consultations had proven effective, and there was no reason to depart from this practice in these proceedings.

7.68 The United States was also concerned by the implication of the consultation of the experts as a group instead of on an individual basis. The requirement that a response be coordinated within the group of experts could lead to substantial delays and potentially limit the Panel's ability to hear and weigh the spectrum of opinions as they relate to the hormones at issue in this dispute. Also, given the spectrum of areas of expertise at issue, there would not seem to be much value to a "group" report since each expert was going to be consulted on different areas.[361]

7.69 The **European Communities** commented that its request was based on a desire to ensure the legitimacy of the Panel's findings by providing for a systematic, coherent and non-polarizing approach to complex scientific issues. Conversely, if experts acted as individuals, the Panel ran the risk of having to review and decide between competing scientific views amongst the Panel's experts as well as the experts advising the parties. This would normally be very difficult, if not impossible, to do in a way that would ensure transparency, excellence and credibility in this contested area of scientific research.

7.70 The European Communities also drew the Panel's attention to Article 13.2 and Appendix 4 of the DSU, Article 11.2 of the *SPS Agreement* and Article 14.2 and Annex 2 of the *TBT Agreement* which, most probably for the reasons just mentioned above, all refer to the possibility to establish *expert review groups*. The European Communities did not see any reason to deviate from this normal procedure which the drafters of the WTO Agreements clearly preferred.[362]

7.71 The **Panel** reached its final decision on the working procedures for consultations with scientific and/or technical experts on 25 November 2005.[363] Regarding the form the consultation of the experts should take, the Panel was not persuaded that the EC suggestion to consult an expert review group was the preferable option. Firstly, the fields of competence proposed by the parties were quite varied, rendering it difficult to find individual experts with competence in most or all of these fields to serve in an expert review group. The fact that no expert would have a comprehensive knowledge of all the relevant subjects made it even more important for the Panel to seek advice from the experts on an individual basis on their respective fields of expertise. Secondly, the Panel wished

[361] US's letter to the Panel of 8 November 2005.
[362] EC's letter to the Panel of 11 November 2005.
[363] Annex A-5 to this Report. The Panel also decided that the meeting with the experts would be open for observation by the public in the same manner as the meeting with the parties.

to hear any dissenting or minority views among the experts rather than receiving a consensus text from an expert review group. The Panel did not consider that the risk that experts may have diverging opinions would generate difficulties as serious as those alleged by the European Communities. The Panel rather saw the risk that an expert review group would only agree on a minimum common position, thus depriving the Panel of a full picture of the problems. It was also worth noting that so far, all WTO panels had preferred to consult scientific and/or technical experts on an individual basis.

7.72 The Panel does not deem it necessary to add to the reasons mentioned above, except to clarify that, in its view, none of the provisions cited by the European Communities sets a preference for expert review groups. On the contrary, the consultation of expert review groups is mentioned only as one option, both in Article 13.2 of the DSU and in Article 11.2 of the *SPS Agreement* and the terms of those provisions suggest that panels enjoy wide discretion in deciding to seek or not the assistance of an expert review group rather than that of individual experts. Indeed, Article 13.2 of the DSU provides that:

> "Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group."[364]

7.73 Article 11.2, second sentence, of the *SPS Agreement* provides that:

> "To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative."[365]

7.74 We read these provisions as leaving a wide margin of discretion to the Panel. We find confirmation of this reading in the Appellate Body Report on *EC – Hormones*, where the Appellate Body recalled that:

> "Both Article 11.2 of the *SPS Agreement* and Article 13 of the DSU enable panels to seek information and advice as they deem appropriate in a particular case ...
>
> We find that in disputes involving scientific or technical issues, neither Article 11.2 of the *SPS Agreement*, nor Article 13 of the DSU prevents panels from consulting with individual experts. Rather, both the *SPS Agreement* and the DSU leave to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate."[366]

7.75 We therefore conclude that our decision complies with the DSU, the *SPS Agreement* and the practice of the Appellate Body.

(c) Experts selection process

7.76 One single expert selection process was carried out for the two cases WT/DS320 and WT/DS321.[367]

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[364] Emphasis added.

[365] Emphasis added. *A contrario*, Article 14.2 of the *TBT Agreement* cited by the European Communities expressly limits the choice of the panel to a technical expert group.

[366] Appellate Body Report on *EC – Hormones*, para. 147.

[367] In this section, the term "Panel" refers to the Panel in case WT/DS320 and the Panel in case WT/DS321. The same individuals served as panelists in the two cases.

7.77 After receiving input from the parties, the Panel, in its letter of 20 January 2006[368], identified the need for expert advice in seven fields, namely:

(a) risk analysis, in particular, the conduct of a risk assessment as it relates to food safety;

(b) animal science, including good veterinary practices in relation to the administration of the six hormones[369] to cattle through implants or other means;

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[368] Letter from the Panel to the parties of 20 January 2006.
[369] The six hormones can be defined as follows:

Oestradiol-17β

Oestradiol-17β is the most potent mammalian oestrogenic sex hormone, responsible for female characteristics. It is a member of a class of compounds called steroids. In females, it functions in the ovarian cycle and maintains uterine health; in males it inhibits the synthesis of testosterone. It is produced primarily by the ovaries and the placenta. In cattle, it is administered either alone or in combination with testosterone, progesterone and trenbolone by a subcutaneous implant to the base of the ear to improve body weight and feed conversion in cattle. The ear is discarded at slaughter. (Replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 1; 7-8; 17)

Progesterone

Progesterone is the major mammalian progestational hormone, responsible for maintaining pregnancy. It is a steroid and is secreted primarily by the corpus luteum in the ovary of adult females and in the placenta. Progesterone is used as a contraceptive and to correct abnormalities in the menstrual cycle. In cattle, it is administered to steer, usually in combination with oestradiol-17β or oestradiol benzoate by a subcutaneous implant to the base of the ear to improve body weight and feed conversion in cattle. The ear is discarded at slaughter. (Replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 2; 9-10; 18)

Testosterone

Testosterone is a mammalian androgenic hormone, responsible for male characteristics. It is a steroid and is produced primarily in the testes of adult males. In cattle, testosterone is administered in combination with oestradiol -17β or oestradiol benzoate by a subcutaneous implant to the base of the ear to improve body weight and feed conversion in cattle. The ear is discarded at slaughter. (Replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 3; 11; 19)

Trenbolone acetate

Trenbolone acetate is a synthetic steroid with anabolic (growth-stimulating) properties several fold above that of testosterone. In cattle, it is administered alone or in combination with oestradiol-17β by a subcutaneous implant to the base of the ear to improve body weight and feed conversion in cattle. The ear is discarded at slaughter. (Replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 5; 12; 20).

Zeranol

Zeranol is an oestrogenic substance produced by certain fungal, or mold, species. It is a non-steroidal anabolic (growth-stimulating) agent and has been used for the management of menopausal and menstrual disorders. Zeranol is administered to cattle either alone, or in combination with trenbolone acetate by a subcutaneous implant to the base of the ear to

(c) toxicology, including genotoxicity[370], and carcinogenicity[371] risks arising from the six hormones in meat;

(d) inspection, sampling and testing methods, particularly in relation to residue analysis and characterization with respect to the six hormones;

(e) human endocrinology[372], including endogenous[373] production of hormones by humans, in particular prepubertal children;

(f) dietary intake studies and epidemiology[374] linked to meat consumption;

(g) physiology, in particular related to the possible effects of the six hormones when consumed in meat on the immune and nervous systems, and growth and reproduction.

7.78 As stipulated in the Working Procedures for Consultations with Scientific and/or Technical Experts adopted by the Panel on 25 November 2005 after consultation with the parties[375], the Panel sought information not only from selected experts but also from three relevant international entities, the Codex Alimentarius Commission (Codex)[376], the Joint FAO/WHO Expert Committee on Food

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improve body weight and feed conversion in cattle. The ear is discarded at slaughter (replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 6; 13-14; 21). Although zeranol occurs naturally, it is sometimes referred to as one of the synthetic hormones, together with trenbolone and melengestrol acetate.

Melengestrol acetate

Melengestrol acetate (MGA) is an orally active synthetic progestogen about 30 times as active as progesterone. It is fed to female cattle to improve body weight and feed conversion (replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel Question 1 to the experts. Annex D, paras. 4; 15-16; 22).

[370] Ability to cause damage to genetic material (DNA). Such damage may be mutagenic and/or carcinogenic (Replies of Dr. Boobis and Dr. Guttenplan to Panel question 2 to the experts. Annex D, paras. 41 and 58. See also Transcript of the Panel meeting with the experts, Annex G, paras. 85-90).

[371] Process of induction of malignant neoplasms (cancer) by chemical, physical or biological agents (Replies of Dr. Boobis and Dr. Guttenplan to Panel question 2 to the experts. Annex D, paras. 44 and 60).

[372] *Endocrinology:* "A subspecialty of internal medicine concerned with the metabolism, physiology, and disorders of the endocrine system." (Webster Online Dictionary) The *endocrine system* is defined by the same dictionary as "The system of glands that release their secretions (hormones) directly into the circulatory system. In addition to the endocrine glands, included are the chromaffin system and the neurosecretory systems."

[373] *Endogenous:* "Produced inside an organism or cell. The opposite is external (exogenous) production." (Webster's Online Dictionary)

[374] "A branch of medical science that deals with the incidence, distribution, and control of disease in a population; the sum of the factors controlling the presence or absence of a disease or pathogen" (Merriam-Webster Online Dictionary (http://www.m-w.com/dictionary/epidemiology)).

[375] Annex A-4, letter from the Panel to parties on 25 November 2005, Annex A-5, Working Procedures for Consultations with Scientific and/or Technical Experts.

[376] The Codex Alimentarius Commission was established by FAO and WHO, under the Joint FAO/WHO Food Standards Programme, to develop international food standards, guidelines and other recommendations such as codes of practice; its First Session met in 1963. The main purposes of this Programme are protecting health of the consumers, ensuring fair trade practices in food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Codex Alimentarius Commission is one of the three international standard-setting organizations referenced in the *SPS Agreement* (reference: Codex Alimentarius website – www.codexalimentarius.net). Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice

Additives (JECFA)[377], and the International Agency for Research on Cancer (IARC).[378] While the questions to experts focused on the seven areas identified, the questions to the above-mentioned entities focused on institutional and procedural issues as well as definitions relevant to the case.

7.79 Pursuant to the Working Procedures the Panel, on 29 November 2005, requested the Secretariats of the Codex Alimentarius Commission, JECFA and the IARC to recommend names of candidate experts in the relevant fields. The Panel contacted the 22 experts suggested by those international entities and requested that those experts interested and available to provide advice to the Panel submit their curriculum vitae, including publication lists, and disclose potential conflicts of interests. Eleven experts were interested and available. The Panel provided all the information received from the experts to the European Communities, the United States and Canada, requesting them to indicate any compelling reasons why particular experts should not be chosen to provide advice to the Panel in this dispute. The parties provided their comments on the proposed experts on 16 January 2006. The United States provided comments on one issue in the EC comments on 19 January 2006, i.e. the exclusion of experts who had participated in JECFA's risk assessment work. The European Communities responded to the US comments on 30 January 2006.

7.80 Because the parties' positions with respect to the candidate experts differed significantly, on 20 January 2006, the Panel requested the parties to suggest further names of candidate experts, in application of paragraph 6 of the Working Procedures.

7.81 On 31 January 2006, the Secretary to the Panel sent letters to 49 additional experts suggested by the parties. The Panel Secretary requested that experts interested and available to provide advice to the Panel submit their curriculum vitae including a list of publications and a disclosure of any potential conflicts of interests.

7.82 Of the 71 experts suggested by the international organizations and the parties to the two disputes, 40 experts indicated that they were available and 35 responded to the request for curriculum vitae and information regarding potential conflicts of interests.

7.83 The information provided by the experts was sent to the parties. The parties were once again given the opportunity to comment on each expert and to provide any compelling reasons why particular experts should not be chosen to provide advice to the Panel in these disputes.

7.84 The parties provided their comments on the second set of experts names on 22 February 2006. The European Communities replied to comments from the United States and Canada on certain experts proposed by the European Communities in an additional letter to the Panel of

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on risk management lies with the Commission and its subsidiary bodies while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations.

[377] The Joint FAO/WHO Expert Committee on Food Additives (JECFA), which has been meeting since 1956, is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Its work includes the evaluation of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food. JECFA serves as an independent scientific committee which performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations. The requests for scientific advice are in general channelled through the Codex Alimentarius Commission (Codex). Some countries use information from JECFA in the establishment of national food safety control programmes and Codex adopts standards based on evaluations by JECFA (reference: *Fact Sheet – What is JECFA? See* Annex 1 attached to Annex E-2).

[378] The International Agency for Research on Cancer (IARC), established in 1965, is part of the World Heath Organization. IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships (reference: IARC website – www.iarc.fr).

27 February 2006. The United States and Canada commented on the EC letter of 27 February on 1 and 2 March respectively. One party or another submitted objections with regard to all but one of the experts by arguing either that an expert lacked sufficient expertise in the areas of the dispute identified as needing scientific or technical expertise, or was affiliated with the government of a party to this dispute; or was affiliated with JECFA; or had received funding from the pharmaceutical industry; or had been involved in the regulatory approval of any of the six hormones.

7.85 On 24 March 2006, the Panel informed the parties of the names of the experts that it had selected. The Panel wishes to recall that, in the selection process, it amply consulted the parties and selected the experts in accordance with procedures previously determined by the Panel in consultation with the parties.[379] The Panel excluded experts with close links with governmental authorities directly involved in policy-making regarding the six hormones and experts with close links to pharmaceutical companies or involved in public advocacy activities. The Panel chose not to exclude *a priori* experts who had participated in the preparation and drafting of JECFA's risk assessments because this would deprive the Panel and the parties of the benefit of the contribution of internationally recognized specialists[380] and because the Panel was of the opinion that experts familiar with the JECFA reports would be well-placed to assist the Panel in understanding the work of JECFA extensively referred to by the parties in their submissions, in particular by the European Communities. Moreover, the Panel, who was fully aware of the fields of competence of these experts, considered that they would be competent to answer questions with respect to risk assessment regarding the hormones at issue. The Panel also decided not to exclude *a priori* all experts who were current or past governmental employees unless a potential conflict of interests could reasonably be assumed from their official functions. In selecting the experts, the Panel also had in mind the need to choose experts with expertise to cover all the fields identified as at issue in the dispute.

7.86 The experts selected by the Panel were:

> Dr. Jacques Boisseau, Former Director, French Agency for Veterinary Medicinal Products;
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> Dr. Alan R. Boobis, Director, Experimental Medicine & Toxicology Division of Medicine, Faculty of Medicine, Imperial College London (also Professor of Biochemical Pharmacology at Imperial College London);
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> Dr. Hubert De Brabander, Professor and Head of Faculty of Veterinary Medicine, Department of Veterinary Public Health & Food Safety, University of Ghent, Belgium;
>
> Dr. Ronald L. Melnick, US National Institute of Environmental Health Sciences;
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> Dr. Wolfgang G. Sippell, Deputy Director, Department of Pediatrics, University of Kiel; Head of the Division of Pediatric Endocrinology & Diabetology, Children's Hospital, Christian-Albrechts-University of Kiel, Germany;
>
> Dr. Kurt Straif, Scientist, Unit of Carcinogenic Identification and Evaluation, International Agency for Research on Cancer, Lyon, France.

7.87 On 28 March 2006, the European Communities requested that the Panel reconsider its choice of two of the experts, reiterating concerns already discussed above by the Panel and arguing that these experts had real or perceived conflicts of interests that should disqualify them from assisting the Panel. The Panel carefully considered the European Communities' request, including the information

[379] Appellate Body Report on *EC – Hormones*, para. 148.

[380] See Annex E-2, JECFA's replies to Panel question 14, regarding the selection process of experts involved in JECFA's work.

given regarding potential conflicts of interests. The Panel found in particular that the statement that one expert had made before the French Senate in 1996 had not been made in relation to hormones used for growth promotion purposes. Rather, it had been made with respect to hormones used for medical treatment purposes. The Panel also found that the links of another expert with two companies involved in research and counselling were not in the area of veterinary drugs or hormonal substances. The Panel concluded that the EC objections regarding those two experts were not justified. Therefore, on 31 March 2006, the Panel gave notice to the parties that it had found no reason to change its decision concerning the selection of experts.[381] In addition, having considered the information available about the various candidates, the Panel found that these two experts were the best choices among the very few individuals available with expertise in the area of risk assessment and would be able to provide the Panel with insight on international standards on the hormones at issue.[382]

7.88 On 12 April 2006, the Panel gave notice to the parties that Dr. Melnick and Dr. Straif were no longer available to assist the Panel and that the Panel had chosen to replace these experts with:

> Dr. Vincent Cogliano, Head of Programme, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer, Lyon, France; and
>
> Dr. Joseph Guttenplan, Professor, Department of Basic Science, New York University Dental Center; Research Associate Professor, Department of Environmental Medicine, New York University Medical Center.

7.89 In choosing experts to replace Dr. Melnick and Dr. Straif, the Panel was especially mindful of the need to replace these experts with others who could cover the same fields of expertise. Of the final six experts selected, three were amongst those originally suggested by the European Communities and three were suggested by the international organizations consulted by the Panel.

7.90 The United States submitted an objection, on 19 April 2006, to the Panel's selection of an expert originally recommended by the European Communities to replace one of the unavailable experts.

7.91 The United States, in a letter dated 20 April 2006, also requested that the Panel amend its list of experts to include an expert with relevant experience in animal science, including good veterinary practices as they relate to the administration of the six hormones to cattle. In a letter dated 10 May 2006, the European Communities objected to the request for an animal science expert made by Canada and the United States, stating that all relevant questions could already be answered by the six experts.

7.92 In light of the experts' replies as to which questions they would not be in a position to answer, and in light of the parties' comments, the Panel decided that it would first consider the written replies from the experts to the questions and then would determine if it was necessary to seek advice from additional experts. The Panel decided not to amend the list of selected expert unless there was a real need in the future and communicated its decision to the parties in a letter dated 10 May 2006.

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[381] Letter dated 31 March 2006 from the Panel to parties.

[382] The Panel wishes to highlight the challenges it encountered in selecting experts There was a limited number of specialists suggested and actually available in each of the fields on which the Panel needed assistance and almost always one or more of the parties objected to that specialist. For example, only six of the identified available experts were deemed to have extensive expertise in risk analysis. All of these experts were objected to by at least one party.

7.93 Because the Panel had requested Dr. De Brabander and Dr. Boisseau to answer the questions on good veterinary practices to the extent that they could, and because all questions were ultimately answered by at least one of the selected experts, the Panel did not find a need to consult additional experts.

7.94 In accordance with the Working Procedures for Consultations with Scientific and/or Technical Experts adopted by the Panel in consultation with the parties, the experts were requested to act in their individual capacities and not as representatives of any entity.

7.95 On 24 February 2006, the Panel sent to the parties the draft questions to scientific experts and international organizations for comments. The parties provided the Panel with their comments on 15 March 2006. After considering the parties' comments and after revising the draft questions as necessary, the Panel sent its 62 written questions to the individual scientific experts and its 26 written questions to the three international organizations (namely Codex, JECFA and IARC) on 13 April 2006, together with the parties' submissions and accompanying exhibits.

7.96 The Panel requested that the experts and the international entitities provide their written replies to the scientific and technical questions by 12 June 2006.[383]

7.97 The Panel, after receiving replies from experts and Codex, JECFA, and IARC, forwarded these replies to the parties on 14 June for their comments. The parties provided their comments on these replies on 30 June 2006.[384] Afterwards, parties were given a further opportunity to comment on each other's comments on experts' replies and replies from international organizations. Parties provided these second rounds of comments on 12 July 2006.[385]

7.98 The Panel met with the six experts and four representatives from Codex, JECFA and IARC in the presence of the parties on 27-28 September 2006 in a meeting that was open for public observation through a closed-circuit television broadcast. In this meeting, Dr. Vincent Cogliano, Head of the IARC Monographs Programme, served both as an individual scientific expert and as the representative of the IARC. The other representatives were WHO JECFA Secretary Dr. Angelika Tritscher, FAO JECFA Secretary Dr. Annika Wennberg, and Codex Secretary Dr. Kazuaki Miyagishima. The meeting provided an opportunity for the parties and the Panel to ask questions to the experts and for the experts to clarify points that they had made in their written responses to the questions.[386] This meeting was followed by the Panel's joint second substantive meeting with the parties on 2-3 October 2006.

7.99 The Panel wishes to record its appreciation to the experts and the representatives of the international entities for their contributions. They were provided with large volumes of scientific materials and a limited timeframe to reply to a long set of questions. They were also requested to reply to extensive questions from the parties and the Panel during the two-day meeting in Geneva. They provided detailed and comprehensive responses. They provided the necessary scientific input to assist the Panel in understanding the issues raised by the parties and resolve the trade dispute before it. The clarity of their explanations and their professionalism were particularly appreciated by the Panel.

[383] A compilation of the written replies received from the scientific experts can be found in Annex D. The written replies from the Codex Alimentarius Commission, JECFA and IARC can be found in Annex E-1, Annex E-2, and Annex E-3, respectively.

[384] See Annexes F-1, F-2, and F-4.

[385] See Annexes F-3 and F-5.

[386] A copy of the transcript of the meeting (hereafter the "transcript") can be found in Annex G.

3. Other procedural issues

(a) Request by the European Communities that relevant scientific evidence and data be provided by the United States

7.100 In a letter dated 21 October 2005, the **European Communities** requested that the United States provide the scientific studies on the basis of which it conducted its risk assessments and approved the six hormones at issue for animal growth promotion so that the Panel, the experts and the European Communities could be given an opportunity to consider them.

7.101 The **United States** objected to this request arguing that a panel was not expected to make a *de novo* review of the safety of the hormones and draw its own scientific decisions on whether a Member should apply a measure. Nor was a panel called upon to conduct its own risk assessment. The US decision to allow the use of the six growth promoting hormones was not within the Panel's terms of reference. Rather, it was the EC import ban, and the purported risk assessments and studies allegedly underpinning that ban, which speak to whether or not the European Communities has complied with the DSB's recommendations and rulings in the *EC – Hormones* dispute.[387]

7.102 In a letter to the Panel dated 8 November 2005, the **European Communities** argued that the scientific basis of the EC measure at issue was being challenged with reference to assessments done by other bodies or institutions, including the defending party's own regulatory bodies. If the Panel and the experts were to assess objectively the relevance and sufficiency of the scientific information on which the European Communities relied in order to ban these substances, they would have to review also the underlying evidence on which JECFA and some WTO Members relied in order to conclude that the hormones at issue were safe. Due process required that the Panel request the defending party to submit its underlying scientific studies.

7.103 In addition, the European Communities requested that the Panel ask Codex to submit to the Panel the underlying scientific evidence and data that served as the basis of the JECFA's assessments, which were invoked by the defending party in these proceedings. In the view of the European Communities, the Panel was competent to request the information at issue both from the defending party and from Codex under Article 13 of the DSU.[388]

7.104 The **United States** replied to the EC comments in a letter of 9 November 2005, that it did not refer to its own risk assessment but to determinations of the relevant international standard setting bodies (Codex and JECFA) regarding the safety of the hormones at issue. At the same time, the United States agreed with the European Communities that an examination of JECFA's and Codex's conclusions regarding the hormones may be useful for an overall review of the EC characterization of its ban as a "provisional measure" for five of the hormones and of the EC purported risk assessment for the sixth hormone.

7.105 The **European Communities** replied to the comments by the United States and Canada in a letter to the Panel dated 11 November 2005. The European Communities observed that a substantial amount of data on which JECFA based its findings came from, and were available only with, the United States' and Canada's authorities since JECFA had to rely exclusively on data provided to it, *inter alia*, by its members and the relevant industry. Thus, in the case of the six hormones in question, JECFA, where it did not base itself on scientific evidence publicly available, examined and relied on evidence that was available only with the United States' and Canada's regulatory authorities. Most of these studies were old and had never been published in peer reviewed scientific journals.

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[387] US's letter to the Panel of 3 November 2005.
[388] EC's letter to the Panel of 8 November 2005.

7.106 The European Communities added that, because the Panel had decided to examine the scientific basis of the EC compliance measure, this examination had to be carried out in the light of the assessments on which the responding party explicitly based itself in order to question the European Communities' risk assessment and continue its unilateral suspension of concessions, i.e, its own risk assessments and those of Codex/JECFA.

7.107 On 17 November 2005, the **United States** commented on the EC arguments by mentioning that what was at issue in these proceedings was whether or not the European Communities had, through the studies it had chosen to rely upon and the Opinions it had put forward in support of its bans, based its measures on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement* or imposed a provisional ban within the meaning of Article 5.7 of the *SPS Agreement*. In carrying out its task to examine these issues, the question was whether what the European Communities had produced and put forward as evidence in support of its ongoing ban met the requirements of the *SPS Agreement*.

7.108 Furthermore, according to the United States, detailed summaries of the studies and materials relied upon by JECFA were available for each of the hormones at issue in this proceeding in the WHO Technical Report Series publications.[389]

7.109 The **European Communities** commented on 21 November 2005 that, because the Panel was to make an objective assessment of the matter before it, it would also have to evaluate the conclusions of JECFA. Since the European Communities and JECFA had come to differing conclusions, the question was whether they had done so on the basis of the same data. In particular, it was not enough to refer to the summaries in the Technical Report Series because they were too concise to allow such an assessment, and they referred to old and unpublished US data from the 1970s.

7.110 The **Panel** considered the parties' arguments in its letter to the parties on the finalized working procedures for consultation with scientific and /or technical experts:

> "With respect to the EC's request that the Panel ask the US and Canada to provide the studies underlying the risk assessments of the US, Canada (and JECFA), the Panel is not in a position to fully assess the necessity for this information at this stage. This said, the Panel notes that its task is not to conduct a comprehensive assessment of the safety of hormones in meat. Rather, should the Panel consider it necessary for the resolution of the present dispute, it would assess the compatibility of the EC's measure with the provisions of the *SPS Agreement*. Nevertheless, to the extent that this information becomes necessary for the Panel to make its determination in this case, the Panel cannot exclude that it may request part or all of the information referred to by the EC. More generally, the Panel expects the Parties' full collaboration in gathering the information necessary for an objective assessment of the matter before it. The Panel also recalls that it is for each party to submit sufficient evidence in support of its assertions."[390]

7.111 In addition, the Panel wishes to recall its comments above on its discretionary power to seek information or not pursuant to Article 13 of the DSU. The Panel also agrees with the parties that, while it has to make an objective assessment of the matter before it, including an objective assessment of the facts, it is not supposed to make a *de novo* review of factual information, including scientific evidence, regarding the six hormones at issue. Thus, the Panel considered primarily in this context the measure taken by the European Communities to comply with the recommendations and rulings of the DSB in the *EC – Hormones* dispute. Having regard to the allocation of the burden of proof, the

[389] US's letter to the Panel of 17 November 2005.
[390] Panel letter to the parties of 25 November 2005.

Panel deemed it appropriate to rely more particularly on the extensive amount of evidence submitted by the European Communities and the United States in their submissions. The Panel also took into account the opinions of the experts and the inputs from the international entities it consulted under Article 13 of the DSU. To the extent that the parties and the experts discussed the EC implementing measure in the context of the work of JECFA and Codex, the Panel believes that it was sufficiently informed to make an objective assessment of the facts and did not need to ask the United States and Codex to provide the information requested by the European Communities.

(b) Request by the United States to exclude materials not cited in the EC risk assessment as well as those published after the completion of its risk assessment by the European Communities and the adoption of the ban

7.112 On 14 March 2006, the **United States** sent a letter to the Panel requesting it not to provide to scientific experts materials that had not been cited in the EC risk assessment, nor those published after the completion of the EC risk assessment and the adoption of the ban at issue. The United States also requested the Panel not to consider nor base its findings on these extraneous materials provided by the European Communities.

7.113 The United States recalled that Directive 2003/74/EC[391] which the European Communities claimed complies with the recommendations and rulings of the DSB in the underlying *EC – Hormones* dispute, was based on the results of its 1999, 2000, and 2002 Opinions which, the European Communities contended, demonstrated that the amended ban satisfied the conditions of Articles 5.1 and 5.7 of the *SPS Agreement*.

7.114 Accordingly, materials that had no apparent relationship to the European Communities' alleged risk assessment, including materials published after the completion of the EC risk assessment and the adoption of its ban, were extraneous for purposes of the Panel's examination in this dispute.

7.115 To the extent that the European Communities, by submitting these materials, was inviting the Panel (or the experts) to review them as part of a *de novo* risk assessment, this was not a proper role for either the Panel or the experts. Rather, the question presented was whether the risk assessment identified by the European Communities actually had brought the European Communities into compliance with its WTO obligations.[392]

7.116 The **European Communities** stated that it had fundamental objections to the requests of the defending party. They were contrary to the Appellate Body's interpretation of the requirements of a "risk assessment", as set out in *EC – Hormones*. They were in violation of the Panel's Working Procedures in this case, and they ran diametrically counter to the whole purpose of an expert consultation by the Panel.

7.117 According to the European Communities, the issue of whether a measure could be considered to be based on scientific evidence that was not cited or had not been taken into account in a risk assessment, or both, had already been settled by the Appellate Body in its report on *EC – Hormones*, at paragraphs 188 through 191. There the Appellate Body had dismissed the proposition by the complaining parties and the finding by the panel that scientific evidence had to be cited in the risk assessment, as a "minimum procedural requirement". The European Communities failed to understand why the defending party now re-opened an issue that had already been decided.

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[391] Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having hormonal or thyrostatic action and beta-agonists, Official Journal No. L 262, 14 October 2003, p. 178 (hereinafter also "the Directive").

[392] US's letter to the Panel of 14 March 2006.

7.118 The European Communities had submitted new materials as exhibits in its replies to the Panel's questions and as part of its second written submission. They were, therefore, lawfully before the Panel and were directly covered by Paragraph 13 of the Expert Working Procedures.

7.119 In this context, the European Communities also pointed to the fact that the United States itself had submitted materials that had been published after the EC risk assessment (see e.g. US – Exhibits 7, 16, 20; CDA – Exhibits 20, 26, 27, 28, 33). The US request was, therefore, based on a double standard: In case recent evidence served the objectives of the United States it had to be admitted, whereas evidence that was unfavourable to the United States should not be taken into account.

7.120 According to the European Communities, the United States' request had to be dismissed in view of the purpose of the experts' consultation. The principal objective of consulting experts was to provide the Panel with *objective* information and advice on questions related to the scientific basis of Directive 2003/74/EC. In order to fulfil this task, the experts could not ignore the most recent and directly relevant scientific evidence that is publicly available.[393]

7.121 On 31 March 2006, the **Panel** addressed this issue in its letter to parties informing the parties that it would not reject *a priori* any piece of evidence at that stage. However, the Panel decided to ask experts to specify whether their reply would have been different at the time of adoption of Directive 2003/74/EC and why. The Panel also requested the parties to identify, among the exhibits submitted, those studies to which they had had access before their publication date.

> "With respect to the issues raised in the letter of the United States on 14 March 2006, in Canada's comments of 15 March 2006, and in the European Communities' letter of 23 March 2006, the Panel is reluctant to reject a priori any piece of evidence at this stage. It will revert to this matter in its findings, as appropriate. In the meantime, and without prejudice to its final decision, the Panel has decided to amend some of its questions to the experts and request them to specify whether their reply would have been different at the time of adoption of the measure at issue (September 2003) and, if not, why.
>
> In this respect, the Panel would be grateful if the parties could specify by Friday, 7 April 2006, among the exhibits they submitted, those studies to which they had access before their official publication dates and, if so, specify the date on which they had access to each of them."[394]

7.122 Also, in its guideline letter sent on 30 March 2006 to the selected scientific and technical experts, the Panel specified that "wherever reference is made to scientific or technical facts, or comment is made on scientific evidence or literature, you are requested to provide references to the relevant studies and publications".[395]

7.123 The Panel considers that its approach allowed it to have a better understanding of the situation at the time of the adoption of Directive 2003/74/EC. However, since nothing has been submitted that became available subsequent to the adoption of the Directive and that differed in any fundamental way from the evidence available at that time[396], the Panel does not deem it necessary to address this issue any further.

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[393] EC's letter to the Panel of 23 March 2006.
[394] Panel letter to the parties of 31 March 2006.
[395] Panel guideline letter to selected experts of 30 March 2006.
[396] This was confirmed by the experts when they were requested to specify in their replies to questions of the Panel whether their views would have been different at the time of the adoption of Directive 2003/74/EC.

(c) A new version of Exhibit EC-107, submitted by the European Communities on 29 May 2006.

7.124 On 29 May 2006, the **European Communities** submitted a new version of its Exhibit EC-107, entitled "The sensitivity of the child to sex steroids: possible impact of exogenous estrogens", a study published on 2 May 2006. The European Communities stated that it would leave it to the Panel to decide whether to forward this version to experts.[397]

7.125 The **Panel** decided on 23 June 2006 not to forward this version of Exhibit EC-107 to the scientific experts for the following reasons:

> "With regard to the EC letter of 29 May and its attachment, the Panel takes note of the fact that the study submitted as Exhibit EC-107 has now been published. However, the Panel notes that the version of the study submitted as Exhibit EC-107 and the version attached to the EC letter of 29 May are somewhat different and that the difference are apparently not merely editorial. In this respect, the Panel recalls that the parties had been given until 21 December 2005 to submit factual evidence to the experts. Therefore, the Panel has decided not to send the published version of the study contained in Exhibit EC-107 to the experts."[398]

7.126 We confirm the position we took in this letter. We note that previous panels dealing with SPS measures have, in the context of proceedings under Article 21.5 of the DSU, considered *measures* adopted after the establishment of the panel.[399] However, as far as *evidence* is concerned, panels have generally refused to accept evidence submitted after a certain date, generally after the first substantive meeting, except for rebuttal purposes or upon a showing of good cause. In this particular case, the parties had been given until 21 December 2005, i.e. several weeks after their second written submissions, to provide factual evidence that they deemed relevant. The Panel considered also that submitting a modified study to experts at a relatively late stage of the expert consultation proceedings could generate confusion.

(d) Procedure for allowing the parties to comment on each other's replies to questions after the second Panel meeting

7.127 On 18 October 2006, the **United States** requested the Panel to provide the parties with the opportunity to comment on each other's replies to questions posed to the parties by the Panel and the parties following the second Panel meeting.[400]

7.128 On 20 October 2006, the **Panel** confirmed to the parties that the deadline for such counter comments would be 31 October 2006.[401]

(e) Request by the European Communities to be allowed to correct factual errors allegedly contained in the other party's comments on its replies to questions following the second Panel meeting

7.129 On 13 November 2006, the **European Communities** informed the Panel that it had studied the comments submitted by the United States and Canada on 31 October 2006 and had identified a number of inaccuracies and factual errors in their comments likely to affect the adjudication of the cases.

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[397] EC's letter to the Panel of 29 May 2006.
[398] Panel letter to the parties of 23 June 2006.
[399] See *Australia – Salmon (Article 21.5 – Canada)*, *Japan – Apples* (*Article 21.5 – US)*.
[400] US's cover letter to its replies to the questions of the Panel after the second substantive meeting, dated 18 October 2006.
[401] Panel letter to the parties of 23 October 2006.

7.130 The European Communities requested that the Panel allow the parties to submit comments on the factual allegations contained in the comments on the responses. These comments would be restricted to factual matters and would not seek to further discuss any of the legal issues. This would enable the Panel to make an objective assessment of the facts and ensure a high quality panel report.[402]

7.131 According to the **United States**, the European Communities had already had the opportunity to present what it considered to be the facts and there was no reason to give it another opportunity to present its view of the facts. Given the brevity of the US comments and the amount of time that the European Communities had had to study them, the EC request was untimely.

7.132 The United States considered that the Panel was more than capable of performing the task assigned to it by the Dispute Settlement Body and sorting out the various factual elements without the need for additional filings from the parties. Finally, the parties would presumably have an opportunity to point out any factual errors in their comments on the descriptive part and comments on the interim report.[403]

7.133 The **Panel** decided, on 20 November 2006, to reject the EC request:

> "Having carefully reviewed the arguments of the parties, the Panel does not consider it appropriate to offer them another opportunity to comment on alleged factual errors made by the other party. Procedurally, the Panel does not see any difference between comments on factual elements and comments on legal arguments; both can easily lead to endless discussions. The Panel is concerned that giving such an opportunity to parties could open the door to further delays in these proceedings since it would be difficult, once the Panel has allowed comments not foreseen in its timetable, to reject requests for additional comments on the other party's comments. At this juncture, the Panel believes that it has been sufficiently informed by the parties and the experts to be able to make an objective assessment of the case and deems it preferable to continue with the preparation of its report without further exchanges of comments between the parties. The Panel notes in this respect that the DSU provides opportunities for the parties to submit written comments, at a later stage, on the descriptive (factual and arguments) sections of the Panel Report and to request the Panel to review precise aspects of its Interim Report."[404]

7.134 The Panel does not deem it necessary to add anything to the reasoning above.

(f) Request by the European Communities for tape recordings of the transcript of the Panel meeting with scientific experts

7.135 On 31 January 2007, the **Panel** sent to the parties a draft written transcript of the hearing with the experts, for their review and comments.

7.136 On 14 February 2007, the **European Communities**, in the cover letter accompanying its comments on the transcript, requested the Panel to provide the parties with the tape recordings of the meeting with the experts to check the accuracy of the transcription of the experts' replies. The European Communities argued that the replies of some of the experts were not properly or not fully

[402] EC's letter to the Panel of 13 November 2006.
[403] US's letter to the Panel of 13 November 2006.
[404] Panel letter to the parties of 20 November 2006.

reflected in the transcript, but did not identify specific parts of the transcript where such errors allegedly occurred.[405]

7.137 The **Panel**, in a letter dated 19 February 2007, requested the European Communities to identify in the draft transcript the places where the European Communities believed the replies of the experts during the meeting had not been properly reflected. The Panel added that, once the information had been provided, the Panel itself would further review the draft and make appropriate corrections if necessary. The Panel added that the parties had until 5 April 2007 to submit such information.

7.138 The **European Communities** responded to the Panel on 28 February 2007, confirming that it was not in a position to identify in advance all the places where the transcript may not be entirely accurate, unless it was given copies of the tapes. The European Communities added that some of its doubts had already been pointed out by the United States and some more doubts existed as regards the statements by one expert and by the representatives of the WHO and JECFA. The European Communities also stated that the tapes had been provided to parties in the past in the *EC – Hormones*, the *EC – Asbestos* and the second *EC – Bananas* cases.[406]

7.139 The **Panel** replied that, to its knowledge, in circumstances similar to the present dispute, panels had never provided the tape recordings used in transcripts of meetings with scientific or technical experts to parties for review. As the Panel indicated in its message on 19 February to all parties, parties were welcome to identify any places in the draft transcript where they believed inaccuracies could exist and the Panel would further review the draft and make appropriate corrections if necessary.[407]

7.140 On 28 March, the **European Communities** replied that tapes of recordings had been provided previously upon request. In support of its allegation, it submitted a transmission slip of 21 April 1997 in the *EC – Hormones* panel procedure. The European Communities added that it was entitled to expect that tapes be provided in this case as well.

7.141 The European Communities also pointed out that the written transcript of the meeting of the Panel with the scientific experts had been sent with considerable delay to the parties for verification. In view of the time which had elapsed, it was very difficult to verify the transcript with the required degree of certainty, in the absence of the recordings.

7.142 The **United States** commented on the EC remarks on 5 April 2007, arguing that the experts had reviewed the draft transcript in order to ensure that the transcript accurately reflected their interventions and to make any necessary clarifying changes. Accordingly, in the view of the United States, the only purpose for which the European Communities could be seeking access to the tapes was to verify the transcript with respect to its own interventions. The United States did not see a reason why the tapes would be needed for this purpose.

7.143 In response to the EC argument that it needed the tapes because time had elapsed between the preparation of the transcript and the experts meeting, the United States argued that in every panel proceeding there was significant time between panel meetings and the preparation of the descriptive part of a panel's report. No party in any dispute to which the United States had been a party had ever claimed that it needed access to the tapes of a panel meeting in order to be able to verify that the descriptive part accurately presented the interventions of that party at the panel meeting. Presumably, if there were a particular portion of the transcript of concern to the European Communities, the

[405] EC's letter to the Panel of 14 February 2007.
[406] EC's e-mail to the Panel of 28 February 2007.
[407] E-mail of the Panel to the parties of 26 March 2007.

European Communities could have identified that in its earlier communications and the Panel could have consulted the tapes to confirm that the transcript was accurate with respect to that portion.

7.144 The United States indicated that the transmission slip attached by the European Communities to its communication raised a number of questions while failing to demonstrate the EC claim of "entitlement" to the tape recordings. There was no evidence that copies of the audio tapes from the meeting with the experts in the original proceedings had been provided to the United States for review or that similar tapes of expert meetings were provided to the United States in other dispute settlement proceedings. The European Communities had failed to mention that the transmission slip was not related to the tapes of the experts meeting in the original *EC – Hormones* dispute. The United States noted that the cover slip submitted by the European Communities to the Panel cited a date (7 January 1997) that neither corresponded to the dates of the meeting with the scientific experts in the original dispute (17-18 February 1997), nor did it correspond to any of the meeting dates in the original *EC – Hormones* dispute between the United States and the EC (WT/DS26). Furthermore, that transmission slip involved a separate dispute with different panelists and different terms of reference than the current proceeding. The United States therefore disagreed that the transmission slip in question was relevant to sharing recordings of meetings with scientific experts with the parties to a dispute.[408]

7.145 The **Panel** sent to the parties an additional message on 18 April 2007, rejecting the EC request for tape recordings:

> "Since the latest message from the Panel to the parties on 26 March 2007, the Panel has received from the European Communities an additional communication on 28 March, indicating that tape recordings had been provided to the European Communities in the original *EC – Hormones* panel proceedings.
>
> The Panel subsequently received a letter from the United States indicating that the EC failed to mention that the transmission slip it submitted together with its 28 March letter is not related to the tapes of the expert meeting in the original *EC – Hormones* dispute because the date mentioned on that slip (7 January 1997) does not correspond to the date of the experts meeting (17-18 February 1997) in the original *EC – Hormones* dispute between the United States and the European Communities (WT/DS26).
>
> The Panel found that the meeting date mentioned on the slip provided by the EC was the date of the first substantive meeting of the panel in the original *EC – Hormones* dispute between the European Communities and Canada. The meeting with experts in the two disputes was jointly held on 17-18 February 1997, while the meetings with parties were held separately. After further verification, we can confirm that, to the best of our knowledge, the tape recordings of the experts meeting on 17 and 18 February in the two original *EC – Hormones* panels were never provided to the parties.
>
> The Panel recalls that the European Communities' request is based on its desire to check whether the experts' replies at the experts meeting have been accurately reflected in the transcript. Consistent with the practice of other panels, the Panel has invited the parties and the experts to verify the accuracy of their own interventions during the meetings. In addition, the Panel invited the parties to identify any places in the draft transcript where they believe inaccuracies could exist and the Panel was

[408] US's letter to the Panel of 5 April 2007.

ready to review those portions of the transcript and make appropriate corrections if necessary.

By 5 April 2007, a deadline date set by the Panel in its communication to the parties on 26 March 2006, none of the parties had identified any such inaccuracies.

Therefore, on the basis of the above, the Panel does not deem it necessary to provide the tape recordings of the meeting with the experts to the parties."[409]

7.146 The **European Communities** sent another message to the Panel on 11 May 2007, commenting on the Panel's decision:

"The European Communities appreciates the e-mail of the Panel of 18 April replying to our additional communication on 28 March, indicating that the tape recordings that had been provided to the European Communities in the original *EC – Hormones* panel proceedings were not from a hearing with scientific experts.

In that case we did indeed receive (and still have in our archives) from the panel five tapes of 90 minutes each of the meeting held on 7 January 1997, which was indeed a meeting not with scientific experts. The point we were making is that since panels have provided the parties in the past tapes of a regular hearing, why is it not possible to provide the tapes of a hearing with scientific experts (where verification of what exactly was said is even more important)?

More generally, panels send to parties the factual part of the draft report for verification (which is essentially done on the basis of the written submissions of the parties). The hearing with scientific experts is also part of the factual part of the report. So, one can expect that the tapes from such a hearing with scientific experts can also be sent for verification. This is all the more important in the case of a hearing with scientific experts, because it is impossible both for the scientific experts and the parties to take verbatim notes of a hearing that lasted two days and with the speed at which the oral exchanges take place in such hearing. Indeed, the scientific experts presumably did not take verbatim notes of what they said during the hearing and so they are in the same difficult position as the parties to remember what exactly they have said several months ago. For example, the European Communities has some doubts whether the following paragraphs of the draft report it has received reflect accurately what exactly has been said by the experts during the hearing on 27-28 September 2006: paragraphs 353, 386, 388, 390, 421-422, 500, 690, 706, 710, 719-720, 734, 779, 785, 891, 994, 1018, 1028. Furthermore, the European Communities considers that something may be wrong or missing between paragraphs 972 and 973 of the draft report.

The European Communities respectfully requests the Panel to reconsider its position. If the Panel still feels unable to provide the European Communities with the tapes, it would ask the Panel to set out its reasons for refusing this request in the Report."

7.147 The **United States** sent a letter to the Panel on 14 May 2007 in response to the EC message of 11 May 2007 stating that:

"As noted by the Panel in its April 18, 2007, communication to the Parties on this issue, '[c]onsistent with the practice of other panels, the Panel has invited the parties

[409] Panel letter to the parties of 18 April 2007.

> and the experts to *verify the accuracy of their own interventions during the meetings*.' (Emphasis added). The United States was therefore surprised to note that all but two of the paragraphs (972-73) cited by the EC in its request relate to interventions of experts (specifically Drs. Boobis and Boisseau):
>
> Paragraphs 353 (Boobis); 386 (Boobis); 388 (Boobis); 390 (Boobis); 421-22 (Boobis); 500 (Boobis); 690 (Boobis); 706 (Boobis); 710 (Boobis); 719-20 (Boisseau); 734 (Boisseau); 779 (Boobis); 785 (Boobis); 891 (Boisseau); 994 (Boobis); 1018 (Boobis); 1028 (Boobis).
>
> It is unclear why it took the EC several months to identify these paragraphs. Indeed, the EC has missed the deadline set by the Panel (April 5, 2007) for identifying specific issues with the transcript by more than a month. It is even more perplexing why the EC, when it finally provided a list of "doubts" regarding the transcript, cited non-EC interventions, ignoring the Panel's clear instructions in its January 31, 2007 communication to the parties. The United States considers that Drs. Boobis and Boisseau, both preeminent experts in their respective fields, are more than capable of confirming that what they said or did not say is accurately reflected in the transcript, without the assistance of the EC or any other party. Were it otherwise, the parties to a dispute would be afforded the opportunity to rewrite expert opinions after the fact and based upon their six-month old recollections, thereby calling into question the purpose of consulting independent experts in the first place.
>
> As for the other two paragraphs cited by the EC (972-73) that actually appear to relate to EC interventions, the United States considers that the Panel, should it decide to set aside its April 5, 2007 deadline for identifying problematic portions of the transcript, is more than capable of double-checking the accuracy of this discrete portion of the transcript without the need to circulate copies of the tapes of the expert meetings to the Parties (see e-mail from the Panel dated March 26, 2007, in which the Panel indicated that, by April 5, 2007, the 'parties are welcome to identify any places in the draft transcript where they believe inaccuracies could exist and the Panel will further review those portions of the transcript and make appropriate corrections if necessary')."

7.148 On 5 June 2007, the Panel informed the parties that the European Communities had not identified the relevant paragraphs in the draft transcript that it wanted the Panel to review before the deadline of 5 April 2007, as specified by the Panel in its earlier communication to the parties. At such a late stage, the Panel had every reason to disregard the request for review of the paragraphs identified by the European Communities in its letter of 11 May 2007. Nevertheless, as a matter of prudence, the Panel checked the relevant paragraphs in the draft transcript against the original tape recordings and did not find any discrepancy beyond minimal editorial adjustments. Therefore, the Panel saw no reason to reverse its decision not to provide tape recordings of the meeting with scientific experts to the parties for further review.

7.149 The Panel believes that the reasons for its decision not to provide tape recordings of the meeting with scientific experts were sufficiently described in its communications. It does not deem it necessary to elaborate on them any further.

4. Scope of the Panel's mandate

(a) The measure at issue and the claims of the European Communities

7.150 The matter before this Panel is the alleged failure of the United States to comply with the DSU and the GATT 1994 in response to the adoption and notification to the DSB of an alleged compliance measure by the European Communities in the *EC – Hormones* case.[410]

7.151 The measure at issue is the continued application by the United States, after the notification to the DSB of Directive 2003/74/EC by the European Communities, of its decision to apply, as from 29 July 1999, import duties in excess of bound rates by imposing a 100% ad valorem duty on a number of products imported from certain member States of the European Communities[411] without recourse to the procedures under the DSU. This decision had been taken pursuant to an authorization granted by the DSB to the United States to suspend concessions and other obligations on 26 July 1999.[412]

7.152 In its request for establishment of a panel, the European Communities lists Articles I and II of the GATT 1994 and Articles 23.1, 23.2(a) and (c); 3.7, 22.8 and 21.5 of the DSU as having been breached by the United States. However, in its first written submission and subsequently, the European Communities elaborates on the scope of those claims. More particularly, it divides its claims between a set of *main* claims and one *conditional* claim.[413]

7.153 The European Communities also specifies how its *main* claims of violation of the DSU should be addressed. The European Communities makes a first series of main claims, alleging a violation of Article 23 of the DSU and, more particularly, Article 23.2(a) read in conjunction with Articles 21.5 and 23.1 of the DSU. The European Communities also makes a second series of main claims, alleging a violation of Article 23.1, read in conjunction with Articles 22.8 and 3.7 of the DSU. In support of the second series of claims, the European Communities alleges that it enjoys a presumption of good faith compliance "which cannot be undermined by a unilateral and unsubstantiated determination by the United States."[414]

7.154 The European Communities also specifies in its first submission that Directive 2003/74/EC, which it claims implemented the recommendations and rulings of the DSB in the *EC – Hormones* case, is compatible with Article 5.1 and 5.7 of the *SPS Agreement*. However, there is no reference to provisions of the *SPS Agreement* in the EC request for establishment of a panel.

7.155 The *conditional* claim, that of a violation of Article 22.8 of the DSU *per se,* is "made in the alternative and only on the condition that the Panel does not establish any violation under Articles 23.1, 23.2(a), 3.7, 22.8 and 21.5 of the DSU".[415]

7.156 This *conditional* claim is, like the second series of main claims raised by the European Communities, based on the EC view that it has complied with the recommendations and rulings of the DSB in the *EC – Hormones* case by adopting Directive 2003/74/EC and properly notifying it to the DSB. The difference is that, under the conditional claim, the European Communities alleges actual compliance, and not that it should be presumed to have complied in good faith.

7.157 The EC implementing measure imposes a definitive import prohibition on meat and meat products from animals treated for growth promotion purposes with oestradiol-17β and a provisional

[410] WT/DS26.
[411] US Federal Register, Vol. 64, No. 143 of 27 July 1999, p. 40638.
[412] WT/DSB/M/65, p. 19.
[413] EC's first written submission, para. 8.
[414] EC's first written submission, para. 72.
[415] EC's first written submission, para. 132.

ban on meat and meat products from animals treated for growth promotion purposes with testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. The EC implementing measure is allegedly "based on a comprehensive risk assessment and, thus, is fully compliant with the DSB recommendations and rulings. In particular, [according to the European Communities and] as stipulated by the Appellate Body, the results of the risk assessment 'sufficiently warrant' the definite import prohibition regarding one of the hormones (Article 5.1 of the *SPS Agreement*), [footnote omitted] and provide the 'available pertinent information' on the basis of which the provisional prohibition regarding the five hormones has been enacted (Article 5.7 of the *SPS Agreement*)."[416]

(b) Are the indications provided by the European Communities on how it wants its claims to be addressed part of the mandate of the Panel?

7.158 As a preliminary remark, the Panel notes that, when dealing with the scope of panel terms of reference, panels and the Appellate Body so far addressed situations where panel requests were alleged to be insufficiently precise. In the present case, the EC request for the establishment of a panel, while not as explicit as the EC first written submission, explains in its section 2 ("The object of the dispute") some of the elements of the approach that the European Communities wants the Panel to follow. Yet, it does not outline its claims as was done in the EC first written submission. For instance, the request for the establishment of a panel lists Article 22.8 but it does not differentiate between the main "systemic" claim relating to Article 22.8 (violation of Article 23.1, read in conjunction with Articles 22.8 and 3.7 of the DSU) and the conditional "direct" claim of violation of Article 22.8. Likewise, in the request for establishment of a panel, each provision is identified separately, without any terms like "read together with" or "read in conjunction with."

7.159 In *Korea – Dairy*, the Appellate Body defined the meaning of *claim* and *arguments* as follows:

> "By *claim*, we mean a claim that the respondent party has violated, or nullified or impaired the benefits arising from, an identified provision of a particular agreement. Such a *claim of violation* must, as we have already noted, be distinguished from the *arguments* adduced by a complaining party to demonstrate that the responding party's measure does indeed infringe upon the identified treaty provision."[417]

7.160 In the opinion of the Panel, the approach of the European Communities as developed in its first written submission does not amount to "arguments" insofar as it does not "demonstrate that the responding party's measure does indeed infringe upon the identified treaty provision". In fact, it does not purport to explain to what extent the EC claims are justified, but simply circumscribes their scope.

7.161 We further note that, in *US – Carbon Steel*, the Appellate Body stated that:

> "[I]n considering the sufficiency of a panel request, submissions and statements made during the course of the panel proceedings, in particular the first written submission of the complaining party, may be consulted in order to confirm the meaning of the words used in the panel request and as part of the assessment of whether the ability of the respondent to defend itself was prejudiced. Moreover, compliance with the requirements of Article 6.2 must be determined on the merits of each case, having considered the panel request as a whole, and in the light of attendant circumstances."[418]

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[416] EC's first written submission, para. 17.
[417] Appellate Body Report on *Korea – Dairy*, para. 139
[418] Appellate Body Report on *US – Carbon Steel*, para. 127.

7.162 The Panel is mindful that this statement was made in relation to a situation where the terms of reference were alleged not to cover specific claims. On the contrary, in the present case, the European Communities narrows the terms of reference of the Panel insofar as it requires a specific approach to the provisions allegedly breached. However, this statement equally applies in the present circumstances to the extent that the EC first written submission may be consulted in order to confirm the meaning of the words used in the request for establishment of a panel.

7.163 In that context, it can be considered that the approach to this case requested by the European Communities and contained in its first written submission is actually a clarification of the claims listed in its request for establishment of a panel and not arguments, and that it informs those claims.

7.164 We therefore conclude that the EC approach outlined in its first written submission is part of the Panel's terms of reference. One consequence is that since the claim of "direct" violation of Article 22.8 is made *in the alternative*, the Panel cannot and will not address it unless the European Communities fails to establish its main claims. The other consequence is that we should address the main claims as elaborated by the European Communities in its first written submission and subsequently.

(c) Meaning of "read together with" and "in conjunction with" in the EC submissions

7.165 The main or principal claims of the European Communities raise an additional question, i.e. whether the European Communities alleges a violation of Article 23 of the DSU alone or of all the provisions cited in its submission in support of its claim of violation of Article 23.

7.166 The Panel notes that in questions put to the European Communities after the first substantive meeting, and in its second written submission, the United States challenges the EC claim of violations of Article 21.5 "together with" Article 23.2(a) and of Article 22.8 "in conjunction with" Article 23.1 on two grounds:

(a) the United States alleges that the European Communities abandoned its claims of specific violations of each of these provisions *per se;*

(b) the United States argues that the EC approach is inconsistent with the customary rules of interpretation of international law by trying to impose obligations that are not supported by the text of the provisions concerned.

7.167 The European Communities replies that the United States is acting contrary to Articles 23.1, 23.2(a) and 21.5 read together and that, as a result, the European Communities maintains its claim under Article 21.5. As far as Article 22.8 is concerned, the European Communities states that the panel request lists all the relevant provisions which the United States is currently violating and, in particular, Article 22.8 and Article 23.1. The European Communities also considers that its approach consisting of citing various provisions to substantiate a claim was approved by the Panel in *US – Certain EC Products*.

7.168 The Panel recalls that the request for establishment of a panel made by the European Communities refers to "Article 23.1; 23.2(a) and (c); 3.7; 22.8 and 21.5 of the DSU". Thus, examining the conformity of the US measures with Articles 3.7, 21.5 and 22.8 of the DSU is part of the Panel mandate.

7.169 The Panel does not believe that the European Communities abandoned its claims under Articles 3.7, 21.5 and 22.8 of the DSU because it alleged a violation of those provisions "read together with" or "in conjunction with" other provisions. This is confirmed by the European Communities itself in its reply to questions of the United States referred to above.

7.170 The Panel notes the argument of the United States that the European Communities is trying to impose obligations that are not supported by the text of the provisions concerned. We recall that paragraph 1 of Article 31 of the Vienna Convention on the Law of Treaties, embodying the customary rules of interpretation of public international law referred to in Article 3.2 of the DSU, provides that:

> "A treaty shall 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."

7.171 The Panel does not exclude that there could be situations where the rights or obligations of Members could vary depending on which other provision a particular article of the DSU is read together with. However, either the terms of the provisions concerned interpreted in their ordinary meaning, in their context and in the light of the object and purpose of the treaty or the provisions support the claim, or they do not. Likewise, it is often the case that the violation of a particular provision will have consequences on the legality of the measure at issue under other provisions of the same or of other covered agreements.

7.172 We note that, in *US – Certain EC Products*, the panel stated that:

> "Since we have already concluded that the 3 March Measure constituted a measure taken to redress a WTO violation (covered by Article 23.1), we proceed to examine whether the same 3 March Measure violated the provisions of the sub-paragraph 2(c) of Article 23 of the DSU, as well as Articles 3.7 and 22.6 of the DSU."[419]

7.173 In other words, it would appear that the panel in *US – Certain EC Products*, even though it considered the effects of a finding of violation of one provision on the other – this is probably what it meant by "Article 23.1 together with Articles 23.2(c), 3.7 and 22.6 of the DSU" in the title of the section where the above quotation is found – nevertheless made findings of violation of each provision individually. We note that, likewise, the Appellate Body assessed the panel findings on each provision separately.[420]

7.174 The European Communities states that, if it had not specified Articles 21 and 22 in its request for establishment of a panel, the United States would have probably argued that these provisions were not part of the terms of reference of the Panel. This would suggest that the European Communities is actually requesting findings only in relation to Article 23.1 and 23.2(a), the references to the other provisions being part of the context in which the obligations under Article 23 have to be assessed. This seems to be confirmed by the EC conclusion in its first written submission where the European Communities states that the United States violates Article 23 of the DSU and, more particularly, Article 23.2(a) read in conjunction with Articles 21.5 and 23.1 of the DSU and violates Article 23.1, read in conjunction with Articles 22.8 and 3.7 of the DSU.

7.175 We note, however, that the European Communities listed all these provisions in its request for establishment of a panel and confirmed in its reply to the US question referred to above that it "is maintaining its claim under Article 21.5". As far as Article 22.8 is concerned, the European Communities states that the panel request lists all the relevant provisions which the United States is currently violating and, in particular, Article 22.8 and Article 23.1.

7.176 While the European Communities seems to insist on the violations of Article 23, the Panel does not believe that the terms "read together with/read in conjunction with" were meant to limit its findings of violation to Article 23. Rather, the European Communities is seeking findings on all the

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[419] Panel Report on *US – Certain EC Products*, para. 6.36.
[420] Appellate Body Report on *US – Certain EC Products*, para.106 *et seq*.

provisions cited but, because of the broadly cast wording of Article 23, the European Communities seeks to circumscribe the context in which that violation is to be found. In other words, it wants us to articulate any findings of violation of Article 23 with the violations of Articles 21.5, 22.8 and 3.7 of the DSU.

7.177 The Panel concludes that the fact that the European Communities is seeking findings of violation of Article 23 "read together with" or "read in conjunction with" should not be understood as meaning that the European Communities exclusively claims a violation of Article 23. The Panel believes that its mandate includes Articles 21.5, 22.8 and 3.7 of the DSU.

(d) Conclusion

7.178 From the above we conclude that:

(a) the indications given by the European Communities on how it wants this case to be addressed (main claims and alternative claim) are part of the Panel's mandate;

(b) the indication by the European Communities that certain provisions referred to in its request for establishment of the Panel be "read together" or "in conjunction with" does not mean that the Panel is not expected to make findings on each of these provisions.

5. Approach of the Panel on the basis of its mandate

7.179 We are mindful of the EC position that this case is primarily about alleged violations of the DSU and, in particular, Article 23 thereof. We note in particular the EC argument that it brought this case because the United States refused to initiate a procedure under Article 21.5 of the DSU and did not agree to any other procedural arrangement.[421] We note that the European Communities also claims that the United States breaches Article 23 of the DSU read together with Article 22.8 because it failed to withdraw its suspension of obligations in spite of the EC removal of the measure found to be inconsistent with a covered agreement.

7.180 We also recall that the United States' defence consists of arguing first that the European Communities has failed to prove that the United States has breached Article 22.8 of the DSU. The position of the United States is that it does not breach Article 22.8 of the DSU because the European Communities has failed to comply with the recommendations and ruling of the DSB in the *EC – Hormones* case. In support, it argues that Directive 2003/74/EC still breaches provisions of the *SPS Agreement*, more particularly Articles 3.3, 5.1 and 5.7 thereof. The other violations of the DSU and GATT 1994 are only addressed by the United States in a second stage.

7.181 In our opinion, the EC claims of violation of Article 23.2(a) read together with Articles 21.5 and 23.1 are not premised on compliance by the European Communities with the DSB recommendations and ruling in the *EC – Hormones* case, whereas the claims of violation of Article 23.1, read together with Articles 22.8 and 3.7 of the DSU, are. Indeed, the EC claims of violation of Article 23.2(a), read together with Articles 21.5 and 23.1 of the DSU are premised on the fact that the respondent would have maintained a measure that could be deemed to be a "determination to the effect that a violation has occurred" without having recourse to dispute settlement in accordance with the DSU. Such a determination could take place whether or not the European Communities has complied with the DSB recommendations and rulings in *EC - Hormones*. Comparatively, the second series of EC claims is, to the extent that it includes Article 22.8, premised on the requirement that the respondent measure can "only be applied until such time as the measure

[421] EC's first written submission, para. 5.

found to be inconsistent with a covered agreement has been removed", as claimed by the European Communities. Thus, addressing the second series of main claims of the European Communities entails that we review the question of the presumed or actual compliance of the EC implementing measure with the DSB recommendations and rulings in the *EC – Hormones* case.

7.182 We believe that these two series of claims, as presented by the European Communities, are independent from each other and can be addressed completely separately. However, while we are free to structure the order of our analysis as we see fit[422], we see no reasons not to review the EC claims in the order followed by the European Communities in its submissions. We therefore proceed now with the first series of claims raised by the European Communities.

B. FIRST SERIES OF EC CLAIMS: VIOLATION OF ARTICLE 23.2(A) READ TOGETHER WITH ARTICLES 21.5 AND 23.1

1. Summary of the main arguments of the parties[423]

7.183 The **European Communities** argues that by maintaining its suspension of obligations, the United States is seeking redress of a perceived violation of the WTO Agreement. Pursuant to Article 23 of the DSU, any attempt to seek "redress" can take place only pursuant to the rules and procedures of the DSU. The US continued suspension of obligations is contrary to the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU. Instead, the United States should have introduced a compliance procedure under Article 21.5 of the DSU. By not doing so, the United States has violated the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU. This violation of Articles 23.2(a) and 21.5 constitutes at the same time a violation of Article 23.1 of the DSU.

7.184 The European Communities, referring to the panel report in *US – Section 301 Trade Act,* notes that the following three conditions need to be fulfilled in order to find a violation of Article 23.2(a) of the DSU.

(a) First, given the "chapeau" of Article 23.2, it needs to be established that a Member is seeking to redress a WTO violation. In the opinion of the European Communities, this is the case here.

(b) Second, Article 23.2(a) of the DSU requires that a Member has made a "determination to the effect that a WTO violation has occurred." Such a decision need not have a specific form, and can be inferred from action. The suspension of concessions or other obligations is the very means (albeit of last resort) of reacting to a violation and therefore necessarily implies a decision that there is a violation. The multilateral determination at the origin of the current US suspension of concessions was, however, made with respect to the measures previously applied by the European Communities. Logically, it could not and did not apply to the measures subsequently adopted and properly notified to the WTO by the European Communities. If the United States continues to apply the suspension of concessions and related obligations, it necessarily implies that it has unilaterally determined that there continues to be a violation. It has, in addition, explicitly said so.

[422] Appellate Body Report on *Canada – Wheat Export and Grain Imports*, paras. 126-129.

[423] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

(c) Third, Article 23.2(a) of the DSU is violated if the determination is not made in accordance with the rules and procedures of the DSU or is not consistent with the findings of a dispute settlement organ. The DSU provides for a specific procedure, namely Article 21.5 of the DSU, to address the situation that Members disagree over the existence or consistency of measures taken to comply with the recommendations and rulings of the DSB.

7.185 In the view of the European Communities, there exists obviously a disagreement as to whether or not, by adopting Directive 2003/74/EC, the European Communities has implemented the recommendations and rulings from the DSB in the *EC – Hormones* case. Article 21.5 of the DSU requires that that disagreement *shall* be decided through recourse to dispute settlement. To date, the United States has refused to initiate a compliance procedure under Article 21.5 (or, for that matter, any other dispute settlement procedure under the DSU). Instead, it continues to apply the suspension of concessions and other obligations as if no "measure to comply" had been taken or the non-compliance of the new directive of the European Communities had already been multilaterally established.[424]

7.186 The **United States** argues that it does not seek anything within the meaning of Article 23.1 with respect to the EC declaration of compliance. The United States has already sought and obtained redress through the multilateral dispute settlement system for a violation found by the DSB. There is no provision in the WTO Agreement that provides that a single Member can unilaterally invalidate the multilateral decision of the DSB to authorize suspension of concessions. The European Communities has not provided any evidence that it has complied with the conditions of Article 22.8 of the DSU.

7.187 According to the United States, Article 23.2(a), like Article 23.1, applies only in situations where a Member is "seeking redress for a violation" of a WTO obligation. The United States has not, through the continued application of the DSB authorization, sought redress for another Member's violation. Likewise, the United States did not make a "determination" within the meaning of Article 23.2(a). The United States has simply continued to act according to the DSB authorization. The United States did not need to make further determinations to continue to apply the suspension of concessions.

7.188 The United States believes that none of the statements made by the United States and referred to by the European Communities constitute a determination within the meaning of Article 23.2(a). They are simply statements of the status of the US evaluation of the EC measure at that point in time based on the information available. The statements referred to by the European Communities make no reference to a WTO violation. The United States remained open to discussing any further information that the European Communities might have developed in support of its declaration of compliance and to this end engaged in informal consultation and technical discussions and made a request under Article 5.8 of the *SPS Agreement* seeking all of the material underpinning the EC import ban.

7.189 For the United States, under the European Communities' reading of Article 23.2(a), a complaining Member need not actually indicate any definitive view on the WTO consistency of an implementing Members' measure to have made a determination. The implementing Member can force a complaining Member into breach of Article 23.2(a) by making a unilateral declaration of compliance that the complaining Member does not immediately agree with or test through the immediate invocation of Article 21.5 proceedings.

7.190 The United States adds that the *US – Section 301 Trade Act* panel report concluded that a "determination" must be sufficiently firm and immutable, in other words "a more or less final

[424] EC's first written submission, paras. 35-68.

decision". The definition of the term "determination" emphasizes not only the finality of the decision, but also its formality. It does not contemplate that a determination can be implicit. The ordinary meaning of the term makes it clear that the opinions and views of the United States cited by the European Communities did not rise to the level of "determinations" within the meaning of Article 23.2(a).

7.191 The United States argues that the EC Article 21.5 claim fails because the European Communities has not established that there is a "disagreement as to the existence or consistency with a covered agreement of measures taken to comply". Article 21.5 sets no deadline by which such a proceeding must be brought and nothing in the text of Article 21.5 places the onus of initiating a compliance proceeding on the original complaining party (in this case, the United States). Finally, the phrase "these dispute settlement proceedings" in Article 21.5 is not restricted to proceedings under Article 21.5, but rather could include proceedings such as arbitration under Article 22.6 of the DSU, proceedings under Article 25 of the DSU, or the proceedings of a *de novo* panel, as the European Communities has sought in this instance.[425]

7.192 Regarding the term "seeking redress" in Article 23.1, the **European Communities** argues that a DSB authorization which has been granted in view of an original WTO-inconsistent measure cannot justify the continued application of sanctions against a different measure which has never been found multilaterally to constitute a WTO violation. Any present application of sanctions must be linked to a present measure. The US argument leads to the absurd result that the United States could continue to apply sanctions irrespective of any event occurring after the DSB authorization. The United States fails to acknowledge that the original situation has been altered by the adoption of the EC implementing measure. The United States is under no obligation to continue to suspend obligations. The very fact that it does it in this new situation demonstrates that it indeed considers that there is a causal link between the continuation of the suspension and the determination of inconsistency of the EC compliance measure. If one considers that the United States continues to apply sanctions because of an import ban as such, it would do so against a new measure, since the current import ban is different from the one which the DSB found WTO inconsistent.

7.193 With respect to the term "determination" in Article 23.1(a), the European Communities argues that it is clear from the panel report in *US – Section 301 Trade Act*, that even an implicit determination through the continuation of sanctions would be covered by this requirement. Article 23 aims at preventing that a Member seek the redress of a violation on the basis of a unilateral determination. In light of the overall context and fundamental importance of Article 23, it is justified to look at a Member's behaviour as a whole when confronted with a particular situation. Not every policy statement may be equal to a "determination" or made with the purpose of "seeking a redress of a violation". However, in the present case the United States has clearly stated that it does not consider the EC compliance measure to be sufficient. For instance, the US statement at the DSB meeting of December 2003 is evidence that the United States expressed a definitive judgement about the EC measure. The United States also continues to apply sanctions. There is no way to consider this as "inaction" on the part of the United States, just because stopping the sanctions would require some action. The European Communities also recalls that it notified its implementing measure in 2003, which begs the question when the United States will make a "determination". If the United States truly wanted to reflect further before making any "determination" or initiating any procedure under Article 21.5, it could have suspended the application of sanctions. Article 23 does not prohibit any determination, it prohibits only unilateral determinations of non-compliance.

7.194 The **United States** argues that the Panel findings in *US – Certain EC Products* cited by the European Communities are based on the lack of any DSB recommendations and rulings. The panel found that the United States acted without having yet been authorized to do so by the DSB. The

[425] US's first written submission, paras. 177-202.

European Communities appears to insinuate that its declaration of compliance has placed the parties back in the position they found themselves in the *US – Certain EC Products* case.

7.195 The United States also argues that, as a procedural matter, the EC interpretation of Article 23.2(a) is complicated by the lack of clarity regarding when a determination on the part of the suspending Member would be inferred. The European Communities argues that there is a reasonable period of time during which the suspending Member may review the measure before a determination is either inferred or due. However, no such reasonable period is set out in the text of Article 23.

7.196 The United States adds that a critical element of the US evaluation is the review of the studies and Opinions underpinning the EC ban. The United States has not had the opportunity to review all of these documents. This is why it has not yet been able to reach a determination on the EC ban. The EC has only recently informed the United States of a number of studies that were not referenced in its response to the US request for information under Article 5.8 of the *SPS Agreement*. Given the difficulty in procuring the material supporting the EC measure, it is perfectly understandable why the United States has not yet made a "determination" as to the WTO-consistency of the EC import ban.[426]

2. Reasoning of the Panel

(a) Introduction

7.197 The European Communities claims a violation of Article 23.2(a), read together with Articles 21.5 and 23.1. Article 23.2(a) contains specific obligations compared with Article 23.1. We therefore deem it relevant to address the violation of Article 23.2(a) first.[427]

7.198 Article 23.2(a) reads as follows:

> "2. In such cases, Members shall:
>
> (a) not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;"

7.199 In order to decide whether the United States has or has not breached Article 23.2(a) in this case, the Panel must first find whether the determination was made "in such cases", i.e. when the conditions of Article 23.1 are met.

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[426] US's second written submission, paras. 15-22.

[427] We note in this respect that, as mentioned by the Appellate Body in *Canada – Wheat Export and Grain Imports*, paras. 126-129:

> "As a general principle, panels are free to structure the order of their analysis as they see fit. In so doing panels may find it useful to take account of the manner in which a claim is presented to them by a complaining Member. Furthermore, panels may choose to use assumptions in order to facilitate resolution of a particular issue ..."

7.200 Article 23.1 reads as follows:

> "When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding."

7.201 In other words, the Panel must first establish whether the United States, in relation to the facts of this case, has been seeking redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements, within the meaning of Article 23.1 of the DSU.

7.202 Thereafter, the Panel will proceed with determining whether the United States has breached Article 23.2(a). Once this is done, it will review the alleged violation of Articles 21.5 and 23.1, as necessary.

(b) "[S]eeking the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements" (Article 23.1 of the DSU)

7.203 The United States argues that it does not *seek* anything within the meaning of Article 23.1 with respect to the EC declaration of compliance with the WTO Agreement. The United States alleges that it has already sought and obtained redress through the multilateral dispute settlement system for a violation found by the DSB.

7.204 We agree with the United States that Article 23.1 of the DSU is not breached when a Member's suspension of concessions or other obligations has been multilaterally authorized by the DSB, because the Member concerned "ha[d] recourse to, and abide[d] by, the rules and procedures of [the DSU]", within the meaning of Article 23.1. Indeed, the United States already sought redress against the original EC ban under the DSU.

7.205 In the opinion of the Panel, Article 23.1 applies in this case only with respect to a determination against a measure which has not yet been subject to a recourse to the rules and procedures of the DSU. We must therefore determine first whether Directive 2003/74/EC is such a measure.

7.206 We note the arguments of the European Communities that it adopted a new directive which it considers implements the recommendations and rulings of the DSB in the *EC – Hormones* case.[428] We also note that the United States recognized before the DSB that the EC had adopted a "revised ... measure" and a "new directive".[429] We first note that Directive 2003/74/EC has never been as such subject to recourse to the rules and procedures of the DSU by the United States. For instance, no panel has been established at the request of the United States to review the conformity of Directive 2003/74/EC with the covered agreements. Second, the fact that both parties consider that the EC implementing measure is not the same measure as that which was found in breach of the WTO Agreement by the DSB in the *EC – Hormones* case is confirmed by the allegations they made in relation to that implementing measure before this Panel. The European Communities considers that its ban on oestradiol-17β is compatible with Article 5.1 of the *SPS Agreement*, whereas its ban on the other five hormones is justified by Article 5.7. The United States alleges, *inter alia*, the incompatibility of the ban on oestradiol-17β with Article 5.1 and 5.2, and of the provisional ban on the other five hormones with Article 5.7. These are different provisions than those invoked in the *EC*

[428] EC's first written submission, para. 17.
[429] WT/DSB/M/157, paras. 29-30.

– *Hormones* case with respect to the same hormones.[430] Thus, the United States acknowledges that the measure is different from the original measure found in breach of the WTO Agreement not only formally but also in substance and legally, even though an import ban on meat treated with hormones for growth promotion purposes is still applied.

7.207 We note that the original ban remains in force. We consider, however, that this is insufficient to conclude that Directive 2003/74/EC is not different from the measure originally found in breach of the WTO Agreement and should be deemed for that reason to have been subject to the rules and procedures of the DSU. We recall that it is not the ban on meat treated with growth promotion hormones as such that was found illegal in the *EC – Hormones* case, but the justification for this ban which was found insufficient. The European Communities is not prevented by the *SPS Agreement* from imposing any ban on import of meat treated with growth promotion hormones. The European Communities can impose such a ban provided it is compatible with the relevant requirements of the *SPS Agreement*. As a result, the Panel does not consider that the fact that the ban remains in place means that no new measure has been adopted.

7.208 The United States argues that its suspension of obligations was, and remains, multilaterally authorized by the DSB. To date, the authorization to suspend concessions and other obligations granted on 26 July 1999 to the United States by the DSB has not been revoked by the DSB and the United States continues to act pursuant to that authority.[431] The United States also argues that there is no provision in the WTO Agreement that provides that a single Member can unilaterally invalidate the multilateral decision of the DSB to authorize suspension of concessions. According to the United States, the European Communities has not provided any evidence that it has complied with the conditions of Article 22.8 of the DSU.

7.209 We agree with the United States that it was *authorized* to suspend concessions and that this authorization has not been revoked. We note however, that this is only an *authorization*, not an *obligation* imposed by the DSB. The Panel agrees with the European Communities in this respect: "authorization by the DSB" does not mean "obligation to suspend concessions". This is confirmed by the practice under the DSU pursuant to which, in a number of cases where authorizations to suspend concessions have been requested, no suspensions was subsequently applied, in spite of the DSB authorization.[432] In other words, the fact that, after the notification of Directive 2003/74/EC, the United States continues to apply its suspension of concessions even though it has no obligation to do so is evidence that the United States is actively "seek[ing] the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements".

7.210 We note that the DSU does not provide for any procedure regarding the revocation of an authorization to suspend concessions. The adoption of a decision to revoke such an authorization by the DSB would require consensus[433], which would in turn require an absence of objection from the Member suspending concessions or other obligations, which may be difficult to obtain. We consider that this is not necessary, essentially because the DSB grants an *authorization,* which the Member concerned is free to apply or not. We also note that Article 22.8 of the DSU does not provide for any decision of the DSB for a suspension of concessions or other obligations to cease to apply. The first sentence of Article 22.8 simply provides that:

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[430] In the original *EC – Hormones* dispute, the panel noted the EC 's statement that its measures were not provisional measure in the sense of Article 5.7 of the *SPS Agreement*. See Panel Report on *EC – Hormones* (US), para. 8.249.

[431] US's first written submission, para. 26.

[432] In the *Brazil – Aircraft* case and the *Canada – Aircraft Credits and Guarantees* case, the DSB authorized Canada and Brazil respectively to suspend obligations, but neither of them applied the authorization. In the *EC – Bananas III* case, Ecuador was authorized to retaliate but did not exercise its right.

[433] See Article 2.4 of the DSU.

> "The suspension of concessions or other obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits, or a mutually satisfactory solution is reached." (Emphasis added)

7.211 In none of the circumstances foreseen by Article 22.8 does this provision require a decision of the DSB. In other words, it is for the respondent in this case to take appropriate steps to ensure that the suspension of concessions or other obligations is only applied until such time as foreseen in Article 22.8.

7.212 We also note that, pursuant to Article XVI:4 of the Agreement Establishing the WTO, Members must ensure the conformity of their laws, regulations and administrative procedures with their obligations as provided in the agreements annexed to the Agreement Establishing the WTO, including the DSU.

7.213 We conclude that the United States does not need a multilateral decision in order to terminate the suspension of concessions or other obligations for which it got authorization from the DSB.

7.214 For the reasons stated above, we consider that the EC implementing measure is, compared with the measure for which the United States was granted authorization to suspend concessions and other obligations by the DSB, a measure which has not been subject to a recourse to the rules and procedures of the DSU.

7.215 The United States, by maintaining its suspension of concessions even after the notification of the EC implementing measure, is seeking redress of a violation with respect to the EC implementing measure, within the meaning of Article 23.1 of the DSU. If it were not, as mentioned above, the United States would not have to maintain that suspension.

7.216 We now proceed to assess whether the United States breached Article 23.2(a).

(c) Violation of Article 23.2(a)

(i) Introduction

7.217 In order to assess whether the United States breaches Article 23.2(a), we must review the following conditions:[434]

(a) whether the United States made a determination that the EC implementing measure violates the WTO Agreement;

(b) whether the United States failed to make such determination through recourse to dispute settlement in accordance with the rules and procedures of the DSU; and assuming that it did,

(c) whether the United States failed to make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding.

7.218 We will review these requirements successively.

[434] We note that a similar approach was applied by the Panel in *US – Section 301 Trade Act*, footnote 657.

(ii) Did the United States make a determination that the EC implementing measure violates the WTO Agreement?

7.219 We note that, in the present case, the European Communities notified its implementing measure on 27 October 2003.[435] At the DSB meeting of 7 November 2003 the United States made the following statement which is worth quoting in full in order to better understand its scope:

> "The representative of the United States said that her country had reviewed the communication placed by the EC on the agenda of the present meeting and had listened to the statement that the EC had just made. The United States failed to see how the revised EC measure could be considered to implement the DSB's recommendations and rulings in this matter. For nearly 15 years, the EC had banned the importation of nearly all meat and meat products from the United States. The purported basis of the EC ban was that the consumption of meat from cattle raised in the United States with growth-promoting hormones posed a risk to human health. It was a bedrock principle of the *SPS Agreement*, however, that banning a product for purported health reasons had to be based on science. The EC measure was not based on science. To the contrary, after repeated study, no increased health risk had ever been associated with the consumption of meat from animals treated with growth-promoting hormones. The Joint FAO/WHO Expert Committee on Food Additives had found that there was a wide margin of safety for these products. For example, it had determined that consumption of beef from treated animals resulted in amounts of estradiol that were 300 times lower than the acceptable daily intake level. Moreover, hormones such as estradiol were already produced in abundance by both the human body and cattle, and were naturally present in many everyday foods. For example, each person daily produced amounts of estradiol ranging from 2,000 to 30,000 times more, or higher, than the amount consumed from eating a 250-gram serving of meat from treated animals. Due to high levels of naturally-occurring hormones in cattle, it was not even possible to distinguish any residues of such hormones administered for purposes of growth promotion. A single chicken egg contained many times more estradiol equivalents than the estradiol contained in a 250 gram serving of meat from a treated animal. A litre of milk from an untreated cow contained approximately 18 times as much estradiol as a 250 gram serving of meat from a treated animal.
>
> In February 1998, the DSB had adopted findings that the EC ban was not based on an appropriate risk assessment, as required by Article 5.1 of the *SPS Agreement*, and had recommended that the EC bring its measure into compliance with its WTO obligations. Near the conclusion of the 15-month compliance period, on 30 April 1999, the EC had issued a report by an EC veterinary committee claiming increased health risks from the use of growth-promoting hormones. However, this claim was not based on science. Just like the reports relied upon by the EC before the panel and the Appellate Body, the April 1999 report consisted of general discussions of types of risks, but had never actually assessed or found any increased risk from the consumption of meat from animals produced with growth-promoting hormones. And, indeed, the EC had never, until now, claimed to the DSB that the April 1999 report was an appropriate basis for adopting a ban on US beef. To the contrary, during the arbitration under Article 22.6 on the level of nullification and impairment suffered by the United States, the EC had acknowledged that – even after the issuance of the April 1999 report – it had not implemented the recommendations and rulings of the DSB. For example, in its opening submission filed on 11 June 1999, the EC had written that it "accepts that it has not taken the required measures to comply with the

[435] WT/DS26/22.

> DSB recommendations". In July 1999, the DSB had authorized the United States and Canada to suspend concessions. Again, the EC had never claimed that its April 1999 report served as an appropriate basis for its ban on meat from treated animals. At the present meeting, the EC had presented Directive 2003/74 to the DSB, and claimed that this directive implemented the DSB's recommendations and rulings. The Directive, however, neither removed the EC's unjustified ban on US beef, nor presented an appropriate risk assessment as a basis for the ban. Further, aside from the ban on estradiol, the directive relabelled its ban on the other five growth-promoting hormones covered in this matter as "provisional measures". A decision by the EC to relabel its measures, however, could not bring it into compliance with its obligations under the *SPS Agreement*. Nearly six years had passed since the DSB had recommended that the EC bring its ban on US beef into compliance with its obligations. The United States, however, could not understand how this new directive presented now could amount to implementation of the DSB's recommendation."[436]

7.220 The United States made another statement at the DSB meeting of 1 December 2003:

> "The representative of the United States said that she would transmit the statement made by the EC at the present meeting to her authorities for their consideration. As had been explained at the 7 November DSB meeting, the United States failed to see how the revised EC measure could be considered to implement the DSB's recommendations and rulings in this matter. The United States had always been ready to discuss with the EC any matters regarding its compliance with the DSB's recommendations and rulings. The United States would be pleased to discuss with EC officials any outstanding issues regarding the EC's ban on certain beef produced in the United States, including their reactions to the detailed points that the United States had raised in its statement at the 7 November DSB meeting. With regard to the suggestion made by the EC at the present meeting that multilateral proceedings be initiated, the United States would be happy to discuss this suggestion with the EC along with other procedural options."[437]

7.221 The European Communities also refers to other statements by the United States.[438]

7.222 We recall that the Panel in *US – Section 301 Trade Act* defined a "determination" as follows:

> "[W]e consider that – given its ordinary meaning – a "determination" implies a high degree of firmness or immutability, i.e. a more or less final decision by a Member in respect of the WTO consistency of a measure taken by another Member."[439]

7.223 The two statements quoted above were delivered by an official of the US government at a formal meeting of a WTO body. There is no formal difference between that statement and any other statement where a formal decision of a Member is conveyed to the DSB.

7.224 We note that the second statement quoted above suggests that the United States was ready to consult with the European Communities, including on procedural issues. The Panel notes that, in response to one of its questions, the parties specified the extent of the consultations that took place

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[436] WT/DSB/M/157, paras. 29-30.
[437] WT/DSB/M/159, para. 25.
[438] See US press release of 8 November 2003 and 2005 Trade Policy Agenda and 2004 Annual Report of the President of the United States on the Trade Agreements Program, Exhibit EC-5.
[439] Panel Report on *US – Section 301 Trade Act*, footnote 657.

after the notification of Directive 2003/74/EC. The Panel notes that they largely related to procedural issues.[440]

7.225 This said, even if the United States showed readiness in its statement to discuss with the European Communities and even if discussions actually took place, the United States position at the time of its statement before the DSB was quite clear, as illustrated by remarks such as: "[t]he United States failed to see how the revised EC measure could be considered to implement the DSB's recommendations and rulings in this matter"; "Directive [2003/74/EC], however, neither removed the EC's unjustified ban on US beef, nor presented an appropriate risk assessment as a basis for the ban"; "[a] decision by the EC to relabel its measures, however, could not bring it into compliance with its obligations under the *SPS Agreement*"; "[t]he United States, however, could not understand how this new directive presented now could amount to implementation of the DSB's recommendation"; or "[as] had been explained at the 7 November DSB meeting, the United States failed to see how the revised EC measure could be considered to implement the DSB's recommendations and rulings in this matter."

7.226 The style and content of the statement are such that they can be reasonably deemed to convey, with a high degree of firmness and immutability, a more or less final decision. Nowhere in that statement is there any indication that the United States was still reviewing the new EC Directive, or that it was expecting more information or planning to seek more information from the European Communities. In this respect, it merely expressed "readiness to discuss". The United States expressed a clear opinion as far as the legality of the EC notified measure was concerned. The United States might have still been in the process of reviewing the EC implementing measure, but this does not show from this statement or from any other statement referred to by the parties. Moreover, the United States had obviously taken the decision to maintain its suspension of concessions, since the latter continued to apply. We therefore consider that the US statement meets all the requirements of the definition in the Panel Report in *US – Section 301 Trade Act* and that the United States made a "determination" within the meaning of Article 23.2(a).

7.227 The United States argues that a critical element of the US evaluation is the review of the studies and Opinions underpinning the EC ban. The United States claims that it has not had the opportunity to review all of these documents. This is why it has not yet been able to reach a determination on the EC ban. The United States notes that the European Communities has only recently informed the United States of a number of studies that were not referenced in its response to the US request for information under Article 5.8 of the *SPS Agreement*. The United States adds that, given the difficulty in procuring the material supporting the EC measure, it is perfectly understandable why the United States has not yet made a "determination" as to the WTO-consistency of the EC import ban.[441]

7.228 We are not convinced by this argument. There is no element in the statements of the United States before the DSB indicating that it was still reviewing the documents or even that it contemplated difficulties in obtaining the studies underpinning the EC new Directive.

7.229 As far as the request under Article 5.8 is concerned, the US letter on this subject was sent on 13 December 2004, more than one year after the notification of the implementing measure by the European Communities and after consultations on the present case were requested by the European Communities. Thus, the Panel finds it difficult to conclude that this request was linked to any review of the EC implementing measure that the United States would have been carrying out since the notification of Directive 2003/74/EC.

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[440] See Annex B-3, US's replies to Panel questions after the first substantive meeting, question 50.
[441] US's second written submission, paras. 19-22.

7.230 Even if one were to consider that the US statements at the DSB were provisional comments, the subsequent continuation of the suspension of concessions by the United States without alteration and without saying that it was still studying the EC implementing measure is evidence that the statements before the DSB meant that the United States had no intention to remove its retaliatory measure, at least until further notice. We note in this respect that the term "determination" does not necessarily imply a formal decision, all the more so as such a formal decision was not necessary in order to continue the suspension of concessions. The continuation of the suspension of concessions corroborates the fact that the US statements before the DSB constituted "determinations" within the meaning of Article 23.2(a).

7.231 The United States argues that no period of time is provided for in Article 23 within which a Member shall make a determination and that, under the interpretation advocated by the European Communities, the European Communities can force the United States into a violation of Article 23.2(a) by making a unilateral declaration of compliance that the complaining Member does not immediately agree with or test through the immediate invocation of Article 21.5 proceedings.[442]

7.232 We agree with the United States that there is no deadline in Article 23 by which a Member shall have recourse to the DSU. This, however, is not the issue before this Panel. The issue is whether the United States made a determination within the meaning of Article 23.2(a) or not. We have found that the United States has made such determination by making its statements before the DSB on 7 November and 1 December 2003. Even if the determination was not fully made on that date, the continued suspension of concessions by the United States over the period between the EC notification and the date of request of consultations by the European Communities in this case is evidence that the United States made such a determination.

7.233 In this case, the United States could have clearly stated that it was reviewing the EC implementing measure and expressly stated that it needed more time and more information to do so. It did not. On the contrary, it stated before the Dispute Settlement Body that it " failed to see how the revised EC measure could be considered to implement the DSB's recommendations and rulings in this matter" and went on to explain in details why it thought so.

7.234 We note the argument of the United States that the situation in this case is different from that in *US – Certain EC Products*, where no DSB authorization had been granted to the United States at the time of the measure at issue. However, we have concluded above that the authorization to suspend concession or other obligations on the basis of which the United States imposed its sanctions had been granted with respect to the original measure. As far as the implementing measure is concerned, it has not even been subject to a recourse to the rules and procedures of the DSU.

7.235 The United States also argues that the EC interpretation would lead to an endless loop of litigation because any Member could notify a "scam legislation" and force the original complainant to request a panel under Article 21.5 of the DSU.

7.236 We are mindful that this argument was raised by the United States in relation to its alleged violation of Article 21.5 of the DSU. We nonetheless believe that we should address it to the extent that the notification of an implementing measure would be the type of measure which could, according to the United States, start such an "endless loop of litigation".

7.237 First, we believe that not only scam legislation, but also any other implementing measures could lead to recurrent litigations. One could envisage that, in a complex case, a Member could notify in good faith an implementing measure which would be subsequently found not to fully comply with the original recommendations and ruling of the DSB. This Member would have to submit a revised

[442] US's second written submission, para. 17.

measure which could, once again, be challenged and found to comply only partly with the covered agreements. Such repeated inconsistencies could have to do with the fact that, pursuant to Article 19.1 of the DSU, panels and the Appellate Body may only recommend that the Member concerned bring its legislation into conformity with the covered agreement(s) found to be breached, and may only make non-binding suggestions regarding ways in which the Member concerned could implement their recommendations. Since Members remain free to implement recommendations and rulings as they deem appropriate, differences in the interpretation of the recommendations of the DSB cannot be excluded, which can result in old inconsistencies remaining in the implementing measure or in new ones creeping into it.

7.238 Second, we recall that our findings are limited to the facts of this particular case. In this case, the European Communities has adopted Directive 2003/74/EC at the outcome of a lengthy and complex internal decision-making process. The Panel notes in this respect that the Commission proposal was submitted in 2000 and 2001 and that the procedure for the adoption of the Directive was the procedure provided for in Article 251 of the Treaty establishing the European Community. This procedure involved a number of steps, including an Opinion of the European Parliament (1 February 2001), a Common Position of the Council of the European Union (20 February 2003) and finally a Decision of the European Parliament (2 July 2003), a Decision of the Council of the European Union (22 July 2003) and an adoption by the European Parliament and the Council of the European Union on 22 September 2003.[443] Without prejudice to the question whether Directive 2003/74/EC is actually based on the three opinions of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) of 1999, 2000 and 2002[444] within the meaning of the *SPS Agreement*, the Panel notes that this Directive expressly refers to those opinions[445] and that, as a result, they were part of the process that led to the adoption of the Directive. The Panel also notes the efforts of the European Communities to have the conformity of its measure reviewed under the DSU.[446] Even if the EC implementing legislation were ultimately found not to comply with the *SPS Agreement*, the Panel considers that it shows all the signs of an implementing measure having gone through all the formal process required for its adoption and showing, on its face, all the signs of a measure adopted in good faith.

7.239 We therefore conclude that the United States made a "determination" within the meaning of Article 23.2(a) in relation to Directive 2003/74/EC.

(iii) Did the United States fail to make such determination through recourse to dispute settlement in accordance with the rules and procedures of the DSU?

7.240 We note that the United States argues that it has not made any *determination* in respect of the EC implementing measure and therefore did not have to have recourse to the dispute settlement procedures of the DSU. However, we found above that it made a determination within the meaning of Article 23.2(a). Therefore, we conclude that the United States made a determination without having recourse to the DSU, thus breaching Article 23.2(a) of the DSU.

7.241 The United States also argues that it benefits from a multilateral authorization to suspend concessions in relation to the breach by the European Communities of the *SPS Agreement*, as a result of the recommendations and rulings of the DSB in the *EC – Hormones* case.

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[443] See Directive 2003/74/EC, Preamble and footnote 3.

[444] Hereafter the "1999 Opinion", the "2000 Opinion" and the "2002 Opinion" or, together, the "Opinions".

[445] See Directive 2003/74/EC, whereas clauses 5 and 8.

[446] See EC's replies to Panel questions after the first substantive meeting, question 50, Annex B-1.

7.242 This is not the issue, however. The issue is whether the authorization to suspend concessions or other obligations granted to the United States under Article 22 of the DSU amounts to a multilateral determination of inconsistency of the EC *implementing measure* (i.e., Directive 2003/74/EC) with the covered agreements through recourse to the DSU. In our opinion, the answer is no.

7.243 We therefore conclude that the United States has not made any determination *through recourse to dispute settlement* in accordance with the rules and procedures of the DSU.

(iv) Did the United States fail to make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under the DSU?

7.244 Since the United States has not made any determination through recourse to dispute settlement in accordance with the rules and procedures of the DSU, we conclude *a fortiori* that the United States has failed to make any such determination *consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under the DSU*.

(v) Conclusion

7.245 For the reasons stated above, we find that the United States has breached Article 23.2(a) of the DSU.

(d) Violation of Article 21.5 of the DSU

7.246 We note that the European Communities claims that the United States should have had recourse to Article 21.5 of the DSU. The United States argues that it is not obligated to initiate a compliance procedure under Article 21.5.

7.247 We note that Article 23.2(a) provides that a determination must not be made "except through recourse to dispute settlement in accordance with [the DSU]". It does not specify which procedure under the DSU should be followed. While the procedure under Article 21.5 of the DSU could be one of the mechanisms available, in our view, the term "recourse to dispute settlement in accordance with the rules and procedures of this Understanding" encompasses any of the means of dispute settlement provided in the DSU, including consultation, conciliation, good offices and mediation.

7.248 The last proposition of Article 23.2(a) provides that such determination shall be consistent with the "findings contained in the *panel* or *Appellate Body* report adopted by the DSB or an *arbitration award* rendered under this understanding."[447] We do not consider, however, that that proposition *requires* that Members have recourse to a panel or to arbitration. In the opinion of the Panel, the last proposition of Article 23.2(a) only requires the Member *which decides to have recourse to a panel or to arbitration* to abide by the recommendation of the panel or the Appellate Body or the award of the arbitrator.[448]

7.249 As a result, we do not find it necessary to make a finding on whether the United States breached Article 21.5 by not having recourse to the procedure under that provision. Indeed, the United States did not have recourse to any procedure under the DSU with respect to the EC implementing measure (Directive 2003/74/EC). Under those circumstances, we deem it sufficient to

[447] Emphasis added.

[448] Comparatively, there was no need for the negotiators of the DSU to refer to compliance with the results of consultations, mediation, conciliation or good offices since the results of such means of dispute resolution have, by their very nature, to be accepted by the parties in order to produce effects.

limit our findings to Article 23 and exercise judicial economy with regard to the EC claim under Article 21.5 of the DSU.

(e) Violation of Article 23.1 of the DSU

7.250 Since we found that the United States has sought the redress of a violation with respect to the EC implementing measure (Directive 2003/74/EC) and made a determination without having "recourse to dispute settlement in accordance with the rules and procedures of [the DSU]" within the meaning of Article 23.2(a), we conclude that the United States failed to "have recourse to, and abide by, the rules and procedures of [the DSU]", in breach of Article 23.1 of the DSU.

3. Conclusion

7.251 On the basis of the above, the Panel concludes that the United States has violated Article 23.1 and 23.2(a) of the DSU by seeking redress of a violation of the WTO Agreement through a determination that the EC implementing measure did not comply with the DSB recommendations and rulings in the *EC – Hormones* case without having recourse to dispute settlement in accordance with the rules and procedures of the DSU.

C. SECOND SERIES OF EC CLAIMS: VIOLATION OF ARTICLE 23.1, READ TOGETHER WITH ARTICLES 22.8 AND 3.7 OF THE DSU

1. Summary of the main arguments of the parties[449]

7.252 The **European Communities** argues that, under Article 23.1 of the DSU, the United States is obliged to have recourse to, and abide by, the rules and procedures of the DSU, which encompass, *inter alia*, Articles 22.8 and 3.7 of the DSU.[450] The European Communities argues more particularly that Article 22.8 prohibits the continued unilateral application of the suspension of concessions or other obligations when the measure which has been found inconsistent is removed.[451]

7.253 The European Communities argues that the suspension of obligations should only apply where and as long as justified and necessary. This is a practical consequence of the fact that suspension of concessions should only be applied as "a last resort", as specified in Article 3.7 of the DSU.

7.254 According to the European Communities, one objective of the suspension of concessions is to induce compliance. This entails, however, that once a Member has adopted implementing measures which are not properly challenged by the complaining Member, the suspension of concessions or other obligations can no longer be applied. The objective to induce compliance can only revive after it has been properly established that the implementing measure has been insufficient to remedy a WTO violation.

7.255 In the opinion of the European Communities, Article 22.8 of the DSU prohibits the continued unilateral application of the suspension of concessions or other obligations when the measure which has been found inconsistent is removed. The term "removed" thereby refers to the compliance by a WTO Member because this provision is based on the respect of the WTO obligations by the Member concerned.

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[449] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[450] EC's first written submission, para. 73.

[451] EC's first written submission, para. 81.

7.256 The European Communities argues further that Article 22.8 of the DSU does not specify how the removal of the WTO inconsistency is determined. However, in the light of its context, i.e. Articles 21.5 and 23.2(a) of the DSU, and given the exceptional nature of countermeasures, it is clear that a Member cannot unilaterally determine that the WTO inconsistency persists despite the notification of a compliance measure. Likewise, a Member cannot decide to continue to suspend concessions or other obligations unilaterally. Unless a procedure under Article 21.5 concludes that the compliance measure does not fully implement the DSB recommendations and rulings, it cannot be presumed that this is the case.

7.257 According to the European Communities, this also follows from the general principle of good faith as it applies in international State relations, under which States are normally considered to act in conformity with their obligations. This principle has been widely confirmed in the international jurisprudence and in the WTO dispute settlement system. Therefore, it is clear that the United States could not unilaterally determine that the European Communities implemented the DSB recommendations and rulings in a WTO inconsistent way. To the contrary, the European Communities must be presumed to have complied with its WTO obligations, if the United States refuses to establish the contrary.

7.258 The European Communities adds that once the inconsistency of the measure has been removed, Article 22.8 of the DSU provides that "the suspension of concessions or other obligations shall [not be] applied [any longer]." This provision does not leave any margin of discretion to the retaliating Member. Under the same logic, Article 22.8 of the DSU does not allow for the application of countermeasures on the basis of a *unilateral* determination regarding the WTO inconsistency of the measure. It can be inferred from Article 22.8 read together with Article 23.1 of the DSU that the suspension of obligations should not continue to be applied until the WTO inconsistency of the properly notified measure has been positively determined by the DSB.

7.259 According to the European Communities, the DSB authorization cannot justify the maintenance of suspension of concessions or other obligations if a Member properly complies with its obligations after the imposition of these measures and if its compliance measure is not challenged in an Article 21.5 proceeding. Again, the mere temporal difference of the new implementing measure does not mean that the DSB authorization, once received, serves as a blank authorization for a Member to continue the application of the suspension of concessions or other obligations indefinitely in the future and on the basis of unilateral determinations.

7.260 Furthermore, the European Communities notes that, from a systemic point of view, Article 22.8 of the DSU is subsequent to Article 22.7 of the DSU. This indicates that once the situation under paragraph 8 occurs it overtakes the authorization granted under paragraph 7. Paragraph 8 conditions paragraph 7. As it must be assumed that the DSU negotiators followed a logical sequencing in the way they drafted Article 22, it is clear that Article 22.8 of the DSU was supposed to impact on the authorization under Article 22.7 of the DSU. Indeed, to assume that the removal of the inconsistency of the measure under paragraph 8 has no impact on the DSB authorization under paragraph 7 is not legally coherent or reasonable.

7.261 Finally, following the jurisprudence by the Appellate Body, once a Member violates Article 23.1 read in conjunction with Article 22.8 of the DSU, it necessarily also acts contrary to Article 3.7 of the DSU.

7.262 The **United States** argues that Article 22.8 establishes three conditions under which a DSB-authorized suspension of concessions may no longer be applied: (a) the Member imposing the WTO-inconsistent measure "removes" the measure; (b) that Member "provides a solution to the nullification or impairment of benefits"; or (c) the parties to the dispute reach a "mutually satisfactory

solution." In order to prevail in its claim that the United States is breaching Article 22.8, the European Communities must establish that one of these conditions has been met.

7.263 According to the United States, the assertion of the European Communities that it has removed its measure or provided a solution is not supported by any demonstration that it actually has done either. Instead, the European Communities relies on an already rejected legal theory that a Member found to have breached its WTO obligations is to be excused from its burden of proof in dispute settlement if it invokes "good faith." This argument is no more valid today than when a WTO panel last rejected it, and the EC failure to meet its burden on the critical element of its case under Article 22.8 means that the EC claim must likewise fail. The United States continues to apply the suspension of concessions to the European Communities in a WTO-consistent manner, fully in accordance with the authorization of the DSB.

7.264 The United States adds that the European Communities failed to demonstrate that it has in fact removed its WTO-inconsistent measure, the import ban on meat and meat products from cattle treated with hormones for growth promotion purposes or that it has "provide[d] a solution" to the nullification or impairment of benefits to the United States caused by the ban.

7.265 According to the United States, Article 22.8 nowhere provides that the issue of removal of a measure or providing a solution can be decided by a Member's simple assertion that it has developed a new, WTO-consistent measure, or that it alone has deemed that it has provided a "solution" to WTO nullification or impairment, without a DSB determination. Indeed the EC proposed interpretation is directly at odds with the last sentence of Article 22.8 which makes it clear that these are questions for ongoing *DSB* surveillance. Article 22.8 stresses that "the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings", in situations where "concessions or other obligations have been suspended but the [DSB] recommendations ... have not been implemented." This statement that the DSB's role is to monitor an implementing Member's compliance with DSB recommendations as well as the complaining Member's suspension of concessions further emphasizes that Article 22.8 is concerned with *multilateral* review of compliance. The European Communities errs in claiming that under Article 22.8, the US authorization to suspend concessions could be withdrawn in the absence of a DSB determination to that effect. Furthermore, the EC approach would fundamentally undermine the operation of several critical DSU provisions, most notably the right of complaining parties to seek authorization to suspend concessions through a DSB decision taken by negative consensus under Article 22.6 or Article 22.7 of the DSU.

7.266 In the view of the United States, the European Communities argues that the Panel should find that it has "removed" its WTO-inconsistent measure within the meaning of Article 22.8 analysis because it "must be presumed to have complied with its WTO obligations, if the United States refuses to establish to the contrary." However, the *EC – Bananas III (Article 21.5 – EC)* panel highlighted that there is no basis in the WTO Agreement for the EC's argument that it is presumed compliant with its obligations absent a finding against its measures. Similarly, there is no presumption of compliance for the EC amended ban in this proceeding. Because compliance of the EC amended ban is a condition precedent to several of the claims raised by the European Communities as a complaining party, the European Communities bears the burden in this proceeding of demonstrating its compliance.

7.267 The **European Communities** argues that, contrary to what the United States asserts, the prohibition to continue the application of sanctions under Article 22.8 does not depend on whether the DSB authorization has been formally removed. Article 22.8 is unequivocal in the sense that the suspension of concessions and related obligations may only be "applied" until the inconsistency of the measure has been removed. In addition, Article 22.8 subjects the application of sanctions to a measure which has been found inconsistent. Article 22.8 is also of self-executing nature and the termination of the application of sanctions under this provision does not depend on a specific finding of the DSB or a

withdrawal of the DSB authorization. Rather, once the conditions under Article 22.8 of the DSU are met – including in the presence of an unchallenged compliance measure – the application of suspension "shall" automatically stop.

7.268 Moreover, the European Communities does not agree with the United States that the principle of good faith is not relevant for WTO proceedings in general or only relevant for the issue of burden of proof. This radical position is not supported by general public international law, which also applies to the WTO, as for instance expressed in Article 26 of the Vienna Convention on the Law of Treaties (1969). In this context, the European Communities also considers that due to the specific circumstances for the adoption of its compliance measure as explained in detail in its various submissions and in the absence of a concrete challenge by the United States and in the light of the time that has passed since the measure was prepared and adopted, it is fully entitled to invoke the principle of good faith and the presumption of compliance.

7.269 The **United States** argues that the European Communities has failed to make a prima facie case of a US violation of Article 22.8 of the DSU. Rather than presenting any evidence of how it has satisfied the conditions of Article 22.8 (removal of WTO-inconsistent measure; provision of solution to nullification or impairment of benefits; mutually satisfactory solution), it posits its claim "in conjunction with" Article 23 and asserts that the "presumption of good faith" or compliance satisfies its burden of proof. Even were one to presume that the European Communities implemented its amended bans in good faith, this fact would not in turn demonstrate that the EC bans actually satisfy the elements of Article 22.8, *e.g.*, the European Communities could be acting in good faith, but still be wrong about the WTO-consistency or compliance of its amended measure.

2. Approach of the Panel

(a) Duty of the Panel to make an objective assessment of the matter before it

7.270 In light of the EC statement that this case is about procedural violations under the DSU[452], and in view of our findings above, we could normally exercise judicial economy and complete our review of this case at this juncture. Indeed, we found that the United States committed a procedural error under the DSU, breached Article 23.1 and 23.2(a) and should have had recourse to dispute settlement in accordance with the rules and procedures of the DSU if it wanted to seek redress of a violation of the WTO Agreement through a determination of violation of the WTO Agreement with respect to Directive 2003/74/EC.

7.271 However, the European Communities claims a separate violation of Article 23.1, read together with Article 22.8 and Article 3.7 of the DSU. Under those claims, the European Communities alleges *inter alia* that the United States breached Article 22.8 because it failed to withdraw its suspension of concessions even though the European Communities removed the measure found to be inconsistent with a covered agreement. We also note the US argument that it did not breach Article 22.8 of the DSU because the EC implementing measure does not *comply* with the *SPS Agreement*.

7.272 We recall that we considered that the two series of main EC claims were such that they could be addressed independently from each other.[453] Our findings of violation of Article 23.1 and 23.2(a) under the first series of main EC claims are completely unrelated to whether the European Communities implemented the DSB recommendations and rulings in the *EC – Hormones* dispute in substance. Indeed, our findings are based on the failure of the United States to have recourse to the procedures under the DSU as a result of the notification of Directive 2003/74/EC – a purely

[452] EC's first written submission, para. 24.
[453] See para. 7.182 above.

procedural step. In contrast, we note that the second series of main EC claims – and the alternative claim of "direct" violation of Article 22.8 of the DSU for that matter – are not premised on the mere existence of an EC implementing measure, but on its *conformity* (presumed or actual) with the *SPS Agreement*.

7.273 Under those circumstances, one cannot exclude that no violation of Article 23.1 of the DSU may be found under the second series of main EC claims even though a violation of Article 23.1 was found under the first series of main EC claims, if only because they are based on different premises.

7.274 We recall in this regard that Article 11 of the DSU instructs us to assist the DSB in discharging its responsibilities and provides that, accordingly, a panel should make an objective assessment of the matter before it. In this case, the matter raised by the European Communities contains two separate elements: a series of claims related to the procedural obligations of the responding party and a series of claims premised on the violation by the responding party of Article 22.8 of the DSU due to compliance by the European Communities with its obligations under the WTO Agreement. We should therefore address both series of claims.

7.275 In addition, we also note that, since our report may be appealed and the Appellate Body can only rule on issues of law, we must provide sufficient factual basis to allow the Appellate Body to complete the analysis, if necessary.[454] In that context, in order to ensure in all instances a positive resolution of this dispute, we consider that proceeding with a review of the second series of main claims raised by the European Communities is appropriate.

7.276 Before proceeding with the review of this second series of claims, we want to stress that in reviewing the EC claims of violation of Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU, our intention is not to substitute ourselves for a compliance panel under Article 21.5 of the DSU. We will make findings with respect to the second series of main claims of the European Communities with the only purpose to reach a conclusion on the violation of the provisions referred to in those claims.

(b) Order of review of the second series of main claims by the European Communities

7.277 We recall that the second series of EC claims is that the United States breaches Article 23.1, read together with Articles 22.8 and 3.7 of the DSU. We also note that the European Communities argues more particularly that Article 22.8 prohibits the continued unilateral application of the suspension of concessions or other obligations when the measure which has been found inconsistent is removed. We conclude from this that the EC claim under Article 23.1 is conditioned by the EC claim under Article 22.8 or, more precisely, that the findings that the European Communities wants us to make in relation to Article 23.1 are dependent on the findings that the European Communities wants us to make under Article 22.8. In other words, the second series of claims of the European Communities is premised on a violation by the United States of its obligations under Article 22.8.

7.278 We therefore conclude that we should begin our analysis of the second series of main claims of the European Communities with a review of the compatibility of the US measure at issue with Article 22.8 of the DSU. We consider that:

(a) if we find a breach of Article 22.8 of the DSU, we will proceed with reviewing the EC claims of violation of Articles 23.1 and 3.7 of the DSU, read together with Article 22.8;

[454] See, e.g., Appellate Body Reports on *Canada – Periodicals*, DSR 1997:I, p. 449 at 469; *Australia – Salmon*, para. 118; and *Korea – Dairy*, para. 92.

(b) if we find no violation of Article 22.8, there will be no need for us to proceed any further with the review of these second series of claims by the European Communities.

7.279 We now proceed with our review of the EC claim under Article 22.8 of the DSU.

3. Violation of Article 22.8 of the DSU

(a) Preliminary remarks

7.280 Article 22.8 reads as follows:

> "The suspension of concessions or other obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits, or a mutually satisfactory solution is reached. In accordance with paragraph 6 of Article 21, the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings, including those cases where compensation has been provided or concessions or other obligations have been suspended but the recommendations to bring a measure into conformity with the covered agreements have not been implemented."

7.281 In light of terms of Article 22.8 and the arguments of the parties, we believe that two preliminary questions have to be addressed with respect to the violation of Article 22.8:

(a) one is when the suspension of concessions should cease to be applied;

(b) another one is what is meant by "the measure found to be inconsistent with a covered agreement".

7.282 Regarding the first question, we recall that the terms of Article 22.8 make it clear that countermeasures may remain in place only until such time as the measure found to be inconsistent by the DSB is removed. In other words, the removal of the illegal measure by the losing party must lead, without delay, to the removal of the suspension of obligations by the Member authorized by the DSB to suspend concessions.

7.283 Regarding what is meant by "the measure found to be inconsistent with a covered agreement", one interpretation could be to consider that the measure found to be inconsistent was Directive 96/22/EC.[455] This measure was removed. However, such an interpretation is unsatisfactory, as Directive 96/22/EC was replaced by Directive 2003/74/EC which also imposes an import ban. The Panel notes that the European Communities agrees that the phrase "until such time as the measure found to be inconsistent with a covered agreement has been removed" means that the illegality itself, and not only the measure, has been removed.[456]

7.284 The Panel believes that the term "measure" should not be interpreted narrowly as applying only to the legislation at issue. What the United States challenged as a complainant in the *EC – Hormones* case was an import restriction on meat and products from cattle treated with growth promoting hormones. We consider that this interpretation is confirmed by the second sentence of

[455] Official Journal of the European Communities, No. L 125, 23 May 1996, p. 3

[456] See EC's first written submission, para. 81, EC's replies to Panel questions after the first substantive meeting, question 55, Annex B-1.

Article 22.8 which refers to the DSB keeping under surveillance situations where obligations have been suspended "but the recommendations to bring a measure into conformity with the covered agreements have not been implemented". We read this phrase as implying that what is to be achieved is not the removal of the measure but the actual compliance with the recommendations or rulings of the DSB.

7.285 We therefore conclude that Article 22.8 may be breached only if the European Communities has complied with the recommendations and rulings of the DSB and the United States has failed to immediately remove its suspension of concessions or other obligations.

7.286 We recall that the European Communities considers that this case is *not* about its compliance with the recommendations and rulings of the DSB in the *EC – Hormones* case. We nonetheless note that the European Communities requests us to make findings in relation to Article 22.8 under its main claim and that it did not exclude the possibility for the Panel to review the substance of the EC implementation measure in the context of its conditional allegation of "direct" violation of Article 22.8. We note, however, that such claim was made "in the alternative", i.e. if the Panel found no violation of the DSU under the other EC claims. In the context of its second series of main claims, the European Communities alleges that it does not have to demonstrate that it has complied with the recommendations and rulings of the DSB since it should benefit from a presumption of good faith compliance with respect to Directive 2003/74/EC. We note that the United States argues that the European Communities has not removed the measure found to be inconsistent with a covered agreement or provided a solution to the nullification or impairment of benefits. More particularly, the United States argues that the EC implementing measure breaches the *SPS Agreement*.

7.287 Having regard to the arguments of the parties regarding the conformity of the EC implementing measure with the *SPS Agreement*, the Panel believes that it must determine the scope of its jurisdiction in this respect.

(b) Jurisdiction of the Panel

(i) Introduction

7.288 This case is not the first one about compliance of a Member with its obligations under the DSU and, in particular, under Article 23.[457] However, because of the claim raised by the European Communities under Article 22.8 of the DSU, the arguments of the United States and the links between this case and the *EC – Hormones* case – in particular through the question of the compliance of the EC implementing measure with the *SPS Agreement* – the second series of main claims by the European Communities raises a number of questions which, to our knowledge, were never directly addressed before by a panel established under Article 6 of the DSU.

7.289 In support of its claim under Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU, the European Communities alleges in substance that it does not have to demonstrate that its implementing measure is compatible with the *SPS Agreement*. Rather, the European Communities argues that it should be presumed to have removed in good faith the measure found inconsistent with the *SPS Agreement* in the *EC – Hormones* dispute and that this presumption could only be rebutted through a recourse to Article 21.5 of the DSU by the responding party.

[457] In *US – Section 301 Trade Act* case, Article 23.2(a) and (c) of the DSU was at issue, in *US – Certain EC Products*, Article 23.1 and 23.2(c) as well as 23.2(a) of the DSU was addressed by the panel and the Appellate Body.

7.290 The United States disagrees that the European Communities benefits from any presumption of compliance and argues, on the contrary, that the European Communities failed to demonstrate that it has complied with the *SPS Agreement*.

7.291 Therefore, before we proceed any further, we believe that we should answer the two following questions:

(a) In light of the EC claim that it benefits from a presumption of good faith compliance, do we need to determine whether the EC implementing measure *actually* complies with the *SPS Agreement* in order to address the EC claim of violation of Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU?

(b) if yes, do we have the jurisdiction to address the conformity of the EC implementing measure with the *SPS Agreement*?

(ii) Does the Panel need to determine whether the EC implementing measure actually complies with the SPS Agreement in order to address the EC claim of violation of Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU?

Summary of the main arguments of the parties[458]

7.292 The **European Communities** considers that, in order to demonstrate that the United States is in violation of Article 23.1, read in conjunction with Articles 22.8 and 3.7 of the DSU, it is not required to explain in full the substance of its compliance measure and why this measure implements the DSB recommendations and rulings. Rather, for the purposes of establishing a violation of DSU rules under these claims, the European Communities considers that it is sufficient to refer to the presumption of good faith which is a cornerstone of the DSU and cannot be undermined by a unilateral and unsubstantiated determination by the United States.[459]

7.293 The European Communities further argues that the WTO inconsistency of the implementing measure can only be determined in accordance with the appropriate procedure, namely Article 21.5 of the DSU. Unless such a procedure concludes that the compliance measure does not fully implement the DSB recommendations and rulings, it cannot be presumed that this is the case. This also follows from the general principle of good faith as it applies in international state relations (Article 26 of the Vienna Convention on the Law of Treaties (1969)), under which States are normally considered to act in conformity with their obligations. This principle has been recurrently recognized in WTO jurisprudence. The presumption of good faith also applies for implementing measures, as has been clearly spelt out in Article 21.5 proceedings.

7.294 For the European Communities, the United States could not unilaterally determine that the European Communities implemented the DSB recommendations and rulings in a WTO inconsistent way. On the contrary, the European Communities must be presumed to have complied with its WTO obligations, if the United States refuses to establish the contrary. This presumption is even more justified as the EC implementation measure required conducting extensive scientific studies and performing a comprehensive risk assessment over several years in a transparent and objective manner, to which the United States had access and could provide comments on at any time.[460]

[458] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[459] EC's first written submission, para. 72.

[460] EC's first written submission, paras. 86-94.

7.295 The European Communities understands that the United States is denying the good faith principle in this case because it considers that the European Communities has not correctly implemented its obligations. By doing so, however, the defending party confuses the notion of good faith and a possible violation under a covered agreement. In the present case, the European Communities bases itself on the same *rationale* as the Appellate Body in the *Byrd Amendment* case. Thus, even though the defending party alleges that the European Communities is still in violation of the *SPS agreement*, this does not in any event affect the presumption of good faith.

7.296 The European Communities recalls that in *EC – Bananas III (Article 21.5 – EC)* the panel merely said that a Member should not be presumed to agree that another Member is in compliance. Thus, the decision dealt with what a complaining Member is presumed to believe or not to believe. Yet, the general principle of good faith is an *objective* criterion that applies to compliance measures properly adopted and notified to the WTO. This is even more obvious if the other Members do not challenge the legality of the new implementing measures under Article 21.5 within a reasonable timeframe.

7.297 The **United States** considers that the European Communities relies on an already rejected legal theory that a Member found to have breached its WTO obligations is to be excused from its burden of proof in dispute settlement if it invokes the phrase "good faith."[461] The United States continues to apply the suspension of concessions to the European Communities in a WTO-consistent manner, fully in accordance with the authorization of the DSB.[462]

7.298 The United States first considers that the reports cited by the European Communities do not find a "presumption" but simply highlight the issue of burden of proof for complaining parties in Article 21.5 proceedings, or WTO proceedings generally, rather than setting forth a "presumption of good faith." The United States does not disagree that, in WTO dispute settlement, the initial burden rests with the complaining party alleging a WTO violation. In the view of the United States, the European Communities appears to believe that the concept of good faith would operate only in favour of the European Communities and either believes no other Member would be able to avail itself of the concept of good faith, or ignores that it would apply with respect to the United States. In this proceeding, the European Communities, as the complaining party, bears the burden of proving its prima facie case against the United States. The European Communities has failed to satisfy this burden because it has not demonstrated removal of its measure or that it has provided a solution to US nullification or impairment within the meaning of Article 22.8.[463]

7.299 The United States recalls that, in the *EC – Bananas III (Article 21.5 – EC)* proceeding already, the European Communities argued that its measures taken to comply were "presumed to conform with WTO rules unless their conformity has been duly challenged under the appropriate DSU procedures." The panel disagreed, highlighting that there is simply no basis in the *WTO Agreement* for the EC argument that it is presumed compliant with its obligations absent a finding against its measures. Similarly, there is no presumption of compliance for the EC amended ban in this proceeding.

7.300 According to the United States, there is no presumption of compliance or good faith in WTO dispute settlement that attaches to measures taken by WTO Members. Such a presumption is not found in the text of the DSU, nor is it found in the covered agreements, in the light of relevant provisions of which panels are charged with examining a matter under DSU Article 7.1. The findings of that evaluation then form the basis of the DSB recommendations and rulings, which "cannot add to

[461] *See* Panel Report on *EC – Bananas III (Article 21.5 – EC)*, para. 4.13.
[462] US's first written submission, para. 106.
[463] US's first written submission, footnote 124.

or diminish the rights and obligations provided in the covered agreements" pursuant to Article 3.2 of the DSU.

7.301 The United States argues that, while Article 3.10 of the DSU uses the term "good faith", it does not do so in a manner indicating that a presumption of good faith attaches to measures taken by Members. Article 3.10 provides, in relevant part, as follows: "It is understood ... that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute." Article 3.10 is not a general incorporation of "good faith" principles of public international law. On the one hand, Article 3.10 is an understanding, not an obligation. On the other, Article 3.10 simply notes that, when a dispute has been initiated, Members will make best efforts to resolve it. It makes no reference whatsoever to a presumption of good faith which attaches to Member's measures, making them "presumed compliant" or WTO-consistent.

7.302 The United States adds that presumptions *per se* are not applicable in WTO dispute settlement. The only concept that comes close to resembling a presumption in dispute settlement is that the complaining party bears the burden of proof in making its prima facie case of the WTO inconsistency of another Member's measure. Rather than a presumption of good faith in dispute settlement, this instead is testament to the fact that there is *no presumption of bad faith* that attaches to measures taken by a WTO Member.

7.303 The United States considers that the established rules of burden of proof in dispute settlement already ensure that a complaining party establish its prima facie case, thereby obviating any need for such a presumption.

7.304 In the opinion of the United States, the European Communities has failed to demonstrate that such a presumption exists in WTO dispute settlement. When the arbitrator's statement in the *EC – Hormones (Article 22.6)* proceeding is viewed in context, it becomes clear that it was simply discussing relevant burdens of proof in WTO dispute settlement, noting that once a Member has claimed WTO-inconsistency of a measure in a dispute, it must prove that this is indeed the case.

7.305 The United States further notes that two other disputes cited by the European Communities, *Canada – Aircraft (Article 21.5 – Brazil)* and *Chile – Alcoholic Beverages,* do not mention a presumption of good faith whatsoever. Rather, they state that there is *no presumption of bad faith* in WTO dispute settlement. In these proceedings, the European Communities, as the complaining party, bears the burden of proving its prima facie case against the United States. The EC has failed to satisfy this burden because it has not demonstrated removal of its WTO-inconsistent measure or that it has provided a solution to US nullification or impairment within the meaning of Article 22.8.

7.306 The United States recall that the European Communities cites an opinion of the International Court of Justice discussing good faith. However, nowhere in the covered agreements is this presumption or principle discussed. As a panel established under Article 6 of the DSU, this Panel is charged under its terms of reference (DSU Article 7.1) with examining this matter "in light of the relevant provisions in [the covered agreements]". The relevant provisions of the DSU and the *SPS Agreement* do not contain a presumption of good faith in dispute settlement.[464]

7.307 Finally, in the opinion of the United States, even were one to presume that the European Communities implemented its amended bans in good faith, this fact would not in turn demonstrate that the EC's bans actually satisfy the elements of Article 22.8, *e.g.*, the EC could be acting in good faith, but still be wrong about the WTO-consistency or compliance of its amended measure.

[464] US's replies to Panel questions after the first substantive meeting, question 61, Annex B-3.

Reasoning of the Panel

Introductory remarks

7.308 Having regard to the arguments of the parties, the Panel considers that it needs to determine:

(a) whether the European Communities can invoke a presumption of good faith compliance; and, if yes,

(b) whether, and how, such a presumption could be rebutted.

7.309 The Panel notes that, generally, when good faith is referred to in a dispute, this is in relation to the measure adopted by the defending party[465], not with respect to a measure adopted by the complaining party – in this case the European Communities. Normally, a complainant does not have to show that it applies a measure in good faith, since this is normally not the measure at issue in the dispute. However, the demonstration by the European Communities of a violation of Article 22.8 by the United States in this case implies that it proves that it has removed the measure found to be inconsistent with a covered agreement in the *EC – Hormones* case. The Panel also recalls that it found above that the United States should have had recourse to the DSU in relation to the EC implementing measure. If the United States had had recourse to the dispute settlement procedures under the DSU – including the procedure provided in Article 21.5 – the European Communities would have been the defending party and its implementing measure would have benefited from a presumption of compatibility with WTO rules.[466] For these reasons, the Panel deems it appropriate not to take position on whether good faith can be invoked only by the defendant. Instead, it will address the issue by disregarding the status of the European Communities as complaining party in this case.

Applicability of the principle of good faith in the WTO and under the DSU

Introduction

7.310 We note that what the European Communities claims in this respect is the existence of a presumption of good faith compliance based on the international law principle of good faith. We are mindful of the position expressed by the United States that the impact of general international law on the DSU is limited to the application of the customary rules of interpretation of public international law embodied in the Vienna Convention on the Law of Treaties (cf. Article 3.2 of the DSU). However, we note that Article 31.3(c) provides that

> "[t]here shall be taken into account, together with the context: ... (c) any relevant rule of international law applicable to the relations between the parties."

7.311 Having regard to the overarching nature of the principle of good faith in international legal relations, we deem it appropriate to determine first whether there is any basis in public international law for the principle to which the European Communities refers. If this is the case, we will then proceed with determining whether the WTO Agreement in general and the DSU in particular exclude the application of this principle.

[465] See, e.g., Appellate Body Report on *US – Carbon Steel*, para. 157.

[466] See, e.g., Appellate Body Report on *Canada – Dairy (Article 21.5 – New Zealand and US II)*, para. 66.

General international law

7.312 We note that what the European Communities refers to in its submissions is a presumption that it acted in good faith and thus must be presumed to have complied with the recommendations and rulings of the DSB.

7.313 We are of the view that the principle of good faith could be analysed mainly in respect of the following categories:

(a) good faith conduct in a dispute settlement procedure;

(b) substantive good faith, i.e. with respect to the substantive obligations of a State;

(c) good faith in the interpretation process (Article 31 of the Vienna Convention on the Law of Treaties).

7.314 What the European Communities invokes in this case seems to fall primarily within the category of substantive good faith.

7.315 This allegation of the European Communities raises, in our opinion, two related but distinct issues under general international law:

(a) the first one is whether a presumption that States act in good faith exists under general international law;

(b) the second one is whether such presumption of good faith can be assimilated to a presumption of compliance.

7.316 Good faith is one of the basic principles regarding the creation and execution of legal obligations in public international law.[467] This principle is expressed *inter alia* in Article 26 of the Vienna Convention on the Law of Treaties:

> "Every treaty in force is binding upon the parties to it and must be performed by them in good faith."

7.317 It is implicit from the duty to perform treaty obligations in good faith that a party to an international agreement should be deemed to have acted in good faith in the performance of its treaty obligations. More generally, even though Article 26 provides for an obligation and not a presumption, *pacta sunt servanda* is but only one expression of the principle of good faith. Good faith is a general principle of international law that governs all reciprocal actions of States.[468] We are therefore inclined to agree with the European Communities that every party to an international agreement must be presumed to be performing its obligation under that agreement in good faith.

7.318 Having concluded that, under general international law, States enjoy a presumption of good faith, we now proceed to determine whether presumption of good faith can be equated with presumption of compliance with treaty obligations.

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[467] See, e.g., ICJ, *Nuclear Tests Case*, Judgement of 20 December 1974, ICJ Reports 1974, p. 473, para. 49.

[468] See also UN Charter, Art.2.2; Malcom N. Shaw: International Law (5th edition), p. 811-812: "[Pacta sunt servanda] underlies every international agreement for, in the absence of a certain minimum belief that States will perform their treaties obligations in good faith, there is no reasons for countries to enter into such obligations with each other."

7.319 The Panel notes in this respect that good faith has been defined as a:

> "disposition d'esprit de loyauté et d'honnêteté consistant en ce qu'un sujet de droit ne tente pas de minorer ses obligations, quels qu'en soit l'origine et le fondement ..."[469]

7.320 According to this definition, a State acting in good faith should be honestly seeking to comply with its obligations. A presumption of good faith could thus extend to compliance. It is the understanding of the Panel that States benefit in their actions from the principle that a breach of the principle of good faith cannot be presumed and that any State alleging an abuse of right (*abus de droit*) or, more particularly, a breach of the principle of good faith, must prove it.[470]

7.321 As a result, we note that, under general international law, the European Communities would be entitled to claim a presumption of good faith compliance.

7.322 However, that does not mean that the State invoking good faith compliance, while acting in total good faith, actually complied with its treaty obligations. It could make an illegal interpretation of its obligations without breaching the principle of good faith. Thus, if good faith compliance is presumed, it cannot be a non-rebuttable or *juris et de jure* presumption.

7.323 An additional element to consider is that, under general public international law, *every* State benefits from the application of the principle of good faith. We therefore agree with the United States that if the European Communities can claim good faith compliance, the United States too should also benefit from the same presumption. Unlike in "normal" cases where only the measure adopted by one Member is at issue, in this case the legality of the US measure challenged by the European Communities depends on whether the measure taken by the European Communities to comply with DSB recommendations and rulings is WTO consistent. In other words, both parties can invoke the presumption of good faith. However, we do not see the fact that both parties can invoke good faith in relation to diametrically opposed positions as affecting the applicability of this principle in this case. Indeed, we are only dealing with presumptions, not with evidence. As long as these presumptions can be rebutted before a panel, we see no inherent problem to the fact that both parties claim good faith.

The text of the DSU

7.324 The Panel first notes that, with the exception of Articles 3.10 and 4.3, there is no reference to good faith in the DSU. Of those two references, that in Article 4.3 relates specifically to consultations. Only that in Article 3, entitled "General Provisions", could have a relevance in this case. However, Article 3.10 reads as follows:

> "It is understood that requests for conciliation and the use of the dispute settlement procedures should not be intended or considered as contentious acts and that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute. It is also understood that complaints and counter-complaints in regard to distinct matters should not be linked."

7.325 The Panel understands the reference to good faith in Article 3.10 of the DSU to relate to the manner in which parties to a dispute should participate in the dispute (i.e., procedural good faith, as

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[469] Jean Salmon: *Dictionnaire de droit international public*, p. 134. Black Law Dictionary, 6th ed., para. 693:

> "In common usage the term is ordinarily used to describe that state of mind denoting honesty of purpose, freedom from intention to defraud and, generally speaking, means being faithful to one's duty or obligation."

[470] PCIJ, *Upper Silesia Case*, Judgement of 25 May 1926, Series A. No. 7, p. 30.

described above), not specifically to whether Members should be presumed to be acting in good faith. Indeed, the reference to good faith is made in relation to "engage[ing] in [DSU] procedures in good faith *in an effort to resolve the dispute*" (emphasis added) and the preceding phrase provides that DSU procedures "should not be intended or considered as contentious acts".

7.326 The Panel therefore considers that Article 3.10 is of limited direct relevance to determine whether the European Communities should benefit from a presumption of good faith compliance under the DSU.

7.327 However, the references to good faith in the DSU are evidence that the DSU does not exclude the application of the principle of good faith in the resolution of disputes. The Panel is of the view that, since the application of the principle of good faith is not expressly excluded by the DSU, it is applicable to WTO Members.[471]

The panel and Appellate Body practice

Presumption and burden of proof

7.328 The Panel notes that, in *US – Wool Shirts and Blouses*, the Appellate Body recalled that:

> "[W]e find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof."[472]

7.329 However, the Appellate Body also mentioned in *Japan – Apples* that:

> "[T]he Appellate Body statement in *EC – Hormones* does not imply that the complaining party is responsible for providing proof of all facts raised in relation to the issue of determining whether a measure is consistent with a given provision of a covered agreement. In other words, although the complaining party bears the burden of proving its case, the responding party must prove the case it seeks to make in response."[473]

7.330 We believe that, in arguing that it enjoys a presumption of good faith compliance, the European Communities is not merely *asserting* its claim of violation of Articles 23.1, 22.8 and 3.7. The EC allegation of existence of a presumption of good faith compliance is only one part – although an essential one – of the EC argumentation supporting its claims. Moreover, the European Communities is not directly asserting that it has complied in relation to the conformity of the US measure with Article 22.8, but that it enjoys, as a matter of principle, a presumption that it complied in good faith with its own obligations.

7.331 On its part, the United States argues as a defence that the European Communities did not comply with the recommendations and rulings of the DSB. One may argue that the parties' respective

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[471] The Panel is not of the view that the fact that some covered agreements, such as the *SPS Agreement* (see Article 2.4) expressly provide that measures of a Member which conform to a given agreement shall be presumed to be in accordance with the obligations of that Member under another covered agreement would imply that the presumption of good faith does not apply in the WTO Agreements unless expressly referred to. The Panel considers that the reference to presumption in Article 2.4 of the *SPS Agreement* is to a legal presumption and is intended to address potentially conflicting interpretations between two provisions. The reference in Article 3.2 of the *SPS Agreement* can be explained by the fact that the "international standards, guidelines or recommendations" are not part of the WTO Agreement.

[472] Appellate Body Report on *US – Wool Shirts and Blouses*, DSR 1997:I, p. 323 at 335.

[473] Appellate Body Report on *Japan – Apples*, para. 154.

burdens are unbalanced because the European Communities, if one agrees with its position, does not have to demonstrate prima facie that it has complied with the recommendations and rulings of the DSB. However, it should first be recalled that what is at issue in this case is not directly whether the European Communities has complied with the recommendations and rulings of the DSB, but whether the United States complied with its obligations under Articles 23.1, 22.8 and 3.7 of the DSU. By taking this route, the European Communities takes the risk that its claims may be rejected if the Panel disagrees with the existence of a presumption of good faith compliance.

7.332 We therefore conclude that by invoking a presumption of good faith compliance, the European Communities is not merely asserting its claims under Article 22.8, but rather supporting its claims which are, in essence, claims of violations by the United States, not claims of compliance by the European Communities.

7.333 We therefore find that the European Communities' reliance on a presumption does not amount in this case to merely asserting a claim.

Presumption of good faith

7.334 The Panel notes that the Appellate Body has, on several occasions, recalled that the principle of good faith applies to WTO Members in their relations under the WTO Agreement. The Panel recalls that, in *US – FSC*, the Appellate Body stated that:

> "This pervasive principle [of good faith] requires both complaining and responding Members to comply with the requirements of the DSU (and related requirements in other covered agreements) in good faith." (emphasis added)[474]

7.335 Furthermore, it seems that the Appellate Body understands the obligation to comply with the requirements of the DSU in good faith as implying that Members are to be presumed to act in good faith. In *EC – Tube or Pipe Fittings*, the Appellate Body found that:

> "This excerpt demonstrates that the Panel took into account the European Communities' responses to its questions before reaching its finding. It also indicates that the Panel did not rely exclusively on the presumption of good faith, as Brazil suggests, given that some of the Panel's questions were directed at the *validity* of Exhibit EC-12. If the Panel had placed total reliance on the presumption of good faith, it would have simply accepted the European Communities' assertion that Exhibit EC-12 formed part of the record of the investigation and would not have posed questions to assess the consistency of Exhibit EC-12 with other evidence contained in the record. Therefore, we are satisfied that the Panel "took steps to assure [itself] of the validity of [Exhibit EC-12] and of the fact that it forms part of the contemporaneous written record of the EC investigation." (footnotes omitted – emphasis added)[475]

7.336 As mentioned above, there is no express exclusion of the application of the principle of good faith in the DSU or in the WTO Agreement. As noted by the panel on *Korea – Procurement*:

> "Article 3.2 of the DSU requires that we seek within the context of a particular dispute to clarify the existing provisions of the WTO agreements in accordance with customary rules of interpretation of public international law. However, the relationship of the WTO Agreements to customary international law is broader than

[474] Appellate Body Report on *US – FSC*, para. 166.
[475] Appellate Body Report on *EC – Tube or Pipe Fittings*, para. 127.

> this. Customary international law applies generally to the economic relations between the WTO Members. Such international law applies to the extent that the WTO agreements do not 'contract out' from it. To put it another way, to the extent there is no conflict or inconsistency, or an expression in a covered WTO agreement that implies differently, we are of the view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO."[476]

7.337 More precisely, in *US – Section 211 Appropriations Act*, the Appellate Body recalled that:

> "... where discretionary authority is vested in the executive branch of a WTO Member, it cannot be assumed that the WTO Member will fail to implement its obligations under the *WTO Agreement* in good faith. Relying on these rulings, and interpreting them correctly, the Panel concluded that it could not assume that OFAC would exercise its discretionary executive authority inconsistently with the obligations of the United States under the *WTO Agreement*. Here, too, we agree." (emphasis added)[477]

7.338 The parties have argued on the relevance of the report in *EC – Bananas III (Article 21.5 – EC)*. The European Communities notes that this report was never adopted by the DSB. We nevertheless recall that the Appellate Body, in *Japan – Alcoholic Beverages II*, found that panels may seek guidance from unadopted panel reports. In *EC – Bananas III (Article 21.5 – EC),* the panel rejected the EC assertion of a presumption of consistency. In that case, the EC requested the panel to find that its implementing measures "must be presumed to conform to WTO rules unless their conformity has been duly challenged under the appropriate DSU procedures". This position seems largely similar to the position adopted by the European Communities in the present case, where it claims that the United States will breach Article 23 even if it rebuts the presumption of compliance because it failed to use the right forum to contest it (i.e. Article 21.5 of the DSU).

7.339 The panel in *EC – Bananas III (Article 21.5 – EC)*, agreed with the European Communities that there was normally no presumption of inconsistency attached to a Member's measures in the WTO dispute settlement system. This was subsequently confirmed by the Appellate Body in *Chile – Alcoholic Beverages*[478]and it is now well established that no presumption of bad faith can be applied to a Member's measure. However, the panel in *EC – Bananas III (Article 21.5 – EC)* considered that the failure, as of a given point in time, of one Member to challenge another Member's measures could not be interpreted to create a presumption that the first Member accepts the measures of the other Member as consistent with the WTO Agreement.[479]

7.340 First, we find the above reasoning of the Panel in *EC – Bananas III (Article 21.5 – EC)* convincing.

7.341 Second, in the present case, however, the European Communities does not actually allege that there is a presumption of acceptance by the United States that the measure is consistent with the WTO Agreement because the United States failed to challenge the measure. The European Communities claims that there is a presumption of compliance based on the presumption of good faith and that this presumption can only be rebutted in the appropriate forum, i.e. by invoking Article 21.5 of the DSU.

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[476] Panel Report on *Korea – Procurement*, para. 7.96.

[477] Appellate Body Report on *US – Section 211 Appropriations Act*, para. 259. (original footnote omitted)

[478] Appellate Body Report on *Chile – Alcoholic Beverages*, para. 74.

[479] Panel Report on *EC – Bananas III (Article 21.5 – EC),* para. 4.13.

7.342 The United States argues that the presumption of good faith compliance cannot supersede the multilateral authorization of the DSB to the United States to suspend concessions.

7.343 As already mentioned, we first note that Article 22.2 and 22.7 of the DSU refers to "authorization" of the DSB. The United States has no obligation under the DSU to apply the sanctions authorized by the DSB.[480] Second, we note that Article 22.8 provides that the suspension of obligations "shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the Member that must implement recommendations or rulings provides for a solution to the nullification or impairment of benefits". There is no reference to the DSB in that phrase and nothing in this provision suggests that a Member suspending concessions can continue to do so as long as the authorization of the DSB has not been repealed by the DSB. On the contrary, it seems that it is for the Member concerned to draw the consequences of a removal of the violation. In other words, the removal of the measure found to be inconsistent with a covered agreement supersedes the DSB authorization to suspend concessions.

7.344 The United States also argues that, if the presumption of good faith compliance were accepted, nothing would prevent the European Communities from notifying a "scam legislation". The United States argues that this could open an endless loop of litigation[481], as a mere notification of a compliance measure would force the United States to initiate a dispute settlement procedure under Article 21.5 of the DSU.

7.345 We recall that we are called upon to solve this dispute, not to make generally applicable interpretations of the DSU. We have found above that the EC implementing legislation was not a "scam legislation". Therefore, we do not find it necessary to address the situation that would result from our finding if a Member notified a "scam legislation".

Is the presumption of good faith compliance rebuttable only in a specific forum?

7.346 We note that the European Communities claims that the presumption of good faith compliance is rebuttable, but only in the appropriate forum, i.e. by the complaining party in the original case taking the initiative of having recourse to a dispute settlement procedure under Article 21.5 of the DSU.[482] The European Communities alleges a "jurisprudential" need for an irrebuttable presumption to fill up a gap in the DSU and allow respondents to exit from post-retaliation situations.

7.347 The United States argues, on the contrary, that an Article 21.5 proceeding is not the only avenue available if there is a disagreement as to the adoption of a compliance measure and that, in any event, it is not open exclusively to the United States, but also to the European Communities.

7.348 It is therefore important for the Panel to determine the extent to which the unavailability of any legal recourse for the European Communities in a post retaliation situation may justify that the presumption of good faith compliance be irrebuttable, except through recourse to the procedure provided in Article 21.5 of the DSU.

7.349 We first note that nowhere does the DSU provide that a presumption of good faith compliance should be rebuttable only through recourse to Article 21.5 of the DSU.

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[480] See, e.g., *Canada – Aircraft Credits and Guarantees* and *Brazil – Aircraft*. In both cases authorization of retaliation has been granted by the DSB but the complaining party has not applied the authorized sanctions.

[481] See, e.g., US's reply to Panel question 40 after the first substantive meeting, Annex B-3, para. 6.

[482] EC's reply to Panel question 4(b) after the first substantive meeting.

7.350 Second, it appears that, even under the current DSU, several means seem *a priori* to be available to the European Communities to obtain termination of the suspension of concessions or other obligations:

(a) Good offices and consultations;[483]

(b) Article 21.5 of the DSU;

(c) Arbitration under Article 25 of the DSU; and

(d) recourse to a normal panel against the continuation of the retaliations (as in this case).

7.351 The Panel is mindful that the option naturally coming to mind when it comes to reviewing compliance is the procedure provided under Article 21.5 of the DSU. The Panel is aware of the broad language ("such dispute shall be decided through recourse to these dispute settlement procedures") used in Article 21.5 and that such language could be deemed to encompass any procedure available under the DSU for the resolution of disputes. The Panel is, however, of the opinion that other terms in Article 21.5 support the view that the Article 21.5 procedure is actually a panel procedure with a shorter deadline. In this regard, the Panel reads the phrase "including whenever possible resort to the original panel" not as meaning that resort to a panel is generally preferred, but as requesting resort to the panelists that reviewed the original case, rather than to other individuals.

7.352 The Panel also notes that this dispute is evidence that a practicable alternative exists to a recourse to Article 21.5. We recall in this respect that even though the European Communities claims a violation of the DSU by the United States, its claim under Article 22.8 of the DSU is based on the compliance of its implementing measure with the WTO Agreement, whether presumed (as part of the second series of main EC claims under Article 23.1 read together with Article 22.8 and Article 3.7) or demonstrated (as in its alternative "direct" claim of violation of Article 22.8). While Members enjoy complete discretion in the way they bring the measure at issue into conformity with the covered agreements, the findings already made by the Panel with respect to Article 23.2(a) and 23.1 of the DSU and the findings the Panel will make under Article 22.8 will have an impact on whether the United States may maintain, suspend or withdraw the suspension of obligations it currently applies.

7.353 We recall that the European Communities considered that Article 21.5 was not an avenue open to the party claiming compliance, but only to the complainant in the original case.[484] Both parties have discussed the relevance of the only case where a party found in breach of its obligations requested an Article 21.5 panel, i.e. the *EC – Bananas III (Article 21.5 – EC)* panel.

7.354 We note that, in the *EC – Bananas III (Article 21.5 – EC)* case, the panel did not conclude that it could not perform its duties under Article 21.5. The panel, referring to the comments made by Japan as a third party, noted that allowing the defendant before the original panel to initiate a procedure under Article 21.5 presented certain "practical problems or anomalies". The panel was also sympathetic to the concerns of India as a third party that, in an appropriate case, a respondent-initiated Article 21.5 proceeding should be allowed.[485] The Panel concluded:

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[483] Such a solution seems to be implicitly suggested by the United States when it refers to Article 22.8 which mentioned that "a mutually satisfactory solution is reached".

[484] EC's reply to Panel question 1 after the first substantive meeting, Annex B-1; EC's second written submission, para. 61.

[485] Panel Report on *EC – Bananas III (Article 21.5 – EC)*, para. 4.18.

> "In our view, we would not rule out the possibility of using Article 21.5 in such a manner, particularly when the purpose of such initiation was clearly the examination of the WTO-consistency of implementing measures."[486]

7.355 We are therefore not convinced that Article 21.5 is the only avenue available to address a claim of compliance by a Member alleging to have complied with recommendations and rulings of the DSB. Neither do we believe that proceedings under Article 21.5 are open only to the original complainant.

7.356 For these reasons, the Panel does not agree that the presumption of good faith compliance which the European Communities enjoys should be rebuttable only through a recourse by the complainants in the original case to Article 21.5 of the DSU.

(iii) Conclusion

7.357 On the basis of the above:

(a) We note that, under general international law, the corollary to the obligation to perform treaty obligations in good faith is the presumption that Members act in good faith when performing such obligations.

(b) We find that the general principle of good faith and the presumption of good faith performance of a Member's obligations apply in relation to Members' obligations under the WTO Agreements, including the DSU, as interpreted in accordance with customary rules of interpretation of public international law.

(c) We also note that there is no presumption of bad faith under general international law and find that no presumption of bad faith applies under the DSU as interpreted in accordance with customary rules of interpretation of public international law.

(d) We find that the presumption of good faith compliance alleged by the European Communities is at best legally identical to the principle of good faith performance of treaty obligations. We do not find in the DSU as interpreted in accordance with customary rules of interpretation of public international law any ground supporting a specific presumption of compliance for Members having to implement DSB recommendations and rulings.

(e) Moreover, we find no support in the DSU to suggest that this presumption may only apply to the measure taken by the European Communities and not to the measures adopted by the United States.

(f) As a consequence, while we agree with the existence of a presumption of good faith compliance, we do not agree with the European Communities that the presumption of good faith that it enjoys may only be rebutted in an Article 21.5 procedure. We find, on the contrary, that this presumption, because it applies to measures taken by all parties, must be rebuttable before this Panel. Just as the EC allegations are intended to rebut the presumption of good faith conformity of the US retaliatory measures with Article 22.8 of the DSU, the United States should be allowed to rebut the presumption of EC compliance by proving actual non-compliance.

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[486] Ibid.

7.358 In reaching these conclusions, we do not consider that we add to or diminish the rights and obligations of WTO Members. We do not apply the presumption of good faith compliance independently from the obligations of the European Communities under the WTO Agreement. The European Communities has an obligation to comply with the WTO Agreement in general[487] and with the recommendations and rulings of the DSB and the general principle of good faith implies that the European Communities do so in good faith. In doing so we apply the principle of good faith consistently with WTO law and general public international law.[488]

7.359 We have also found above that we could not agree with the European Communities and base our findings of violation of Article 23.1 read in conjunction with Article 22.8 and 3.7 of the DSU on an irrebuttable presumption of good faith compliance by the European Communities. Whereas the European Communities enjoys a presumption of good faith compliance, this presumption is rebuttable. We agree that, for all practical purposes, this amounts to addressing the EC "alternative" claim of violation of Article 22.8 *per se*. However, this is not the result of us merely disregarding the order in which the European Communities wanted us to review this case. We are still reviewing the EC claim of violation of Article 23.1, read together with Articles 22.8 and 3.7. We are not reviewing a claim of violation of Article 22.8 in isolation.

(iv) Does the Panel have jurisdiction to address the compliance of the EC implementing measure with the SPS Agreement?

7.360 We are mindful that our terms of reference do not include any provision of the *SPS Agreement* referred to by the parties during these proceedings and that "[A] panel cannot assume jurisdiction that it does not have."[489] *Stricto sensu*, the conformity of the EC measure with the provisions of the *SPS Agreement* referred to in this case is not part of our mandate. This means that reviewing alleged violations of the *SPS Agreement* is not part of our mandate either and that we are not expected to make *findings* on those provisions.

7.361 However, this absence of reference to the *SPS Agreement* is understandable since the European Communities is not seeking a finding of violation of the *SPS Agreement* by the responding party.

7.362 Moreover, we note that the European Communities claims in its request for establishment of a panel that the United States breached Article 22.8

> "[b]y failing to apply the suspension of concessions or other obligations only until such time as the measure found to be inconsistent with a covered agreement has been removed, or the implementing Member has provided a solution to the nullification or impairment of benefits previously caused to the United States."[490]

7.363 This statement, which essentially repeats the terms of Article 22.8, must be read in conjunction with other relevant remarks of the European Communities in its request for establishment of a panel. For instance, in the introduction, the European Communities stated that:

> "[t]his request concerns the United States' continued suspension of concessions and other obligations under the covered agreements, without recourse to the procedures established by the DSU, after the European Communities has removed the measures

[487] See Article XVI:4 of the WTO Agreement.
[488] As explicitly expressed in Article 2.2 of the Charter of the United Nations, as well as in Article 26 of Vienna Convention on the Law of Treaties.
[489] Appellate Body Report on *India – Patents (US)*, para. 92.
[490] WT/DS320/6.

found to be inconsistent with WTO law in case DS26, *European Communities – Measures concerning meat and meat products (Hormones)* ('*EC – Hormones*')."[491]

and subsequently:

"[t]he European Communities subsequently removed the measure found to be inconsistent with a covered agreement. It adopted Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. The Directive was published and entered into force on 14 October 2003.

In conformity with the recommendations and rulings of the DSB and the covered agreements, the new EC legislation is based on comprehensive risk assessments, in particular on the opinions of the independent Scientific Committee on Veterinary Measures relating to Public Health. The risk assessments focussed on potential risks to human health from hormone residues in bovine meat and meat products, in particular such risks arising from residues of six hormonal substances: oestradiol-17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. In carrying out the risk assessments, the European Communities initiated and funded a number of specific scientific studies and research projects. It addressed specific requests to the United States, Canada and third countries to provide any recent scientific data and information in their possession. It took account of the findings of various independent expert bodies.

In light of the risk analyses carried out, the European Communities concluded that the avoidance of intake of oestradiol-17β is of absolute importance to human health and that, consequently, the placing on the market of meat containing this substance should be prohibited. With respect to testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate, and on the basis of the available pertinent scientific information reflected in the above-mentioned risk analyses, the European Communities provisionally prohibited the placing on the market of meat containing these substances because the relevant scientific evidence was insufficient.

On 27 October 2003, the European Communities notified to the DSB the adoption, publication and entry into force of this Directive as well as the preceding scientific risk assessments. In the same communication, the European Communities explained that it considers itself to have fully implemented the recommendations and rulings of the DSB in the *EC – Hormones* dispute and that, as a consequence, it considers the United States' suspension of concessions vis-à-vis the European Communities to be no longer justified."[492]

7.364 In the Panel's view, one instance of violation of Article 22.8 occurs when the suspension is maintained even though the "measure found to be inconsistent ... has been removed". The lengthy explanation above demonstrates that the claims of the European Communities under Article 22.8 are related to its alleged removal of the "measure found to be inconsistent" with the *SPS Agreement*.

7.365 The Panel notes the arguments of the parties in reply to a question on its jurisdiction to review the compatibility of the EC implementing measure with the *SPS Agreement*. The United States replied that, pursuant to Article 7 of the DSU, a panel's standard terms of reference include the

[491] WT/DS320/6 (emphasis added).
[492] WT/DS320/6 (original footnotes omitted).

provisions referred to by the responding party.[493] The European Communities replied that, in light of the Appellate Body practice, the Panel has, in the present case, no jurisdiction to address Articles 3.3, 5.1 and 5.7 of the *SPS Agreement*. The European Communities adds that, at best, one could venture to draw an analogy to affirmative defences.[494]

7.366 The Panel is not convinced by any of the views of the parties. Regarding the argument of the United States, the Panel recalls that the matter before the Panel is defined by the request for establishment of the Panel.[495] The matter before this Panel is whether the measure maintained by the United States suspending concessions or other obligations *vis-à-vis* the European Communities has breached, *inter alia*, Article 22.8 of the DSU, not whether the European Communities has complied with the *SPS Agreement*. As a result, the US references to provisions of the *SPS Agreement* are not claims. The Panel may address them, however, to the extent necessary to make an objective assessment of the matter, including an objective assessment of the EC claims, as part of its findings on Article 22.8 of the DSU.

7.367 Neither does the Panel consider that an analogy could be drawn between the reference by the parties to provisions of the *SPS Agreement* in this case and the notion of "affirmative defence". In the opinion of the Panel, an affirmative defence would imply that the responding party invoke a provision of a covered agreement as a justification for a breach of another provision. This is not the case here. The United States does not argue the incompatibility of the EC implementing measure as a *justification* for a breach of Article 22.8. Nor does it seem to invoke the incompatibility of the EC implementing measure as a justification for a breach of Article 23. The Panel concludes that any jurisdiction it may have to review the compatibility of the EC implementing measure with the *SPS Agreement* cannot result from the fact that the United States would have invoked the *SPS Agreement*, including as an affirmative defence.

7.368 We also note the argument of the European Communities that:

> "[this] issue is a perfect illustration of the problems arising if an implementing member is forced to bring a case alleging compliance, instead of the original complaining party bringing a case alleging non compliance ... The terms of reference become wholly devoid of their meaning and the panel's jurisdiction turns into a moving target depending on whatever allegations of inconsistency the 'defending' parties will come up with. It is clear that the dispute settlement system is not designed to accommodate such a procedural constellation."[496]

7.369 We do not agree that the terms of reference of the Panel become wholly devoid of meaning because of the references made by the parties to provisions of the *SPS Agreement*. Neither do we consider that this modifies our terms of reference. We recall that the European Communities claims a violation by the United States of Article 22.8 of the DSU which is premised on the compliance of the EC implementing measure (Directive 2003/74/EC) with the *SPS Agreement*. A discussion of the

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[493] US's reply to Panel question 65 after the first substantive meeting, Annex B-3, para. 64.
[494] EC's reply to Panel question 65 after the first substantive meeting, Annex B-1, paras. 239-241.
[495] See Appellate Body Report in *Brazil – Desiccated Coconut*, DSR 1997:I, p. 186:

> "… the 'matter' referred to a panel for consideration consists of the specific claims stated by the parties to the dispute in the relevant documents specified in the terms of reference. We agree with the approach taken in previous adopted panel reports that a matter, which includes the claims composing that matter, does not fall within a panel's terms of reference unless the claims are identified in the documents referred to or contained in the terms of reference."

[496] EC's reply to Panel question 65 after the first substantive meeting, Annex B-1, para. 240. See also EC's reply to Panel question 62 after the first substantive meeting, Annex B-1.

compatibility of the measure with provisions of the *SPS Agreement* is, thus, the immediate consequence of the inclusion of Article 22.8 of the DSU in the EC request for establishment of a panel. As such, our mandate remains defined by the EC request for establishment of a panel.

7.370 We are mindful that the responding party could bring several allegations of violations with respect to the EC implementing measure. We note however that the European Communities did not exclude the possibility for the Panel to consider the actual compatibility of Directive 2003/74/EC with the *SPS Agreement* as part of its alternative "direct" claim under Article 22.8 of the DSU. Such a review would imply that the Panel address the compatibility of the EC implementing measure with the *SPS Agreement*. While the Panel must comply with its terms of reference, nothing in the DSU prevents the Panel from considering the compatibility of the EC implementing measure with the *SPS Agreement* if this is necessary in order to make the findings required by those terms of reference.

7.371 Moreover, we note that, whereas the European Communities "[did] not believe that it [was] necessary for the Panel to look into any scientific issue to make its necessary findings and rulings within its terms of reference in this particular case", the European Communities did not exclude that the Panel could address the scientific issues at stake since it suggested that, in such a case, the consultation of scientific experts would be absolutely necessary.[497] The parties have extensively discussed the question of the compatibility of the EC implementing measure with certain provisions of the *SPS Agreement*, have agreed to the consultation of experts on the scientific issues relating to the compatibility of the measure with the *SPS Agreement* and have extensively commented on these scientific issues.

7.372 We conclude from this that the Panel should be entitled to determine whether the European Communities has removed the measure found to be inconsistent with a covered agreement in order to establish whether Article 22.8 has been breached by the United States. Indeed, the Panel considers that, since the European Communities made a claim of violation of Article 22.8, the compatibility of its implementing measure becomes *ipso facto* an issue that the Panel will have to address if it reviews any of the EC claim relating to Article 22.8. The fact that the European Communities alleges that it benefits from a presumption of good faith compliance does not affect this conclusion. Under both of its Article 22.8 claims, the European Communities needs to demonstrate that it has removed the measure found to be inconsistent. The presumption of good faith compliance does not affect what needs to be demonstrated. It simply shifts the burden of proof since, in application of the presumption of good faith compliance, the European Communities has, in this dispute, made a prima facie case of violation of Article 22.8 which the United States has to rebut.

7.373 The Panel notes that, pursuant to its mandate, it is only expected to make findings of violation in relation to Article 22.8 of the DSU, the breach of which is alleged by the complaining party. The Panel nonetheless recalls that, for the reasons mentioned above and irrespective of which one of the two Article 22.8 claims is addressed, it will have to determine whether the European Communities has removed the measure found to be inconsistent. Since what has to be demonstrated is a consistency or inconsistency with provisions of the *SPS Agreement*, this is not really an issue of fact but a legal question, which adds to the complexity of the situation before the Panel.

7.374 The Panel is fully conscious of the challenges attached to assessing whether the EC implementing measure is not inconsistent with the provisions of the *SPS Agreement* referred to by the parties in this case. The Panel also notes that, in a case like this one, it is largely dependent on the responding party, not on the complainant, as far as allegations of incompatibility of the EC

[497] EC's reply to Panel question 74 after the first substantive meeting, Annex B, para. 275. The Panel notes that the European Communities raised an alternative claim of violation of Article 22.8 of the DSU and Articles I and II of the GATT 1994, based on its alleged actual compliance with the recommendations and rulings of the DSB in the *EC – Hormones* case.

implementing measure are concerned. However, we believe that it is in the interest of the responding party to demonstrate the incompatibility of the implementing measure. We can count on its full cooperation in this respect, and we have experienced it in this case. The Panel also agrees that, since the allegations of violation of the *SPS Agreement* were not exhaustively listed in its terms of reference and depended on the parties raising them in the course of the procedure, this could have made it difficult to circumscribe the scope of its review under the *SPS Agreement*. We note, however, that in this particular case the legal arguments regarding the conformity of the EC implementing measure with the *SPS Agreement* were all raised early in the proceedings and that no party complained that it had not been given sufficient opportunity to comment on the other party's allegations.

7.375 We therefore conclude that we should address the compatibility of the EC implementing measure with the provisions of the *SPS Agreement* referred to by the parties to the extent necessary to determine, with respect to the EC claim relating to Article 22.8, whether the EC "measure found to be inconsistent" in the *EC – Hormones* case has been removed. We are mindful of the procedural problems raised by this approach, but we do not consider that, by proceeding in this manner, we are exceeding our jurisdiction to the extent that such a review is necessary in order to address the EC claims under Article 22.8.

7.376 The Panel notes in this respect that it is not the first time that a dispute settlement entity, when confronted with a procedurally a-typical issue, decided to adopt a pragmatic solution and perform functions similar to those of an Article 21.5 panel. In the Article 22.6 arbitration in the *EC – Bananas III* case the arbitrator decided to adopt the most "logical way forward":

> "4.10 ... the European Communities argues that we should not consider the consistency of its new banana regime. First, it argues that to do so would go beyond our terms of reference, which it suggests are limited to determining the level of suspension and its equivalence to the level of nullification or impairment. As noted above, however, setting the level of nullification or impairment may require consideration of whether there is nullification or impairment flowing from a WTO-inconsistency of the new banana regime."

7.377 We too believe that our approach to consider, to the extent necessary, the compatibility of the EC implementing measure with the *SPS Agreement* is the most logical way forward under the circumstances, having regard to our duty to assist the parties and the DSB in solving this dispute and, in particular, to determine whether, as claimed by the European Communities, there is a violation of Article 23.1 in conjunction with Article 22.8 and Article 3.7 of the DSU. This is consistent with our duty to make an objective assessment of the matter before us pursuant to Article 11 of the DSU.[498]

7.378 We also note that panels have not hesitated in the past to consider other provisions than those on which findings had been requested as part of the context of those provisions.[499]

7.379 Therefore, the Panel believes that these are sufficient reasons for it to conclude that it has jurisdiction to consider the compatibility of the EC implementing measure with the *SPS Agreement* as part of its review of the claim raised by the European Communities with respect to Article 22.8 of the DSU.

(c) Burden of proof

7.380 We note that the European Communities considers that it has made a prima facie case of violation of the DSU provisions, and that, since it cannot be requested to prove a negative, it is for the

[498] See Section VII.C.2.(a) above.
[499] Panel Report on *India – Quantitative Restrictions*, para. 5.26.

United States to prove a violation of the *SPS Agreement* by the EC implementing measure. The European Communities also argues that it enjoys a presumption of good faith compliance with the recommendations and rulings of the DSB in the *EC – Hormones* dispute.[500] The United States considers that it is for the European Communities to show that it has complied with Article 22.8 of the DSU and, thus, to demonstrate that its implementing measure actually complies with the provisions of the *SPS Agreement*.[501]

7.381 The principles regarding allocation of burden of proof have been well established since the early days of the WTO dispute settlement system and the Panel did not deem it necessary to repeat them in relation to the other claims of the European Communities. However, having regard to the importance given by the parties to the question of burden of proof in relation to the compatibility of the EC measure with the *SPS Agreement*, the Panel considers that it needs to clarify how it addressed burden of proof in relation to the EC claim under Article 22.8.

7.382 First, we deem it necessary to recall that, in *US – Wool Shirts and Blouses*, the Appellate Body stated that:

> "... various international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof thereof. Also, it is a generally-accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence."[502]

7.383 With respect to the violation of Article 22.8 as such, the Panel considered that it had, in principle, no reason to address burden of proof any differently than any other panel established under Article 6 of the DSU. Indeed, as stated by the Complainant itself, this case is about a measure taken by the United States. The fact that this dispute takes place in the context of the EC alleged compliance with the recommendations and rulings of the DSB in the *EC – Hormones* dispute should have no impact on the question of the burden of proof regarding the actual *claim* before us. This means that the principles identified by the Appellate Body above apply, and that the European Communities must prove its claim that the United States breaches Article 22.8 of the DSU.

7.384 Yet, one of the particularities of this case is that the EC claim of violation of Article 22.8 of the DSU by the United States is premised on the removal of the EC measure found to be inconsistent with the *SPS Agreement*. In other words, in order to demonstrate that the United States has breached Article 22.8, the European Communities also alleges that its implementing measure is itself in conformity with the *SPS Agreement*.

7.385 In theory, this should not raise any difficulty in terms of burden of proof since it is well established that each party has to prove its own allegations. We agree, however, with the European Communities that in a case like this one, this could generate for the complainant at the beginning of the proceedings a situation equivalent to having to "prove a negative", since the spectrum of provisions against which the legality of the EC measure may have to be reviewed remains very broad as long as the respondent has not made its own allegations of inconsistency of the implementing measure. However, we recall that we found above that the European Communities enjoyed a presumption of good faith compliance, even though that presumption was rebuttable before this Panel.

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[500] EC's first written submission, paras. 92-94.
[501] US's first written submission, paras. 102, 103 and 106.
[502] Appellate Body Report on *US – Wool Shirts and Blouses*, p. 14. See also Appellate Body Report on *Canada – Dairy (Article 21.5 – New Zealand and US II)*, para. 66.

As soon as the European Communities established a prima facie case[503] thanks to the presumption of good faith compliance, the burden shifted on the United States to rebut that presumption. We recall that "... a prima facie case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favour of the complaining party presenting the prima facie case."[504] We believe that the United States sufficiently refuted the EC allegation of compliance in its first written submission through positive evidence of breach of the *SPS Agreement* by the European Communities. In its subsequent submissions before the Panel, the European Communities responded to the allegations of violation made by the United States. Thus, the European Communities never actually had to "prove a negative" in this case.

7.386 While the presumptions based on good faith enjoyed by each party may have played a role in the burden of proof in the early stage of the Panel proceedings, it is the opinion of the Panel that they eventually "neutralized" each other since each party also submitted evidence in support of its allegations. Ultimately, each party had to prove its specific allegations in response to the evidence submitted by the other party.[505] Thereafter, when considering whether an allegation had been proven or not, the Panel followed the practice of other panels to weigh all the evidence before it.

(d) Compatibility of the EC implementing measure with the provisions of the *SPS Agreement*

(i) The EC implementing measure

7.387 As already noted, the European Communities has had a ban on the placing on the market, including a ban on the importation, of beef treated with certain hormones for growth promotion purposes since 1988. The hormones concerned are oestradiol-17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. We note that the European Communities stated in its first submission that the DSB recommendations in the *EC – Hormones* cases had been implemented through the adoption, on 22 September 2003, of Directive 2003/74/EC the transposition deadline of which was 14 October 2004.

7.388 The European Communities claims that the Directive is based on a risk assessment the results of which "sufficiently warrant" the definitive import prohibition on meat and meat products treated with oestradiol-17β and "provide the available pertinent information" on the basis of which the provisional prohibition regarding the other five hormones has been enacted.

7.389 The Panel understands that, according to the European Communities, its risk assessment:

(a) is composed of three opinions issued by the EC Scientific Committee on Veterinary measures relating to Public Health (SCVPH) in 1999, 2000 and 2002, the 2000 and 2002 Opinions constituting reviews of the 1999 Opinion;

(b) is supported by the 17 studies initiated and funded by the European Communities between 1998 and 2001 in order to obtain as much as possible of the missing scientific information that was identified by the panel and the Appellate Body in the *EC – Hormones* case.

7.390 Specifically, the European Communities argues that the 17 scientific studies it commissioned resulted in numerous publications which, along with the pre-existing scientific data, were examined by the SCVPH. The SCVPH issued its first opinion entitled "Assessment of Potential Risks To

[503] See Appellate Body Report on *EC – Hormones*, para. 98.
[504] Appellate Body Report on *EC – Hormones*, para. 104.
[505] See Appellate Body Report on *Japan – Apples*, para. 154.

Human Health From Hormone Residues in Bovine Meat And Meat Products" on 30 April 1999 (hereafter the "1999 Opinion").

7.391 The 1999 Opinion contained the following major conclusions:

(a) As concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer had been identified with different levels of conclusive evidence for the six hormones in question.

(b) In the case of oestradiol-17β, there was a substantial body of recent evidence suggesting that it had to be considered as a complete carcinogen, as it exerted both tumour initiating and tumour promoting effects. The data available did not, however, allow a quantitative estimate of the risk.

(c) For the other five hormones at issue, in spite of the individual toxicological and epidemiological data described in the report, the current state of knowledge did not allow a quantitative estimate of the risk.

(d) For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged. Of the various susceptible risk groups, prepubertal children was the group of greatest concern. Again the available data did not enable a quantitative estimate of the risk.

(e) In view of the intrinsic properties of the hormones and in consideration of epidemiological findings, no threshold levels could be defined for any of the six substances.[506]

7.392 In 2000, the SCVPH reviewed two reports, one from the Committee on Veterinary Medicinal Products and one from the UK Veterinary Products Committee, to determine whether the science contained within warranted altering the findings and conclusions of the 1999 Opinion. In May 2000, the SCVPH concluded the following:

> "The reports of the UK's Veterinary Products Committee subgroup and of the Committee on Veterinary Medicinal Products presented for review to the Scientific Committee, as well as recent scientific information, did not provide convincing data and arguments demanding revision of the conclusions drawn in the opinion of the SCVPH of April 30th, 1999, on the potential risks to human health from hormone residues in bovine meat and meat products.
>
> The SCVPH discussed again the obvious gaps in the present knowledge on target animal metabolism and residue disposition of the hormones under consideration, including the synthetic hormones. The SCVPH expects that the ongoing EU research programs will provide additional data on both topics."[507]

7.393 Finally, in 2002, the SCVPH reviewed both the 2000 Opinion and the 1999 Opinion and found that review of the 17 studies launched by the European Commission and recent scientific literature allowed the following conclusions:

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[506] 1999 Opinion, p. 73 (Exhibit US-4).
[507] 2000 Opinion, p. 4 (Exhibit US-17).

(a) Ultra-sensitive methods to detect residues of hormones in animal tissues had become available, but needed further validation.

(b) Studies on the metabolism of oestradiol-17β in bovine species indicated the formation of lipoidal esters, disposed particularly in body fat. These lipoidal esters showed a high oral bioavailability[508] in rodent experiments. Thus, the consequence of their consumption needed to be considered in a risk assessment.

(c) Experiments with heifers, one of the major target animal groups for the use of hormones, indicated a dose-dependent increase in residue levels of all hormones, particularly at the implantation sites. Misplaced implants and repeated implanting, which seemed to occur frequently, represented a considerable risk that highly contaminated meats could enter the food chain. There was also a dose-dependent increase in residue levels following the oral administration of melengestrol acetate at doses exceeding approved levels, with a corresponding increased risk that contaminated meats could enter the food chain.

(d) Convincing data had been published confirming the mutagenic and genotoxic potential of oestradiol-17β as a consequence of metabolic activation to reactive quinones. *In vitro*[509] experiments indicated that oestrogenic compounds *might* alter the expression of an array of genes. Considering that endogenous oestrogens also exerted these effects, the data highlighted the diverse biological effects of this class of hormones.

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

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

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

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

(i) Model experiments with rabbits treated with zeranol, trenbolone actetate or melengestrol acetate, mirroring their use in bovines, were designed to study the consequences of pre- and perinatal exposure to exogenous hormones. All compounds

[508] Bioavailability is the capacity of a substance to enter the general blood circulation and to diffuse into the whole body of the animal or the human being administered this substance, or the fraction of a dose of a substance that is available for systemic circulation (replies of Dr. Boisseau, Dr. Boobis and Dr. Guttenplan to Panel question 43 to the experts, Annex D, paras. 344-357).

[509] *In vitro* means outside of the body, usually in a cell-based system in a test tube or culture dish. (Transcript of the Panel meeting with the experts, Annex G, para. 96 (Dr. Boobis)).

crossed the placental barrier easily and influenced to varying degrees the development of the foetus, at the doses used in the experiments.

(j) Epidemiological studies with opposite-sexed twins suggested that the exposure of the female co-twin *in utero* to hormones resulted in an increased birth weight and consequently an increased adult breast cancer risk.

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

7.394 After re-appraisal of the data from the 17 studies and recent scientific literature, the SCVPH confirmed the validity of its previous Opinions (in 1999 and 2000) on the Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products, and that no amendments to those opinions were justified.[510]

7.395 A year and a half later, the European Parliament and the Council of the European Union amended Directive 96/22/EC, which was the subject of the original *EC – Hormones* dispute, by adopting Directive 2003/74/EC. In Directive 2003/74/EC, the European Communities restated the SCVPH assessment that "recent evidence suggests that [oestradiol-17β] has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of the risk."[511]

7.396 The European Communities went on to conclude in its amended Directive that oestradiol-17β "can potentially be used in all farm animals and residue intake for all segments of the human population and in particular the susceptible groups at high risk can therefore be especially relevant. The avoidance of such intake is of absolute importance to safeguard human health."[512]

7.397 Finally, the European Communities concluded that in order to achieve its chosen level of protection from the risks posed, in particular to human health, by the routine use of these hormones for growth promotion and the consumption of residues found in meat derived from animals to which these hormones have been administered for growth promotion purposes, it was necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol-17β, and provisionally ban the other five hormones at issue.

(ii) Scope of the Panel review

7.398 Given the particular circumstances under which we engage in a review of the compatibility of the EC implementing measure with the *SPS Agreement*, we deem it necessary to clearly circumscribe the scope of our review under that Agreement.

7.399 Indeed, the EC claim of violation of Article 22.8 of the DSU by the United States is premised on the alleged compatibility of the EC implementing measure with the *SPS Agreement*. We note in this respect that the European Communities itself stated in its first written submission that:

> "The new Directive provides that the use for animal growth promotion of one of the six hormones in dispute is permanently prohibited while the use of the other five is

[510] 2002 Opinion, pp. 21-22 (Exhibit US-1).
[511] EC Directive 2003/74/EC.
[512] Directive 2003/74/EC, whereas clause 9.

> provisionally forbidden. It is based on a comprehensive risk assessment and, thus, is fully compliant with the DSB recommendations and rulings. In particular, as stipulated by the Appellate Body, the results of the risk assessment 'sufficiently warrant' the definite import prohibition regarding one of the hormones (Article 5.1 of the *SPS Agreement*),[513] and provide the 'available pertinent information' on the basis of which the provisional prohibition regarding the other five hormones has been enacted (Article 5.7 of the *SPS Agreement*). Consequently, through Directive 2003/74/EC the European Communities has implemented the rulings and recommendations in the *Hormones* case."[514]

7.400 In its subsequent submissions, the European Communities has argued the compatibility of its implementing measure with the provisions referred to in the quotation above (i.e. Article 5.1 and 5.7 of the *SPS Agreement*). This is, in our view, indicative of the provisions within the scope of which the European Communities considers its implementing measure to fall. Yet, we do not consider that the scope of our review of the *SPS Agreement* can be determined exclusively on the basis of the EC allegations of compatibility.

7.401 Indeed, we note the argument of the United States in reply to a question from the Panel that:

> "[T]he EC must demonstrate that it has brought its measure into conformity with the DSB recommendations and rulings in the *Hormones* dispute. Those recommendations and rulings include findings of EC breaches of SPS Articles 5.1 and 3.3. The EC argues that it has satisfied the DSB recommendations and rulings by basing its permanent ban for estradiol on a risk assessment and satisfying the four conditions of SPS Article 5.7 for the other five hormones in lieu of a risk assessment. These arguments call for findings as to whether or not the EC has in fact demonstrated that it has brought itself into conformity with the DSB's recommendations and rulings, as these findings are integral part of the EC's Article 22.8 claim."[515]

7.402 As already mentioned above, we consider that we must determine whether the European Communities has removed the measure found to be inconsistent with the covered agreement or has provided a solution to the nullification or impairment of benefits. Therefore, we agree with the United States that we need to review the EC measure against (a) the recommendations and rulings of the DSB in the *EC – Hormones* case and (b) the provisions which the European Communities claims to comply with as part of its claim of violation of Article 22.8 of the DSU by the United States.

7.403 This said, we also agree with the European Communities that it is difficult for the complainant in a case like this one to identify all potential problems of incompatibility. We see other difficulties if, in cases like this one where a finding of violation by a Member is conditioned by the compliance of a measure of the complainant with the WTO Agreement, the scope of review of that measure is defined only by the complainant. Indeed, the complainant could limit the scope of the panel review to provisions with which it believes that its measure is most likely to be found compatible.

7.404 Under those circumstances, we find it preferable, both from a legal and a practical point of view, to consider *all* the allegations and arguments raised by each party, as long as the other party had

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[513] The European Communities refers to the Appellate Body Report on *EC – Hormones*, para. 253 lit. (l).

[514] EC's first written submission, para. 17.

[515] US's replies to Panel questions after the second substantive meeting, Annex C-3, para. 24.

the opportunity to comment on those allegations and arguments.[516] We consider that this was the case in these proceedings, since both parties were granted ample opportunities and time to reply to each other's submissions.

7.405 We note that the United States argues an incompatibility of the EC implementing measure with Article 5.1 with respect to the import ban relating to meat and meat products treated with oestradiol-17β. The United States alleges an incompatibility of the EC implementing measure with Article 5.7 with respect to the provisional import ban on meat and meat products treated with testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. The United States alleges an incompatibility of the EC implementing measure with Article 3.3 of the *SPS Agreement* regarding each of the bans applied under that measure with respect to meat from cattle treated with growth promotion hormones for which international standards exist, i.e. oestradiol-17β, testosterone, progesterone, trenbolone acetate and zeranol.[517]

7.406 We nonetheless note that the United States referred to other provisions of the *SPS Agreement* in its submissions. These are Articles 5.2 and 5.6. The United States also makes a reference to Article 2.2 in its rebuttal.[518]

7.407 At our request, the United States clarified that the reference to Article 2.2 of the *SPS Agreement* "was not intended to elicit a finding of a breach of Article 2.2".

7.408 However, "[t]he United States believes that a finding of compliance or non-compliance with the requirements of Article 5.2 would be appropriate as part of the Panel's analysis of whether the EC has based its measure on a risk assessment within the meaning of Article 5.1". We note that the United States argued a violation of Article 5.2 of the *SPS Agreement* in its second written submission.[519]

7.409 With respect to the allegation of the United States regarding a violation of Article 5.2 of the *SPS Agreement*, we note that the European Communities, in its comments of 31 October 2006 on the US replies to the questions of the Panel after the first meeting, states that:

> "The European Communities takes note of the United States reply that the Panel would be required to look only at Articles 3.3, 5.1 (including an examination of Article 5.2) and 5.7 [of the *SPS Agreement*]."

7.410 We consider that the European Communities does not exclude that the Panel may review the compatibility of its implementing measure with Article 5.2 of the *SPS Agreement* as part of its review of the compatibility of the EC implementing measure with Article 5.1. Therefore, we will also review the compatibility of the EC implementing measure with Article 5.2.

7.411 We conclude that we shall review, to the extent necessary, the compatibility of the EC implementing measure with Articles 5.1, 5.2, 5.7 and 3.3 of the *SPS Agreement*. We therefore proceed with a review of the compatibility of the EC implementing measure with those provisions in the following sections, once we have addressed other procedural issues.

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[516] We are aware of the risk that the responding party may make a new allegation of violation at a late stage of the proceedings, thus making it difficult for the complainant to reply to this allegation. We nonetheless consider that such a circumstance will not have any impact on due process as long as the complaining party is given sufficient opportunities to comment.

[517] US's reply to Panel question 20 after the second substantive meeting, Annex C-3. The Panel notes that, as far as melengestrol acetate is concerned, JECFA has conducted a risk assessment, set an ADI, and proposed an MRL. However, Codex has not yet adopted an MRL.

[518] US's second written submission, para. 27.

[519] US's second written submission, paras. 50-65.

(iii) Standard applicable to the review of the compatibility of the EC implementing measure with the SPS Agreement

7.412 We believe that, in light of the importance and complexity of the scientific information provided by the parties and the experts, it is necessary to lay down the way we plan to review all this information.

7.413 As recalled by the Appellate Body in *EC – Hormones*, the standard of review applicable to legal and factual issues regarding measures reviewed against the *SPS Agreement* is found in Article 11 of the DSU which reads in relevant part that "...a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case".

7.414 In *EC – Hormones*, the Appellate Body recalled that:

> "So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU; the applicable standard is neither *de novo* review as such, nor 'total deference', but rather 'the objective assessment of the facts'."[520]

7.415 The Appellate Body further noted that "under current practice and systems, [panels] are in any case poorly suited to engage in such a [*de novo*] review."[521]

7.416 We note that we have a duty to consider the evidence presented to us and to make factual findings on the basis of that evidence. It is also generally within our discretion to decide which evidence we choose to utilise in making findings.[522] Likewise, a panel is not expected to refer to all statements made by the experts advising it and should be allowed a substantial margin of discretion as to which statements are useful to refer to explicitly[523] as long as we do not deliberately disregard or distort evidence.[524]

7.417 We also recall that we consulted six scientific experts individually, and not as an expert review group. This may have some consequences in terms of the sometimes diverging views which they expressed. We note that, in *EC – Hormones*, the Appellate Body considered with respect to divergent views taken into account in risk assessment that:

> "We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community … In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a

[520] Appellate Body Report on *EC – Hormones*, para. 117.
[521] Appellate Body Report on *EC – Hormones*, para. 117.
[522] Appellate Body Report on *EC – Hormones*, para. 135.
[523] Appellate Body Report on *EC – Hormones,* para. 138.
[524] Appellate Body Report on *EC – Hormones*, para. 139.

> clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects."[525]

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

7.419 Likewise, in *EC – Asbestos,* the Appellate Body stated that:

> "In justifying a measure under Article XX(b) of the GATT 1994, a Member may also rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion. Therefore, a panel need not, necessarily, reach a decision under Article XX(b) of the GATT 1994 on the basis of the 'preponderant' weight of the evidence."[526]

7.420 We note that, in some circumstances, only one or two experts have expressed their views on an issue. Sometimes these views were similar or complemented each other. In other circumstances, a larger number of experts expressed opinions and, sometimes, they expressed diverging opinions. While, on some occasions, we followed the majority of experts expressing concurrent views, in some others the divergence of views were such that we could not follow that approach and decided to accept the position(s) which appeared, in our view, to be the most specific in relation to the question at issue and to be best supported by arguments and evidence. As we have told the parties and the experts during these proceedings, this Panel is not composed of scientists.[527] The experts were also made fully aware of their role – which was *inter alia* to present scientific issues to the Panel members in a way that could be understood by them – and of the role of the Panel in the WTO dispute settlement system – which is *inter alia* one of trier of fact. In assessing the scientific advice received from the experts, we also fully took into account the comments of the parties, when appropriate.

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[525] Appellate Body Report on *EC – Hormones*, para. 194.

[526] Appellate Body Report on *EC – Asbestos*, para. 178.

[527] In the letter sent to the experts in relation to the preparation of their written replies, the Panel made the following remark:

> "In drafting your replies, please remember that the three panelists serving on the case have no scientific background and are trying to digest the extensive scientific material submitted by the parties with your help. Therefore, please provide concise answers which clarify the issues at hand and which will eventually assist the Panel in reaching its legal findings." (Emphasis in the original)
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> Likewise, at the outset of the meeting with the experts, the Chairman mentioned the following:
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> "Last but not least, I would like to recall that the Panel members do NOT have scientific expertise. Therefore, I would like to ask the experts to bear this in mind in replying to questions and explain issues in layman's terms, providing information on underlying concepts as necessary. In order to get a clearer picture with respect to each of the six hormones at issue, I would also like to invite all those taking the floor to clarify which of the six hormones their question or reply applies to."

However, as already mentioned, we disregarded those comments that attempted to put into question the objectivity of specific experts. We believe that such questions had to be dealt with separately.[528]

7.421 We also recall that we are expected to make findings with respect to each of the hormones concerned. Indeed, in *Japan – Apples*, the Appellate Body recalled that findings should be made for each precise agent that may possibly cause the harm (in this case each of the hormones concerned):

> "Under the *SPS Agreement*, the obligation to conduct an assessment of 'risk' is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of a phytosanitary measure. The Appellate Body found the risk assessment at issue in *EC — Hormones* not to be 'sufficiently specific' even though the scientific Articles cited by the importing Member had evaluated the 'carcinogenic potential of entire *categories* of hormones, or of the hormones at issue *in general*.' In order to constitute a 'risk assessment' as defined in the *SPS Agreement*, the Appellate Body concluded, the risk assessment should have reviewed the carcinogenic potential, not of the relevant hormones in general, but of 'residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes'. Therefore, when discussing the risk to be specified in the risk assessment in *EC – Hormones*, the Appellate Body referred in general to the harm concerned (cancer or genetic damage) *as well as* to the precise agent that may possibly cause the harm (that is, the specific hormones when used in a specific manner and for specific purposes)."[529]

7.422 We will therefore address the compatibility of the EC implementing measure with respect to each hormone concerned, as appropriate. However, in situations where, for instance, information and evidence are similar for all hormones, or where information was not provided for each hormone in spite of our insistence, specific issues are addressed with respect to the hormones concerned as a whole.

7.423 There is another question raised in these proceedings which the Panel believes it must address at this stage. It is the issue of "old" versus "new" evidence, data or studies. Indeed, the European Communities relied extensively on the date of the evidence relied upon by JECFA to support its view that the risk assessments performed by JECFA are outdated and the ensuing recommendations of Codex unreliable.

7.424 In its submissions before the Panel and during the hearing with the scientific experts, the European Communities contested the validity of JECFA's findings[530] on the basis that it had relied in its assessments on studies that dated back to the 1960s, 1970s and 1980s. The Panel sought the views of the experts on this point.[531] Dr. Boisseau pointed out that "It is just a banality to say that JECFA is provided with new data when it is requested to assess veterinary drugs recently placed on the market and older data in the case of veterinary drugs already marketed since a long time ago. Anyway, the quality and the number of the available data are more important than the dates at which these data have been produced."[532]

7.425 During the hearing with the experts, the European Communities sought the view of Dr. De Brabander as to whether the validity of "old" data from the 1970s and 1980s should be put in doubt

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[528] See Section VII.A.2(c) above.

[529] Appellate Body Report on *Japan – Apples*, para. 202. (original footnotes omitted)

[530] For a comprehensive list and explanation of JECFA's risk assessment on the six hormones concerned, *see* Annex E-2, JECFA's reply to Panel question 17.

[531] See questions 34 and 35 of the Panel to the scientific experts, Annex D.

[532] Reply of Dr. Boisseau to question 35 of the Panel, Annex D.

because they are old and they have been measured with measurement methods which, it argues, are by today's standards not credible, or are not accurate, because there are new, more powerful and more accurate analytical methods.[533] Dr. De Babander replied: "[t]hat is my conclusion. I cannot say that the data are bad, I don't say that, I just say you don't know that they are good."[534]

7.426 During the same hearing, Dr. Wennberg specified that: "... even if [the studies used by JECFA] were older [than the 1970s], if the methodology that was used, and if the methods had been validated properly, there is no reason to discredit any studies because they were done a long time ago."[535] Dr. Boisseau added that:

> "What the Commission said is true as regards the results that are at the level of the limits of detection of the methods previously used. But once the results obtained are clearly over the limits of detection, what counts is the precision of the method and its reproducibility. The fact that the method used to provide these results is old is irrelevant to the extent that they have been validated. Indeed, we need only concern ourselves with the uncertainty that we may have regarding the very low values at the level of the limits of detection."[536]

7.427 The Panel first notes that the experts agree that data do not become invalid only because they are old, but that more recent measurement or analytical methods may be more accurate. The Panel notes, however, that a problem related to accuracy is likely to occur with respect to results at the level of the detection limits of the older methods. Outside this particular situation, what matters is whether the method has been validated. The Panel thus concludes that whether a study is old or not is not *per se* a criterion to put in doubt the validity of this study.

(iv) Whether the EC implementing measure is an SPS measure

7.428 Before the Panel can determine whether the EC ban is consistent with the *SPS Agreement*, we must first determine whether the measure is subject to the disciplines of the *SPS Agreement*, *i.e.*, whether the measure is an SPS measure. In order to determine whether the ban is an SPS measure, the Panel will determine whether the measure fits within the definition of an SPS measure set forth in Annex A(1) of the *SPS Agreement*.[537]

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[533] Transcript of the Panel meeting with the experts, Annex G, para. 674.
[534] Transcript of the Panel meeting with the experts, Annex G, para. 675.
[535] Transcript of the Panel meeting with the experts, Annex G, para. 651.
[536] Transcript of the Panel meeting with the experts, Annex G, para. 679.
[537] Article 1 of the *SPS Agreement* reads as follows:

> "General Provisions
>
> 1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
>
> 2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
>
> 3. The annexes are an integral part of this Agreement.
>
> 4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement."

Annex A, paragraph 1, to the *SPS Agreement* reads as follows:

7.429 As the panel in *EC – Approval and Marketing of Biotech Products* explained, in determining whether a measure is an SPS measure, regard must be had to such elements as the purpose of the measure, its legal form and its nature. The purpose element is addressed in Annex A(1)(a) through (d) ("any measure applied to"). The form element is referred to in the second paragraph of Annex A(1) ("laws, decrees, regulations"). Finally, the nature of measures qualifying as SPS measures is also addressed in the second paragraph of Annex A(1) ("requirements and procedures, including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; [etc.]").

7.430 The European Communities explained in Directive 2003/74/EC that the purpose of the ban on the six hormones at issue is to prevent meat and meat products from cattle treated with such hormones for growth promotion purposes from being placed on the EC market.[538] The Panel notes that Annex A(1)(b) defines an SPS 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."

7.431 Consistent with the Panel in *EC – Approval and Marketing of Biotech Products* we consider that a substance which a human being or an animal consumes for nutritional reasons may be classified as a "food".[539] The Panel also takes notice of the footnote to Annex A, which specifically defines

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DEFINITIONS [footnote 4]

"1. Sanitary or phytosanitary measure – Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

Footnote 4 to Annex A reads as follows:

"For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter."

[538] Directive 2003/74/EC, Article 1.
[539] Panel Report on *EC – Approval and Marketing of Biotech Products*, paras. 7.291-7.292.

"contaminants" as including veterinary drug residues, such as the residues of the hormones which are the subject of the EC measure.

7.432 Comparing the definition of an SPS measure in Annex A(1)(b) to the stated purpose of the EC ban on the hormones at issue, the Panel concludes that the purpose of the EC measure is that of an SPS measure within the meaning of Annex A(1)(b) of the *SPS Agreement*.

7.433 The second paragraph of Annex A states that sanitary or phytosanitary measures include all relevant laws, decrees and regulations as well as requirements and procedures.[540] In this instance, the EC measure is a directive adopted by the Council of the European Union and the European Parliament which was published in the Official Journal of the European Communities. Therefore, this Panel finds that the measure in question is included within the phrase "all relevant laws, decrees, regulations ..." as used in Annex A of the *SPS Agreement*. This Panel also agrees with the panel in *EC– Approval and Marketing of Biotech Products* that a ban may be considered a "requirement" within the meaning of the second paragraph of Annex A of the *SPS Agreement.*[541] Therefore, this Panel finds that the EC measure constitutes such a "requirement".

7.434 In conclusion, because the EC Directive 2003/74/EC was adopted for the purpose of protecting human life from contaminants in food and takes the form and nature contemplated in the second paragraph of Annex A, this Panel finds that the EC Directive 2003/74/EC is an SPS measure within the meaning of Annex A(1)(b) and the second paragraph of Annex A.

(e) Compatibility of the EC implementing measure with Article 5.1 and Article 5.2 of the *SPS Agreement* with respect to oestradiol-17β

(i) Introduction

7.435 The Panel notes that the European Communities has asserted that it adopted the Directive banning the placing on the market of meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes based on a risk assessment conducted by the SCVPH consistent with Article 5.1 of the *SPS Agreement*.

7.436 Specifically, the European Communities states that in order to comply with the rulings and recommendations of the DSB in the *EC – Hormones* dispute, it conducted a comprehensive risk assessment, which focused on potential risks to human health from hormone residues in bovine meat and meat products.[542] The European Communities also asserts that Directive 2003/74/EC, which provides for a permanent ban on meat and meat products from animals treated for growth promotion purposes with oestradiol-17β, is based on the above referenced risk assessment.[543]

7.437 The DSB found in the *EC – Hormones* dispute that the ban on meat and meat products from cattle treated with the six hormones for growth promotion purposes, according to good veterinary practice ("GVP"), was inconsistent with Article 5.1 of the *SPS Agreement* because it was not based on a risk assessment within the meaning of that Article. In this case, the European Communities has asserted that it has removed that inconsistency with respect to oestradiol-17β by conducting a comprehensive risk assessment and basing its implementing measure on that risk assessment so that

[540] "Including *inter alia* end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

[541] Panel Report on *EC – Approval and Marketing of Biotech Products*, para. 7.1334.

[542] EC's first written submission, para. 142.

[543] EC's first written submission, para. 145.

the measure is now consistent with Article 5.1 of the *SPS Agreement*. We also recall that the United States has claimed that the EC definitive ban on oestradiol-17β breaches Article 5.1 and 5.2 of the *SPS Agreement*. Therefore, as mentioned above, the Panel considers that it should address the conformity of the EC implementing measure with Article 5.1 and 5.2 of the *SPS Agreement*.

7.438 Article 5.1 of the *SPS Agreement* reads as follows:

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

7.439 An analysis under Article 5.1 consists of two fundamental questions. First, was a risk assessment, appropriate to the circumstances and taking into account risk assessment techniques developed by the relevant international organizations conducted? Second, is the sanitary measure based on that risk assessment? The Panel will address each question successively.

7.440 This said, Article 5.2 of the *SPS Agreement* further instructs Members on how to conduct a risk assessment. Specifically, Article 5.2 states that:

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

7.441 The Panel agrees with the panel in *Japan – Apples* that Articles 5.1 and 5.2 "directly inform each other, in that paragraph 2 sheds light on the elements that are of relevance in the assessment of risks foreseen in paragraph 1".[544] This is because, in the opinion of the Panel, if it were possible for a risk assessment that did not take into account the factors listed in Article 5.2 to be consistent with Article 5.1, Article 5.2 would have no purpose and we must construe the covered agreements in a way that gives meaning to each provision.[545] Essentially, "Article 5.2 imparts meaning to the general obligation contained in paragraph 1 to base measures on an 'assessment ...of risks'."[546] Therefore, we must also consider whether the European Communities took into account the elements contained in Article 5.2 in the course of our analysis under Article 5.1.

(ii) Is there a risk assessment within the meaning of Article 5.1 of the SPS Agreement?

7.442 In assessing whether a measure is based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement,* the Panel must first determine whether a risk assessment was conducted at all. The Panel is aware that the Appellate Body in *EC – Hormones* determined that "Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment … The SPS measure might well find its objective justification in a risk

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[544] Panel Report on *Japan – Apples*, para. 8.230.

[545] Article 31.1 of the Vienna Convention on Law of Treaties requires that "[a] treaty shall be interpreted in good faith ..." Article 26 requires that "[e]ach treaty is binding upon the parties to it and must be performed by them in good faith". Given these fundamental principles in the Vienna Convention, it is unreasonable to assume that a provision of a treaty is written without any meaning at all. The Appellate Body also stated in *Japan – Alcoholic Beverages II*, that "a fundamental tenet of treaty interpretation flowing from the general rule of interpretation set out in Article 31 [of the Vienna Convention] is the principle of effectiveness (*ut res magis valeat quam pereat*)", p. 12.

[546] Panel Report on *Japan – Apples,* para. 8.232.

assessment carried out by another Member, or an international organization".[547] In the present case, the European Communities has asserted that the three Opinions produced by the SCVPH, an organ of the European Communities, constitute the required risk assessment. Therefore, the task before the Panel is to determine whether the European Communities conducted a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*.

7.443 To determine whether the Opinions constitute a risk assessment, the Panel must measure the European Communities' actions against the requirements of the *SPS Agreement*. The Panel recalls that it is not the appropriate role of the Panel to conduct its own risk assessment based on scientific evidence gathered by the Panel or submitted by the parties during the Panel proceedings.[548] Similarly, the Panel believes that it is not its role to impose any scientific opinion on the European Communities. The Panel must objectively measure the Opinions against the relevant standard for whether a risk assessment has been conducted, which can be found in the texts of Articles 5.1 (including an examination of Article 5.2) as well as Annex A(4) of the *SPS Agreement*. Therefore, we examined and evaluated the evidence – including the information received from the experts advising the Panel – and the arguments put before us in light of the relevant WTO provisions and based our conclusions on this evidence and these arguments.[549]

7.444 The text of Article 5.1 requires that in the assessment of risks the Members take into account risk assessment techniques developed by the relevant international organizations. Article 5.2, likewise, prescribes several factors that a Member must take into account when making its assessment of the risks. Additionally, Annex A(4) provides a definition of what constitutes a risk assessment. Finally, as the Panel and Appellate Body explained in *Japan – Apples,* for a risk assessment to be valid the science evaluated must support the conclusions reached in the risk assessment.[550]

7.445 The European Communities asserts that the 1999, 2000, and 2002 Opinions constitute its risk assessment for oestradiol-17β. Therefore, in determining whether these Opinions are indeed a risk assessment as appropriate to the circumstances, within the meaning of Article 5.1 of the *SPS Agreement*, the Panel will examine whether the Opinions (1) took into account risk assessment techniques of the relevant international organizations; (2) took into account the factors listed in Article 5.2; (3) satisfied the definition in Annex A(4) and: (4) whether the conclusions in the Opinions are supported by the scientific evidence evaluated.

Do the Opinions take into account risk assessment techniques of the relevant international organizations?

Introduction

7.446 Article 5.1 includes the proviso that Members, when developing sanitary and phytosanitary measures based on risk assessments, take into account risk assessment techniques developed by the relevant international organizations. The *SPS Agreement* does not specifically identify the relevant international organizations for purposes of Article 5.1. However, the Preamble of the *SPS Agreement* speaks of harmonizing SPS measures between Members on the basis of international standards,

[547] Appellate Body Report on *EC – Hormones*, para. 190, followed in the Panel Report on *EC – Approval and Marketing of Biotech Products*, para. 7.3024.

[548] Panel Report on *EC – Hormones (Canada)*, para. 8.104; Panel Report on *EC – Hormones (US)*, para. 8.101.

[549] Panel Report on *Australia – Salmon*, para. 8.41. A similar statement was made by the Panel on *Japan – Agricultural Products II*, in para. 8.42.

[550] This is not to say, as already recalled above, that a risk assessment cannot be based on a minority opinion of the scientists. A risk assessment can be based on a minority opinion which is supported by sufficient scientific evidence. See Appellate Body Report on *EC– Hormones*, para. 194; and Panel Report on *EC– Approval and Marketing of Biotech Products*, para. 7.3240.

guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission (Codex). Additionally, Annex A(3) states that for food safety the standards, guidelines and recommendations established by the Codex Alimentarius Commission (Codex) relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice will constitute international standards, guidelines, and recommendations within the meaning of the *SPS Agreement*. Article 3.2 states that SPS measures which conform to the above referenced standards are deemed to be necessary to protect human, animal, or plant life or health and are presumed to be consistent with the *SPS Agreement* and *GATT 1994*. Moreover, Article 3.4 of the *SPS Agreement* requires Members to participate fully in Codex work, within the limits of their resources. After an examination of these provisions of the *SPS Agreement* and the context of Article 5.1 as part of the process for adopting SPS measures which are consistent with the *SPS Agreement*, the Panel concludes that the Codex Alimentarius Commission constitutes a "relevant international organization" within the meaning of Article 5.1.

7.447 The parties in this dispute as well as the experts have made significant references to JECFA's work. JECFA, while officially not part of the Codex structure, provides independent scientific expert advice to the Codex Alimentarius Commission and its specialist Committees. JECFA conducts risk assessments on various substances, establishes ADIs[551] where appropriate, and in the case of residues of veterinary drugs in foods, recommends MRLs[552] for consideration by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). The MRLs adopted by Codex with respect to oestradiol-17β and four of the other five hormones[553] are based on the recommendations of JECFA. Therefore, this Panel believes that the risk assessment techniques of JECFA are also relevant to an analysis of compliance with Article 5.1.

[551] The Codex Committee on Residues of Veterinary Drugs in Foods defines an Acceptable Daily Intake (ADI) as "[a]n estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg)." Glossary of Terms and Definition (CAC/MISC 5-1993). The "Glossary of Terms and Definition" has been elaborated by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with a view to providing information and guidance to the committee and is intended for internal Codex use only. (The definition was previously established and adopted by JECFA and modified by the Codex Committee on Veterinary Drugs in Foods). More information on how ADIs are set is contained in Annex E-2, responses by JECFA to questions 9 and 10.

[552] Codex defines the maximum limit for residues of veterinary drugs (MRLVD) as the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available. From: Definitions for the Purposes of the Codex Alimentarius, Codex Alimentarius Commission Procedural Manual (15th Edition), FAO and WHO, 2006, page 43. More information on how MRLs are set is contained in Annexes E-1 and E-2, responses by Codex and JECFA to questions 9 and 10.

[553] Progesterone, testosterone, zeranol and trenbolone acetate (http://www.codexalimentarius.net/mrls/vetdrugs/jsp/vetd_q-e.jsp).

7.448 Codex and JECFA have developed definitions of the relevant phases of a risk assessment as well as guidelines and practices for conducting a risk assessment.[554] The European Communities indicated in the 1999 Opinion, that the accepted definition of a risk assessment, as used by both Codex and JECFA, is an assessment which is "structured to address independently the intrinsic properties of the compound under consideration (hazard identification), the evaluation of the nature of effects in terms of a dose-response relationship (hazard characterization), the estimate of the dose/concentration of a compound in a daily diet (exposure assessment) resulting in the assessment of the incidence and severity of potential adverse effects".[555] In its Procedural Manual, Codex defines the four phases of risk assessment as follows:

(a) *hazard identification*: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

(b) *hazard characterization*: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose-response assessment[556] should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

(c) *exposure assessment*: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, or physical agents via food as well as exposures from other sources if relevant.

(d) *risk characterization***:** The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.[557]

7.449 Although Codex and JECFA base their relevant work on some general principles and the definition of risk assessment stated above and JECFA relies on a variety of guidance documents on how to conduct a risk assessment with respect to veterinary drug residues in food, the experts confirmed that no specific "techniques" or guidelines had thus far been formally adopted by Codex for use by national governments in conducting risk assessments of veterinary drug residues.[558]

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[554] In response to the Panel's questions regarding international guidance documents for conducting a risk assessment, in particular with respect to veterinary drug residues, the representative of Codex and JECFA as well as the experts referred to a variety of documents from the Codex Alimentarius Commission, JECFA, the World Health Organization, the Food and Agriculture Organization, and other scientific bodies, see replies of the Codex Alimentarius Commission and JECFA to Panel questions 3 and 4, Annexes E-1 and E-2 respectively, and replies by the scientific experts to Panel questions, Annex D, paras. 62-71.

[555] 1999 Opinion, page 70.

[556] Codex defines a dose-response assessment as the determination of the relationship between the magnitude of exposure (dose) to a chemical, biological, or physical agent and the severity and/or frequency of associated adverse health effects (response). *Codex Alimentarius Commission*, Procedural Manual, Fifteenth Edition (2005), p. 45.

[557] Ibid.

[558] At its 30th session in July 2007, the Codex Alimentarius Commission adopted "Working Principles for Risk Analysis for Food Safety for Application by Governments".

Summary of the main arguments of the parties[559]

7.450 The **United States** recalls that the *EC – Hormones* panel noted that, "even though no formal decision has as yet been taken by Codex with respect to [sanitary] risk assessment techniques, Codex, and more particularly JECFA, has a long-standing practice with respect to the assessment of risks related to veterinary drug residues (including hormone residues)."[560]

7.451 The United States believes that the Opinions predominantly focus on the first step of risk assessment (*hazard identification*). The United States argues that the potential biological effects of hormones, some of which are adverse, are generally not in dispute in the scientific community. The United States argues that the European Communities failed to engage in adequate *hazard characterization*. Specifically, the United States alleges that the European Communities did not conduct a dose-response assessment.

7.452 The United States argues that the Opinions also fail to complete an exposure assessment in terms useful for estimating risks to consumers. The United States alleges that a risk assessment evaluating the potential risk from hormone residues in meat and meat products to consumers, in the absence of a discussion of actual residues, should include a thorough analysis of the relevant pathway, starting with cattle treated with hormones for growth promotion purposes according to good veterinary practices, processing and shipping meat and meat products from those cattle and ending with the consumption of any residues from that meat by humans (*e.g.,* taking into account how humans process ingested hormones). The United States argues that the European Communities' purported risk assessment fails to evaluate either the available residue data or these steps in the exposure pathway.[561]

7.453 The United States considers that the Opinions evaluate identified sources of high exposure inconsistently by dismissing the introduction of pregnant heifers with high levels of endogenous oestradiol-17β into the food chain in Europe while assuming that misplaced and repeated implanting, as well as the entry of the implants into the food chain, are frequent and represent a considerable risk.[562]

7.454 The United States also argues that the European Communities fails to take into account the relative impact on exposure assessment of the low bioavailability of the six hormones for growth promotion purposes, in light of JECFA's conclusion that oestradiol is generally inactive when given orally because it is transported to the liver where it is rapidly inactivated.[563]

7.455 The **European Communities** agrees that the risk assessment techniques developed by Codex are relevant and contemplated in Article 5.1's requirement to take into account the risk assessment techniques developed by relevant international organizations. However, the European Communities maintains that the risk assessment criteria as developed by the WTO dispute settlement bodies are clearly more relevant to the application of the *SPS Agreement*.[564]

7.456 The European Communities also points out that there is no Codex standard specifically on the risk assessment of the effect of residues of veterinary drugs and that Codex techniques or standards

[559] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[560] US's first written submission, para. 139, citing Panel Report on *EC – Hormones*, para. 8.103.

[561] US's first written submission, para. 144.

[562] US's first written submission, para. 145.

[563] US's first written submission, para. 146, citing 52nd JECFA Report (2000), p. 58 (Exhibit US-5).

[564] EC's second written submission, para. 192; EC's replies to Panel questions after the first substantive meeting, question 24, Annex B-1.

exclusively apply to risk assessments on food safety and not to other risk assessments such as those for animal health and environmental risks.[565]

7.457 The European Communities maintains that its Opinions take into account the conventional risk assessment techniques in addition to other factors that are expressly permissible under the definition of a risk assessment in Article 5.1.[566] The European Communities argues that it went beyond the international standards for a risk assessment to consider "real life" situations as contemplated by the Appellate Body's ruling in *EC – Hormones.*

7.458 The European Communities argues that the risk assessment at the basis of Directive 2003/74/EC precisely follows the four steps of risk assessment as defined by Codex, enabling it to identify different levels of risks presented by different uses, and that this Directive then adapts the management of these risks accordingly.[567] However, the European Communities also notes that the Codex approach has serious limitations in non-linear situations, such as with regard to these hormones. The European Communities argues that the currently available Codex guidance poorly addresses cases such as this where the risks are embedded in changes in exposure to biologically active molecules which may, with minute differences in their bioavailability, have dramatic effects, such as turning on or off complete developmental programmes of the human genome, or inducing pathological conditions.[568]

7.459 Specifically, the European Communities argued that with hormones that are also produced endogenously when you add more of the same kind of hormone, such as oestrogen, you are just increasing the response that is already taking place, and in that case there cannot be a threshold. The threshold has already been exceeded by the concentration of hormones in circulation. So this specific set of conditions results in dose-response curves that will have no threshold, and if there is no threshold, there is no safe dose, unlike the suggestion that there is an acceptable daily intake.[569]

7.460 The European Communities asserts that it is generally recognized that for substances which have genotoxic potential (as is the case with oestradiol-17β) a threshold cannot be identified. This would mean that there is no level below which intakes from residues should be considered to be safe. The fact that the doses used in growth promotion are low is not of relevance.[570] Therefore, the European Communities argues that it was not required to do a quantitative evaluation of the dose-response.[571]

7.461 As regards the level of the risk, the European Communities argues that it has undertaken specific studies to evaluate the exposure resulting from real as well as experimental situations of abuse and/or misuse in the market of the United States. The European Communities notes that it

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[565] EC's second written submission, para. 192.

[566] 1999 Opinion, p. 2 (citing Appellate Body Report on *EC – Hormones* for the premise that the risk to be evaluated is "not only risk ascertainable in a laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words the actual potential for adverse effects in human health in the real world where people live and work and die.")

[567] EC's replies to Panel questions after the first substantive meeting, question 24, Annex B-1, para. 142.

[568] EC's replies to Panel questions after the first substantive meeting, question 24, Annex B-1, para. 140.

[569] Transcript of the Panel meeting with the experts, Annex G, para. 252.

[570] EC's second written submission, paras. 201-202.

[571] EC's second written submission, para. 200.

carried out specific veterinary inspections in the United States and argues that it has made a specific calculation of the level of the risk for imports coming from the United States.[572]

Reasoning of the Panel

7.462 In determining whether the European Communities took into account the risk assessment techniques of the relevant international organizations in the Opinions, the Panel requested that the experts evaluate the Opinions in light of the Codex definitions, guidelines, and practices.

7.463 The experts who answered the Panel's question on this issue concluded that the Opinions were not entirely consistent with the Codex guidelines and definitions.

7.464 Dr. Guttenplan pointed out that the European Communities had done a thorough hazard identification, but that its hazard characterization was limited and that the extrapolation of the one animal model study from hamster kidney to humans was uncertain. He noted that the European Communities also relied on older studies with no reports of replication and had no epidemiological studies comparing cancer incidence or prevalence in populations consuming hormone-treated or untreated meat.[573] Dr. Boobis stated that the European Communities had not identified the potential for adverse effects on human health of residues of oestradiol in meat as a result of the cattle being treated with the hormone for growth promotion purposes. This was because the analysis undertaken was focused primarily on hazard identification. There was little in the way of hazard characterization, and no independent exposure assessment was undertaken. Dr. Boobis stated that because no adequate exposure assessment was undertaken it was not possible to complete the risk characterization phase of the assessment.[574] In sum, Dr. Boobis concluded that the European Communities' risk assessment of oestradiol did not follow the four steps of the Codex risk assessment paradigm.[575]

7.465 Dr. Boobis indicates in his written replies that a "hazard-based" approach, which is making recommendations as to potential safety based on intrinsic capacity to cause harm rather than on the probability of harm occurring is most commonly used for substances that are genotoxic or have genotoxic potential, although not all such substances would be treated this way.[576] Dr. Boobis further explained the "hazard-based" approach at the meeting with the Panel where he stated that if, for example, a compound is shown to be a direct-acting genotoxicant, this is considered unacceptable at any level of exposure. As permitting exposure would not be appropriate, one stops the risk assessment at that point. It does not need to take account of exposure, because any level of exposure is deemed to be of concern.[577] Dr. Cogliano agrees that there have been cases where calling something a carcinogenic hazard has led an agency to make a decision just on the qualitative element alone.[578] However, Dr. Tritscher, the representative of JECFA maintains that a hazard identification is not a risk assessment; a risk assessment comprises the four steps.[579]

7.466 Both Drs. Cogliano and Boobis explain that the issue of thresholds and whether an acceptable daily intake can be established and all four steps of a risk assessment as defined by Codex can be

[572] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 15, citing Exhibit EC-67 and Exhibit EC-73.
[573] Replies by the scientific experts to Panel question 14, Annex D, para. 149.
[574] Replies by the scientific experts to Panel question 13, Annex D, para. 144.
[575] Replies by the scientific experts to Panel question 14, Annex D, para. 148.
[576] Replies by the scientific experts to Panel question 36, Annex D, paras. 310-311.
[577] Transcript of the Panel meeting with the experts, Annex G, para. 385.
[578] Transcript of the Panel meeting with the experts, Annex G, para. 438.
[579] Transcript of the Panel meeting with the experts, Annex G, para. 453.

conducted has to do with the assumptions and interpretations that the scientists conducting the risk assessment are willing to make.[580]

7.467 Although there was considerable debate among the parties and the experts advising the Panel about whether the European Communities followed all four steps of a risk assessment as defined by Codex or indeed whether it was even necessary to do so in the case of a substance such as oestradiol-17β, the Panel must concur with the reasoning of the panel in *Japan – Apples*, that the requirement to "take into account" the risk assessment techniques of international organizations:

> "[D]oes not impose that a risk assessment under Article 5.1 be 'based on' or 'in conformity with' such risk assessment techniques. This suggests that such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, *per se*, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1."[581]

7.468 This means that although the risk assessment techniques of Codex and JECFA are relevant and must be considered by the risk assessor, compliance with Codex or JECFA risk assessment techniques is not required by the *SPS Agreement*. What is required is that the risk assessor take those techniques into account and that it comply with the other requirements of Article 5 and Annex A of the *SPS Agreement* with respect to conducting a risk assessment.

7.469 It is undisputed that the European Communities was aware of the Codex and JECFA guidelines and considered them in the preparation of the Opinions. Therefore, the Panel concludes that although it may not have strictly followed them, the European Communities did take into account the risk assessment techniques of the relevant international organizations in the conduct of the Opinions.

Do the Opinions take into account the factors listed in Article 5.2?

Summary of the main arguments of the parties[582]

7.470 The **United States** argues that whether the European Communities engaged in a proper evaluation of the Article 5.2 factors, in particular relevant inspection, sampling, and testing methods, would inform a decision on whether or not it has indeed properly assessed the risk of failure to satisfy good veterinary practices within the meaning of Article 5.1 and Annex A of the *SPS Agreement*. The United States asserts that the European Communities has not engaged in the necessary evaluation of the factors under Article 5.2.[583]

7.471 The United States reasons that Article 5.2 is not mutually exclusive of Article 5.1 of the *SPS Agreement*; rather, it sets out the specific components of the risk assessment on which Members are required to base their measures for purposes of Article 5.1. The United States argues that if the European Communities has not satisfied the requirements of Article 5.2, it has not conducted a risk assessment, as appropriate to the circumstances and, as such, the permanent ban on oestradiol-17β cannot be based on a risk assessment within the meaning of Article 5.1.[584]

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[580] Transcript of the Panel meeting with the experts, Annex G, paras. 1021-1027.

[581] Panel Report on *Japan – Apples*, para. 8.241.

[582] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[583] US's second written submission, para. 52.

[584] US's replies to Panel questions after the second substantive meeting, Annex C-4, para. 26.

7.472 The United States argues that the Opinions ignore or fail to take into account available scientific evidence with respect to the bioavailability of oestradiol-17β, evidence relating to susceptible populations, and evidence relating to *in vivo*[585] repair mechanisms.[586]

7.473 The United States argues that the Opinions fail to adduce scientific evidence of a risk to consumers posed by meat from cattle treated with oestradiol-17β for growth promotion purposes according to good veterinary practices. Assessments which conclude otherwise (*i.e.,* that such a risk exists), such as the 1999, 2000 and 2002 Opinions, do not "take into account available scientific evidence" as required by Article 5.2 of the *SPS Agreement* and are not risk assessments as appropriate to the circumstances within the meaning of Article 5.1 of the *SPS Agreement.*[587]

7.474 The United States argues that the European Communities fails to assess the specific risks at issue in this dispute because it does not consider the available evidence directly related to the expected doses from dietary exposures to hormones. In particular, the United States contends that the European Communities did not make use of relevant bioavailability data, and used unrealistic scenarios to calculate possible exposure estimates.[588]

7.475 Additionally, the United States argues that the Opinions' study of the potential adverse effects from use of hormones without regard to good veterinary practices does not take into account the actual inspection, sampling, and testing methods of the US regulatory agencies, but is rather based on hypothetical violations of GVP induced in a laboratory.

7.476 The **European Communities** argues that the 1999 Opinion took account of all pertinent scientific information available at the time, including JECFA's revised assessment of the three natural hormones oestradiol-17β, testosterone, and progesterone that had been issued in February 1999.[589] The European Communities also points out that the Opinions have found that the data on which JECFA based its finding on bioavailability are incorrect or insufficient.[590]

7.477 The European Communities contends that it examined relevant inspection, sampling, and testing methods when it specifically examined the issue of the risks to human health if GVP was not observed in the United States.[591] In the *Working Document on Assessment of Risks of hormonal growth promoters in cattle with respect to risks arising from abusive use and difficulties of control*, the European Communities points to the Appellate Body finding in the *EC – Hormones* case that Article 5.2 in conjunction with Article 8 and Annex C authorizes "the taking into account of risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice."[592]

7.478 The European Communities argues that its findings regarding misplaced implants, off-label use, black-market drugs, and secondary risks, are based on realistic conditions of use and the

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[585] *In vivo* means in the whole organism, the intact organism (transcript of the Panel meeting with the experts, Annex G, para. 96 (Dr. Boobis)).

[586] US's second written submission, paras. 41-46.

[587] US's second written submission, para. 47, footnote 89.

[588] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 72.

[589] EC's second written submission, para. 103.

[590] EC's second written submission, para. 123.

[591] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 83.

[592] Assessment of risks of hormonal growth promoters in cattle with respect to risks arising from abusive use and difficulties of control, Exhibit EC-73, p. 5, citing Appellate Body Report on *EC – Hormones*, para. 205.

possibilities of abuse or misuse which these hormones offer to farmers and are documented as regards the United States in the *Working Document*.[593]

Reasoning of the Panel

7.479 The United States has specifically alleged that the European Communities, in formulating the Opinions, failed to take into account two of the elements listed in Article 5.2, specifically the available scientific information and the relevant inspection, sampling, and testing methods. Therefore, the Panel must determine first whether the Opinions take into account the available scientific information and, second, whether the Opinions take into account relevant inspection, sampling, and testing methods.

7.480 As noted above in the context of risk assessment techniques, taking available scientific evidence into account does not require that a Member conform its actions to a particular conclusion in a particular scientific study. The available scientific information may contain a multiplicity of views and data on a particular topic. It is the view of the Panel that the requirement in Article 5.2 is to ensure that a Member, when assessing risk with the aim of formulating an appropriate SPS measure, has as wide a range as possible of scientific information before it to ensure that its measure will be based on sufficient scientific data and supported by scientific principles.

7.481 The United States' argument can be reduced to the contention that because the conclusions in the Opinions are not supported by the scientific evidence, the European Communities must not have considered the available scientific evidence when it formulated the Opinions. However, whether the conclusions in the Opinions are supported by the scientific evidence considered by the European Communities is a question that is not relevant to the issue of whether the European Communities took the available scientific evidence into account in formulating the Opinions, within the meaning of Article 5.2.

7.482 The Opinions specifically addressed the evidence available with respect to bioavailability, susceptibility of sensitive populations, and DNA adducts and DNA damages. The Opinions even included reference to the very scientific studies the United States is alleging they did not take into account. Therefore, the Panel concludes that the European Communities did take the available scientific information into account as required by Article 5.2.

7.483 The second question before the Panel with respect to whether the European Communities took into account the factors listed in Article 5.2 is whether the Opinions take into account relevant inspection, sampling, and testing methods. The Panel notes that the European Communities has compiled a *Working Document* on the abusive use and difficulties of control in the administration of hormones for growth promotion purposes. The European Communities details visits to US regulatory agencies and on-site inspections as well as a review of data related to failures in the US inspection regime. The SCVPH also dedicated a significant portion of the 1999 Opinion to discussing the issue. Whether the conclusions the European Communities reached regarding the likelihood of abuse or misuse of hormone implants given relevant inspection, sampling, and testing methods in the United States are scientifically supported is of no relevance in an analysis of whether the European Communities fulfilled its obligations pursuant to Article 5.2 to take such methods into account.

7.484 Because the European Communities considered the available scientific information as well as relevant inspection, sampling, and testing methods in the preparation of its Opinions, the Panel concludes that the European Communities took these factors into account as required by Article 5.2 of the *SPS Agreement*.

[593] EC's second written submission, para. 126, citing Exhibit EC-73.

Do the Opinions satisfy the definition in Annex A(4) of the *SPS Agreement*?

Introduction

7.485 Annex A(4) defines a risk assessment as:

> "[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; *or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs*." (Emphasis added)

7.486 In this dispute, the measure at issue is intended to protect human health as a sanitary measure defined in Annex A(1)(b) and, thus, is to be based on a risk assessment in the sense of the second definition in Annex A(4).[594]

Summary of the main arguments of the parties[595]

7.487 The **United States** argues that the Opinions do not appear to be risk assessments within the meaning of Article 5.1.[596]

7.488 The United States refers to the definition for a risk assessment established by the panel in *EC – Hormones* that a risk assessment must "(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 ... occurrence of these effects." In the case of an import ban on meat and meat products such as that maintained by the European Communities, the relevant "evaluation" is that of "the potential for adverse effects arising from the presence in food of the hormones in dispute."[597]

7.489 The United States notes that the European Communities relies on studies that demonstrate adverse effects of hormones at concentrations exponentially greater than would be present in residues of meat from cattle treated with hormones for growth promotion purposes, and discusses the effects of substances, such as diethylstilbestrol ("DES"), that have been banned in the United States for decades in support of the notion that hormones can be harmful.[598] The United States argues that the European Communities fails to hone the general risk, or identified hazards, down through hazard characterization and an exposure assessment in order to demonstrate (*i.e.*, identify and evaluate) a specific risk to consumers.[599]

7.490 The United States argues that the Opinions are not a risk assessment within the meaning of Article 5.1 and Annex A of the *SPS Agreement* because they fail to examine relevant pathways, explore the fate of the relevant risk (that posed by meat products to consumers) or to support their

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[594] Panel Report on *Australia – Salmon*, paras. 8.72 and 8.116 (finding that because the measure at issue was meant to protect animal health as a sanitary measure as defined in Annex A(1)(a), the first definition in Annex A(4) applied).

[595] A more detailed account of the parties' arguments can be found in Section IV the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[596] US's first written submission, para. 137.

[597] US's first written submission, para. 138 citing Panel Report on *EC – Hormones*, paras. 8.98, 8.127.

[598] US's first written submission, para. 141.

[599] US's first written submission, para. 142.

conclusions with scientific evidence. The United States contends that the Opinions neither "identify the adverse effects on human health" arising from the consumption of meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice nor "evaluat[e] the potential for adverse effects on human or animal health" arising from consumption of meat products from cattle treated with hormones for growth promotion purposes.[600]

7.491 The United States faults the European Communities for relying upon statements from the US Department of Health and Human Services that estrogens generally are known to be human carcinogens. The United States argues that the conclusions in the report cited by the European Communities are based upon epidemiological tests focused on women and the use of hormone replacement therapies and oral contraception which contain estrogens and are based upon levels of oestradiol-17β or other estrogens high enough to have a hormonal effect on the consumer, not the levels of oestradiol-17β found in meat from cattle treated with the hormone for growth promotion purposes according to good veterinary practices. Such levels of oestradiol-17β that are found in meat, the United States asserts, are exponentially lower than those causing hormonal effects.[601]

7.492 The United States argues that scientific evidence concerning the need to regulate the use of hormones generally is different from specific evidence concerning the health risk associated with consumption of meat and meat products from cattle treated with hormones for growth promotion purposes.[602] The United States asserts that the European Communities did not consider whether consumer dietary exposure to hormone residues in meat and meat products from cattle is specifically a source of risk.[603]

7.493 The United States argues that the European Communities continues to rely on studies such as the 1999 IARC Monograph, which have already been found by the Appellate Body to "constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."[604] The United States maintains that although the potential for adverse effects from hormones at these high levels is not in dispute, the materials and findings cited by the European Communities (1999 IARC Monograph; 11th Report on Carcinogens) are not, however, evidence of a risk from meat from cattle treated with oestradiol for growth promotion purposes.[605]

7.494 The **European Communities** argues that the Opinions do constitute a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*. Specifically, the European Communities argues that there is a difference between a scientific risk assessment in the narrow sense referred to by the United States and the risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*.[606]

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[600] US's first written submission, para. 147.
[601] US's second written submission, para. 38.
[602] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 70.
[603] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 72.
[604] US's replies to Panel questions after the second substantive meeting, para. 23 citing Appellate Body Report on *EC – Hormones*, Annex C-4, para. 200.
[605] US's replies to Panel questions after the second substantive meeting, Annex C-4, para. 24.
[606] EC's second written submission, para. 191; EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 135 *et seq.*

7.495 The European Communities argues that the Appellate Body has confirmed that a risk assessment within in the meaning of Article 5.1 includes a risk management stage which is the responsibility of the regulator to carry out and not of the scientific bodies.[607]

7.496 Although the European Communities agrees that in principle the risk resulting from human consumption of meat from cattle treated with oestradiol-17β for growth promotion purposes, according to good veterinary practice is the relevant risk, it argues that the assessment of such a risk is qualified by the difficulty in estimating the intake of such hormones. Specifically, the European Communities argues that human beings, including the populations at risk, are exposed to cumulative and synergistic effects, as they may be exposed to multiple sources of hormones and hormone residues, via several intake routes, as well as from endogenous production of some of these hormones. The European Communities contends that it is extremely difficult or impossible to assess accurately consumer exposure patterns, or other exposures from other environmental or endogenous sources, but it is also virtually impossible to assess all cumulative and synergistic effects that may arise from all potential exposure patterns, including for simultaneous exposure to several of these hormones.[608]

7.497 The European Communities argues that the only rationale that can be inferred from the available scientific data is that the higher the exposure to residues from these hormones, the greater the risk is likely to be.[609] The European Communities points out that the Opinions noted that the DNA-damaging effects of oestrogen indicate that no threshold exists for the risk from oestrogen metabolites. The Opinions concluded that, in light of the recent data on the formation of genotoxic metabolites of oestradiol, suggesting that 17β-oestradiol acts as complete carcinogen by exerting tumour initiating and promoting effects, it has to be concluded that no quantitative estimate of risk related to residues in meat could be presented.[610]

7.498 The European Communities goes on to say that the risk resulting from human consumption of meat from cattle treated with oestradiol-17β for growth promotion purposes, according to good veterinary practice, is "assessed in the real world" where "people live, work and die", or may be suffering from clinical disorders, or may be particularly vulnerable segments of the population (*e.g.*, like prepubertal children), etc.[611] The European Communities asserts that it considered in its assessment the potential risks resulting from the actual residues from non-treated as well as treated animals for growth promotion, and came to the conclusion that under realistic conditions of use such residues from treated animals for growth promotion do pose a higher risk and that it could not achieve the level of protection it has considered appropriate in its territory.[612]

7.499 The European Communities argues that it is not necessary to compare the two situations and then try to quantify how much one is more risky than the other and to what measurable level the risk is likely to occur, but rather to assess a situation of additive risks arising from the cumulative exposures of humans to multiple hazards, in addition to the endogenous production of some of these hormones by animals and human beings.[613]

7.500 The European Communities contends that evidence from both the health risk associated with the use of hormones generally and the administration of hormones in animals for growth promotion

[607] EC's second written submission, para. 191.
[608] EC's replies to Panel questions after the first substantive meeting, Annex B-1, paras. 92-96.
[609] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 94.
[610] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 38.
[611] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 96.
[612] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para.151.
[613] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 151.

purposes, is relevant for the performance of a risk assessment in the sense of the *SPS Agreement*, because both sources of evidence impact upon and inform each other.[614]

7.501 The European Communities notes that it is scientifically undisputed that life-time exposure of humans to the levels of endogenous production of oestrogen (and in particular to oestradiol-17β and its metabolites) is sufficient to cause and/or promote cancer in some individuals. This is frequently called risk of cancer from background (endogenous) exposure. This kind of exposure (and the attentive risk of cancer) cannot be avoided. The European Communities also notes that humans are exposed daily to variable levels of residues of oestradiol-17β from many exogenous sources where these hormones naturally occur, which likewise cannot be avoided.[615]

7.502 The European Communities argues that "additive risk" refers to exposure which is "further added on humans from the levels of residues in meat from animals treated with these hormones for growth promotion." Such exposure leads to a risk of cancer which is "added" to the cancer risk from the existing endogenous exposure through the background levels of hormones and through the exposure to exogenous sources, such as non-treated natural food. The European Communities cites to the 2002 US Report on Carcinogenesis and argues that it agrees with the conclusions in the SCVPH Opinions that "veterinary use of steroidal estrogens to promote growth and treat illness can increase estrogens in tissues of food-producing animals to above their normal levels", in general substantially higher than the normal (endogenously produced) levels. The European Communities argues that exposure to residues from hormone-treated meat is avoidable because these hormones are chemical substances that are deliberately added to meat.[616]

7.503 The European Communities states in response to the Panel's questions on additive risk:

> "The risk of cancer from the consumption of residues in hormone-treated meat are 'additive' (to risk of cancer from the two other sources of exposure), irrespective of whether these hormones are genotoxic carcinogens or only promote cancer through receptor-mediated mechanisms. Indeed, if they cause cancer by direct genotoxic action, the addition of such exposure increases the likelihood of the adverse effect to occur. If they act only through receptor-mediated mechanism, the risk from such exposure will be again 'additive', when they cause the presumed threshold to be exceeded. The risk assessment of the European Communities has established that oestradiol-17β is a proven genotoxic carcinogen and that the other two natural hormones (testosterone and progesterone) are also suspected to be genotoxic. Moreover, the risk assessment of the European Communities has also demonstrated that the ADIs recommended by JECFA for all these hormones will be exceeded under realistic conditions of use of these hormones in the US and Canada. They will also be exceeded in any case if the more recent data on the endogenous production of the natural hormones by pre-pubertal children is taken into account."[617]

Reasoning of the Panel

7.504 In *EC – Hormones*, with respect to the methodology for a risk assessment under the second definition of paragraph 4 of Annex A of the *SPS Agreement*, the panel stated 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

[614] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 254.
[615] EC's replies to Panel questions after the second substantive meeting, Annex C-1, paras. 48-49.
[616] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 50.
[617] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 51.

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".[618]

7.505 Although the Appellate Body did not disagree with the panel, in its report in *EC – Hormones* it noted "that the Panel's use of 'probability' as an alternative term for 'potential' creates a significant concern. The ordinary meaning of 'potential' relates to 'possibility' and is different from the ordinary meaning of 'probability'. 'Probability' implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk."[619]

7.506 In *Australia – Salmon,* the Appellate Body further elaborated on the distinction between the two standards for risk assessment contained in Annex A(4) and the need for a substantive distinction between the evaluation of "likelihood" in the first sentence and the evaluation of "potential" in the second sentence. Specifically, the Appellate Body stated:

> "[w]e note that the first type of risk assessment in paragraph 4 of Annex A is substantially different from the second type of risk assessment contained in the same paragraph. While the second requires only the evaluation of the potential for adverse effects on human or animal health, the first type of risk assessment demands an evaluation of the likelihood of entry, establishment or spread of a disease, and of the associated potential biological and economic consequences. In view of the very different language used in paragraph 4 of Annex A for the two types of risk assessment, we do not believe that it is correct to diminish the substantial differences between these two types of risk assessments ..."[620]

7.507 Therefore, the Panel considers that it is necessary to clarify what constitutes a risk assessment as defined by Annex A(4), second sentence. The Panel considers that Annex A(4) requires a Member to (a) identify the additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs at issue (if any); (b) identify any possible adverse effect on human or animal health; and (c) evaluate the potential for that adverse effect to arise from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

7.508 The Panel concludes that the European Communities has satisfied the first requirement of Annex A(4) second sentence, in that it has identified the contaminant and food at issue; namely meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes. The European Communities has also identified the possible adverse effects on human or animal health, namely neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity, and carcinogenicity.[621]

7.509 The Panel must now evaluate whether it has satisfied the third requirement of the definition of a risk assessment. To do so, the Panel needs to define the terms "potential" and "arise from." The Oxford English Dictionary defines potential as "[p]ossible as opposed to actual; having or showing the capacity to develop into something in the future; latent; prospective."[622] Additionally, in *EC – Hormones* the Appellate Body observed that the ordinary meaning of 'potential' relates to

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[618] Panel Report on *EC – Hormones (Canada)*, para. 8.101; Panel Report on *EC – Hormones (US)*, para. 8.98.
[619] Appellate Body Report on *EC – Hormones*, para. 184.
[620] Appellate Body Report on *Australia – Salmon*, footnote 69.
[621] 1999 Opinion, page 72, Exhibit US-4.
[622] *The New Shorter Oxford English Dictionary* (Thumb Index Edition, 1993), p. 2310.

'possibility'.[623] The American Heritage Dictionary defines "arise" as to come into being, originate, to result, issue or proceed.[624]

7.510 The Appellate Body's findings in both *EC – Hormones* and *Japan – Apples* inform the definition of risk assessment in Annex A(4) second sentence. The Appellate Body has found that the requirement to conduct a risk assessment is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of a sanitary of phytosanitary measure.[625]

7.511 Specifically, in *EC – Hormones* the Appellate Body concluded that a risk assessment in this instance required not a general evaluation of the carcinogenic potential of entire categories of hormones, but rather should include an examination of residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes.[626]

7.512 In *Japan – Apples* the Appellate Body clarified that a risk assessment should refer in general to the harm concerned *as well as* to the precise agent that may possibly cause the harm.[627] In a footnote, the Appellate Body explained

> "Indeed, we are of the view that, as a general matter, 'risk' cannot usually be understood only in terms of the disease or adverse effects that may result. Rather, an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause. For example, the abstract reference to the 'risk of cancer' has no significance, in and of itself, under the *SPS Agreement*, but when one refers to the 'risk of cancer from smoking cigarettes', the particular risk is given content."[628]

7.513 Given the Appellate Body's guidance and the ordinary meaning of the terms "potential" and "arising from", the Panel concludes that the European Communities was required to evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of oestradiol-17β in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes.

7.514 The Panel, as noted above, will not conduct its own risk assessment or impose its own scientific opinions on the European Communities.[629] However, the Panel must make an objective assessment of whether the Opinions issued by the SCVPH satisfy the definition contained in Annex A(4) to the *SPS Agreement*.

7.515 As a preliminary matter, the Panel notes that there has been significant debate between the parties about the relevance of the Codex and JECFA definitions of the various phases of a risk assessment as well as about a risk assessment's role in the larger process of risk analysis, which consists of three components: risk assessment, risk management, and risk communication.[630]

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

[624] *The American Heritage Dictionary of the English Language* (4th ed., 2000).

[625] Appellate Body Report on *Japan – Apples*, para. 202.

[626] Appellate Body Report on *EC – Hormones*, para. 200.

[627] Appellate Body Report on *Japan – Apples*, para. 202.

[628] Appellate Body Report on *Japan – Apples*, at footnote 372.

[629] See para. 7.443 above.

[630] Codex Procedural Manual, 15th ed., p. 44.

7.516 The Panel also recalls that the European Communities argues that the broader concept of risk analysis, as defined by Codex, including the risk management phase, must be considered in evaluating whether the European Communities conducted a risk assessment within the meaning of Article 5.1 and Annex A(4).

7.517 Specifically, the European Communities points out that, as defined by Codex, risk assessment is normally considered to be only the first component of a three part process.[631] The European Communities argues that the United States ignores the second component of risk analysis, which has to be completed *after* the completion of the four steps of risk assessment, namely risk management. The European Communities defines risk management as the process of "weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures."[632] The European Communities also asserts that the Appellate Body has confirmed that a risk assessment within the meaning of Article 5.1 includes a risk management stage which is the responsibility of the regulator to carry out and not of the scientific bodies.[633]

7.518 The Panel agrees with the European Communities that the relevant definition against which to measure the EC Opinions in order to determine whether they constitute a risk assessment is the one contained in the *SPS Agreement,* namely that set forth in Annex A(4). As noted above, the Panel has found that the text of Annex A(4) second sentence defines a risk assessment as evaluating the possibility that an identified adverse effect came into being, originated, or resulted from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

7.519 The European Communities argues that the Appellate Body in the original *EC – Hormones* case confirmed that a risk assessment within the meaning of Article 5.1 includes a "risk management" stage which entails weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. Although the Appellate Body disapproved of the original panel's distinction between "risk assessment" and "risk management" because it had no textual basis in the Agreement, this Panel can find no statement by the Appellate Body confirming that what the European Communities describes as risk management is included within the definition of a risk assessment as set forth in Annex A(4) of the *SPS Agreement*. In fact, the Appellate Body stressed that Article 5 and Annex A speak of *risk assessment* only and that the term *risk management* is not to be found either in Article 5 or in any other provision of the *SPS Agreement*.[634]

7.520 The Panel agrees with the Appellate Body that its role as a treaty interpreter is to "read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used."[635] The Panel takes note of the Appellate Body's finding that a risk assessment can take into account "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences."[636] However, the Panel finds that neither that finding nor the text of the Agreement includes within the definition of a risk assessment the concepts put forward by the European Communities as "risk management." Therefore, the Panel maintains that it must determine whether the European Communities evaluated the possibility that the identified adverse effects came into being, originated, or resulted from the presence of residues of oestradiol-17β in meat or meat products as a result of the

[631] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 135.
[632] EC's replies to Panel questions after the first substantive meeting, Annex B-1, paras. 136-137.
[633] EC's second written submission, para. 191.
[634] Appellate Body Report on *EC – Hormones*, para. 181.
[635] Appellate Body Report on *EC – Hormones*, para. 181.
[636] Appellate Body Report on *EC – Hormones*, para. 187.

cattle being treated with the hormone for growth promotion purposes. To that end, the Panel requested the opinions of the scientific experts on what, exactly, the European Communities evaluated in its Opinions.

7.521 The Panel specifically asked the experts whether the EC Opinions identified the potential for adverse effects on human health, including the carcinogenic or genotoxic potential, of the residues of oestradiol-17β found in meat derived from cattle to which this hormone had been administered for growth promotion purposes in accordance with good veterinary practice and to what extent the Opinions evaluated the potential occurrence of these adverse effects.[637]

7.522 Dr. Boobis concluded that "the EC has not identified the potential for adverse effects on human health of residues of oestradiol found in meat from treated cattle. This is because the analysis undertaken was focused primarily on hazard identification. There was little in the way of hazard characterization, and no independent exposure assessment was undertaken.[638]

7.523 Dr. Guttenplan concluded that the European Communities had done a thorough job in identifying the potential for adverse effects on human health of oestradiol-17β found in meat derived from cattle to which this hormone had been administered. Specifically, Dr. Guttenplan found that the European Communities had identified a number of potential adverse effects, established metabolic pathways relevant to these effects, and examined mechanisms of these effects. In addition it had performed thorough studies of residue levels in cattle, and the environment. Dr. Guttenplan also concluded that the evidence evaluating the occurrence of adverse effects is weak. He found that the animal models were very limited and the target organs do not coincide well with the target organs in humans. He also pointed out that there are "basically no epidemiological studies comparing matched populations consuming meat from untreated and hormone-treated cattle. Thus, little can be inferred about the potential occurrence of the adverse effects, the potential for adverse effects seems reasonable."[639]

7.524 Dr. Boisseau noted that "in the 1999 report, SCVPH concluded also that '... it is clear that exogenous oestrogens, present in oral contraceptives or used in hormonal replacement therapy in women, are responsible for an increase of endometrial cancer and, to lesser extent, some increased risk of breast cancer, [but] there is no direct evidence on the consequences of the contribution of exogenous oestradiol-17β originating from the consumption of treated meat'."[640]

7.525 Dr. Cogliano observed that even though the European Communities does demonstrate through scientific evidence that oestradiol-17β is genotoxic, the issue is whether this genotoxicity would occur at levels found in meat. In that respect, Dr. Cogliano concluded that the European Communities has not established that genotoxicity and cell proliferation would be induced by levels found in treated meat added to the pre-existing levels occurring in exposed humans.[641]

7.526 The Panel specifically asked the experts whether the European Communities had demonstrated that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth promotion purposes. Dr. Boisseau concluded that the European Communities did not demonstrate that a potential for adverse effects on human health arises from the consumption of meat from cattle treated with any of the six hormones in dispute for growth promotion purposes. Additionally, Dr. Boisseau stated that the kind of evidence required to demonstrate such potential adverse effects should be (a) toxicological

[637] Panel question 13 to the scientific experts, Annex D, p. 22.
[638] Replies by the scientific experts to Panel questions, Annex D, para. 144.
[639] Replies by the scientific experts to Panel question 13, Annex D, para. 145.
[640] Replies by the scientific experts to Panel questions, Annex D, para. 132.
[641] Replies by the scientific experts to Panel questions, Annex D, para. 180.

data indicating that the values of the ADIs established by JECFA are not conservative enough, and (b) data on residues in treated/non-treated cattle and on daily production of hormones in sensitive individuals[642] indicating that the hormonal residue intake associated with the consumption of meat from treated cattle is such that the established ADIs would be exceeded in the case of use of growth promoters.[643]

7.527 Dr. Boobis stated that, in his view, none of the information provided by the European Communities demonstrates the potential for adverse effects in humans of any of the six hormones in meat from cattle in which they are used for growth promotion purposes at the levels to which those consuming such meat would be exposed. The studies on genotoxicity provide no convincing evidence of potential for harm in consumers. The carcinogenic effects observed are entirely consistent with a hormonal mode of action that exhibits a threshold that would be well above the intake arising from consumption of meat from treated cattle.[644]

7.528 Dr. Guttenplan found that the levels in meat could result in bioavailable oestrogen exceeding the daily production rate of oestradiol in pre-pubertal children. "For pre-pubertal children, even with the low bioavailabilty of estrogen ... and its low levels in meats, it appears possible that intake levels would be within an order of magnitude of those of the daily production rate. This is greater than FDA's ADI and suggests some risk to this population. If there [are] genotoxic effects of estradiol in children, they may be reflected over a lifetime, as mutations arising from DNA damage are permanent. It seems the more accurate methods of analysis could now be used to measure the effect of eating hormone-treated beef on blood levels of estrogen in children and post-menopausal women. If practical, this experiment would be important in establishing or refuting the arguments of the EC."[645]

7.529 To the extent that the European Communities argues that the relevant risk from hormones is an "additive risk" the experts concluded that the European Communities did not assess the extent to which residues of hormones in meat and meat products as a result of the cattle being treated with the hormones for growth promoting purposes contribute to additive risks arising from the cumulative exposures of humans to multiple hazards, in addition to the endogenous production of some of these hormones by animals and human beings.[646]

7.530 Dr. Cogliano explains that even if the fact that a substance is a carcinogenic hazard led an agency to make a decision on the qualitative element alone, many agencies still prefer to examine the exposure in their country to determine what to do.[647] Indeed Dr. Boobis indicates that stopping the risk assessment once it was identified that the hazard was such that the dose response was going to be linear, i.e. there is no threshold, would be an unusual circumstance. He states that in most circumstances one would want to understand the relationship between the hazard and the level of exposure that was occurring. For that reason one would progress at least to a semi-quantitative evaluation of the exposure and risk, rather than just stopping at a simple identification of hazard.[648]

7.531 Finally, the Panel has looked at the Opinions and found statements that indicate that specific studies on the potential for the adverse health effects identified by the European Communities to arise from consumption of meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes were not conducted.

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[642] Such as prepubertal children.
[643] Replies by the scientific experts to Panel questions, Annex D, para. 406.
[644] Replies by the scientific experts to Panel questions, Annex D, para. 408.
[645] Replies by the scientific experts to Panel question 52, Annex D, para. 413.
[646] Replies by the scientific experts to Panel question 56, Annex D, paras. 422-431.
[647] Transcript of the Panel meeting with the experts, Annex G, para. 438.
[648] Transcript of the Panel meeting with the experts, Annex G, para. 442.

7.532 The 1999 Opinion looked at three main areas of potential adverse effects: developmental effects on different stages of life; the relationship between oestrogens and cancer; and the effect of sex hormones on the immune system. In each of these areas, little or no data was presented directly that any of the potential adverse health effects identified come into being, originate, or result from the consumption of meat and meat products which contain veterinary residues of oestradiol-17β as a result of the cattle being treated with the hormone for growth promoting purposes.

7.533 With respect to the developmental effects of exogenous sex hormones, the 1999 Opinion recites generally the biological functions of sex hormones in the biological development of a human being and cites to studies that involve the application of diethylstilbestrol (DES) in experimental settings, even though, as the United States notes, DES is not one of the possible sources of oestradiol-17β residues in meat from treated cattle.[649] With respect to prepubertal children, the 1999 Opinion again cites studies having to do with DES as well as testosterone and allylestrenol (a steroid used in prevention of spontaneous abortion).[650] Although the developmental effects of oestrogens are discussed generally, including some potential adverse health effects, there is no examination of whether these effects arise from the presence of residues of oestradiol-17β in meat and meat products as a result of the cattle being treated with the hormone for growth promotion purposes. In fact, the 1999 Opinion states that "the information available so far falls short of the ideal, or even the sufficient standard to allow observers a well informed judgment when assessing exposure regarding what is acceptable from what is not."[651]

7.534 Regarding cancer, the 1999 Opinion states that "no study has assessed the effects of hormones as growth promoters in farm animals on cancer occurrence in humans. Arguments to be considered when evaluating the hypothesis of a potential link between the use of food promoters in farm animals and cancer in humans come both from descriptive epidemiology, including studies in migrants, and etiologic epidemiology on diet and cancer as well as on hormones and cancer."[652] "Currently one cannot confirm nor refute the association between high rates of breast cancer and high hormone-treated meat consumption in North-America. This should be urgently studied."[653] Additionally, the 1999 Opinion noted that:

> "The difficulty of evaluating health effects at low dose is here compounded by the fact that the data on exposures of human populations are exceedingly limited. No large data are available on representative samples of foods collected in countries allowing or banning growth promoters in farm animals. Most often, published levels concern measurements realized by the producers of the substances themselves under experimental conditions. However, data on the concentration of hormones and their metabolites present in edible tissues of treated animals are lacking. In addition, the methods used for measurements require a critical reappraisal. Data on the nature and amount of metabolites produced by the target animal are missing."[654]

7.535 Finally, in examining the effect of sex hormones on the immune system, the 1999 Opinion states that "no sound epidemiological data are currently available to establish a link between nutrition, especially meat consumption, and the occurrence of (and apparent current increase in) autoimmune diseases."[655] Additionally, the 1999 Opinion found that relevant data:

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[649] 1999 Opinion, pp. 5-16.
[650] 1999 Opinion, p. 13.
[651] 1999 Opinion, p. 6.
[652] 1999 Opinion, p. 16.
[653] Ibid.
[654] Ibid., p. 20.
[655] 1999 Opinion, pp. 22-23.

> "[I]ndicate that oestrogens modulate the immune system in many species. Direct human data at near physiological levels of oestradiol are lacking. Vingerhoets et. al., (1998) have conducted a self-reporting questionnaire study of DES daughters. A statistically significant difference in the incidence of infections was identified compared with control. This may be considered to be linked to imprinting by DES in utero.
>
> In conclusion, at relatively high doses oestradiol does produce a number of adverse effects on the immune system in humans, e.g. allergy to topical oestradiol (Boehnke and Gall, 1996). The above findings while indicating a possible concern are insufficient to identify whether immune effects could occur in consumers from the ingestion of meat or meat products containing oestradiol residues."[656]

7.536 The 1999 Opinion cited a new method for determining blood levels of oestradiol which suggested that the levels were 100 fold lower than previously determined and the metabolic clearance rate too high by a factor of 10. The 1999 Opinion concluded that if these methods were correct the acceptable daily intake established by the US Food and Drug Administration for meat and meat products derived from treated cattle would be at least 85 fold and possibly as much as 1,700 fold too high. However, the 1999 Opinion went on to note that "[g]iven all of the uncertainties in these estimates, it appears that the data are insufficient to form the basis of a sound risk assessment."[657]

7.537 All of the statements of the experts, and indeed statements from the Opinions, indicate that the European Communities has evaluated the potential for the identified adverse effects to be associated with oestrogens in general, but has not provided analysis of the potential for these effects to arise from consumption of meat and meat products which contain residues of oestradiol-17β as a result of the cattle they are derived from being treated with the hormone for growth promotion purposes. The Panel, therefore, concludes that although the European Communities has evaluated the association between excess hormones and neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity, and carcinogenicity, it has not satisfied the requirements of the definition of a risk assessment contained in Annex A(4) because it has not evaluated specifically the possibility that these adverse effects come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-17β as a result of the cattle being treated with the hormone for growth promotion purposes.

Does the science support the conclusions of the Opinions?

Introduction

7.538 The Panel agrees with the reasoning of the Panel in *Japan – Apples (Article 21.5 – US)* that "the scientific evidence which is being evaluated must support the conclusions of the [risk assessment]. Therefore, if the conclusions of the risk assessment are not sufficiently supported by the scientific evidence referred to in the [risk assessment], then there cannot be a risk assessment appropriate to the circumstances, within the meaning of Article 5.1".[658] Although the Panel has already found, above, that the Opinions do not satisfy the definition of a risk assessment in Annex A(4) of the *SPS Agreement*, the Panel wishes to ensure that it has conducted a complete and objective assessment of the facts. Therefore, in determining whether the European Communities complied with Article 5.1, the Panel will determine whether the scientific evidence referred to in the Opinions supports the conclusions contained therein.

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[656] 1999 Opinion, p. 45.
[657] 1999 Opinion, pp. 38-39.
[658] Panel Report on *Japan – Apples (Article 21.5 – US)*, para. 8.136 (original footnote omitted).

Summary of the main arguments of the parties[659]

7.539 The **United States** points out that the United Kingdom's Sub-Group of the Veterinary Products Committee, a service of the UK's Department for Environment, Food and Rural Affairs, concluded that "none of the publications reviewed in the 1999 Opinion provide any substantive evidence that oestradiol is mutagenic/genotoxic at relevant levels of exposure from residues in meat."[660]

7.540 The United States also refers to the report of the Committee for Veterinary Medicinal Products ("CVMP") (a subcommittee of the European Medicines Agency) on the Safety Evaluation of Steroidal Sex Hormones, also from 1999. The United States notes that the CVMP reaffirmed its conclusions that oestradiol-17β is mainly devoid of genotoxic activity and exerts its carcinogenic action after prolonged exposure and/or at levels considerably higher than those required for a physiological response.[661] Additionally, the CVMP concluded that the previous data as well as the recent EC studies described in the 1999 Opinion, support the notion that oestradiol belongs to the group of non-genotoxic carcinogens. According to the CVMP, the new studies "indicate that the presumed genotoxicity alone would not be sufficient to elicit the carcinogenic effects observed in the target tissues."[662]

7.541 The United States argues that the European Communities relies on studies that demonstrate adverse effects of hormones at concentrations exponentially greater than would be present in residues of meat from cattle treated with hormones for growth promotion purposes, and discusses the effects of substances, such as DES, that have been banned in the United States for decades in support of the notion that hormones can be harmful.[663]

7.542 The United States argues that the European Communities draws conclusions on the effects of oestradiol-17β in concentrations in the normal physiological range (*i.e.,* concentrations equivalent to those found in both treated and untreated meat) based solely on observations of DNA damage from doses greatly exceeding that range. This extrapolation fails to take into account the available data on, *e.g.*, differences between oestradiol metabolism at high compared to low concentrations in tissues, the potential for threshold doses for adverse biological effects and the possibility of different dose-response relationships for high and low doses of the compound.[664]

7.543 The United States notes that a central underpinning of the European Communities' determination to ban the importation of meat or meat products from cattle treated with hormones for growth promotion purposes according to good veterinary practices is that oestradiol-17β is genotoxic.[665] However, the United States argues, the European Communities has not in fact demonstrated through scientific evidence that oestradiol has carcinogenic effects other than through the receptor mediated, cell division stimulating activity of the hormone – in other words, at levels exerting a hormonal effect on consumers, and not at the exponentially smaller levels that would be found in meat residues.[666]

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[659] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[660] US's first written submission, para. 83, citing the "UK Report" in Exhibit US-12.

[661] US's first written submission, para. 90, citing the "CVMP Report" in Exhibit US-13.

[662] US's first written submission, para. 91.

[663] US's first written submission, para. 141.

[664] US's first written submission, para. 154.

[665] US's second written submission, para. 35.

[666] US's second written submission, para. 36.

7.544 The United States argues that the European Communities reliance upon the JECFA conclusion that oestradiol has "genotoxic potential" for its conclusion that oestradiol is genotoxic is misplaced, because it fails to take into account JECFA's findings that oestradiol-17β did not cause gene mutations *in vitro*, although in some other assays, sporadic but unconfirmed positive results were obtained.[667]

7.545 The United States also argues that although the European Communities relies on the JECFA report to support its argument that oestradiol-17β is genotoxic, the European Communities ignores the ultimate conclusion of the JECFA report, *i.e.*, that a maximum residue level for oestradiol-17β in meat need not be specified because there is a "wide margin of safety for consumption of residues in food when the drug is administered according to good practice in the use of veterinary drugs."[668]

7.546 The United States argues that the Opinions focus on several hypothetical "failure of control" scenarios that ignore actual regulatory processes in the United States, and for which the European Communities presents no support. The European Communities asserts that these scenarios "clearly identify a risk for excessive exposure of consumer to residues from misplaced or off-label used implants and incorrect dose regimes." Yet, the European Communities, according to the United States, fails to produce any evidence identifying a real risk of failure of controls or failure to satisfy good veterinary practices in the United States.[669]

7.547 The United States relies upon the conclusions of the panel in *Japan – Apples (Article 21.5 – US)* for the premise that evidence relied upon by a Member must actually support the conclusions reached in that Member's risk assessment. The United States argues, therefore, that the European Communities may not simply set out conclusions in its Opinions that are not actually grounded in the studies or evidence it cites as support.[670]

7.548 The United States argues that the European Communities continues to rely on studies such as the 1999 IARC Monograph, which have already been found by the Appellate Body to "constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."[671] The United States maintains that although the potential for adverse effects from hormones at these high levels is not in dispute, the materials and findings cited by the European Communities (1999 IARC Monograph; 11th Report on Carcinogens) are not, however, evidence of a risk from meat from cattle treated with oestradiol for growth promotion purposes.[672]

7.549 The **European Communities** argues that it is important to understand that the issue of the dose administered is not relevant for the *in vivo* genotoxicity in the case of oestradiol-17β. The European Communities goes on to note that it appears that the doses used to elicit *in vivo*

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[667] US's second written submission, para. 37, citing the 52nd JECFA Report (2000), p. 58 (Exhibit US-5).

[668] US's second written submission, para. 37, citing the 52nd JECFA Report (2000), p. 74, footnote 1 (Exhibit US-5).

[669] US's second written submission, para. 56.

[670] US's second written submission, para. 56, citing the Panel Report on *Japan – Apples (Article 21.5 – US)*, para. 8.145.

[671] US's reply to questions from EC after the second substantive meeting, para. 23, citing Appellate Body Report on *EC – Hormones*, para. 200, Annex C-4.

[672] Ibid., para. 24.

mutagenicity[673] are not massively high, but rather that they seem to fall within the safety margin established by JECFA, which means that the residues in meat from hormone-treated cattle are also capable of producing this adverse effect.[674]

7.550 The European Communities argues that the only rationale that can be inferred from the available scientific data is that the higher the exposure to residues from these hormones, the greater the risk is likely to be.[675] The European Communities goes on to say that the risk resulting from human consumption of meat from cattle treated with oestradiol-17β for growth promotion purposes, according to good veterinary practice, is "assessed in the real world" where "people live, work and die", or may be suffering from clinical disorders, or may be particularly vulnerable segments of the population (*e.g.*, like prepubertal children), etc.[676]

7.551 The European Communities notes that it is scientifically undisputed that life-time exposure of humans to the levels of endogenous production of oestrogen (and in particular to oestradiol-17β and its metabolites) is sufficient to cause and/or promote cancer in some individuals. This is frequently called risk of cancer from background (endogenous) exposure. This kind of exposure (and the attentive risk of cancer) cannot be avoided. The European Communities also notes that humans are exposed daily to variable levels of residues of oestradiol-17β from many exogenous sources where these hormones naturally occur, which likewise cannot be avoided.[677]

Reasoning of the Panel

7.552 The Panel's task is to determine whether the scientific evidence supports the conclusions in the Opinions. The Panel notes in this respect that the 1999 Opinion concluded that "for oestradiol genotoxicity has already been demonstrated explicitly."[678] The 1999 Opinion also concluded that oestradiol-17β is a complete carcinogen that exhibits tumour initiating and tumour promoting effects.[679] Finally, the 1999 Opinion found that "any excess exposure towards 17β-oestradiol and its metabolites resulting from the consumption of meat and meat products presents a potential risk to public health in particular to those groups of the population which have been identified as particularly sensitive, such as prepubertal children.[680] In the 2000 and 2002 Opinions, the SCVPH concluded that none of the additional science developed in the intervening years justified changing those conclusions.

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

7.554 The European Communities urged the Panel to disregard the responses of two particular experts because their positions are "purely theoretical" and for the additional reason that they have "never done any specific research on these hormones nor have they published something on these substances."[681] In that vein, the European Communities cites to the Appellate Body's rejection of an opinion given by a scientist in the original *EC – Hormones* dispute in 1998 because it did not "purport to be the result of scientific studies carried out by him or under his supervision focusing specifically

[673] Ability of a physical, chemical, or biological agent to induce heritable changes (mutations) in the genetic material in a cell as a consequence of alterations or loss of genes or chromosomes (or parts thereof) (replies of Dr. Boobis and Dr. Guttenplan to Panel question 2 to the experts. Annex D, paras. 34 and 55).
[674] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 23.
[675] EC's replies to Panel questions after the first substantive meeting, Annex B-1, paras. 94 and 96.
[676] Ibid.
[677] EC's replies to Panel questions after the second substantive meeting, Annex C-1, paras. 48-49.
[678] 1999 Opinion, p. 75, Exhibit US-4.
[679] 1999 Opinion, p. 73.
[680] 1999 Opinion, p. 71.
[681] EC's comments on experts replies to Panel questions, Annex F-1, pp. 35-36.

on residues of hormones in meat from cattle fattened with such hormones ..."[682] However, the Panel finds that Appellate Body in its report on *EC – Hormones* spoke to a different issue. In that instance the scientist was making specific estimates about the likelihood of breast cancer being caused by eating meat containing oestrogens, even though the scientist had not studied the matter.

7.555 In this case, the Panel has asked the experts not to make their own scientific conclusions but to evaluate the Opinions as experts in the conducting of risk assessments on food additives and contaminants and to assist the Panel in determining whether the evidence relied upon by the SCVPH supports the conclusions in its Opinions. To that end the Panel found the comments by all the experts helpful in its analysis and none shall be disregarded.

7.556 In response to specific questions from the Panel, the experts provided the following information.

7.557 With respect to the genotoxicity of oestradiol-17β, Dr. Boisseau explained that JECFA's conclusion that oestradiol-17β had genotoxic potential was based on the general agreement that oestradiol-17β is associated with a genotoxic effect, thus

> "... although it recognized that oestradiol-17β does not lead to positive results in all the classical tests which have been used to demonstrate its genotoxicity and its mutagenicity (oestradiol-17β did not cause gene mutations *in vitro* and gives, in some assays, sporadic but unconfirmed positive results), JECFA, in its fifty second session held in 1999 concluded 'that oestradiol-17β has genotoxic potential.' "[683]

7.558 In evaluating the EC assertion that the fact that doses of oestradiol-17β used in growth promotion are low is irrelevant because there is no threshold for substances which have genotoxic potential, Dr. Boisseau stated that the general principle did not apply to naturally occurring hormones, which are produced by both humans and food producing animals. Dr. Boisseau noted that even in the absence of any consumption of food coming from animals treated by growth promoting hormones, humans are naturally and continuously exposed to these natural hormones through, among others, (a) their own production of these hormones which may be very high, for example in the case of pregnant women, (b) the consumption of meat from non treated cattle, (c) the consumption of meat from other food producing animals, (d) the consumption of milk and eggs. There is no epidemiological survey indicating that this continuous exposure of humans to these natural hormones results in any identified risk for health.[684]

7.559 Dr. Cogliano explained that "the EC's statement that a threshold cannot be identified reflects their view of genotoxic mechanisms, just as the contrary statement that there is a threshold and that this threshold is above the levels found in meat residues reflects how Canada and the US view genotoxic mechanisms. Neither statement has been demonstrated by the scientific evidence, rather, they are different assumptions that each party uses in their interpretation of the available evidence."[685]

7.560 Dr. Guttenplan replied that:

> "[T]he data referred to by the EC supports a genotoxic mechanism as well as a hormonal mechanism. It is true that there is no reason to expect a threshold to exist for a genotoxic chemical. Although DNA repair can occur, it presumably is

[682] EC's comments on experts replies to Panel questions, Annex F-1, p. 14, citing Appellate Body Report on *EC – Hormones*, para. 198.
[683] Replies by the scientific experts to Panel questions, Annex D, paras. 134-135.
[684] Replies by the scientific experts to Panel questions, Annex D, para. 182.
[685] Replies by the scientific experts to Panel questions, Annex D, para. 186.

> occurring at all doses and the fraction of DNA damage repaired probably does not change at physiological levels, because the repair enzymes are unlikely to be saturated. The statement that, 'the fact that doses used in growth promotion are low is not of relevance' is not necessarily true. (para. 118-119 of EC Rebuttal Submission (US case)). For any toxin the dose determines the risk. When exposure is very low risk will be very low. However, one can argue about the definition of 'low'. It should also be noted that at very low levels of genotoxic carcinogens the decrease in risk is more than proportional than the decrease in applied dose."[686]

7.561 Dr. Cogliano stated in his written responses that the identification of oestradiol-17β as a human carcinogen indicates that there are potential adverse effects on human health when oestrodiol-17β is consumed in meat from cattle treated with hormones for growth promotion purposes.[687] At the meeting with the Panel, Dr. Cogliano clarified that the IARC has classified oestradiol-17β as possibly carcinogenic based on sufficient evidence in experimental animals. The agents that are known to be carcinogenic in humans are the steroidal oestrogens, non-steroidal oestrogens, and various oestrogen-progestin combinations as used either as birth-control pills or menopausal therapy.[688]

7.562 Dr. Boobis concluded that there is no good evidence that oestradiol is genotoxic *in vivo* or that it causes cancer by a genotoxic mechanism. Indeed the evidence is against this. Hence, the scientific evidence does not support the European Communities' position that the levels of the hormones in meat from treated cattle are not of relevance.[689]

7.563 In a review of the scientific literature and the 1999 report of the Committee for Veterinary Medicinal Products of the European Medicine Agency, Dr. Boisseau concluded that the demonstration remains to be made that the observed indicator effects are representative of mutagenesis at the gene or chromosome level and also occur in somatic cells *in vivo*. This is not likely in the view of the following: earlier studies had mostly indicated that hormones do not induce micronuclei or other chromosomes aberration types *in vivo*. With the exception of the study reported by Dhillon and Dhillon, the recent data confirm the earlier findings and clearly indicate that hormones and/or their synthetic analogues are not associated with genotoxicity properties in the bone marrow micronucleas assay *in vivo.*[690]

7.564 With respect to the carcinogenic and tumour promoting qualities of oestradiol-17β, Dr. Boisseau noted that if the SCVPH, in the 1999 Opinion, expresses its concern in concluding that "[f]inally, in consideration of the recent data on the formation of genotoxic metabolites of oestradiol suggesting oestradiol-17β acts as complete carcinogen by exerting tumour initiating and promoting effects ... no quantitative estimate of the risk related to residues in meat could be presented," it provides no data indicating that oestradiol-17β is associated with the increase of tumours in tissues or organs which are not hormone dependent.[691] Dr. Boisseau concludes that "the EC risk assessment did not support that residues of oestradiol-17β, despite the genotoxic potential of this hormone, can initiate and promote tumours in humans."[692]

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[686] Replies by the scientific experts to Panel questions, Annex D, para. 187.
[687] Replies by the scientific experts to Panel questions, Annex D, para. 154.
[688] Transcript of the experts meeting with the Panel, Annex G, para. 327.
[689] Replies by the scientific experts to Panel questions, Annex D, para. 184.
[690] Replies by the scientific experts to Panel questions, Annex D, para. 136.
[691] Replies by the scientific experts to Panel questions, Annex D, para. 141.
[692] Replies by the scientific experts to Panel questions, Annex D, para. 142.

7.565 In addition, Dr. Boisseau concluded that the scientific evidence relied upon in the Opinions does not support the conclusion that carcinogenic effects of oestradiol-17β are related to a mechanism other than hormonal activity.[693]

7.566 Dr. Boobis also pointed out that the evidence is against direct modification of DNA *in vivo* by hormones in meat from treated animals, or by their metabolites produced *in vivo*. Indirect modification could conceivably come about by product of reactive oxygen species. The DNA repair[694] processes for this are amongst the most efficient (*Arai et al, 2006; Russo et al, 2004)* and even if such modification did occur, it is anticipated that no heritable change would result, because of DNA repair (*Arai et al, 2006)*. This would be true even at the levels of exposure that could arise should GVP not be followed.[695]

7.567 Dr. Boisseau also expressed his opinion that epidemiological studies carried out in humans during long enough to take into account this "long latency period" will not be able to discriminate, in the case of a possible but limited increase of tumours, between the responsibilities of (a) hormone residues resulting from the treatment of food producing animals by growth promoting hormones, (b) hormone residues resulting from the endogenous production of these animals, and (c) other components of the diet including other food additives and contaminants. That is the reason for which, to his knowledge, even though the hormones in dispute have already been used as growth promoters over a significant number of years, the epidemiological studies in humans already carried out in this domain have failed to identify any relation between the occurrence of hormonally dependent tumours and the consumption of meat containing hormonally active residues resulting from the treatment of cattle with growth promoters.[696]

7.568 In response to the citation by the European Communities of data indicating different cancer rates between the United States and Europe, Dr. Boobis stated that there is no scientific evidence demonstrating any association between consumption of meat from animals treated with growth promoting hormones and the risk of cancer in humans. Dr. Boobis acknowledged that an appreciable number of studies show an association between a risk of certain cancer types and the consumption of meat, however he pointed out that the studies show little relationship with whether the meat is from animals treated with growth promoting hormones or not. Dr. Cogliano noted that although it is possible that differences in exposure to exogenous hormones could be one cause of the different breast cancer rates in the United States and the European Communities, the data are not sufficiently specific to establish a link. Dr. Guttenplan also concluded that the epidemiological studies do not identify a relationship between cancer and residues of hormonal growth promoters.[697]

7.569 Additionally, in response to direct questioning during the Panel meeting with the experts, Drs. Boobis, Boisseau, and Guttenplan all agreed that there is no appreciable risk of cancer from residues of oestradiol-17β in meat and meat products from cattle treated with the hormone for growth promotion purposes. While all the experts who responded to the question agreed that a zero risk could not be guaranteed, the actual level of risk was in their view so small as to not be calculable.[698]

7.570 Finally, the Opinions themselves contain statements that indicate that the science does not support the conclusions in the Opinions. The 1999 Opinion considered that the link, if any, between

[693] Replies by the scientific experts to Panel questions, Annex D, para. 156.

[694] DNA repair mechanisms refer to the ability of an organism to recognize different types of damage to DNA and repair it (replies of Dr. Boobis and Dr. Guttenplan to Panel question 22 to the experts. Annex D, paras. 201 and 204).

[695] Replies by the scientific experts to Panel questions, Annex D, para. 202.

[696] Replies by the scientific experts to Panel questions, Annex D, para. 209.

[697] Replies by the scientific experts to Panel questions, Annex D, paras. 224, 230, 231, 238, 239, 241 and 242.

[698] Transcript of the Panel meeting with the experts, Annex G, paras. 707-742.

cancer and consumption of hormone-treated meat cannot, at present, be confirmed nor refuted.[699] It is also important to note that the only study cited with respect to cancer in susceptible populations, such as foetuses and prepubertal children, has to do with *in utero* exposure to DES, which is banned in the United States and is not the source of the oestradiol-17β residues in the meat and meat products that are the subject of the European Communities' ban.[700]

7.571 With respect to the other potential adverse effects identified by the European Communities, the 1999 Opinion also concludes that no sound epidemiological data are currently available to establish a link between nutrition, especially meat consumption, and the occurrence of (and apparent current increase in) autoimmune diseases.[701] As to the developmental effects of exogenous sex hormones on puberty in humans, the 1999 Opinion, noted that although precocious puberty is somewhat common in the United States, "the importance of environmental oestrogenic compounds present in plastics, insecticides, and *meat from animals treated with sex hormones*, while suggestive, remains as only a possibility in affecting an early onset of puberty."[702]

7.572 The Panel has evaluated the evidence. The Panel considered the SCVPH's own characterization of the science in the Opinions as well as the replies of the experts to the Panel's questions, the transcript of the experts meeting with the Panel, and the submissions of the parties. The Panel found that the views expressed by the experts who answered the questions, provided clear and consistent answers, and who had particular expertise in the relevant areas being discussed, were consistent with the statements in the Opinions cited above. The Panel's evaluation of the expert views and the plain language of the Opinions themselves leads the Panel to conclude that the scientific evidence referred to in the Opinions does not support the European Communities' conclusion that for oestradiol-17β genotoxicity had already been demonstrated explicitly[703], nor does it support the conclusion that the presence of residues of oestradiol-17β in meat and meat products as a result of the cattle being treated with the hormone for growth promotion purposes leads to increased cancer risk. Additionally, the scientific evidence does not support the European Communities' conclusions about the adverse immunological and developmental effects of consuming meat and meat products from cattle treated with oestradiol-17β for growth promotion purposes. Therefore, the Panel is of the view that the scientific evidence referred to in the Opinions does not support the conclusions reached by the European Communities.

Conclusion

7.573 On the basis of the above, the Panel concludes that, in its Opinions, the European Communities took into account risk assessment techniques of the relevant international organizations and took into account the factors listed in Article 5.2 of the *SPS Agreement*. The Panel nonetheless concludes that the European Communities has not satisfied the requirements of the definition of a risk assessment contained in Annex A(4) of the *SPS Agreement* and the scientific evidence evaluated does not support the conclusions in the risk assessment. The Panel concludes that the European Communities has not conducted a risk assessment as appropriate to the circumstances within the meaning of Article 5.1 of the *SPS Agreement*.

[699] 1999 Opinion., pp. 17-18.
[700] 1999 Opinion, p. 21.
[701] 1999 Opinion, pp. 22-23.
[702] 1999 Opinion, p. 14. (emphasis added).
[703] 1999 Opinion, p. 75.

(iii) Is the measure "based on" a risk assessment?

Introduction

7.574 The second question to address when determining whether an SPS measure is consistent with Article 5.1 is whether that measure is "based on" a risk assessment. For an SPS measure to be based on a risk assessment, there must be a rational relationship between the measure and the risk assessment.[704]

7.575 Specifically, the Appellate Body in *EC – Hormones* explained that "Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the *SPS Agreement*, requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake."[705] The Appellate Body went on to explain that this requirement is a substantive one.[706]

Summary of the main arguments of the parties[707]

7.576 The **United States** argues that the EC failed to demonstrate that its amended ban is "based on" a risk assessment within the meaning of Article 5.1, i.e. that the results of the risk assessment sufficiently warrant – that is to say, reasonably support – the SPS measure at stake.

7.577 The **European Communities** concludes that the United States has failed to demonstrate that the scientific risk assessment carried out by the SCVPH does not reasonably support the measures adopted.[708] The European Communities argues that not only does the SCVPH's assessment support the ban on oestradiol-17β, but more recent research equally confirms and further reinforces its opinion that the measure is warranted.[709]

Reasoning of the Panel

7.578 The Panel has concluded that the Opinions do not constitute a risk assessment because the Opinions do not satisfy the definition of a risk assessment contained in Annex A(4) second sentence and because the scientific evidence referred to in the Opinions does not support the conclusions therein. Because the Opinions are not a risk assessment as appropriate to the circumstances, the measure cannot be based on a risk assessment within the meaning of Article 5.1.[710]

(iv) Conclusion

7.579 In light of the above, the Panel concludes that the EC implementing measure on oestradiol-17β is not compatible with Article 5.1 of the *SPS Agreement*.

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[704] Appellate Body Report on *EC – Hormones*, para. 193.
[705] Appellate Body Report on *EC – Hormones*, paras. 193-194.
[706] Ibid.
[707] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.
[708] EC's second written submission, para. 210.
[709] EC's second written submission, para. 211.
[710] Panel Report on *Japan – Apples (Article 21.5 – US)*, para. 8.156 (concluding that because the 2004 pest risk assessment did not amount to a risk assessment as appropriate to the circumstances, Japan's measure was not based on a risk assessment).

(f) Compatibility of the EC implementing measure with Article 5.7 of the *SPS Agreement*

(i) Introduction

7.580 We have already concluded that the EC implementing measure does not comply with the provisions of Article 5.1 of the *SPS Agreement*. To the extent that we are not seeking to determine any level of nullification or impairment, but rather whether the European Communities has removed the measure found to be inconsistent with a covered agreement in the *EC – Hormones* dispute, we could conclude at this stage that, by adopting Directive 2003/74/EC, the European Communities has not – fully – removed the measure found to be inconsistent with the *SPS Agreement*. We recall, however, the purpose of our considering the EC claims of violation of Article 23.1 of the DSU, read together with Article 22.8 and Article 3.7 of the DSU. It is to assist the DSB in achieving a satisfactory settlement of the matter in accordance with the rights and obligations under the DSU and under the covered agreements, and to allow the Appellate Body to make findings as may be necessary should it disagree with our findings in relation to Article 23.1 and 23.2(a) of the DSU. We therefore proceed with a review of the conformity of the EC measure with Article 5.7 of the *SPS Agreement*.

(ii) Summary of the main arguments of the parties[711]

7.581 The **European Communities** argues that Directive 2003/74/EC provides that the use of five of the six hormones at issue is provisionally forbidden. This ban is based on a comprehensive risk assessment and, thus, is fully compliant with the DSB recommendations and rulings. In particular, as stipulated by the Appellate Body, the results of the risk assessment provide the "available pertinent information" on the basis of which the provisional prohibition regarding these five hormones has been enacted. Consequently, the European Communities claims that, through Directive 2003/74/EC, it has implemented the rulings and recommendations in the *EC – Hormones* case.[712]

7.582 The **United States** considers that, because the EC ban fails to meet the requirements of Article 5.7, the European Communities is not provisionally exempted from satisfying the obligations set out, *inter alia*, in Articles 2.2 and 5.1 of the *SPS Agreement*.

7.583 The United States recalls that the Appellate Body in *Japan – Agricultural Products II*, clarified that Article 5.7 sets out four requirements that must be cumulatively satisfied in order to adopt and maintain a provisional measure.

7.584 First the United States argues that the European Communities fails to demonstrate how its provisional ban is imposed in a situation where "relevant scientific evidence is insufficient". The United States adds that Codex has adopted standards based on several JECFA risk assessments of the hormones which determined that they are safe at the levels implicated by residues in meat from cattle treated with the hormones according to good veterinary practice. In light of the quality and quantity of scientific evidence relating to the five hormones, there is simply no need to obtain the additional information necessary for a more objective assessment of risk. According to the United States, studies completed since the *EC – Hormones* case reaffirm earlier conclusions. New safety assessments have been conducted for progesterone and testosterone, reaffirming their safety when used according to good veterinary practices.

7.585 In the opinion of the United States, the European Communities also fails to demonstrate how its provisional ban has been adopted on the basis of available pertinent information. For the United

[711] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[712] EC's first written submission, para. 17.

States, the studies relied upon by the European Communities as a basis for its provisional ban do not in fact demonstrate a risk associated with residues in meat and meat products from cattle that have been treated with hormones for growth promotion purposes according to good veterinary practices.

7.586 The United States further argues that the European Communities has not sought to obtain the additional information necessary for a more objective assessment of risk.

7.587 The United States finally argues that the European Communities has not reviewed the measure accordingly within a reasonable period of time. The United States considers that the only apparent change over 15 years of ban is the relabeling of its application from "definitive" to "provisional". The United States is of the view that 15 years is not a reasonable period of time especially given the fact that the ban addresses substances as intensively reviewed and studied as the five hormones at issue.

7.588 The **European Communities** argues that, since the *EC – Hormones* case, the body of evidence has developed and, while still not providing enough knowledge to carry out a complete and definitive risk assessment, supports the conclusion that precautionary measures are required in order to achieve its chosen level of protection.

7.589 According to the European Communities, the evidence, while pointing to a number of risks, is full of gaps in pertinent information and important contradictions have developed that render no longer valid the conclusions reached by JECFA in 1988, 1999 and 2000, thus not allowing a quantitative or qualitative risk assessment. According to the European Communities, a number of significant scientific developments, taken together with all other available evidence, indicates that it is not possible to undertake a definitive risk assessment for the five hormones concerned.

(iii) Approach of the Panel

7.590 As a first remark, the Panel recalls its conclusion that the measure at issue, to the extent that it provisionally bans the import of meat from cattle treated with the hormones progesterone, testosterone, trenbolone acetate, melengestrol acetate and zeranol, is an SPS measure within the meaning of Article 1 of, and paragraph 1 of Annex A to, the *SPS Agreement*.[713]

7.591 Second, both parties address the issue of the compatibility of the provisional ban on the above-mentioned five hormones with the provisions of Article 5.7 of the *SPS Agreement*. None of the parties discussed the compatibility of the ban imposed with respect to these five hormones with Article 5.1.[714] The Panel will therefore limit its review to the conformity of the EC ban on the five hormones with the requirements of Article 5.7.

7.592 Article 5.7 of the *SPS Agreement* provides as follows:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent

[713] See para. 7.434 above.

[714] The Panel asked a question to the parties on a possible "automatic" violation of Articles 2.2 and 5.1 as a result of a violation of Article 5.7 (second series of questions from the Panel to the parties, question 2). The Panel notes, however, that neither the European Communities nor the United States requested the Panel to review the compatibility of the EC implementing measure regarding the five hormones subject to a provisional ban with Article 5.1 or Article 2.2. The Panel also notes that the EC implementing measure is supposed to have removed the violation of Article 5.1 through the adoption of a provisional ban compatible with Article 5.7. In light of our approach to the aspect of this case relating to the compatibility of the EC implementing measure with the *SPS Agreement*, we decided to limit our review to the compatibility of the "provisional ban" with Article 5.7.

> information, including that from the relevant international organizations as well as from sanitary ... measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risks and review the sanitary ... measure accordingly within a reasonable period of time."

7.593 In *Japan – Agricultural Products II*, the Appellate Body recalled that Article 5.7 "set[s] out four requirements that must be satisfied in order to adopt and maintain a provisional measure." These requirements are:

(a) the measure is imposed in respect to a situation where "relevant scientific evidence is insufficient";

(b) the measure is adopted "on the basis of available pertinent information";

(c) the Member which adopted the measure must "seek to obtain the additional information necessary for a more objective assessment of risk"; and

(d) the Member which adopted the measure must "review the ... measure accordingly within a reasonable period of time".[715]

7.594 The Appellate Body noted that the four requirements are "clearly cumulative in nature", and that "[w]henever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[716]

7.595 The Panel recalls that previous panels have addressed each of these requirements successively. Having regard to our duty to review the situation for each of the five hormones concerned by the provisional ban, we will proceed first with the examination of the requirement under (a) above, i.e. whether the measure is imposed with respect to a situation where "relevant scientific evidence is insufficient".

7.596 Moreover, having regard to the arguments of the parties and in line with our duty not to perform a *de novo* risk assessment, we will limit ourselves to review the issues with respect to which the parties exchanged arguments and provided sufficient evidence.

7.597 We also note that the United States' main line of argumentation is based on the fact that "international standards and a significant body of scientific studies exist on the risks posed by each hormone. [JECFA] and several national regulatory bodies have determined that the scientific evidence regarding these hormones is adequate or sufficient to conduct a risk assessment."[717] In that context, we deem it appropriate to determine to what extent relevant scientific evidence can become insufficient within the meaning of Article 5.7 in the presence of international standards.

7.598 The Panel does not believe that the issue of the possibility or not to make a *quantitative* estimate of the risk to consumers constitutes a subject on which a discussion of whether "relevant scientific evidence is insufficient" is needed. The Panel recalls in this respect that the standard applied by the Appellate Body to determine whether relevant scientific evidence is insufficient is that:

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[715] See Appellate Body Report on *Japan – Apples*, para. 176, citing the Appellate Body Report on *Japan – Agricultural Products II*, para. 89.

[716] Appellate Body Report on *Japan – Agricultural Products II*, para. 89.

[717] US's second written submission, para. 29.

> "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, *in quantitative or qualitative terms*, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*."[718]

7.599 Moreover, we note that the Appellate Body considered that Article 5.1 does not require that risk assessments be quantitative, but that qualitative risk assessments are also compatible with Article 5.1.[719] We recall in this regard that Codex itself does not necessarily require the performance of quantitative risk assessments.[720]

7.600 We also deem it important to recall that, in *Japan – Agricultural Products II*, the Appellate Body stated that:

> "Article 5.7 allows members to adopt provisional SPS measures '[i]n case where relevant scientific evidence is insufficient' and certain other requirements are fulfilled. Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless."[721]

7.601 The European Communities also refers to paragraphs 194 (on minority scientific views) and 205 (on Article 5.2 and good veterinary practices) of the report of the Appellate Body in *EC – Hormones*.

7.602 We have already addressed above[722] the question of the treatment of minority views among experts and do not find it necessary to come back on this matter. As far as the second issue is concerned, we note that, as recalled by the Appellate Body in *EC – Hormones*, it is also appropriate for the European Communities to consider situations of misuse:

> "… The *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2 …"[723]

7.603 The above statement was made in relation to the performance of a risk assessment under Article 5.1 and 5.2 of the *SPS Agreement*. We recall that Article 5.7 is applicable when relevant scientific evidence is not sufficient to undertake a risk assessment in conformity with Article 5.1. Whether instances of misuse or abuse in the administration of hormones exist or not is not as such a

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[718] Appellate Body Report on *Japan – Apples*, para. 179 (emphasis added).
[719] Appellate Body Report on *EC – Hormones*, para.187.
[720] Working Principles for Risk Analysis for Application within the Framework of the Codex Alimentarius, para. 20.
[721] Appellate Body Report on *Japan – Agricultural Products II*, para. 80.
[722] See para. 7.420 above.
[723] Appellate Body Report on *EC – Hormones*, para. 206. See also Appellate Body Report on *Japan – Apples*, para. 179.

scientific issue likely to make a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement* impossible. In our opinion, the scientific issue is related to the effect of the ingestion of high doses of hormones residues, not to potential or actual misuse or abuse in the administration of hormones. Therefore, we will not address the issue of non compliance with good veterinary practices in our analysis under Article 5.7 of the *SPS Agreement*.

(iv) When will "relevant scientific evidence" be deemed "insufficient"?

Effect of the level of protection on the consideration of the insufficiency of relevant scientific evidence under Article 5.7

7.604 According to the **European Communities**, whether a risk assessment can reach a definitive conclusion depends not only on the data available but also on how a risk assessment has been framed by the risk manager.[724] The European Communities argues that a Member may disagree with the risk assessment underlying an international standard for scientific reasons and, in particular, on the issue of whether the scientific evidence relied upon is sufficient. Such a disagreement may result from the fact that in order to meet a higher level of protection, a Member may require more information than that provided.[725] The European Communities argues that the evidence which served as the basis for the 1988 and 1999-2000 JECFA evaluations is not sufficient "to perform a definitive risk assessment within the meaning of Article 5.7, in particular by the WTO Members applying a high level of health protection of no risk from exposure to unnecessary additional residues in meat of animals treated with hormones for growth promotion".[726]

7.605 The **Panel** first notes that the European Communities refers to the fact that the evidence is not sufficient to perform a "definitive risk assessment". However, the European Communities nowhere defines what it means by a "definitive risk assessment". The Panel recalls the definition of adequate risk assessment proposed by the European Communities in *EC – Approval and Marketing of Biotech Products*: "one which has been 'delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised'."[727] It is unclear to the Panel whether this is what the European Communities refers to in this case as a "definitive risk assessment". The Panel would like to specify that there is no obligation under the *SPS Agreement* to perform a *definitive* risk assessment for that risk assessment to be valid under Article 5.1. Moreover, the Panel doubts that a *definitive* risk assessment can in practice ever be performed, since new evidence becomes available and risk assessments may need to be reviewed and updated accordingly, or else the measure based on these risk assessments will have to be adjusted to the evolution of the scientific evidence.[728] The Panel understands the terms "based on an assessment, as appropriate to the circumstances" to suggest that the link between the SPS measure adopted by a Member and the risk assessment on which it is based may evolve depending on the circumstances, thus implying that Article 5.1 does not require a definitive risk assessment. This is also confirmed by the fact that risk assessments do not have to be "monolithic" as recalled by the Appellate Body in *EC – Hormones*.[729] In any event, the criterion allowing the adoption of sanitary measures on the basis of available pertinent information under Article 5.7 is that "relevant scientific evidence is insufficient" to permit the performance of a risk assessment as required under Article 5.1 and Annex A(4), not that the risk assessment to be performed

[724] EC's oral statement at the second substantive meeting, para. 22.
[725] EC's replies to Panel questions after the first substantive meeting, question 72, Annex B-1, para. 266.
[726] EC's second written submission, para. 149; EC's replies to Panel questions after the first substantive meeting, question 31, Annex B-1, paras. 167-172.
[727] Panel Report in *EC – Approval and Marketing of Biotech Products*, para. 7.3238.
[728] See Panel Report in *EC – Approval and Marketing of Biotech Products*, paras. 7.3239-7.3240.
[729] Appellate Body Report on *EC – Hormones*, para. 194.

pursuant to Article 5.1 be a definitive one.[730] The Panel is of the view that, by suggesting that a risk assessment be definitive, the European Communities actually disregards the Appellate Body interpretation mentioned above and seeks to impose a higher threshold for compliance with Article 5.1, or a lower one to meet the conditions of Article 5.7. However, the Panel does not believe that this approach is supported by Article 5.1, Annex A(4) or Article 5.7.

7.606 The Panel also notes the EC view that, in determining whether the relevant scientific evidence is insufficient, within the meaning of Article 5.7, the Panel should take into account the level of health protection applied by the Member concerned. More particularly, the European Communities argue that, when the level of health protection of a Member is particularly high and the body of evidence is in the process of moving from a state of sufficiency to a state of insufficiency, that Member should not be required to demonstrate positively the existence of a clear harm.

7.607 Regarding the issue of whether the level of health protection of a particular Member should play a role in its assessment of whether the relevant scientific evidence is insufficient, the Panel notes that the EC level of health protection is that of "no (avoidable) risk, that is a level of protection that does not allow any unnecessary addition from exposure to genotoxic chemical substances that are intended to be added deliberately to food."[731]

7.608 We recall that the Appellate Body in *Japan – Apples* stated that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*.[732]

7.609 The terms of Article 5.1 and Annex A to the *SPS Agreement* and, in particular, the definition of "risk assessment" do not indicate that a Member's level of protection is pertinent to determine whether a risk assessment can be performed or not. We agree with the Panel in *EC – Approval and Marketing of Biotech Products* when it states that:

> "[W]e are not convinced that the protection goals pursued by a legislator are relevant to such a determination. The protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary. And a legislator protection goals are certainly relevant to the determination of the measure ... to be taken for achieving a Member's level of protection against risk. Yet there is no apparent link between a legislator's protection goals and the task of assessing the existence and magnitude of potential risks."[733]

7.610 We note that sufficient scientific evidence is what is needed to make a risk assessment. The assessment whether there is sufficient scientific evidence or not to perform a risk assessment should be an objective process. The level of protection defined by each Member may be relevant to

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[730] The Panel notes in this respect that in *Australia – Salmon,* the Appellate Body stated that:

> "We might add that the existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3, read together with paragraph 4 of Annex A, for a risk assessment."(Appellate Body Report on *Australia – Salmon*, para. 130).

The Panel also notes Dr. Boisseau's remark, that "it is always possible to ask for more data in order to clarify more issues so that the will to eliminate any scientific uncertainty could result in an endless assessment process." Replies by the scientific experts to Panel questions, Annex D, para. 452.

[731] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 69.

[732] Appellate Body Report on *Japan – Apples*, para. 179.

[733] Panel Report on *EC – Approval and Marketing of Biotech Products*, para. 7.3238.

determine the measure to be selected to address the assessed risk, but it should not influence the performance of the risk assessment as such.

7.611 Indeed, whether a Member considers that its population should be exposed or not to a particular risk, or at what level, is not relevant to determining whether a risk exists and what its magnitude is. *A fortiori*, it should have no effect on whether there is sufficient evidence of the existence and magnitude of this risk.

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

7.613 This is not to say, however, that we disagree with the European Communities that when the body of evidence is in the process of moving from a state of sufficiency to a state of insufficiency a Member should not be required "to demonstrate positively the existence of clear harm."[734] In fact, even when the scientific evidence is sufficient, a Member is not required, under the provisions of the *SPS Agreement*, to "demonstrate positively the existence of a clear harm". Rather, the objective of a risk assessment is to evaluate the potential for harm to occur under certain circumstances (e.g., from the consumption of a foodstuff containing certain contaminants).

Can relevant scientific evidence *become* "insufficient"?

7.614 The **United States** notes, and the European Communities agrees, that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. According to the United States, there is more than sufficient evidence to allow performance of an adequate risk assessment for the five provisionally banned hormones.[735] The United States argues that the relevant question is not the specificity of the evidence relating to the five hormones, but whether the evidence *in toto* permits the European Communities to conduct a risk assessment for those hormones.[736] The United States recalls that JECFA has performed risk assessments for the hormones at issue and concludes that, in the case at hand, while any new studies could hypothetically affect the conclusion of the risk assessment, their existence would not make the scientific evidence "insufficient" for conducting such an assessment.[737]

7.615 The **European Communities** considers that Article 5.7 of the *SPS Agreement* is applicable not only when no risk assessment can be made at all, but also when the latest scientific evidence from any credible and objective source raises doubts or puts into question the previously held scientific opinion about the safety or dangerous nature of the substance in question.[738] The European Communities adds that the evidence assessed by the SCVPH, while inconclusive in terms of demonstrating a risk, does nonetheless point to the possible occurrence of certain adverse effects, which invalidate or put into serious doubt previously held assumptions about the safety of these hormones by the defending parties and Codex/JECFA.[739] The European Communities concludes that serious doubt may exist when the pertinent available evidence is contradictory, inconclusive or

[734] EC's second written submission, para. 149.
[735] US's first written submission, para. 124; US's second written submission, para. 28; EC's second written submission, para. 134.
[736] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 67.
[737] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 68.
[738] EC's replies to Panel questions after the first substantive meeting, question 67, Annex B-1.
[739] EC's second written submission, para. 181.

incomplete.[740] To guard against potential abuses, the new evidence should not be arbitrary but credible and should show that there is a genuine scientific disagreement identified in a risk assessment.

7.616 The European Communities further argues that, due to the dynamic nature of scientific knowledge, a risk assessment that may at one point in time have been based on sufficient scientific evidence may need to be reviewed when new scientific evidence becomes available. In addition, new international risk assessment standards may become available that have to be taken into account in new risk assessments.[741]

7.617 The **United States** acknowledges that scientific evidence that at one point in time might be sufficient to conduct a risk assessment could be insufficient at a later point, for example if a new pathway for a risk came to light on which information was insufficient.[742] The United States recalls that in the *EC – Hormones* case, the European Communities argued that its ban on all six hormones was definitive, and that it was based on sufficient scientific evidence. The United States considers that nothing has occurred in the interim to render insufficient the scientific evidence on the safety of residues of the five provisionally banned hormones in meat products as a result of the cattle being treated with these hormones for growth promotion. According to the United States, studies completed since the *EC – Hormones* case, including by JECFA, reaffirm earlier conclusions.[743] The United States indicates that it did not uncover any new evidence of risk when reviewing the European Communities' 17 studies and other materials put forward by the European Communities.[744]

7.618 In response to this argument, the **European Communities** recalls that the Appellate Body had found that what the European Communities had considered sufficient evidence was in fact insufficient, and that this had been confirmed by risk assessment standards developed in the years after the *EC – Hormones* ruling. The European Communities also argues that the body of evidence has developed in the meantime. While the evidence is still insufficient to carry out a "complete and definitive risk assessment", it "supports the conclusion that precautionary measures are required in order to achieve its chosen level of protection".[745]

7.619 First, the **Panel** notes that parties agree to the fact that scientific evidence which was previously deemed sufficient could subsequently become insufficient. Both parties agree that there could be situations where new studies can affect the conclusion of existing risk assessments. The United States considers, however, that in the case at hand the existence of such new studies would not make the scientific evidence "insufficient" for conducting such an assessment.

7.620 The Panel agrees with the parties that there could be situations where existing scientific evidence can be put in question by new studies and information. There could even be situations where evidence which supported a risk assessment is unsettled by new studies which do not constitute sufficient relevant scientific evidence as such to support a risk assessment but are sufficient to make the existing, previously relevant scientific evidence insufficient.[746]

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[740] EC's replies to Panel questions after the second substantive meeting, Annex C-1, para. 43.

[741] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 268-273.

[742] US's replies to Panel questions after the first substantive meeting, question 73, Annex B-3, para. 82.

[743] US's first written submission, paras. 125-128.

[744] US's second written submission para. 29; US oral statement at the second substantive meeting, 3 October 2006, para. 20.

[745] EC's second written submission para. 137; EC's replies to Panel questions after the first substantive meeting, question 19, Annex B-1, paras. 108-109.

[746] See also Article 2.2 which provides that a sanitary measure must not be maintained without sufficient scientific evidence except as provided for in paragraph 7 of Article 5. This seems to imply that the

7.621 Indeed, nothing in Article 5.7 prevents such an interpretation. We also note in this respect that Article 2.2 foresees such a possibility when it mentions that sanitary measures must not be "*maintained* without sufficient scientific evidence except as provided for in paragraph 7 of Article 5."[747] The use of the word "maintained" read together with the reference to Article 5.7 suggests the possibility of an evolution from a situation of sufficient evidence to perform a risk assessment to one where, in substance, a risk assessment can no longer be performed.

7.622 The Panel notes in this respect that a procedure is available for Codex members and observers to request the inclusion of a particular compound for evaluation or re-evaluation on a "priority list" that the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) communicates to JECFA.[748] The European Communities refers to an exchange of letters between the European Commission and Codex and JECFA regarding a postponement of the re-evaluation due to be carried out by JECFA in 1999.[749] The European Communities seems to allege that there was a commitment from Codex and JECFA to re-evaluate the hormones at issue once the studies commissioned by the European Communities would be available.[750] However, this explanation was not confirmed by Codex or JECFA. From the information communicated by the representatives of Codex and JECFA at the meeting of the Panel with scientific experts, it appears on the contrary that the European Communities never actually requested Codex or JECFA to re-evaluate any of the hormones for which risk assessments had been carried out by JECFA and standards adopted by Codex. The representative of Codex stated that there was no record in the reports of the CCRVDF of proposals, either from the European Communities or from Member States of the European Communities to include the five substances at issue in the priority list for re-evaluation by JECFA.[751] The representative of Codex added that, even at the latest session of the CCRVDF in 2006, no such request had been made.[752]

7.623 Second, since the present situation is one where it is alleged that existing relevant scientific evidence has become insufficient, it seems important to determine which circumstances could make such existing evidence insufficient.

7.624 The Panel recalls that, in *Japan – Apples*, the Appellate Body found that:

> " '[R]elevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it 'general' or 'specific', in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan."[753]

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information relied upon under Article 5.7 may include evidence, including relevant scientific evidence and not merely information, as long as that evidence remains insufficient.

[747] Emphasis added.

[748] Statement by Dr. Miyagishima, Codex representative, transcript of the Panel meeting with the experts, Annex G, paras. 523-524.

[749] Exhibit EC-63.

[750] EC statement, Transcript of the Panel meeting with the experts, Annex G, para. 527.

[751] Statement by Dr. Miyagishima, Codex representative, transcript of the Panel meeting with the experts, Annex G, para. 524.

[752] Statement by Dr. Miyagishima, Codex representative, transcript of the Panel meeting with the experts, Annex G, para. 529.

[753] Appellate Body Report on *Japan – Apples*, para. 179.

7.625 We also note that in *EC – Approval and Marketing of Biotech Products*, the panel stated that:

> "[I]t must be determined on a case-by-case basis whether the body of available scientific evidence is insufficient to permit the performance of a risk assessment."

7.626 We agree with the *EC – Approval and Marketing of Biotech Products* panel and we will base our assessment on the evidence submitted by the parties in this case, having regard to the views of the experts on each issue.

7.627 This said, the Panel believes that it needs to determine under which circumstances relevant scientific evidence may more particularly be deemed "insufficient" in this case.

7.628 The Panel first reads the first sentence from the extract of the Appellate Body report in *Japan – Apples* quoted above as meaning that relevant scientific evidence will be deemed insufficient within the meaning of Article 5.7 if the relevant scientific evidence does not make it possible to complete a risk assessment on which a sanitary measure can be based *in substance*. It is always possible to perform the four successive steps of a risk assessment as defined by Codex and ultimately reach the conclusion that relevant scientific evidence is insufficient (as the European Communities did in the case of the five hormones in respect of which it applies a provisional ban). However, the fact that the Codex four steps can be formally completed does not mean that such a process is equated with a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*. There will be a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement* when the assessor has analysed fully the potential for the identified adverse effects to arise from the presence of the substance at issue in food, beverages, or foodstuffs. We believe that this was the intention of the Appellate Body when it used the term *adequate*[754] in "adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*." This is confirmed by the second sentence of Article 5.7 which provides that "Members shall seek to obtain the additional information necessary for a *more objective assessment* of risk."[755] In other words, Article 5.7 will apply in situations where, in substance, the relevant scientific evidence does not allow the completion of an objective evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

7.629 While this gives a general idea of the circumstances under which Article 5.7 may be invoked, we should strive to ascertain more precisely the scope of "insufficient", if possible. In doing that, we should keep in mind that Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence and that an overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless.[756]

7.630 As a first step, we note that, in *Japan – Apples*, the Appellate Body seemed to consider that *relevant* scientific evidence is insufficient if, irrespective of the quantity of evidence available, it has not led to *reliable* or *conclusive* results.[757] It also seems that evidence providing unreliable or inconclusive results should not be confused with "scientific uncertainty", as it appears from the following Appellate Body statement in *Japan – Apples*:

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[754] "commensurate in fitness, sufficient, satisfactory" (*The Shorter Oxford English Dictionary*, fifth ed., 2002, p. 26).

[755] Emphasis added.

[756] Appellate Body Report on *Japan – Agricultural Products II*, para. 80.

[757] Appellate Body Report on *Japan – Apples*, para. 185:

> "We do not read the Panel's interpretation as excluding cases where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results."

> "The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The two concepts are not interchangeable."[758]

7.631 We understand this statement to mean that the existence of scientific uncertainty does not automatically amount to a situation of insufficiency of relevant scientific evidence. In other words, the fact that a number of aspects of a given scientific issue remain uncertain may not prevent the performance of a risk assessment. First, we should exclude theoretical uncertainty, which is the uncertainty that always remains because science can never provide absolute certainty about the safety of a given substance. In *EC – Hormones*, the panel and the Appellate Body concurred in agreeing that theoretical uncertainty was not the kind of risk to be assessed under Article 5.1.[759] In the Panel's view, theoretical uncertainly therefore should also not determine the applicability of Article 5.7.

7.632 Second, we note that in *EC – Hormones*, the Appellate Body stated that the presence of divergent views on an issue could be a form of scientific uncertainty.[760] We nevertheless note that scientific uncertainty may be factored into the conclusions of the risk assessment. We find support for this conclusion in the following comment of the Appellate Body in *Australia – Salmon*:

> "We might add that the existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3, read together with paragraph 4 of Annex A, for a risk assessment."[761]

7.633 This issue was further addressed by the panel in *EC – Approval and Marketing of Biotech Products*, which acknowledged that the conclusions of a risk assessment may not be free from uncertainties or other constraints even though there was sufficient relevant scientific evidence to perform the risk assessment.[762] The panel, in agreement with the Appellate Body in *EC – Hormones*, found "that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken" and that the scientific uncertainties present in a risk assessment may support a range of possible measures and within the range of measures reasonably supported by the risk assessment and consistent with other applicable *SPS Agreement* provisions, the Member was entitled to choose one that best protects human health and/or the environment.[763] As recalled by the panel in *EC – Approval and Marketing of Biotech Products*, Members were also justified in taking into account factors like a limited body of relevant scientific evidence, assumptions and other constraints that would affect the level of confidence in the risk assessment:

> "We consider that if there are factors which affect scientists' level of confidence in a risk assessment they have carried out[764], a Member may in principle take this into account in determining the measure to be applied for achieving its appropriate level of protection from risks.[765] Thus, there may conceivably be cases where a Member

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[758] Appellate Body Report on *Japan – Apples*, para. 184.
[759] Appellate Body Report on *EC – Hormones*, para. 186.
[760] Appellate Body Report on *EC – Hormones*, para. 194.
[761] Appellate Body Report on *Australia – Salmon*, para. 130.
[762] Panel Report on *EC – Approval and Marketing of Biotech Products,* para. 7.1525.
[763] Panel Report on *EC – Approval and Marketing of Biotech Products,* para. 7.1525.
[764] (*footnote original*) *E.g.,* a limited body of relevant scientific evidence may be such a factor.
[765] (*footnote original*) This view is consistent with risk assessment techniques established by relevant international organizations. For instance, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* state that "[t]he report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies

> which follows a precautionary approach, and which confronts a risk assessment that identifies uncertainties[766] or constraints, would be justified in applying (i) an SPS measure even though another Member might not decide to apply any SPS measure on the basis of the same risk assessment, or (ii) an SPS measure which is stricter than the SPS measure applied by another Member to address the same risk".[767]

7.634 The panel explicitly recognized that, even though scientific uncertainty existed, there could still be sufficient scientific evidence to perform a risk assessment.[768]

7.635 We note in this respect the comments of Dr. Boisseau and Dr. Boobis before the Panel on how scientific uncertainty is addressed in risk assessment.[769]

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with the risk manager, not the risk assessors". Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (adopted in June/July 2003), Section III, Codex Procedural Manual, 14th edition, 2004, para. 25. Along similar lines, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* state that "[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties". Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (adopted in June/July 2003), CAC/GL 44-2003, para. 18. Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[t]he uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option". IPPC, ISPM #11: *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 3. The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms.

[766] (*footnote original*) We are not referring here to the theoretical uncertainty which inevitably remains because science can never provide absolute certainty that a product will never have adverse effects on human health or the environment. The Appellate Body has made it clear that this theoretical uncertainty is not the kind of risk which is to be assessed under Article 5.1. Appellate Body Report on *EC – Hormones*, para. 186.

[767] Panel Report on *EC – Approval and Marketing of Biotech Products Products*, para. 7.3065.

[768] Panel Report on *EC – Approval and Marketing of Biotech Products Products,* para. 7.1525.

[769] See replies of Dr. Boisseau and Dr. Boobis to question 12 of the Panel, Annex D, paras. 123-128.

Dr. Boisseau expressed the following views:

> "In assessing the risk for human health associated with the exposure to veterinary drug residues, JECFA adresses the scientific uncertainty by using the safety factors listed above in my reply to the question n°8 describing, among others, how JECFA builds a margin of safety into its final recommendations.
>
> For the hormonal growth promoters, JECFA has considered that, given the quality and the quantity of the available data, it was possible to carry out a complete quantitative risk assessment. For establishing ADIs and MRLs for the three synthetic hormones, melengestrol, trenbolone and zeranol, JECFA has implemented the usual procedure regarding the safety factors. For the three natural hormones, oestradiol-17β, progesterone and testosterone, JECFA has decided that the margin of safety deriving from the values of the established ADIs and from a maximum estimated intake of residue was such that it was not necessary to set up MRLs.
>
> For oestradiol-17β, the European Communities did not consider any scientific uncertainty as it decided that it was not possible, for reason of principle, to establish an ADI for a genotoxic compound. For the five other hormones at issue, the European Communities did not really consider any scientific uncertainty as it decided that the available data were too limited to allow a complete quantitative risk assessment to be carried out."

Dr. Boobis mentioned the following:

> "Scientific uncertainty is dealt with in a variety of ways in risk assessment. ...

7.636 We find further support for this position in the view of the Appellate Body as expressed in *Japan – Apples* that whether relevant scientific evidence is insufficient must be assessed "not in the abstract, but in the light of a particular inquiry".[770]

7.637 While we agree that under certain circumstances what was previously sufficient evidence could become insufficient, we do not believe that the existence of scientific uncertainty means that previously sufficient evidence has in fact become insufficient nor should it *ipso facto* justify the applicability of Article 5.7 of the *SPS Agreement*.

Relationship between insufficiency of the evidence and the existence of an international standard

7.638 The **United States** considers that international standards serve as an indicator that evidence is sufficient to conduct a risk assessment, but since Members may be able to react more quickly to new information than international standard setting bodies, the existence of international standards is not

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One way of dealing with uncertainty is to default to the worst case in the absence of evidence to the contrary. Hence, the most sensitive relevant endpoint in the most sensitive species is used as the basis of the risk assessment. In extrapolating to humans a default factor of 10 is used to allow for species differences, which assumes that humans are more sensitive than the experimental species. A further factor of 10 is included for interindividual differences. These differences may be due to gender, genetics, life stage or other factors. However, to some extent such differences have already been taken into account in the choice of endpoint, as this will usually represent the most sensitive lifestage, gender and to some extent genetics by using data from the most sensitive species. Where there are additional uncertainties, such as no NOEAL or the absence of a non-critical study, an additional safety factor will be included, and this is almost always conservative, as when the data gaps have been completed, the appropriate safety factor is almost always less than that used to account for these data gaps. The residue may be assumed to be all as active as the most active moiety, which is almost always a conservative assumption. Dietary intake is based on conservative data for food consumption. It is also assumed that all meat that could contain veterinary drug residue will contain the residue and that this will be present at the high end of the range (MRL or other appropriate level). In respect of the ADI, the assumption is that intake will be at this high level for a lifetime, when in reality there will be occasions when little or no meat is consumed or that which is consumed contains less or even no residue. In their risk assessment of the hormones, JECFA applied all of these approaches to dealing with the uncertainty.

In dealing with scientific uncertainty much depends on the expert judgment of the risk assessor. Issues such as biological coherence, whether effects are considered compound related, relevance to humans, the reliability of model systems at predicting effects in vivo all impact on the interpretation of the data. Within the EU, it is clear that there are also differences in the interpretation of data, as illustrated by the differing conclusions of the CVMP (1999) and the SCVPH (1999). In part, the EC assessment of the hormones did not go as far as including some of the considerations for uncertainty used by JECFA because of the conclusion that there was insufficient information to determine whether there was a threshold for the carcinogenic effects. However, for some of the compounds this was based on the results of a small number of non-standard tests of genotoxicity, with equivocal of very weak responses. It is not clear whether the EC applied a weight of evidence approach to evaluating the genotoxicity of all of the compounds, taking account the totality of the available data, as was the case by JECFA."

[770] Appellate Body Report on *Japan – Apples*, para. 179. See also Panel Report on *EC – Approval and Marketing of Biotech Products*, where the Panel "agree[ed] that it must be determined on a case-by-case basis whether the body of available scientific evidence is insufficient to permit the performance of a risk assessment." (para. 7.3238).

dispositive under Article 5.7.[771] Although there can be situations where there is insufficient scientific information for a Member to perform a risk assessment even when an international standard exists, in this case international standards and a significant body of scientific studies exist on the risks posed by each of the five hormones, including the JECFA reports and the studies cited therein. According to the United States, it would therefore in this case be very difficult to demonstrate that scientific evidence concerning the hormones at issue is insufficient in the context of Article 5.7.[772]

7.639 The United States argues that JECFA and several national regulatory bodies have determined that the scientific evidence regarding the five provisionally banned hormones is sufficient, and have completed risk assessments on this basis. According to the United States, the European Communities fails to support its argument that the evidence is insufficient to complete a risk assessment with scientific evidence demonstrating risks to consumers from the five hormones when used for growth promotion purposes according to good veterinary practices.

7.640 The **European Communities** notes that the United States acknowledges that there can be situations where there is insufficient scientific information even though a relevant international standard exists. Contrary to the United States, the European Communities believes this to be the case for the five provisionally banned hormones.[773] In addition, the European Communities argues that a Member may disagree with the risk assessment underlying an international standard for scientific reasons and, in particular, on the issue of whether the scientific evidence relied upon is sufficient. Such a disagreement may result from the fact that in order to meet a higher level of protection, a Member may require more information than that provided for the development of the international standard.[774]

7.641 The European Communities further argues that the relevant Codex standards on four of the five provisionally banned hormones are not capable of achieving the chosen high level of protection of the European Communities. According to the European Communities, the overall evidence and recent scientific developments have now "tipped the balance against the previously held assumption (by the defending parties and Codex/JECFA) that residues of these hormones in meat from animals treated for growth promotion pose no risk to human health". The European Communities argues that the evidence which served as the basis for the 1999-2000 JECFA evaluations is not sufficient "to perform a definitive risk assessment within the meaning of Article 5.7, in particular by the WTO Members applying a high level of health protection of no risk from exposure to unnecessary additional residues in meat of animals treated with hormones for growth promotion".[775]

7.642 Referring to the way in which JECFA addresses scientific uncertainty through safety factors, the European Communities states that there is "almost universal agreement that this approach is not scientifically correct". According to the European Communities, a state of uncertainty may result from a number of factors including lacking, incomplete or contradictory data; the quality of the data is more important than the quantity. An issue thought to be clear can become uncertain as more data become available. The European Communities argues that if uncertainty is understood in this sense, it cannot be addressed through safety factors, especially for countries applying a high level of health protection.[776]

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[771] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 82.
[772] US's replies to Panel questions after the first substantive meeting, Annex B-3, para. 81.
[773] EC's second written submission, paras. 133-136.
[774] EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 266.
[775] EC's second written submission, para. 149; EC's replies to Panel questions after the first substantive meeting, question 31, Annex B-1, paras. 167-172.
[776] EC's comments on experts replies to Panel question 12, Annex F-1.

7.643 Having regard to the arguments of the parties, the **Panel** deems it important to recall that international standards, guidelines or recommendations exist with respect to four out of the five hormones at issue in this section.[777] The Panel notes in this respect the important role given to international standards, guidelines or recommendations by the *SPS Agreement*.[778] We also note that Article 3.2 of the *SPS Agreement* reads as follows:

> "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."

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

7.645 As mentioned above, the Panel is also mindful that science continuously evolves. It cannot be excluded that new scientific evidence or information call into question existing evidence. Likewise, it cannot be excluded that different risk assessments reach different interpretations of the same scientific evidence.

7.646 Yet, some meaning has to be given to the role assigned by the *SPS Agreement* to international standards, guidelines and recommendations, even though the rights of Members under Article 3.3 should be acknowledged[779], and this should not lead to the imposition of a special or generalized burden of proof upon the European Communities.[780]

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[777] For melengestrol acetate, the situation is as follows: JECFA concluded its evaluation of MGA at its sixty-sixth meeting in Rome on 22-28 February 2006 and proposed MRLs. These MRLs were considered by CCRVDF in 2006, but because there was no consensus for their adoption, the CCRVDF agreed to consider them again at its session in 2007. (For more detail, including references to relevant Codex and JECFA reports, see Annex E-1, p. 103 and Annex E-2, p. 116). Annex A, paragraph 3 of the *SPS Agreement* defines international standards, guidelines and recommendations for food safety as follows:

"*International standards, guidelines and recommendations*

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice".

[778] See Article 3.1 of the *SPS Agreement*, which reads as follows:

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

[779] See Appellate Body Report on *EC – Hormones*, para. 172. Article 3.3 of the *SPS Agreement* reads as follows:

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

7.647 As a result, we consider that, in order to properly take into account the existence of international standards, guidelines and recommendations in this case, our approach should be to assess whether scientific evidence has become insufficient by determining whether the European Communities has produced any evidence of some sufficient change in the scientific knowledge so that what was once sufficient to perform an adequate risk assessment has now become insufficient (i.e., "deficient in force, quality or amount").[781] In this respect, suggesting hypothetical correlations or merely arguing that there could be more evidence on one concern or another should not be deemed sufficient to successfully claim that relevant scientific evidence has become *insufficient*. Indeed, more studies can always be performed and there can always be more evidence. We note in this regard that the European Communities shares our position in its second written submission, where it makes a "brief description of insufficiency of pertinent scientific information for all five hormones (except oestradiol-17β)". We interpret the use of the word "pertinent" and not "relevant" as in Article 5.7 as meaning that the European Communities agrees that not any insufficiency of relevant scientific evidence would make the performance of a risk assessment impossible. Indeed, "insufficiencies in the evidence" does not necessarily equal "insufficient evidence" to do a risk assessment, as recalled above. Moreover, as mentioned by the Appellate Body in *EC – Hormones*, risk assessments do not need to be based on "monolithic" evidence.

Conclusion

7.648 We therefore conclude that if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that "relevant scientific evidence is insufficient". Having regard to our reasoning above, particularly with respect to scientific uncertainty and the existence of international standards, we consider that, depending on the existing relevant evidence, there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient.[782] In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risks assessments. We therefore need to determine whether this is the case here.

(v) Alleged insufficiencies which should be addressed by the Panel

7.649 The **European Communities** argues that the most important gaps in the evidence are related to carcinogenicity, genotoxicity, dose-response and lack of safe thresholds, endogenous production of hormones by pre-pubertal children, lack of reliable bioavailability data, possibilities of abuse and lack

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international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement." (original footnote omitted)

[780] Appellate Body Report on *EC – Hormones*, para. 102. Regarding the allocation of burden of proof in relation to the *SPS Agreement* in this case, see paras. 7.380-7.386 above.

[781] *The New Shorter Oxford English Dictionary* (1993), p. 1384.

[782] In its second written submission, at para. 149, the European Communities refers to the long latency period of cancer and the numerous confounding factors to claim that it may not be in a position to demonstrate the existence of a clear harm in case of cancer because of the long latency period and the numerous confounding factors that play a role in the development of cancer. We understand this argument to mean that we should accept the "new scientific reality" referred to by the European Communities as constituting a situation where relevant scientific evidence has become insufficient within the meaning of Article 5.7 of the *SPS Agreement*. We do not consider that our test amounts to requesting that the European Communities demonstrate the existence of a clear harm in order for Article 5.7 to apply to its measure. Under the "critical mass" test, the new scientific information and evidence must be such that they are at the origin of a change in the understanding of a scientific issue.

of control. In addition, the European Communities maintains that since the latest SCVPH assessment, new scientific developments further support SCVPH conclusions.[783]

7.650 According to the **United States**, the experts' responses confirm the following points regarding the scientific evidence relating to the six hormones: (a) each hormone has been used for growth promotion purposes in cattle and evaluated for a sufficient period of time with no evidence of adverse effects to address concerns related to long latency periods of cancer; (b) epidemiological studies cited by the European Communities do not identify a link between cancer and hormone residues in meat; (c) the European Communities has failed to demonstrate a risk to sensitive populations; and (d) the European Communities has failed to demonstrate "other risks" to human health from consumption of hormone residues in meat from cattle treated for growth promotion purposes, such as effects on the immune system.[784]

7.651 At this juncture, the **Panel** deems it appropriate to recall that parties have submitted a large amount of materials which was often very intricate and complex. The Panel believes that, as part of its obligations to make an objective assessment of the matter before it, including an objective assessment of the facts pursuant to Article 11 of the DSU, it had to devise an approach which would allow it to address the issues on which insufficiencies were alleged in a clear and transparent manner.

7.652 Whereas, in application of the burden of proof in relation to Article 5.7 of the *SPS Agreement*, it should be for the party challenging the applicability of Article 5.7 to make a prima facie case that the relevant scientific evidence regarding the five hormones is sufficient[785], it is also for the European Communities, in application of the principle that it is for each party to prove its allegations, to support its own allegations with appropriate evidence. This also has to be considered in the light of the fact that, even though in this case the European Communities is the complainant, it also argues as part of its allegations under Article 22.8 of the DSU that its implementing measure complies with Article 5.7 of the *SPS Agreement*. Moreover, we recall the consequence of the presumption of consistency with the *SPS Agreement* and GATT 1994 of measures which conform to international standards, guidelines and recommendations on the risk assessments on which such measures are based.[786] Since, in that context, the European Communities argues that the relevant scientific evidence is insufficient, we consider that it is for the European Communities to identify the issues for which such evidence is insufficient.

7.653 Therefore, we do not consider that, as Panel, we have any obligation to go beyond the insufficiencies identified by the European Communities. We recall that we are neither equipped, nor supposed to make a *de novo* review of the scientific evidence regarding the hormones at issue. Under the circumstances, we deem it appropriate to limit our review exclusively to the "insufficiencies" expressly identified by the European Communities in its submissions to the Panel.

7.654 We note that, in its second written submission, the European Communities considers that the scientific evidence on which JECFA and Codex relied is insufficient with respect to the following issues: (a) carcinogenicity; (b) hormones daily production rate, in particular in pre-pubertal children;

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[783] EC's second written submission, paras. 143-144.

[784] US's comments on experts' replies to Panel questions, Annex F-4, para. 56 (more detail on each point may be found in paras. 57-87).

[785] *See* Appellate Body Report in *Japan – Agricultural Products II*, para. 80; Panel Report in *Japan – Agricultural Products II,* para. 8.13*;* Panel Report in *EC – Approval and Marketing of Biotech Products*, paras. 7.2969-7.2979.

[786] See paras. 7.643-7.647.

(c) dose response and lack of a safe threshold; (d) bioavailability; and (e) misuse or abuse (misplaced implants, off-label use, black market drugs, etc.)[787]

7.655 The European Communities also inserted in its replies to the first series of questions of the Panel and in its second written submission extensive portions of the 1999 and 2002 Opinions.[788]

7.656 In other words, the European Communities made its own description of the issues with respect to which it believes that evidence is insufficient and added quotations in support of its allegations. These passages also identify insufficiencies.

7.657 A number of issues discussed by the European Communities as part of the arguments contained in its submissions seem to overlap with the issues identified in the portions of the Opinions quoted by the European Communities. However, a number of specific issues identified in the quotations are simply not directly *discussed* by the European Communities in its submissions.

7.658 We believe that it is incumbent upon a party making a particular allegation to identify in its submissions the *relevance* of the evidence on which it relies to support its arguments.[789] We consider that, for some of the issues identified in the Opinions, this was not the case. The Opinions were obviously quoted by the European Communities as evidence of the insufficiencies it has identified in its Opinions. However, the European Communities, while stating that the Opinions identified relevant issues, basically left it to the Panel to find out on its own the relevance of certain issues identified in the quotations for the question whether relevant scientific evidence was insufficient or not.[790]

7.659 The Panel is therefore of the view that, in light of its functions under the DSU, it should limit its review of alleged insufficiencies in the relevant scientific evidence to those specifically discussed by the European Communities in its submissions. It will only address the issues identified in the Opinions to the extent they are sufficiently related to an issue *discussed* by the European Communities.

7.660 A second question relates to the fact that, even when a particular insufficiency was specifically discussed by the European Communities, elements were not always available to address this insufficiency on a hormone-specific basis. The arguments and generally the information presented to the Panel were not always specific enough to permit this. In spite of our repeated requests, several questions were addressed by the parties or the experts in general terms, rather than specifically for each of the five hormones, thus making an assessment of particular issues hormone-by-hormone sometimes impossible.

7.661 Under the circumstances, the Panel decided:

(a) first, to address the insufficiencies *as identified and discussed* by the European Communities in its arguments and only to the extent evidence had been submitted by the parties in relation to them. This approach is, in our opinion, consistent with the requirement identified by the Appellate Body in its report on *Japan – Agricultural*

[787] We have already explained in para. 7.603 why we do not believe that abuse or misuse is an issue of insufficency of relevant evidence. To the extent necessary for our finding, this issue has been addressed in para. 7.483.

[788] See EC's reply to questions 22 and 30 of the questions of the Panel after its first substantive meeting, Annex B-1, and paras. 153-172 of the EC's second written submission.

[789] See Appellate Body Report in *Canada – Wheat Exports and Grain Imports*, para. 191.

[790] See Appellate Body Report on *US – Gambling*, para. 140.

Products II that panels refrain from "making a case" for one party in the absence of a prima facie case by that party;[791]

(b) second, to address some concerns aggregately for all of the five hormones at issue, to the extent that information was not submitted on an hormone-specific basis, or to the extent an issue was raised with respect to all hormones, but evidence submitted only for one or two of them; and

(c) third, to address individually for each hormone the issues for which specific information on that hormone was provided to the Panel.

7.662 For these reasons, we have decided to address first, in a "common issues" section, the insufficiencies which were not addressed by the parties and the experts in a hormone-specific manner (i.e. those for which arguments or evidence were not hormone-specific), or which were not addressed specifically enough to justify a separate analysis for each of the hormones concerned. At a second stage, we address for each hormone the alleged insufficiencies which have been discussed in relation to that hormone and for which arguments and evidence were specifically provided.

(vi) Issues common to all five hormones for which evidence was not provided on a hormone-specific basis

Introduction

7.663 We note that, despite our insistence that information be provided for each of the five hormones at issue, arguments, information and opinions have sometimes addressed all or part of the scientific evidence on these hormones together. As a result, in this section, we will address the issues that were specifically discussed by the European Communities in these proceedings in relation to all five hormones in general regarding their use as growth promoters in cattle. More particularly, we will address:

(a) the effects of hormones on certain categories of population, such as pre-pubertal children;

(b) dose response;

(c) bioavailability;

(d) the EC claim that the long latency period of cancer makes it more difficult to demonstrate insufficiency of the relevant evidence regarding the carcinogenicity of the hormones at issue;

(e) the impact of the five hormones at issue on the immune system, and

(f) the impact of the five hormones at issue on development and reproduction.

Effects of hormones on certain categories of population

7.664 Regarding the effect of the hormones at issue on certain categories of populations, we note that the European Communities refers to the conclusions contained in the Opinions. We recall that the 1999 Opinion mentions that prepubertal and postmenopausal women and prepubertal and adult men have the lowest levels of endogenous oestrogens and progesterone and thus would represent the

[791] See Appellate Body Report on *Japan – Agricultural Products II*, para. 129.

individuals most likely to be at increased risk for the adverse health effects that might be associated with exposure to exogenous sources of oestrogens. Likewise, the 1999 Opinion provides that all women and prepubertal men represent the individuals at greatest risk for adverse health effects that might be associated with exposure to exogenous sources of testosterone.

7.665 The 1999 Opinion specifies that the hormone levels on which it relies were determined by radio-immunoassays (RIA) and that the use of these assays has frequently been associated with production of variable results, particularly when used to detect low levels of endogenous hormones. The 1999 Opinion notes that Klein et al. (1994) developed an ultrasensitive assay (100-fold more sensitive than RIAs) which identified values of oestradiol considerably lower than the range of oestradiol levels found through RIAs for prepubertal children. The 1999 Opinion concludes that "[a] corollary is that perhaps the hormone residues in beef, which are also low and which have been determined by RIA are equally variable and over representative of the actual hormones concentration." The 1999 Opinion concludes that this is a critical area requiring additional study.[792]

7.666 We recall our test regarding insufficiency of relevant evidence in this case, i.e. that there must be a critical mass of new evidence and/or information that calls into question the fundamental precepts of knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. In that context, we believe that the question before us is whether the more sensitive detection methods which identified lower hormonal levels in pre-pubertal children than thought until now are such as to call into question the range of physiological levels of the sex hormones in humans currently believed to exist.

7.667 Dr. Sippell specified that:

> "There is no doubt that the development of an ultrasensitive recombinant cell bioassay (RCBA) of E_2 by Karen Klein, Gordon Cutler and co-workers at the N.I.H. in Bethesda, USA (Klein et al 1994) represented a quantum leap in E_2 assay methodology. It opened a new door on our understanding of basic physiological phenomena, e.g. why normal puberty starts so much earlier in girls than in boys or why bone maturation in children differs so much between the sexes. The validity of the N.I.H.-RCBA has now been confirmed by another RCBA of E_2 which was developed by Charles Sultan's group at the University of Montpellier, France (Paris et al 2002). Unfortunately, the complexity of the RCBA so far prevents its wider use for routine measurements in small serum samples from infants and prepubertal children."[793]

7.668 We also note Dr. Sippell's statement that "[t]he risk to children arising from hormones which are naturally present in meat as compared to that from residues of hormonal growth promoters has, to my knowledge, been estimated for E_2 [i.e., oestradiol-17β] only and only in beef (Daxenberger et al. 2001)."[794]

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[792] The 2002 Opinion refers to a new method to detect trace amounts of hormones in meats and to three complementary bioassays involving different recombinant-DNA technology for screening and determination of oestrogenic potency of substances used as growth promoters (2002 Opinion, p. 9). The Panel nonetheless understands that these method and bioassays address a different issue than the identification of endogenous levels of hormones in humans.

[793] Reply of Dr. Sippell to question 40 of the Panel, Annex D, para. 328.

[794] Reply of Dr. Sippell to question 41 of the Panel, Annex D, para. 335.

7.669 We recall the statement of the 2000 Opinion referring to novel techniques in chemical analysis[795] but mentioning that "additional time will be required to validate and apply this methodology in a reliable, accepted fashion before a re-evaluation of this issue can be conducted."[796] This opinion is confirmed by Dr. Boobis.[797] Dr. Boobis expressed additional concerns about the validity of the Klein et al. (1994) study:

> "There is certainly some evidence that endogenous levels of hormones in children are lower than previously thought. However, the suggestion that this is by orders of magnitude is not substantiated by the data. One group has reported very low levels of oestradiol in male children, 0.08 pg/ml *(Klein et al, 1994),* but in a later study *(Klein et al, 1998),* the same group reported mean levels somewhat higher, at 0.27 pg/ml. The reliability of the Klein et al assay has yet to be determined. The assay is particularly sensitive to oestradiol, but there is no obvious explanation for this, as it relies upon affinity for the oestrogen receptor. Diethylstilbestrol is a potent oestrogen yet is much less sensitive than oestradiol in the assay. *Klein et al (1994)* have reported that there are unidentified factors in plasma and in blood collection tubes that can interfere in the assay. In contrast, using a similar yeast-based assay, *Coldham et al (1997)* found that oestradiol and DES had similar potency, and others have found that, if anything, DES is more potent than oestradiol in such assays *(Folmer et al, 2002).* At the very least, this shows that results with the yeast reporter assay are not consistent, and use of such data in risk assessment requires that the assay be adequately validated.[798]
>
> However, there are studies from two other groups using more specific methods than the original radioimmunoassay, reporting that levels were somewhat higher than this. *Ikegami et al (2001)* used a very sensitive, 2-stage immunoassay technique. This was shown to be specific and sensitive. In this assay, mean levels of oestradiol in prepubertal males were 1.85 pg/ml (6.8 pmol/ml). *Paris et al (2002)* used a recombinant oestrogen receptor assay in a mammalian cell line, a similar principle to the assay of Klein et al. In this study, estogenic levels in prepubertal males were found to be 1.44 pg/ml. There are many issues affecting such measurements. These include the presence of binding proteins, relative specificity and sensitivity. None of the assays is entirely specific for oestradiol. Both the oestrogen receptor and the

[795] Results of "hormone" residue analyses of bovine meat and liver imported into the EU and originating from the USA "Hormone Free Cattle Program" analysis – First Interim Report, May 1999 – R.W. Stephany and F. André (rapporteurs).

[796] 2000 Opinion, p. 3.

[797] Transcript of the Panel meeting with the experts, Annex G, para. 572.

[798] Dr. Boobis' reply to question 40 of the Panel, Annex D, para. 324. Dr. Boobis cites to:

> Coldham NG, Dave M, Sivapathasundaram S, McDonnell DP, Connor C and Sauer MJ (1997). Evaluation of a recombinant yeast cell estrogen screening assay. Environ Health Perspect, **105**:734-742
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> Folmar LC, Hemmer MJ, Denslow ND, Kroll K, Chen J, Cheek A, Richman H, Meredith H and Grau EG (2002). A comparison of the estrogenic potencies of estradiol, ethynylestradiol, diethylstilbestrol, nonylphenol and methoxychlor in vivo and in vitro. Aquat Toxicol, **60**:101-110
>
> Klein KO, Baron J, Colli MJ, McDonnell DP and Cutler GB Jr (1994). Estrogen levels in childhood determined by an ultrasensitive recombinant cell bioassay. J Clin Invest, **94**:2475-2480
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> Klein KO, Baron J, Barnes KM, Pescovitz OH and Cutler GB Jr (1998). Use of an ultrasensitive recombinant cell bioassay to determine estrogen levels in girls with precocious puberty treated with a luteinizing hormone-releasing hormone agonist. J Clin Endocrinol Metab, **83**:2387-2389

> antibodies used could cross-react with structurally relayed compounds. Depending on how the assay is performed, protein binding could reduce the concentration of hormone detectable in the assay by sequestering hormone from the assay target. However, it should be noted that whilst binding to protein in plasma my reduce clearance it will also reduce the biologically active dose. In general, it is the free concentration that determines biological activity *(Teeguarden and Barton, 2004)*. Hence, if SHBG is elevated in children this would tend to reduce the effect of an equivalent total plasma concentration by reducing the free concentration.
>
> The advantage of the recombinant assays is that they measure biologically active material, whereas the immunoassays may include cross-reacting less or inactive metabolites. Whilst the recombinant assays may include hormonally active material other than the specific analyte, this does provide an indication of to what the body is exposed in vivo. Hence, on balance, the data of *Paris et al (2002)* may be the most meaningful to date. This presumably reflects circulating total active oestrogenic material, but not that bound to proteins."[799]

7.670 We note that the evidence presented relates only to oestradiol, but that the claim we are examining with regard to the insufficiencies of the evidence are with respect to the five other hormones at issue, not oestradiol. We note furthermore that the 2002 Opinion concludes that these more sensitive detection methods have not yet been validated.[800]

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

Dose response

7.672 The European Communities, in its reply to a question of the Panel[801], quotes an extract of the 1999 Opinion.[802] Whereas this quotation relates to trenbolone acetate, we decided to address it in this general section to the extent that the impossibility to perform a dose-response assessment is referred to by the European Communities with respect to the five hormones at issue.[803]

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[799] Reply of Dr. Boobis to question 40 of the Panel, Annex D, paras.325-326. Dr. Boobis cites to:

Ikegami S, Moriwake T, Tanaka H, Inoue M, Kubo T, Suzuki S, Kanzakili S and Seino Y (2001). An ultrasensitive assay revealed age-related changes in serum oestradiol at low concentrations in both sexes from infancy to puberty. Clin Endocrinol (Oxf), **55**:789-795
Paris F, Servant N, Terouanne B, Balaguer P, Nicolas JC and Sultan C (2002). A new recombinant cell bioassay for ultrasensitive determination of serum estrogenic bioactivity in children. J Clin Endocrinol Metab, **87**:791-797
Teeguarden JG and Barton HA (2004). Computational modeling of serum-binding proteins and clearance in extrapolations across life stages and species for endocrine active compounds. Risk Anal, **24**:751-770

[800] 2002 Opinion, Section 4.1.1, p. 9.
[801] EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1.
[802] 1999 Opinion, para. 4.4.8.
[803] See the following paragraphs of the EC's second written submission:

7.673 The European Communities also questions JECFA's findings on dose response as follows:

> "The above findings establish that the levels of endogenous production of these hormones by **pre-pubertal children** is much lower than previously thought and this finding, which is subsequent to the 1999 JECFA report, casts serious doubts about the validity of JECFA's findings on the dose-response relationship, because the data on endogenous production on which JECFA based its findings are also very old (since 1974)."[804]

7.674 The Panel can only conclude from the comments of the European Communities that it considers that a dose response would be required to complete a risk assessment for the five hormones other than oestradiol-17β, but that it disagrees with JECFA's findings on dose response. The Panel notes that JECFA could identify a dose response for the five hormones at issue. Comparatively, the European Communities has not provided convincing elements to support its view that there is insufficient relevant evidence on dose response. The EC position on dose response, at least for the natural hormones other than oestradiol, seems to be based on the belief that levels of endogenous production of hormones are much lower than previously thought. The Panel notes in this regard that it has been demonstrated that the ultrasensitive assay relied upon by the European Communities to conclude that endogenous production is lower than assumed by JECFA has not yet been validated and applies only to oestradiol.

7.675 For these reasons, the Panel believes that it has not been established that new evidence was such as to put into question existing data on dose response and prevent the performance of a risk assessment.

Bioavailability

7.676 The European Communities argues that another area where recent developments put in doubt the findings of the 1999 JECFA report concerns the bioavailability of residues of the hormones concerned. According to the European Communities, the 1999 and 2002 Opinions have found that data on which JECFA based its findings are incorrect or insufficient.[805]

7.677 The Panel notes that the studies referred to in the 1999 and 2002 Opinions (one of them being study 3 of the 17 studies commissioned by the European Communities)[806] relate to oestradiol-17β, not to any of the specific hormones with respect to which the European Communities applies a

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– para. 155, regarding the effect of progesterone on growth and reproduction: "No assessment of the dose response relationship has been presented yet." Also: " In conclusion, these data indicate that progesterone can cause immuno depression; however, they are insufficient to make any realistic assessment of the dose response relationship." (Both from the 1999 Opinion, pp. 51-55);
– para. 160, regarding the effect of testosterone on growth and reproduction: "No assessment of the dose response relationship has been presented yet." Also: "There are limited experimental data on the effects of testosterone on immuno response but none on the dose response aspects." (Both from the 1999 Opinion, p. 50);
– para. 165, regarding the effects of trenbolone on growth and reproduction: "These data do not allow a realistic assessment of a dose response relationship."(1999 Opinion, p. 60);
– para. 172, regarding melengestrol acetate: "These data do not allow an estimate of the dose response relationship." (1999 Opinion, p. 68);
– para. 168, on the effects of zeranol on growth and reproduction: "No estimate of the dose-response relationship for these effects can be made."(1999 Opinion, p. 65).

[804] EC's second written submission, para. 122.
[805] EC's second written submission, para. 123.
[806] 2002 Opinion, p.12, point 4.1.5, Exhibit US-1.

provisional ban under Article 5.7 of the *SPS Agreement*. Moreover, there is no indication that the conclusions can be applied to other hormones than oestrogens.

7.678 The Panel recalls that the European Communities argued that "similar findings [had been] made for all of the other five hormones."[807] However, the European Communities did not specify where such findings had been made. The European Communities also refers to study 10 of the 17 studies, by Dr. Florence Le Gac, but does not clearly explain to what extent the results of this study establish or discuss the bioavailability of the five other hormones. This allegation of the European Communities has to be considered in light of the statements of Dr. Boisseau and Dr. Boobis according to which the bioavailability of melengestrol, trenbolone and zeranol residues has not been determined.[808]

7.679 The Panel considers that bioavailabity would be an issue if the new evidence suggested that bioavailability in the case of ingestion of meat treated for growth promotion purposes is higher than previously thought. However, it appears that, in the absence of data, JECFA assumed 100% bioavailability.

7.680 In this respect, Dr. Boisseau said:

> "The bioavailability of melengestrol, trenbolone and zeranol residues have not been determined. Therefore all their residues have been considered as being totally bioavailable."[809]

7.681 Dr. Boobis stated, with respect to natural hormones, that "change in bioavailability is likely to be a consequence of changes in the enzymes of metabolism in the liver and/or small intestine."[810]

7.682 Dr. Boobis also confirms for the non-natural hormones:

> "However, it should be noted that in the risk assessment of these hormones by JECFA, the risk characterization involved comparison of the theoretical maximum daily intake with the ADI. No correction was made for bioavailability. Hence, the situation is likely to be similar to that for the natural hormones, in that changes in bioavailability from the normal value would change the margin of safety."[811]

7.683 These statements were not contradicted by Dr. Guttenplan, the third and last expert who replied to question 43 of the Panel, and who limited his remarks to oestrogens. [812]

7.684 We therefore conclude that it has not been established that any new evidence on bioavailability has been developed regarding specifically the five hormones at issue, which would affect the current knowledge on the subject. More particularly, no new evidence has been submitted regarding the three non-natural hormones which would make it impossible to perform a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*.

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[807] EC reply to question 28 of the questions of the Panel after the first substantive meeting, Annex B-1, para. 158.
[808] Dr. Boisseau, Annex D, para. 347.
[809] Annex D, para. 347.
[810] Annex D, para. 350.
[811] Annex D, para. 351.
[812] Annex D, para. 357.

Long latency period of cancer and confounding factors

7.685 Regarding the long latency of cancer, in its second written submission[813], the European Communities claims that it may not be in a position to demonstrate the existence of a clear harm in case of cancer because of the long latency period and the numerous confounding factors that play a role in the development of cancer.

7.686 We first note the importance of latency period in the assessment of cancer, as confirmed by Dr. Cogliano, Dr. Guttenplan and Dr. Boobis:

7.687 Dr. Cogliano stated that:

> "It is definitely necessary to take into account the latency period of cancer in the conduct of a risk assessment. In this regard, the guidelines for developing *IARC Monographs* state, 'Experience with human cancer indicates that the period from first exposure to the development of clinical cancer is sometimes longer than 20 years; latent periods substantially shorter than 30 years cannot provide evidence for lack of carcinogenicity.' [International Agency for Research on Cancer, Preamble to the *IARC Monographs*, http://monographs.iarc.fr]"[814]

7.688 Dr. Guttenplan confirmed that:

> "When epidemiological data is used in performing a risk assessment, the latency period is extremely important. Usually a latent period of 20 years is taken for cancer, but this varies with the carcinogen. It is indeed necessary to determine incidence or prevalence at different times after the onset of exposure. Attempting to perform a risk assessment based on epidemiological data obtained too soon after the onset of exposure can seriously underestimate risk. [815]

7.689 Dr. Boobis stated that:

> "The latency period is an important consideration in risk assessment, both in the design and in the interpretation of studies. Thus, the duration of exposure, either of experimental animals or in epidemiology studies, should be sufficiently long to permit assessment of effects with a long latency period. Most forms of cancer come into this category."[816]

7.690 Dr. Boobis added that:

> "The observational studies of humans (e.g. on HRT or oral contraceptives) and the experimental studies in animals covered a sufficiently long period to encompass the latency period for any carcinogenic effects of the hormones (see *IARC, 1999)*.

7.691 Dr. Boisseau highlighted the practical difficulties resulting from confounding factors, arguing that:

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[813] EC's second written submission, para. 149.
[814] Reply of Dr. Cogliano to question 23 of the Panel, Annex D, para. 213.
[815] Reply of Dr. Guttenplan to question 23 of the Panel, Annex D, para. 214. Dr. Guttenplan cited to Lagiou P. Trichopoulou A. Trichopoulos D. Nutritional epidemiology of cancer: accomplishments and prospects. [Lectures] Proceedings of the Nutrition Society. 61(2):217-22, 2002.
[816] Reply of Dr. Boobis to question 23 of the Panel, Annex D, para. 210.

"[He did] not think possible/useful to take into account the "long latency period" of cancer in order to assess properly and specifically the carcinogenic effects of residues of natural hormones only resulting from the treatment of food producing animals by growth promoting hormones. ... epidemiological studies carried out in humans during [periods] long enough in order to take into account this "long latency period" will not be able to discriminate, in the case of a possible but limited increase of tumours, between the responsibilities of (1) hormone residues resulting from the treatment of food producing animals by growth promoting hormones, (2) hormone residues resulting from the endogenous production of these animals, (3) other components of the diet including other food additives and contaminants. That is the reason for which, ... the epidemiological studies in humans already carried out in this domain have failed to identify any relation between the occurrence of hormonally dependent tumours and the consumption of meat containing hormonally active residues resulting from the treatment of cattle with growth promoters."[817]

7.692 Dr. Boobis added that:

"The long term studies of the hormones undertaken in experimental animals and in humans, involved much higher doses than would be encountered on consumption of meat from animals treated with growth promoting hormones. The maximum risk from such low levels of exposure, even assuming a linear dose-response relationship for cancer, would be such that it would be necessary to study extremely large populations to detect any increase in cancer incidence, particularly as the most likely cancers are quite common. This is because the lower the risk the greater the number of subjects that are required to detect it, a function of the power of the study which takes account the magnitude of the risk and the difference from the background rate *(Hunter, 1997)*. Hence, in the risk assessment of the hormones used as growth promoters, it is questionable whether an increase in risk, even if it existed, could be detected in exposed populations. However, it is still necessary to protect against such a risk. The risk assessment of the hormones conducted by JECFA suggested that there would be no risk at exposure levels up to the respective ADI. Even if duration of exposure were for a sufficiently long period (usually 20-25 years for solid tissue tumours), any increase in risk would probably not be detectable. Hence, a negative result from such an observational study would not resolve the issue.

A second issue with respect to the latency is the significance it has for interpretation of the exposure pattern. Where there is a long latency, and regular exposure is necessary before a carcinogenic response is manifest, as appears to be the case for the hormones in question *(Coombs et al, 2005)*, occasional exposures above the ADI will not pose any additional risk *(Larsen and Richold, 1999)*. Hence, latency is of value in assessing the risks from different exposure scenarios."[818]

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[817] Reply of Dr. Boisseau to question 23 of the Panel, Annex D, para. 209.
[818] Dr. Boobis cites to the following studies:

Coombs NJ, Taylor R, Wilcken N, Fiorica J and Boyages J (2005). Hormone replacement therapy and breast cancer risk in California. Breast J, 11:410-415
Hunter DJ (1997). Methodological issues in the use of biological markers in cancer epidemiology: cohort studies. IARC Sci Publ, **142**:39-46
IARC (1999). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol 72. Hormonal Contraception and Post-menopausal Hormonal Therapy, IARC, Lyon, France
Larsen JC and Richold M (199). Report of workshop on the significance of excursions of intake above the ADI. Regul Toxicol Pharmacol, **30**:S2-12.

7.693 The European Communities acknowledges that epidemiological studies will not be able to discriminate (or separate out) the true origin of cancer because of so many confounding factors. In this respect, we note that Dr. Cogliano specified that it was generally possible to identify confounding factors in epidemiological studies. It was often difficult, however, to determine whether the observed tumours can be attributed to the agent under study or to a confounding factor. Dr. Cogliano adds that "[w]hen a causal interpretation is credible but confounding factors cannot be ruled out, IARC considers this to provide *limited evidence of carcinogenicity*."[819]

7.694 The European Communities insists, however, that this undermines the opinion of the respondent that the hormones at issue have been in use for a sufficiently long time to rule out their carcinogenic effect on humans. The European Communities points at IARC studies showing that the frequency of breast cancer in countries where use of hormones for growth promotion is allowed is higher compared with countries where the hormones have not been used.[820]

7.695 Three experts addressed this issue. Dr. Cogliano mentioned that:

> "The difference between the US and the EC in rates of breast cancer and prostate cancer almost certainly has multiple causes. It is possible that differences in exposure to exogenous hormones can be one cause, but the data are not sufficiently specific to establish a link between these observations."[821]

7.696 Dr. Guttenplan confirmed that:

> "The epidemiological studies do not identify a relationship between cancer and residues of hormonal growth promoters. The references to the higher rates of breast and prostate cancer observed in the United States as compared to the European Communities are not very convincing as there is considerable variation in rates in different geographical locations. Also, the differences in rates of breast and prostate cancer observed in the United States as compared to the European Communities are relatively small. There is no way to definitely establish a link between these statistics and the consumption of meat from animals treated with the hormones at issue as there are many possible confounders, and the differences in cancer rates are small. However, the results are at least consistent with a possible effect of hormones on breast and prostate cancer."[822]

7.697 In this regard, Dr. Boobis added the following:

> "There are an appreciable number of studies showing an association between the risk of certain cancer types, including breast and prostate and the consumption of meat *(Colli and Colli, 2006; Norat et al, 2005; see also SCVPH Opinion, 1999)*. For breast, the incidence is similar in developed countries such as Western Europe, North America and Australasia. The correlation is strongest with meat consumption and shows little relationship with whether the meat is from animals treated with growth promoting hormones or not. For example rates in Iceland (87.2 per 100,000), where such hormones are not used, are not dissimilar to those in the USA (101.1 per 100,000), where they are used. Prostate cancer rates are 124.8/100,000 in the USA

See Reply of Dr. Boobis to question 23 of the Panel, Annex D, para. 212.

[819] Reply of Dr. Cogliano to question 24 of the Panel, Annex D, para. 220. See also Dr. Guttenplan, Annex D, para. 221.

[820] EC's comments on experts replies to questions 23 and 24 of the Panel, Annex F-1, pp. 19-20.

[821] Reply of Dr. Cogliano to question 26 of the Panel, Annex D, para. 241.

[822] Reply of Dr. Guttenplan to question 26 of the Panel, Annex D, para. 242.

> and 90.9 per 100,000 in Sweden *(IARC, 2002)*. For comparison, average daily consumption of meat (as protein) in 2000 was as follows: USA 40.2 g/day; Iceland 29.5 g/day; Sweden 24.8 g/day *(FAO, 2003)*. Hence, there is a much better association with meat consumption and risk of breast or prostate cancer than there is with the use of growth promoting hormones to treat cattle. It is also important not to infer too much from geographical differences in cancer incidence rates with respect to causation. This is because of what is known as the ecological fallacy. This has been defined as the inference that a correlation between variables derived from data grouped in social or other aggregates (ecological units) will hold between persons (individual units) *(Society for Risk Assessment, 2004)*. The difficulty is that many factors will vary between populations, including ethnicity, genetics, health and socioeconomic status, diet, lifestyle and environment. Without considering the possibility of confounding, such ecological data is really only of value in generating hypotheses *(Morgenstern, 1995)*. These would need to be evaluated in more structured investigations, with better control of confounding variables."[823]

7.698 We also note Dr. Boobis statement at the meeting of the Panel with the experts:

> "The paradigm we have, and there is some evidence to justify the case that this is a reasonable assumption, is that the effects observed scale to the lifetime of the organism, and so that is one of the reasons we use shorter-lived organisms in our toxicological testing. We use rats and mice which live for a couple of years; otherwise we would have to test for a lifetime in a longer-lived species which might be 40 or 50 years. So we are working on the principle that effects that are not evident within the lifetime of a rodent would not be evident, all other things being equal, within the lifetime of a human being. And there is actually very good evidence that that is the case. For a number of carcinogens that IARC have evaluated it takes approximately a quarter of a lifetime after an initial exposure for those tumours to become apparent, and that is true in rodents, it's true in dogs and it's true in humans. So I think that the paradigm is reasonable that if there is going to be an effect manifest over a lifetime, it will be revealed in those experimental systems and therefore be predictive of lifetime effects in humans by and large."[824]

7.699 On the one hand, the comments of the experts suggest that epidemiological studies have not been able to single out residues of hormones in meat treated for growth promotion purposes as a cause of cancer, and that this would be quite difficult. On the other hand, the Panel notes that it is possible to assess long term effects through long term studies of experimental animals, even if they involve much higher doses than would be encountered in consumption of meat from animals treated with growth promoting hormones. It has also been possible to take into account the risk attached to latency through the setting of ADI. The European Communities has not identified any evidence quantitatively and qualitatively sufficient to call into question the fundamental precepts of existing knowledge and evidence and the approach followed so far in order to integrate the long latency of cancer in risk assessment.

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[823] Reply of Dr. Boobis to question 26 of the Panel, Annex D, para. 239. Dr. Boobis cited to the following:

> Morgenstern H (1995). Ecologic studies in epidemiology: concepts, principles, and methods. Annu Rev Public Health, 16:61-81
> Society for Risk Assessment (2004). Glossary of Risk Analysis Terms. (http://www.sra.org/resources_glossary.php)

[824] Annex G, para. 1031.

7.700 Having regard to the opinions of the experts, the Panel concludes that it has not been established that the difficulties attached to the long latency of cancer make it impossible to perform a risk assessment within the meaning of Article 5.1 and Annex A(4) of the *SPS Agreement*. More particularly, the European Communities did not point at a "critical mass" of new evidence and/or information that would call into question the fundamental precepts of previous knowledge and evidence in relation to the long latency period of cancer and the existence of confounding factors.

Effect of hormones on the immune system

7.701 The 1999 Opinion considers, for each of the five hormones for which a provisional ban is applied, that there is insufficient evidence as to their effect on the immune system.[825] The Panel notes that no arguments have been raised specifically in relation to the effects of hormones on the immune system with respect to each of the five hormones at issue. The Panel noted, however, the contention of the European Communities that new important gaps, insufficiencies and contradictions had been identified in the scientific information and knowledge now available as a result of the 17 studies commissioned by the European Communities. The Panel considered that an appropriate way to address this question with respect, *inter alia*, to the effect of hormones on the immune system was to seek the views of the scientific experts on the factual question whether the new scientific studies initiated since 1997 and relied upon by the European Communities identify any adverse effects on the immune system from the consumption of meat from cattle treated with the growth promoting hormones at issue.[826]

7.702 Three experts expressed their views on the matter. Dr. Boobis argued that:

> "The evidence on immune effects of hormones such as oestradiol referred to by the EC does not identify any adverse effects on the immune system from consumption of meat from treated cattle. In general, clear evidence for immune effects were observed only at high doses. There is no evidence that doses such as those resulting from consumption of meat from treated animals has any effect on the immune system *(*JECFA*, 2000b; CVMP, 1999)*. It should also be noted, that in the case of immune effects, exposure relative to endogenous levels is a critical issue. Given the large margin of exposure on anticipated intake from residues in meat from treated animals, no effect on the immune system is anticipated, as immune modulation is dependent on dose and there are thresholds for such effects."[827]

7.703 Dr. Guttenplan noted that:

> "The relationship between estrogen and autoimmune diseases has received considerable attention (Opinion SCVPH, April 30, 1999, section 2.4). There is evidence that estrogens can be involved in Lupus, rheumatoid arthritis, thyroiditis. In

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[825] There does not seem to be any additional development on this matter in the 2000 and 2002 Opinions.

[826] Question 59 of the panel to the experts.

[827] Reply of Dr. Boobis to question 59 of the Panel, Annex D, para. 445. Dr. Boobis cited to:

> Barton HA and Clewell HJ 3rd (2000). Evaluating noncancer effects of trichloroethylene: dosimetry, mode of action, and risk assessment. Environ Health Perspect, 108 (Suppl 2):323-334
> Kroes R, Renwick AG, Cheeseman M, Kleiner J, Mangelsdorf I, Piersma A, Schilter B, Schlatter J, van Schothorst F, Vos JG and Wurtzen G; European branch of the International Life Sciences Institute (2004). Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet.Food Chem Toxicol, **42**:65-83

> addition the development of allergies is thought to be at least partially related to estrogens. The studies in experimental animals also did not identify any immune-related effects, although it is not certain the types of possible effects in humans would be detected in experimental animals. No definitive studies have related intake of meat from hormone-treated animals to the above disorders."[828]

7.704 We note that the Panel question related to all hormones and the experts gave details in relation to oestrogens in general. We also note that the European Communities, in its comments on the experts' replies, referred to effects identified by Dr. Guttenplan in relation to oestrogens. The European Communities concludes that it has offered serious evidence and pointed to a number of gaps and uncertainties in the knowledge. The European Communities considers that it is for the United States, Canada and JECFA to "ensure the Panel that adverse immune effects are not possible to occur from residues in meat treated with these hormones for animal growth promotion".[829]

7.705 First, the Panel doubts that, in this particular case, the standard of proof is that the United States should prove to the satisfaction of the Panel that "adverse immune effects are not possible to occur from residues in meat treated with these hormones for animal growth promotion" purposes. As already specified, in this case the United States has to prove its allegation that relevant scientific evidence is not insufficient to perform an adequate risk assessment under Article 5.1 and Annex A(4) of the *SPS Agreement*.

7.706 Second, with regard to the evidence and gaps allegedly identified by the European Communities, the Panel notes that the statement of Dr. Guttenplan on which the European Communities relies relates exclusively to oestrogens. The Panel notes in this respect that the other experts' replies to question 59 of the Panel relate to oestradiol or oestrogens. None of those replies related to any of the five hormones at issue. The Panel notes that the 1999 Opinion itself does not provide evidence of impact on the immune system for testosterone.[830] For progesterone, the data were deemed to indicate that progesterone can cause immuno depression. However they were described as insufficient to make a realistic assessment of the dose response relationship.[831] On trenbolone, the information was deemed insufficient to assess the possible impact of low levels of trenbolone in meat and meat products on consumers.[832] For zeranol, the 1999 Opinion states that no relevant data on the effect of zeranol on the immune system were found.[833] Finally, for MGA, the 1999 Opinion concluded that the information was insufficient to make a scientific judgement on whether MGA may cause effects on the immune system at a level which could occur in meat treated with MGA as a growth promoters. The 2000 and 2002 Opinions do not seem to contradict these findings.

7.707 The Panel also notes that the three experts who replied to question 59 addressed the potential effects of hormones on the immune system through a dose-response approach.[834] The Panel has received no evidence suggesting that a dose response would not apply to the effect of the five hormones on the immune system as a result of the consumption of meat treated for growth promotion purposes.

7.708 We therefore conclude that it is not established that there exists a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge

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[828] Reply of Dr. Guttenplan to question 59 of the Panel, Annex D, para. 447.
[829] EC's comments to experts replies to Panel questions, Annex F-1, pp. 37-38.
[830] 1999 Opinion, p. 51.
[831] 1999 Opinion, p. 55.
[832] 1999 Opinion, p. 60.
[833] 1999 Opinion, p. 66.
[834] See also reply of Dr. Boissau to question 59 of the Panel, Annex D, para. 443.

and evidence so as to make relevant, previously sufficient, evidence on hormones effects on the immune system now insufficient.

Effect of hormones on growth and reproduction

7.709 The Panel notes that no arguments have been raised specifically in relation to growth and reproduction with respect to each of the five hormones at issue, except for the EC reference to the 1999 Opinion. The Panel notes, however, the contention of the European Communities that new important gaps, insufficiencies and contradictions had been identified in the scientific information and knowledge now available as a result of the 17 studies commissioned by the European Communities. The Panel considers that an appropriate way to address this question with respect, *inter alia*, to the effect of hormones on growth and reproduction was to seek the views of the scientific experts on the factual question whether the new scientific studies initiated since 1997 and relied upon by the European Communities actually support its contention.[835]

7.710 Three experts commented on our question, Dr. Boisseau, Dr. Boobis and Dr. Guttenplan. Only Dr. Boobis and Dr. Guttenplan discussed matters related to growth and reproduction. Dr. Guttenplan originally identified a number of gaps that could relate to growth and reproduction.[836] However, Dr. Guttenplan subsequently stated that "on subsequent reading, [he] could not find anything to indicate adverse effect", and he considered that it was possible to undertake a risk assessment.[837] He added that "the ability [to make a risk assessment] varies between compounds, but that does not mean you can't make a risk assessment, it just means the accuracy of the risk assessment is different."[838]

7.711 Dr. Boobis considered in general that:

> "[T]here is little information in the scientific studies initiated by the EC since 1997 that support the contention that they have identified important new gaps, insufficiencies and contradictions in the scientific information and knowledge on the hormones, and that additional studies are necessary before the risks to health of consumption of meat from treated animals can be assessed. Whilst additional information has been obtained on a number of aspects of the hormones in question, this was often not definitive, sometimes it was not relevant, in some instances it confirmed or expanded on previous knowledge. The evidence obtained did not indicate any additional concern regarding the risk from exposure to residues of the hormones in meat from cattle treated for growth promotion."[839]

7.712 Dr. Boobis also discussed the recent data on endocrine and developmental effects of the hormones at issue. Regarding the experimental studies on the effect of in utero exposure of rabbits to the three exogenous hormones: melengestrol acetate, trenbolone acetate and zeranol, also referred to in the 2002 Opinion (study 11), Dr. Boobis noted that, to date, only information on metabolism and disposition had been published *(Lange et al, 2002)*.[840] According to Dr. Boobis:

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[835] See question 62 of the Panel to the scientific experts, Annex D.
[836] Reply of Dr. Guttenplan to question 62 of the Panel, Annex D, paras. 497-499.
[837] Transcript of the Panel meeting with the experts, Annex G, para. 981.
[838] Transcript of the Panel meeting with the experts, Annex G, para. 983.
[839] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 495.
[840] Dr. Boobis noted that, given the time that had elapsed since this paper was published (submitted September 2001), it was somewhat surprising the data from the remainder of the study had not been published yet.

> "[the Lange et al. paper (2002)][841] demonstrates transplacental transfer of the three hormones. This is not surprising given the physicochemical properties of the compounds (lipid solubility, non-polar, molecular size) *(Syme et al, 2004)*.[842] In addition, endogenous hormones are known to cross the placenta. It is notable that in the study of Lange et al, fetal concentrations of the hormones and their metabolites were similar to or less than, sometimes much less than, those in corresponding maternal tissues, suggesting that there was no net accumulation of the compounds in fetal tissues. It is also noted that the number of animals studied was very small, a point commented on by the authors themselves.
>
> The unpublished component of this study was an investigation of the potential health consequences of in utero exposure of rabbits to the three hormones. From the information provided, low dose exposure in utero caused modest changes in some parameters, but was not associated with wither cancer or adverse effects on reproductive capacity. There were no changes in sperm number. It is not clear whether the changes observed were consistent and hence compound-related as a only a single dose was used for each compound. Nor is it apparent whether the magnitude of all of changes discussed reached statistical significance (often the changes were described as slight and no measure of variance is provided). The doses used in this study would have provided much higher levels of exposure than those predicted to arise from residues in meat. In the case of trenbolone acetate and zeranol exposure was via the subcutaneous route, thus bypassing presystemic metabolism in the intestine and/or the liver. In the case of MGA the oral dose was over 16,500 times the ADI. Hence, even if the effects observed were of toxicological significance the ADI would provide a more than adequate margin of protection.
>
> Overall, this study cannot be said to confirm a risk to human health from consumption of meat from animals treated with these hormones."[843]

7.713 While the European Communities commented negatively on other considerations by Dr. Boobis, it does not seem to make any specific comment on the remarks of Dr. Boobis on study 11.

7.714 Dr. Sippell mentioned that "the synthetic androgen Trenbolone and the gestagen Melengestrol bind with high affinity to the human androgen and progesterone receptors, respectively (Bauer et al., 2000). Exposure during pregnancy might result in severe transplacental virilisation of a female fetus."[844]

7.715 We note that Dr. Sippell does not indicate at what doses such an effect might occur. It is also not clear whether the last sentence (about exposure during pregnancy) refers to one of the studies identified by the European Communities, or whether it is expressing Dr. Sippell's own opinion. We note, however, that Dr. Boobis said: "There is no basis to think that the effect of hormone growth

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[841] Dr. Boobis cited to Lange IG, Daxenberger A, Meyer HH, Rajpert-De Meyts E, Skakkebaek NE and Veeramachaneni DN (2002). Quantitative assessment of foetal exposure to trenbolone acetate, zeranol and melengestrol acetate, following maternal dosing in rabbits. Xenobiotica, **32**:641-65; see reply of Dr. Boobis to question 63 of the Panel, Annex D, para. 488.

[842] Dr. Boobis cites to Syme MR, Paxton JW and Keelan JA (2004). Drug transfer and metabolism by the human placenta. Clin Pharmacokinet, 43:487-514.

[843] Dr. Boobis also discussed the study called "Retrospective study on long-term effects in children of following suspected exposure to oestrogen-contaminated meat" (study 12) and the study *"In utero* exposure and breast cancer: a study in opposite sexed twins" (Study 13). However these studies seemed to relates primarily to oestradiol. See reply of Dr. Boobis to questions from the Panel, Annex D, paras. 493 and 491.

[844] Reply of Dr. Sippell to question 41 of the Panel, Annex D, para. 336.

promoters would be different in any way whatsoever from hormones naturally present in meat, at equivalent internal exposure levels."[845]

7.716 In paragraph 804 of Annex G, Dr. Sippell also states that: "It is, of course, difficult to answer such a question as a clinician, but from the experience we have with the low levels, I mentioned this several times before, with the extremely low levels that have been measured by these new recombinant assays, it is conceivable really that this extra burden of oestradiol poses a risk to very small children and particularly prepubertal boys, and this is in line with the very very high sensitivity of prepubertal children to oestrogens induced for other purposes."[846]

7.717 We consider that, in that paragraph, Dr. Sippell merely argues that it is conceivable that there is a risk, but he is not saying that there is evidence of such a risk. Dr. Sippell also stated: "I think that as much as children are concerned, we know really by no means enough and the data are really insufficient to tell or to be confident that this additional exposure from hormone-treated meat poses no risk."[847] Dr. Sippell's statements focused on oestradiol.

7.718 At the hearing, Dr. Guttenplan also mentioned: "So the potential genotoxic damage that is done in an adult would overwhelm that that could be done in a child. However, in boys the levels are even lower, and there I think we have to worry about developmental effects, and there has been less said on that – Dr. Sippell has been the major proponent of that – and I still think that these could be investigated epidemiologically or in some type of study. We might, as Dr. Boobis suggested, need a surrogate, perhaps saliva or urine, but I think it is perhaps the most important issue to address is the sensitivity of children. I should also mention hormone-sensitive cancers in post-menopausal women, it could be another concern."[848]

7.719 These two statement express doubts but do not constitute evidence of risks. The Panel notes that science does not stop studying a substance just because there is sufficient evidence to conduct a risk assessment, but continuously re-evaluates substances. Nothing in the above cited passages suggests that the existing evidence was insufficient to complete a risk assessment. In fact, the Panel notes that the European Communities has once again pointed the Panel to evidence that deals only with oestradiol, a hormone for which it claims to have completed a risk assessment. The European Communities has not explained how the interventions from the experts support a conclusion that the scientific evidence was insufficient to conduct a risk assessment with respect to the other five hormones.

7.720 The European Communities does not provide additional evidence in its comments regarding other hormones than oestradiol.[849]

7.721 Having regard to the opinions of the experts, the Panel is of the view that it has not been established that there is a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient in relation to the growth and reproduction effects of the hormones at issue.

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[845] Reply of Dr. Boobis to question 41 of the Panel, Annex D, para. 333.
[846] Annex G, para. 804.
[847] Annex G, para. 1063.
[848] Annex G, para. 1061.
[849] EC's comments on replies from experts, question 41, Annex F-1, p. 29.

(vii) Is relevant scientific evidence insufficient in the case of progesterone?

Summary of the main arguments of the parties[850]

7.722 The **United States** argues in general that the hormones at the centre of these proceedings have been intensively studied over the last twenty-five years and nothing has occurred since the *EC – Hormones* case, except that the five hormones have been studied in greater details, including by JECFA. New safety assessments were conducted for progesterone in 1999, reaffirming its safety when used according to good veterinary practices. Included in these safety assessments were new, detailed epidemiological studies on the effect of the hormones on post-menopausal women, marking some of the most relevant studies of the effect of hormones on human beings to date.[851] [852]

7.723 The United States adds that the European Communities' CVMP recently re-evaluated the scientific evidence relating to the hormones and reaffirmed its earlier conclusions on the safety of progesterone.

7.724 The United States concludes that there is more than sufficient scientific evidence to permit an adequate assessment of any potential risk.

7.725 The **European Communities** argues that the body of evidence has developed since the *EC – Hormones* case and, while still not providing enough knowledge to carry out a complete and definitive risk assessment, supports the conclusion that precautionary measures are required in order to achieve its chosen level of protection.

7.726 The European Communities, quoting the 1999 Opinion, identifies the following insufficiencies in the evidence:[853]

(a) little knowledge about the specific enzymes in cattle that metabolize progesterone;

(b) considerable uncertainty associated with the validity of daily production rate data used by the US Food and Drug Administration;

(c) no information available on mutagenicity and genotoxicity;

(d) no information available on DNA adducts and DNA damage;

(e) inadequate evidence for carcinogenicity in humans;

(f) regarding effects of progesterone on growth and reproduction, alterations of spermatogenesis can be induced by progesterone treatments, but no assessment of the dose-response relationship is available;

(g) regarding effects on the immune system, there are data indicating that progesterone can cause immuno depression, but they are insufficient to make a realistic assessment of the dose-response relationship.

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[850] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[851] The United States refers to the 52nd JECFA report (2000), pp. 59-60.

[852] US's first written submission, paras. 125-128.

[853] EC's second written submission, para. 155.

7.727 In response to the US reference to the 1999 JECFA assessment, the European Communities notes that the 1999 Opinion took JECFA's assessment into account, expressing concern regarding the determination of the ADI since neither the actual data nor a reference to a peer-reviewed publication were provided, and since the dose-response was limited to two doses and the ADI was estimated from just a single dose rather than a curve derived from all the data available.[854]

7.728 In addition, the European Communities indicates that the Opinions, in particular the 2002 Opinion, have taken the 1999 CVMP assessment into account. The European Communities argues that the CVMP opinion was not used as the only basis of the EC measure for progesterone as a growth promoter because new scientific evidence had appeared since and the SCVPH assessment had identified risks that were incompatible with the level of health protection applied by the European Communities to these hormones when used for animal growth promotion purposes. Secondly, the European Communities argues that the CVMP conclusion applies only when progesterone is used in veterinary *medicinal* products authorized in accordance with relevant EC legislation, which would exclude over the counter products freely available to laypeople.[855]

Reasoning of the Panel

7.729 In light of the arguments of the parties, and having regard to the 1999 and 2002 Opinions[856] and to the fact that some of the insufficiencies identified by the European Communities have been addressed in the common section above or were simply not discussed by the European Communities in its submissions, the Panel will limit its analysis to determining whether relevant scientific evidence is insufficient concerning progesterone with regard to evidence of carcinogenicity in humans.

7.730 We note that the European Communities, referring to the 1999 Opinion, argues that there is no information available on the mutagenicity and genotoxicity of progesterone.[857]

7.731 We recall, however, that with respect to genotoxicity, the 2002 Opinion concludes that "[t]here is no evidence that progesterone or testosterone have genotoxic potential."[858]

7.732 Regarding this aspect, we note that Dr. Boisseau quoted the report of JECFA in its thirty-second session (1999), where it concludes that "[a]lthough equivocal results have been reported for the induction of single-strand DNA breaks and DNA adducts have been seen in vivo and in vitro in some studies, progesterone was not mutagenic … progesterone has no genotoxic potential ". Dr. Boisseau also quotes JECFA's conclusion that "these effects on tumour production occurred only with doses of progesterone causing obvious hormonal effects … the effect of progesterone on tumour production was directly related to its hormonal activity".[859]

7.733 Dr. Boobis concurred with the above by saying that:

> "there is no evidence that the hormones testosterone or progesterone have genotoxic potential. ... Micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-

[854] EC's second written submission, para. 157-158; EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1, para. 126.

[855] EC's second written submission, para. 159; EC's replies to Panel questions after the first substantive meeting, Annex B-1, paras. 130-133, Exhibit US-13, p. 12.

[856] The 2000 Opinion did not identify essentially new toxicological information concerning progesterone and testosterone in the data presented in the toxicological evaluation of the natural hormones oestradiol-17β, progesterone and testosterone in animal production by JECFA (2000 Opinion, section 2.2, p. 4).

[857] EC's second written submission, quoting 1999 Opinion, paras. 155-156.

[858] 2000 Opinion, section 4.3, p. 15.

[859] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 157.

> labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. In no case did any of the compounds produce a mutagenic response. These data are insufficient to support the conclusion that these hormones have genotoxic potential in vivo. Thus, there is no evidence that any of the hormones are genotoxic in vivo at the levels found in meat from treated animals. Even if GVP were not followed, the levels of exposure to the hormones would be such that no genotoxicity would be anticipated in vivo."[860]

7.734 Dr. Guttenplan added that "there is no conclusive evidence presented by the European Communities that the five hormones other than oestradiol-17β, when consumed as residues in meat have genotoxic potential. There is some evidence that certain of the hormones have genotoxic potential, but generally the potential is weak. ... progesterone [is] negative in genotoxic assays. ... Any genotoxic effects of the five hormones are likely to be minimized by good veterinary practice."[861]

7.735 The European Communities considers that JECFA was more prudent than the experts when rejecting the genotoxicity of progesterone in 1999. The European Communities argues that the 1999, 2000 and 2002 risk assessments by the SCVPH provide enough evidence to demonstrate that genotoxicity from these hormones is possible.[862]

7.736 We note that, on the one hand, the SCVPH in its 2002 Opinion concluded "[t]here is no evidence that progesterone or testosterone have genotoxic potential". We note, on the other hand, that the European Communities did not point to any study subsequent to the 2002 Opinion which would contradict this conclusion.

7.737 Regarding evidence of carcinogenicity in humans, we note that IARC has evaluated progestins as *possibly carcinogenic to humans* (Group 2B)[863] based on sufficient evidence of carcinogenicity in experimental animals.[864] We note, however, that IARC's evaluation relates to the

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[860] Reply of Dr. Boobis to question 21 of the Panel, Annex D, para. 198.
[861] Reply of Dr. Guttenplan to question 21 of the Panel, Annex D, para. 200.
[862] EC's comments on experts replies to question 21 of the Panel, Annex F-1, pp. 17-18.
[863] In its reply to question 24 of the Panel, Annex E-3, p. 128, IARC mentioned that it uses the following groupings to characterize potential carcinogenic agents:

> "*Carcinogenic to humans* (Group 1). This category is used when there is *sufficient evidence of carcinogenicity* in humans.
>
> *Probably carcinogenic to humans* (Group 2A). This category is generally used when there is *limited evidence* in humans and *sufficient evidence* in experimental animals.
>
> *Possibly carcinogenic to humans* (Group 2B). This category is generally used when there is *limited evidence* in humans or *sufficient evidence* in experimental animals, but not both.
>
> *Not classifiable as to its carcinogenicity to humans* (Group 3). This category is generally used when there is *inadequate evidence* in humans and *inadequate* or *limited evidence* in experimental animals. Agents that do not fall into any other group are also placed in this category.
>
> *Probably not carcinogenic to humans* (Group 4). This category is generally used when there is *evidence suggesting lack of carcinogenicity* in humans and in experimental animals.
>
> Mechanistic and other relevant data also contribute to the grouping. Further details can be found in the Preamble to the *IARC Monographs* (http://monographs.iarc.fr)."

[864] IARC written replies to question 25 of the Panel, Annex E-3, p. 129.

carcinogenicity of hormones in general, not to the carcinogenicity due to exposure to hormone residues in meat as a result of the cattle being treated with growth promoting hormones.

7.738 Dr. Boisseau mentioned that "[i]n its 1999 report, SCVPH concluded, about the carcinogenicity of progesterone, that 'At present, the data are insufficient to make any quantitative estimate of the risk arising from the exposure to residues in meat.' Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of progesterone are related to a mechanism other than hormonal activity."[865]

7.739 On the basis of the arguments of the parties and of the experts' opinions, we conclude that there is no new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence, now insufficient. We therefore conclude that the elements before us do not support the conclusion that the relevant scientific evidence has become insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, regarding the genotoxicity, mutagenicity and carcinogenicity of progesterone.

Conclusion

7.740 Having regard to our specific conclusions above, we recall that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. In this respect, we note that, at our request, the experts also expressed their views on the more general question whether the scientific evidence available at the time of the adoption of Directive 2003/74/EC and subsequently allowed the conduct of a risk assessment, in relation to meat from cattle treated, *inter alia,* with progesterone. Dr. Boobis replied that:

> "[T]here was sufficient information available to the EC to have enabled it to have conducted an assessment of the risks to human health arising from consumption of meat from cattle treated with any of the six hormones at issue."

7.741 We also note Dr. Guttenplan's comment that:

> "Progesterone, testosterone have been extensively investigated and the assessment seems sound and is based on the no effect level and a safety factor. (JECFA meeting 52, report-WHA TRS 893)."

7.742 These general remarks support our conclusions on the specific elements discussed above. We therefore conclude that it is not established that the relevant scientific evidence is insufficient with respect to progesterone, within the meaning of Article 5.7 of the *SPS Agreement*.

(viii) Is relevant scientific evidence insufficient in the case of testosterone?

Summary of the main arguments of the parties[866]

7.743 As described above, the **United States** argues that JECFA assessments have shown that hormone residues in meat from animals treated for growth promotion are safe and that evidence is sufficient for a risk assessment. The United States also states that new safety assessments have been

[865] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 158.

[866] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

conducted for progesterone and testosterone, reaffirming their safety when used according to good veterinary practices.

7.744 The **European Communities**, quoting the 1999 Opinion, identifies the following insufficiencies in the evidence regarding testosterone:[867]

(a) the mechanism of androgen activity is only partially understood, including the role of androgen receptors in ovarian tumorigenesis;

(b) little information is available about the specific metabolic routes and elimination rates for testosterone in cattle;

(c) there is uncertainty regarding daily production rate data;

(d) genotoxicity of testosterone has not been demonstrated with the limited testing done to date;

(e) no information is available on DNA damage induced by testosterone or its metabolites;

(f) data on carcinogenicity in humans are limited;[868]

(g) no dose-response estimate can be given for effects on growth and reproduction;

(h) there is limited experimental data on the effects of testosterone on the immune system and none on dose-response aspects.

7.745 In response to the US reference to the 1999 JECFA assessment, the European Communities notes that the 1999 Opinion questions the quality of the study that provided the data for JECFA's determination of the ADI. According to the European Communities, neither the actual data nor reference to a peer-reviewed publication were provided, the dose-response was limited to two doses and the ADI was estimated from just a single dose where no effect was observed rather than a curve derived from all the data available.[869]

Reasoning of the Panel

7.746 In light of the arguments of the parties, and having regard to the 1999 and 2002 Opinions[870] and to the fact that some of the insufficiencies identified by the European Communities have been addressed in the common section above, or were simply not discussed by the European Communities in its submissions, the Panel does not deem it necessary to address the mechanism of androgen activity, the metabolic routes and elimination rates for testosterone in cattle or the daily production

[867] EC's second written submission, paras. 160-161.

[868] In its conclusion on carcinogenicity, the SCVPH notes that evidence about the role of endogenous testosterone in the occurrence of prostate cancer is weak, that there is limited data on genotoxicity but that testosterone might be aromatized to oestradiol, which had been found to be genotoxic, and that no conclusive quantitative estimate of the risk arising from the excess intake with meat and meat products from treated animals can be made.

[869] EC's second written submission, para. 162; EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1, para. 124.

[870] The 2000 Opinion did not identify essentially new toxicological information concerning progesterone and testosterone in the data presented in the toxicological evaluation of the natural hormones oestradiol-17β, progesterone and testosterone in animal production by the JECFA (2000 Opinion, section 2.2, p. 4).

rate data since these issues have either not been discussed specifically by the parties, or were addressed above.

7.747 We also note that the 1999 Opinion found that genotoxicity of testosterone has not been demonstrated with the limited testing done to date.[871] The 2002 Opinion adds that "[t]here is no evidence that progesterone or testosterone have genotoxic potential."[872]

7.748 Likewise, the 1999 Opinion states that no information is available on DNA damage induced by testosterone or its metabolites.[873] This said, it states that "testosterone is ... aromatized to oestradiol, which is metabolized to reactive forms that damage DNA and induce mutation." The 1999 Opinion then refers to its section on oestradiol-17β.

7.749 The 1999 Opinion also reports that "[w]hereas the evidence in favour of carcinogenicity was considered sufficient for testosterone in experimental animals, data in humans are limited."[874] This reference has to be read in conjunction with the following paragraph of the 1999 Opinion, which states that the evidence regarding the role of testosterone in prostate cancer is currently weak. In addition, it seems to relate to endogenous testosterone. The 1999 Opinion adds that no conclusive quantitative estimate of the risk arising from the excess intake with meat and meat products from treated animals can be made.

7.750 These comments do not, in our opinion, meet our test that there be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence to make relevant, previously sufficient, evidence now insufficient and would lead us to consider that no risk assessment could be performed. We note in this respect that the 1999 Opinion notes that testosterone is "considered as probable carcinogenic to humans (IARC group 2A)".[875] IARC specified that "this category is generally used when there is limited evidence in humans and sufficient evidence in experimental animals."[876] We also note that IARC assessments are made in general terms, not specifically in relation to consumption of meat treated with hormones for growth promotion purposes.

7.751 Regarding carcinogenicity of testosterone, Dr. Boisseau mentioned that IARC confirms the 1999 Opinion to the extent that it has determined that there is *sufficient evidence of carcinogenicity* in experimental animals and advised, "In the absence of adequate data in humans, it is reasonable, for practical purposes, to regard testosterone as if it presented a carcinogenic risk to humans".[877]

7.752 Dr. Boisseau also stated that "the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of testosterone are related to a mechanism other than hormonal activity."[878]

7.753 Having regard to the positions taken by the SCVPH in its 1999 and 2002 Opinions and the views expressed by the experts, we do not find it necessary to address any further the questions of the genotoxicity and carcinogencity of testosterone in our attempt at determining whether relevant

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[871] 1999 Opinion, section 4.2.5.

[872] 2000 Opinion, section 4.3, p. 15. This was confirmed by the experts who expressed views on this question. For instance, Dr. Guttenplan mentioned that: "there is no conclusive evidence presented by the EC that the five hormones other than oestradiol-17β, when consumed as residues in meat have genotoxic potential." Reply of Dr. Guttenplan to question 21 of the Panel, Annex D, para. 200.

[873] EC's second written submission, para. 160, quoting 1999 Opinion, p. 49.

[874] Ibid.

[875] 1999 Opinion, section 4.2.7.

[876] See IARC reply to question 24 of the Panel, Annex E-3, p. 128.

[877] IARC reply to question 25 of the Panel, Annex E-3, p. 129.

[878] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 160.

scientific evidence is insufficient with respect to this hormone, within the meaning of Article 5.7 of the *SPS Agreement*.

Conclusion

7.754 Having regard to our specific conclusions above, we recall that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. In this respect, we note that, at our request, the experts also expressed their views on the more general question whether the scientific evidence available at the time of the adoption of Directive 2003/74/EC and subsequently allowed the conduct of a risk assessment, in relation to meat from cattle treated, *inter alia,* with testosterone. Dr. Boobis replied that:

> "[T]here was sufficient information available to the EC to have enabled it to have conducted an assessment of the risks to human health arising from consumption of meat from cattle treated with any of the six hormones at issue."

7.755 We also note Dr. Guttenplan's comment that:

> "Progesterone, testosterone have been extensively investigated and the assessment seems sound and is based on the no effect level and a safety factor. (JECFA meeting 52, report-WHA TRS 893)."

7.756 These general remarks support our conclusions on the specific elements discussed above. We therefore conclude that it is not established that the relevant scientific evidence is insufficient with respect to testosterone, within the meaning of Article 5.7 of the *SPS Agreement*.

(ix) Is relevant scientific evidence insufficient in the case of trenbolone acetate?

Summary of the main arguments of the parties[879]

7.757 As described above, the **United States** argues that JECFA assessments have shown that hormone residues in meat from animals treated for growth promotion are safe and that evidence is sufficient for a risk assessment. The United States also notes that the authors of one of the 17 studies relied upon by the European Communities later concluded that none of the three synthetic growth promoters tested demonstrated evidence of genotoxicity.[880]

7.758 The **European Communities**, quoting the 1999 Opinion, identifies the following insufficiencies in the scientific evidence:[881]

(a) the need to further investigate the metabolic fate and chemical nature of covalently bound residues of trenbolone acetate;

(b) in humans, no data are currently available to assess the carcinogenicity of trenbolone acetate;[882]

[879] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.

[880] US's second written submission, footnote 41.

[881] EC's second written submission, para. 165.

(c) regarding effects on reproduction, the available data do not allow a realistic assessment of a dose-response relationship;

(d) investigations of the effects of trenbolone acetate on the immune system are very limited.

7.759 The European Communities adds that the SCVPH concluded that the information is insufficient to assess the possible impacts of low levels of trenbolone acetate in meat on consumers.

7.760 The European Communities indicates that, in its 2002 Opinion, the SCVPH found these conclusions to be compounded by data obtained in certain of the 17 studies and more recent research, none of which was considered by the 1988 JECFA report. The European Communities argues that the only assessment on trenbolone acetate publicly available is that of JECFA, and that the SCVPH took this assessment into account, but disagreed with a number of its basic findings on the basis of more recent scientific research.[883]

Reasoning of the Panel

7.761 In light of the arguments of the parties and of the fact that some of the insufficiencies identified by the European Communities have been addressed in the common section above, or were simply not discussed by the European Communities in its submissions, the Panel will limit its analysis to determining whether relevant scientific evidence is insufficient concerning trenbolone acetate with regard to the following aspects:

(a) metabolism of trenbolone acetate;[884]

(b) inadequate evidence of carcinogenicity in humans.

Metabolism of trenbolone acetate

7.762 The European Communities refers to the 2002 Opinion which states that "experiments with zeranol and trenbolone acetate suggested a more complex oxidative metabolism than previously assumed. These data need further clarification as they might influence a risk assessment related to tissue residues of these compounds."[885]

7.763 We note that Dr. Boobis discussed study 4 of the 17 studies:

> "The metabolism of zeranol and trenbolone had been further investigated (study 4). These data do not appear to have been published in the peer reviewed literature to date.
>
> The data on trenbolone show that the alpha enantiomer in liver slices from bovine is extensively conjugated and hence inactivated. There is some conversion of the alpha to the active β isomer by human liver microsomes, but the kinetics of the reaction and the extent of conjugation have not been determined. No data were presented on

[882] In its conclusion on carcinogenicity, the SCVPH notes that in consideration of the lack of *in vitro* short-term assays on mutagenicity and genotoxicity of certain TBOH metabolites and in consideration of the equivocal results of cell transformation assays and the *in vivo* studies, the available information is insufficient to complete a quantitative risk assessment. 1999 Opinion, section 4.4.7, p 59.

[883] EC's second written submission, paras 166-167; EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1, para. 126.

[884] EC's second written submission, para. 165, quoting 1999 Opinion at pp. 55-60.

[885] 2002 Opinion, section 7, p. 21.

> levels of the alpha enantiomer in meat from treated cattle. However, these data do not affect the risk assessment of trenbolone acetate. This is because a) the toxicological studies were conducted in animals that would have been exposed to the metabolites of concern, b) JECFA considered residues of both the alpha and the β enantiomers in recommending MRLs for trenbolone acetate."[886]

7.764 No other expert expressed views on the subject.

7.765 The Panel is cognizant that the European Communities argues that Dr. Boobis' comments on a number of the studies generated by the European Communities are flawed and has given examples of those alleged flaws.[887] However, it does not expressly address Dr. Boobis' comments on the study discussed above. As a result, the Panel sees no reason not to take the comments of Dr. Boobis fully into account in its assessment of the sufficiency of existing relevant scientific evidence.

Inadequate evidence of carcinogenicity in humans

7.766 The European Communities refers to the 1999 Opinion which recalls that trenbolone acetate is a synthetic androgen and that both the parent compound and its metabolite have been extensively tested for their mutagenic/genotoxic potential. The 1999 Opinion notes that it might be concluded that the genotoxic effects of trenbolone acetate are not related to their hormonal activity. It notes that "[f]ormation of DNA adducts has been observed in rat hepatocytes ... (Metzler, 1999)." On carcinogenicity, the 1999 Opinion mentions *inter alia* that a two-year carcinogenesis[888] bioassay in rats and mice did not provide definitive results. In humans, no data are currently available to assess the carcinogenicity of trenbolone acetate. The 1999 Opinion concludes that the available information is insufficient to complete a quantitative risk assessment.[889]

7.767 Regarding this aspect, Dr. Boisseau mentioned the following:

> "In its thirty second session held in 1987, JECFA concluded from carcinogenic studies in animals that "the liver hyperplasia and tumours in mice … and the slight increase in the incidence of islet-cell of the pancreas of rats arose as a consequence of the hormonal activity of trenbolone". In its thirty fourth session held in 1989, JECFA, having reviewed a comprehensive battery of short term tests, concluded that 'it was unlikely that trenbolone acetate was genotoxic' and decided to confirm its previous conclusion to base the evaluation of trenbolone acetate and its metabolites on their no-hormonal-effect."[890]

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[886] Reply of Dr. Boobis to question 62 of the Panel, Annex D, paras. 479-480.

[887] EC's comments on the replies of the experts, Annex F-1, p. 40.

[888] *Mechanism (or mode of action) of carcinogenesis:*a mode of action is series of key events which are necessary to lead to the formation of a tumour. These key events comprise the biological changes induced by the chemical and subsequent events which then lead to the development of cancer. A mechanism refers to the molecular events that are responsible for those changes. A hormonal mechanism means that it is the endocrine or hormonal effect of a compound that leads to growth or proliferation of certain cells that are responsive to the hormone, resulting in the development of a tumour. A genotoxic mechanism means that there is a mechanism independent of the hormonal action resulting in direct damage to the DNA that leads to a tumour. There are situations where elements of more than one mechanism could apply (Transcript of the Panel meeting with the experts, Annex G, paras. 103-109 (Dr. Boobis, Dr. Cogliano and Dr. Guttenplan)).

[889] 1999 Opinion, pp. 57-59.

[890] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 163.

7.768 The 2002 Opinion refers to the results of study 2 of the 17 studies with respect to mutagenicity and genotoxicity (Metzler and Pfeiffer, 2001).[891]

7.769 Three experts expressed their views in relation to the subject of this study. Dr. Boobis mentions the following:

> "There is no convincing evidence that trenbolone acetate, MGA and zeranol are genotoxic. They were negative in a range of tests for genotoxicity. They were very weakly positive in a micronucleus test, at high (potentially cytotoxic) concentrations. Trenbolone also produced a low level of DNA adducts measured by 32P-post-labelling *(Metzler and Pfeiffer, 2001)*.[892] As indicated above, micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. In no case did any of the compounds produce a mutagenic response. These data are insufficient to support the conclusion that these hormones have genotoxic potential in vivo. Thus, there is no evidence that any of the hormones are genotoxic in vivo at the levels found in meat from treated animals. Even if GVP were not followed, the levels of exposure to the hormones would be such that no genotoxicity would be anticipated in vivo."[893]

7.770 Dr. Boobis added that:

> "Study 4 reports recent observations on the genotoxicity and mutagenicity of zeranol and trenbolone. Both compounds were negative for tests of mutagenicity, i.e. induction of *lac*I mutations in *E coli* and induction of *hprt* mutations inV79 cells. Zeranol did not produce DNA adducts in rat hepatocytes whilst a low level of DNA adducts was observed with trenbolone. Both were very weakly positive in a micronucleus test, at high (potentially cytotoxic) concentrations. As indicated above ..., micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. These data are insufficient, given the number of well conducted studies in which the compounds were negative, to alter the conclusion that neither zeranol nor trenbolone acetate has genotoxic potential in vivo. Indeed, the *SVCPH (2002)* concluded that "both compounds exhibited only very weak effects" in those in vitro tests in which positive effects were observed."[894]

7.771 Dr. Guttenplan confirmed the conclusions of the two other experts:

> "[t]here is no conclusive evidence presented by the EC that the five hormones other than oestradiol-17β, when consumed as residues in meat have genotoxic potential. There is some evidence that certain of the hormones have genotoxic potential, but generally the potential is weak. ... Trenbolone is either negative or marginally active in *in vitro* genotoxic assays. ... Any genotoxic effects of the five hormones are likely

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[891] 2002 Opinion, section 4.4.3.

[892] Dr. Boobis cited to *Metzler M and Pfeiffer E (2001). Genotoxic potential of xenobiotic growth promoters and their metabolites. APMIS,* ***109****:89-95*

[893] Reply of Dr. Boobis to question 21of the Panel, Annex D, para. 198.

[894] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 483.

> to be minimized by good veterinary practice. My reply for the hormones would not have been different in September 2003 (SCVPH 2002 Opinion)."[895]

7.772 The European Communities argues essentially that the 1999, 2000 and 2002 Opinions provide enough evidence to demonstrate that genotoxicity and other adverse effects from these hormones are possible and that there are a number of uncertainties surrounding their mechanism of action to warrant further investigations. The European Communities refers to Dr. Guttenplan's statement.[896]

7.773 We do not read the statement above as the European Communities does. Rather we understand Dr. Guttenplan to say that the genotoxic potential of trenbolone acetate is weak.

7.774 Regarding carcinogenicity, we first note that trenbolone acetate has not been evaluated by IARC, nor have the specific risks from the consumption of meat from cattle treated with this growth promotion hormone.[897]

7.775 Dr. Boisseau made the following comments:

> "In its 1999 report, SCVPH concluded, about the carcinogenicity of trenbolone, that 'in consideration of the lack of in vitro short term assays on mutagenicity and genotoxicity of other trenbolone metabolites other than α-trenbolone and in consideration of the equivocal results of the transformation assays and the in vivo studies, the available information is insufficient to complete a quantitative risk assessment'. Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of trenbolone are related to a mechanism other than hormonal activity."[898]

7.776 The European Communities seeks to refute Dr. Boisseau's comments on the basis that he refers only to the JECFA's reports, which are outdated and based on old data, and that he interprets lack of data as lack of adverse effects.

7.777 We recall our test in order to assess whether relevant scientific evidence is insufficient is that there should be new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence, now insufficient. We note that the European Communities points at possibilities which are not confirmed by the experts who expressed their views. We therefore conclude that the elements before us do not support the conclusion that the relevant scientific evidence has become insufficient, within the meaning of Article 5.7 of the *SPS Agreement*, regarding the carcinogenicity of trenbolone acetate.

Conclusion

7.778 Having regard to our specific conclusions above, we recall that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. In this respect, we note that, at our request, the experts also expressed their views on the more general question whether the scientific evidence available at the time of the adoption of Directive 2003/74/EC and subsequently allowed the conduct of a risk assessment, in relation to meat from cattle treated, *inter alia,* with trenbolone acetate. Dr. Boobis replied that:

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[895] Reply of Dr. Guttenplan to question 21 of the Panel, Annex D, para. 200.
[896] EC's comments on expert replies to question 21 of the Panel, Annex F-1, pp. 17-18.
[897] IARC reply to question 25 of the Panel, Annex E-3, p. 129.
[898] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 164.

> "[T]here was sufficient information available to the EC to have enabled it to have conducted an assessment of the risks to human health arising from consumption of meat from cattle treated with any of the six hormones at issue."

7.779 We also note Dr. Guttenplan's comment that:

> "There is more limited evidence available for Trenbolone and Zeranol and most of it is *in vitro (SCVPH 2002 Opinion)* or not recent (e.g., JECFA meeting 34th report, 1989 and 32nd report, 1988). However, both appear to be potentially significantly estrogenic. Experimental and analytical methods have improved but it does not appear that accurate ADI's can be established at this point. Studies in experimental animals and studies on levels in beef are still needed. However, from the data available at the time of the Directive, the potential for adverse effects could not be ruled out."[899]

7.780 We note, however, that during our meeting with the experts, Dr. Guttenplan clarified, at the EC request, that "the ability [to make a risk assessment] varies between compounds, but that does not mean that you can't make a risk assessment, it just means that the accuracy of the risk assessment is different."[900] Regarding the establishment of accurate ADIs, Dr. Guttenplan clarified that "accurate means – if it's not accurate, there is just a larger range, but you can still do a risk assessment."[901]

7.781 These general remarks support our conclusions on the specific elements discussed above. We therefore conclude that it is not established that the relevant scientific evidence is insufficient with respect to trenbolone acetate, within the meaning of Article 5.7 of the *SPS Agreement*.

(x) Is relevant scientific evidence insufficient in the case of zeranol?

Summary of the main arguments of the parties[902]

7.782 As described above, the **United States** argues that JECFA assessments have shown that hormone residues in meat from animals treated for growth promotion are safe and that evidence is sufficient for a risk assessment. The United States also notes that the authors of one of the 17 studies relied upon by the European Communities later concluded that none of the three synthetic growth promoters tested demonstrated evidence of genotoxicity.[903]

7.783 The **European Communities**, quoting the 1999 Opinion, identifies the following insufficiencies in the evidence:[904]

> (a) there are only few tests with equivocal results on the genotoxic properties of zeranol, which are insufficient for an evaluation of its mutagenic/genotoxic properties;

[899] Reply of Dr. Guttenplan to question 61 of the Panel, Annex D, para. 457.
[900] Transcript of the Panel meeting with the experts, Annex G, para. 983.
[901] Transcript of the Panel meeting with the experts, Annex G, para. 985.
[902] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.
[903] US's second written submission, footnote 41.
[904] EC's second written submission, para. 168.

(b) no data are available on cancer risk for humans linked to meat with zeranol residues;[905]

(c) no dose-response relationship for effects of zeranol on growth and reproduction can be made;

(d) no relevant data on effects on the immune system were found.

7.784 The European Communities notes that, in conclusion, the 1999 Opinion finds that the available data do not allow a quantitative estimate of the risk arising from exposure to zeranol residues, and that further data are needed on the nature of the metabolites formed in bovines. The European Communities indicates that in its 2002 Opinion, the SCVPH found these conclusions to be compounded by data obtained in certain of the 17 studies and more recent research.[906]

7.785 The European Communities cites a study by US scientists according to which meat and serum from zeranol-implanted cattle possess "heat-stable mitogenicity for cultured breast cells, and that both normal and cancerous human breast cells exhibit estrogenic responses to zeranol".[907] These scientists then point to potential tumorigenic effects for oestrogen, including direct genotoxic effects of oestrogen metabolites. They point out that the mechanisms responsible for oestrogen stimulated carcinogenesis remain undefined. The European Communities argues that these studies clearly invalidate the findings of the 1988 JECFA opinion.[908]

7.786 The European Communities also argues that the only assessment on zeranol publicly available is that performed by JECFA in 1988. The European Communities indicates that the SCVPH took this assessment into account, but disagreed with a number of its basic findings on the basis of more recent scientific research, some of which was generated by the 17 studies[909] (studies Nos. 2, 4 and 10) and more recent research.

Reasoning of the Panel

7.787 In light of the arguments of the parties and of the fact that some of the insufficiencies identified by the European Communities have been addressed in the common section above, or were simply not discussed by the European Communities in its submissions, the Panel will limit its analysis to determining whether relevant scientific evidence is insufficient concerning zeranol with regard to the alleged inadequate evidence of carcinogenicity in humans, such as lack of information available on mutagenicity and genotoxicity and lack of information on DNA adducts and DNA damages.

7.788 The 1999 Opinion referred to by the European Communities states that the mutagenicity and genotoxicity of zeranol was investigated only in a few tests which gave equivocal results insufficient for an evaluation of the mutagenic/genotoxic properties of zeranol. As far as carcinogenicity is concerned, the 1999 Opinion concludes that there is clear evidence for the induction of liver

[905] In its conclusion on carcinogenicity, the SCVPH states that considering the limited data on mutagenicity/genotoxicity and the clear evidence for an induction of liver adenomas and carcinomas in hamsters, no assessment of the possible carcinogenicity of zeranol can be made. See 1999 Opinion, section 4.5.7, p. 65.

[906] EC's second written submission, paras. 168-169.

[907] EC's second written submission, paras. 145-146, citing a study by Suling Liu and Young C. Lin, Exhibit EC-8.

[908] EC's second written submission, para. 170.

[909] EC's second written submission, para. 168; EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1, para. 126.

adenomas and carcinomas in one animal species, but no assessment of the possible carcinogenicity of zeranol can be made.[910]

7.789 Five experts provided views on this matter. Dr. Cogliano limited his comments to the study by Norat et al. (2005)[911], one of the three recently published studies on which the Panel sought the views of the experts, which addresses the association between consumption of red meat and colorectal cancer. The comments by Dr. Cogliano are not specific with respect to the question of the potential carcinogenicity of zeranol.

7.790 Dr. Boisseau expressed the following opinion:

> "In its thirty second session held in 1987, JECFA concluded that zeranol and its metabolites, zearalanone and taleranol, were not mutagenic in a number of tests in bacterial and mammalian systems even if it has noted that zeranol gives a positive result in the Rec-assay and taleranol gives a positive result in the test with Chinese hamster ovary cells in the absence of activation but a negative result with activation. After having reviewed the carcinogenicity studies in animals, JECFA concluded that 'the tumorigenic effect of zeranol was associated with its oestrogenic properties'."[912]

7.791 The 2002 Opinion refers to a comparative study (study 4 of the 17 studies) designed to determine the potential of zeranol, trenbolone and melengestrol acetate to cause genetic damages in various *in vitro* systems. The 2002 Opinion states that "[i]n this study zeranol did not induce genotoxicity or mutagenicity."[913]

7.792 Dr. Sippell mentioned that "[S]ynthetic hormone growth promoters such as Zeranol and its metabolites have been shown to be as potent as [estradiol] and diethylstilbestrol (DES) in increasing the expression of estrogen-related genes in human breast cancer cells (*Leffers et al 2001* – study 17)."[914] However, Dr. Boobis specified that:

> "The study referred to (study 17), reported in *Leffers et al (2001)*, showed that a number of oestogenic compounds affected the expression of several genes in the ER positive breast cancer cell line, MCF7. The responsiveness of this cell line to oestrogens is well established. It was of interest that all of the changes reported by *Leffers et al (2001)* were blocked by the selective ERantagonist ICI82.780. The relevance of effects observed in a cultured cell line to the situation *in vivo*, where kinetic and metabolic factors will influence the magnitude of the response is not known, nor is the significance of changes in gene expression to the toxicity of the hormones known. Many of the changes will reflect the proliferative response to an oestrogenic stimulus. However, in general toxicogenomic data, in the absence on any information on the functional consequences, is not considered a sound basis for use in risk assessment *(IPCS, 2003)*."[915]

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[910] 1999 Opinion, sections 4.5.5 to 4.5.7.
[911] Exhibit EC-71.
[912] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 165.
[913] 2002 Opinion, section 4.4.3, p. 16.
[914] Reply of Dr. Sippell to question 41 of the Panel, Annex D, para. 336.
[915] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 475. Dr. Boobis cites to:

IPCS (2003). Toxicogenomics and the Risk Assessment of Chemicals for the Protection of Human Health
(http://www.who.int/entity/ipcs/methods/en/toxicogenomicssummaryreport.pdf)

7.793 Dr. Boobis added that:

> "There is no evidence that the hormones testosterone or progesterone have genotoxic potential. There is no convincing evidence that trenbolone acetate, MGA and zeranol are genotoxic. They were negative in a range of tests for genotoxicity. They were very weakly positive in a micronucleus test, at high (potentially cytotoxic) concentrations. Trenbolone also produced a low level of DNA adducts measured by 32P-post-labelling *(Metzler and Pfeiffer, 2001)*.[916] As indicated above, micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. In no case did any of the compounds produce a mutagenic response. These data are insufficient to support the conclusion that these hormones have genotoxic potential in vivo. Thus, there is no evidence that any of the hormones are genotoxic in vivo at the levels found in meat from treated animals. Even if GVP were not followed, the levels of exposure to the hormones would be such that no genotoxicity would be anticipated in vivo."

7.794 Dr. Boobis, commenting on study 4, added the following:

> "Study 4 reports recent observations on the genotoxicity and mutagenicity of zeranol and trenbolone. Both compounds were negative for tests of mutagenicity, i.e. induction of *lac*I mutations in *E coli* and induction of *hprt* mutations inV79 cells. Zeranol did not produce DNA adducts in rat hepatocytes whilst a low level of DNA adducts was observed with trenbolone. Both were very weakly positive in a micronucleus test, at high (potentially cytotoxic) concentrations. As indicated above ..., micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. These data are insufficient, given the number of well conducted studies in which the compounds were negative, to alter the conclusion that neither zeranol nor trenbolone acetate has genotoxic potential in vivo. Indeed, the *SVCPH (2002)* concluded that 'both compounds exhibited only very weak effects' in those in vitro tests in which positive effects were observed."[917]

7.795 Dr. Guttenplan commented in more general terms that:

> "There is no conclusive evidence presented by the EC that the five hormones other than oestradiol-17β, when consumed as residues in meat have genotoxic potential. There is some evidence that certain of the hormones have genotoxic potential, but generally the potential is weak. .... Zeranol can induce transformation of breast epithelial cells in culture with efficiency similar to that of estradiol, but the mechanism is not known, and it is negative or marginally active in other assays. ... Any genotoxic effects of the five hormones are likely to be minimized by good

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Leffers H, Naesby M, Vendelbo B, Skakkebaek NE and Jorgensen M (2001). Oestrogenic potencies of Zeranol, oestradiol, diethylstilboestrol, Bisphenol-A and genistein: implications for exposure assessment of potential endocrine disrupters. Hum Reprod, **16**:1037-1045.

[916] Dr. Boobis cited to Metzler M and Pfeiffer E (2001). Genotoxic potential of xenobiotic growth promoters and their metabolites. APMIS, **109**:89-95; see Reply of Dr. Boobis to question 21 of the Panel, Annex D, para. 198.

[917] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 483.

veterinary practice. My reply for the hormones would not have been different in September 2003 (*SCVPH 2002 Opinion*)."[918]

7.796 Regarding carcinogenicity of zeranol, Dr. Boisseau mentioned that:

"In its 1999 report, SCVPH concluded, about the carcinogenicity of zeranol, that "in consideration of the lack of data on mutagenicity/genotoxicity and the clear evidence for an induction of liver adenomas and carcinomas in one animal species, no assessment of the possible carcinogenicity of zeranol can be made". Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of zeranol are related to a mechanism other than hormonal activity."[919]

7.797 Referring to the study by Liu S and Lin YC (2002)[920], Dr. Guttenplan stated that:

"The first of the studies suggests a risk from zeranol. That observation was not previously reported. However, the results were obtained in cultured cells and the relevance to human exposure to hormone-treated cannot be extrapolated from this study because of a myriad of uncertainties in such extrapolation. The study does suggest that additional tests of zeranol should be carried out. There is also some evidence that a metabolite of zeranol (zearalenone) induces oxidative damage in cultured cells. This is a possible genotoxic effect, but again it cannot be extrapolated to meat consumption."[921]

7.798 Zeranol has not been evaluated by IARC, nor have the specific risks from the consumption of meat from cattle treated with this growth promotion hormone.[922]

7.799 The European Communities argues that Dr. Guttenplan made a "careful and scientifically sound statement".[923] We note, however, that Dr. Guttenplan concluded that a genotoxic effect cannot be extrapolated to meat consumption, because of the "myriad of uncertainties" that such extrapolation would entail.

7.800 On the basis of the arguments of the parties and of the experts' opinions, we conclude that it is not established that relevant scientific evidence is insufficient in relation to the carcinogenicity of zeranol, within the meaning of Article 5.7 of the *SPS Agreement*.

Conclusion

7.801 Having regard to our specific conclusions above, we recall that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. In this respect, we note that, at our request, the experts also expressed their views on the more general question whether the scientific evidence available at the time of the adoption of Directive 2003/74/EC and subsequently allowed the conduct of a risk assessment, in relation to meat from cattle treated, *inter alia,* with zeranol. Dr. Boobis replied that:

[918] Reply of Dr. Guttenplan to question 21 of the Panel, Annex D, para. 200.
[919] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 166.
[920] Liu S and Lin YC (2004). Transformation of MCF-10A human breast epithelial cells by zeranol and oestradiol-17.β Breast J, 10:514-521, Exhibit EC-62.
[921] Reply of Dr. Guttenplan to question 25 of the Panel, Annex D, para. 234.
[922] IARC reply to question 25 of the Panel, Annex E-3, p. 129.
[923] EC's comments on experts replies to question 25 of the Panel, Annex F-1, p. 21.

> "[T]here was sufficient information available to the EC to have enabled it to have conducted an assessment of the risks to human health arising from consumption of meat from cattle treated with any of the six hormones at issue."

7.802 We also note Dr. Guttenplan's comment that:

> "There is more limited evidence available for Trenbolone and Zeranol and most of it is *in vitro* (*SCVPH 2002 Opinion*) or not recent (e.g., JECFA meeting 34th report, 1989 and 32nd report, 1988). However, both appear to be potentially significantly estrogenic. Experimental and analytical methods have improved but it does not appear that accurate ADI's can be established at this point. Studies in experimental animals and studies on levels in beef are still needed. However, from the data available at the time of the Directive, the potential for adverse effects could not be ruled out."[924]

7.803 We note, however, that during our meeting with the experts, Dr. Guttenplan clarified, at the EC request, that "the ability [to make a risk assessment] varies between compounds, but that does not mean that you can't make a risk assessment, it just means that the accuracy of the risk assessment is different."[925] Regarding the establishment of accurate ADIs, Dr. Guttenplan clarified that "accurate means – if it's not accurate, there is just a larger range, but you can still do a risk assessment."[926]

7.804 These general remarks support our conclusions on the specific elements discussed above. We therefore conclude that it is not established that the relevant scientific evidence is insufficient with respect to zeranol, within the meaning of Article 5.7 of the *SPS Agreement*.

(xi) Is relevant scientific evidence insufficient in the case of melengestrol acetate (MGA)?

Summary of the main arguments of the parties[927]

7.805 The **United States** considers that there is sufficient evidence for a risk assessment on melengestrol acetate and argues that JECFA has carried out a risk assessment. The United States also notes that the authors of one of the 17 studies relied upon by the European Communities later concluded that none of the three synthetic growth promoters tested demonstrated evidence of genotoxicity.[928]

7.806 The **European Communities**, quoting passages the 1999 Opinion, identified the following insufficiencies in the evidence:[929]

(a) only limited data are available concerning residues of melengestrol acetate in treated cattle;

(b) no information is available on mutagenicity and genotoxicity;

(c) no information is available on DNA adducts and DNA damage.;

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[924] Reply of Dr. Guttenplan to question 61 of the Panel, Annex D, para. 457.
[925] Transcript of the Panel meeting with the experts, Annex G, para. 983.
[926] Transcript of the Panel meeting with the experts, Annex G, para. 985.
[927] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.
[928] US's second written submission, footnote 41.
[929] EC's second written submission, paras. 172-173.

(d) carcinogenicity studies have been conducted in only one animal species, which is inadequate to assess the carcinogenic potential of melengestrol acetate;[930]

(e) available data on effects of melengestrol acetate on growth and reproduction do not allow an estimate of the dose-response relationship;

(f) data on the effect of melengestrol acetate on the immune system are also very limited.

7.807 The European Communities adds that the SCVPH concluded that the available information is insufficient for a quantitative estimate of the risk to the consumer of meat from treated animals. The European Communities indicates that in its 2002 Opinion, the SCVPH found these conclusions compounded by data obtained in certain of the 17 studies.

7.808 The European Communities recalls the finding of the Appellate Body in *EC – Hormones* that no risk assessment had been performed and notes that Codex has not adopted an international standard on melengestrol acetate, although JECFA assessed melengestrol acetate in 2000 (and in 2004 as regards calculation of the MRL). The European Communities argues that in the absence of a Codex standard, the opinion of JECFA becomes irrelevant. In addition, the European Communities indicates that JECFA failed to take into account the more recent data generated by its 17 studies and the 2002 Opinion.[931]

7.809 The European Communities argues that the SCVPH took into account the JECFA assessment and noted that no original data had been presented in the JECFA report and that the majority of references were to reports that had not been published in the peer-reviewed scientific literature.[932]

7.810 The European Communities notes that the United States refers to a draft 2005 report from the UK Committee on Veterinary Practices. According to the European Communities, this report notes that there are important gaps in the evidence base for oestradiol-17β and the other five hormonally-active substances, as acknowledged in the Opinions. The cited passage then states a need for certain information, including a number of issues where more information is needed to improve future risk assessments.[933]

7.811 The European Communities concludes that there is no doubt that the 1999-2002 Opinions constitute the only currently available risk assessment on melengestrol acetate, based on the most recent, peer-reviewed, pertinent information available publicly from the European Communities. The European Communities notes that these Opinions reached the conclusion that the current state of scientific knowledge does not permit a more definitive risk assessment to be carried out.[934]

Reasoning of the Panel

7.812 In light of the arguments of the parties and of the fact that some of the insufficiencies identified by the European Communities have been addressed in the common section above, or were simply not discussed by the European Communities in its submissions, the Panel will limit its analysis to determining whether relevant scientific evidence is insufficient concerning melengestrol acetate with regard to the following aspects:

[930] In its conclusion on carcinogenicity, the SCVPH notes that in view of the lack of data on mutagenicity/carcinogenicity and on DNA interaction, and in consideration of carcinogenicity studies conducted only in one animal species, the data are inadequate to assess the carcinogenetic potential of melengestrol acetate.

[931] EC's second written submission, para. 171.

[932] EC's second written submission, para. 174; EC's replies to Panel questions after the first substantive meeting, question 22, Annex B-1, paras. 126-127.

[933] EC's second written submission, para. 175.

[934] EC's second written submission, para. 176.

(a) only limited data are available concerning residues of melengestrol acetate in treated cattle;

(b) inadequate evidence for carcinogenicity in humans, such as no information available on mutagenicity and genotoxicity and no information available on DNA adducts and DNA damage.[935]

7.813 As a preliminary remark, the Panel notes that Codex did not adopt any standard with respect to melengestrol acetate. The Panel recalls, however, that while there is no international standard as such, intensive work has been performed at the international level. JECFA made two assessments of melengestrol acetate in 2000 and 2004 (the second time in order to propose a MRL). It was included in the priority list for recalculation of MRLs and TMDI by the fifteenth session of CCRVDF that met in 2005.[936] The Panel notes in this respect that for melengestrol acetate, the draft MRL is currently at Step 7 of the Codex elaboration procedure.[937] Moreover, the role of JECFA in the international risk assessment process is such that some degree of relevance should be given to that work. The Panel also notes that at no time did the European Communities request that melengestrol acetate be considered by Codex.[938]

Data on residues of melengestrol acetate

7.814 The two main criticisms of the European Communities regarding JECFA' s assessments are that the residue data used by JECFA on melengestrol acetate are outdated and that JECFA did not take into account the more recent studies commissioned by the European Communities. In the 2002 Opinion, the SCVPH noted that in the JECFA report no original data had been presented and that the majority of references were to reports that had not been published in the peer-reviewed scientific literature.[939]

7.815 We sought the views of the experts on this matter and two of them gave an opinion (Dr. Boisseau, Dr. De Brabander). Both concurred in saying that nearly all the studies used by JECFA dated back to the 1960s and 1970s. However, neither of the two experts stated that these studies were no longer valid.[940]

7.816 The Panel first recalls its position on so-called "old" data in paragraph 7.423 *et seq.* above.

7.817 Second, the Panel notes the opinion of Dr. Boisseau: "It is correct to say that nearly all the studies referred to in the 2000 JECFA report on melengestrol acetate date from the 1960s and 1970s. The comment to be made on this issue is [that] JECFA considered a wide series of toxicological studies in its assessment, used as an end point a non hormonal effect dose by far more conservative than a NOAEL based on tumorigenic effect and adopted a 200 safety factor to derive an ADI from this NOAEL."[941]

7.818 Dr. Boobis also expressed his views on the more recent studies commissioned by the European Communities. With respect to the findings of study 4 referred to by the European Communities regarding residues of melengestrol acetate, Dr. Boobis mentioned the following:

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[935] EC's second written submission, para. 172, quoting 1999 Opinion, p. 77.
[936] Dr. Miyagishima, Codex representative, transcript of the Panel meeting with the experts, Annex G, para. 524.
[937] As explained by Dr. Miyagishima, transcript of the Panel meeting with the experts, Annex G, para. 896.
[938] Dr. Miyagishima, transcript of the Panel meeting with the experts, Annex G, para. 524.
[939] 2002 Opinion, p. 16.
[940] Reply of Dr. De Brabander to question 35 of the Panel, Annex D, paras. 304-305.
[941] Reply of Dr. Boisseau to question 35, Annex D, para. 303.

> "In study 4, unpublished preliminary findings on the in vitro metabolism of MGA were reported. This study provided some evidence for the formation of multiple metabolites of MGA by liver from human, rat and bovine. However, these findings do not affect the risk assessment of MGA because a) the toxicological studies were conducted in animals that would have been exposed to all of the metabolites of concern, b) JECFA assumed that all of the residues in meat from animals treated with MGA were as hormonally active as MGA when it proposed MRLs in 2002 *(JECFA, 2002b)*. It was subsequently shown that this was a conservative decision, as not all of the residues were as active as MGA itself *(JECFA, 2006c)."*[942]

7.819 Although the European Communities criticized Dr. Boobis' analysis of some of the 17 studies in its comments on the replies of the experts[943], it did not specifically address Dr. Boobis's comments on study 4.

> Inadequate evidence for carcinogenicity in humans, such as no information available on mutagenicity and genotoxicity and no information available on DNA adducts and DNA damage

7.820 We note that the 2002 Opinion mentions that the genotoxicity of melengestrol acetate was investigated (study 4) and that "[t]he results were negative in several experiments using concentrations in either 15-125 uM for HPRT mutations, 20-100 uM for micronuclei induction, and 400uM for LacI mutations."[944]

7.821 This statement seems to confirm JECFA's conclusions, as recalled by Dr. Boisseau:

> "[I]n its fifty fourth session, JECFA concluded from the review of a range of assays in vitro and in vivo that melengestrol acetate is not genotoxic. It also agreed upon the fact that 'no firm conclusion could be drawn about the carcinogenic potential of melengestrol acetate in ICR mice … the increased incidence of malignant tumors in the highest-dose group of prepubertal C3Han/f mice was assumed to be due not to a direct carcinogenic effect of melengestrol acetate but to the promoting effect of increased prolactin concentrations'."[945]

7.822 Dr. Boisseau's comment is confirmed by Dr. Boobis, referring *inter alia* to study 4 of the 17 studies commissioned by the European Communities:

> "There is no convincing evidence that trenbolone acetate, MGA and zeranol are genotoxic. They were negative in a range of tests for genotoxicity. They were very weakly positive in a micronucleus test, at high (potentially cytotoxic) concentrations. Trenbolone also produced a low level of DNA adducts measured by 32P-post-

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[942] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 484. Dr. Boobis cites to:

– JECFA (2002b). Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper 41/14, Rome, Italy; and

– JECFA (2006c). Residues of some veterinary drugs in animals and foods. FAO, Rome, Italy (in press).

[943] EC's comments on the replies of the experts, Annex F-1, p. 40.

[944] 2002 Opinion, section 4.5.3, p. 18,"The general conclusions", states that "[d]ata on the genotoxicity of melengestrol acetate indicate only weak effects", p. 22.

[945] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 161.

> labelling *(Metzler and Pfeiffer, 2001)*.[946] As indicated above, micronuclei can arise via a non-genotoxic mechanism, particularly at concentrations that may have caused some toxicity. In addition, the 32P-post-labelling assay is not specific, and data cited above suggest that DNA adduction can arise by mechanisms other than direct interaction with DNA. In no case did any of the compounds produce a mutagenic response. These data are insufficient to support the conclusion that these hormones have genotoxic potential in vivo. Thus, there is no evidence that any of the hormones are genotoxic in vivo at the levels found in meat from treated animals. Even if GVP were not followed, the levels of exposure to the hormones would be such that no genotoxicity would be anticipated in vivo."

7.823 Dr. Guttenplan also agreed that:

> "[T]here is no conclusive evidence presented by the EC that the five hormones other than oestradiol-17β, when consumed as residues in meat have genotoxic potential. There is some evidence that certain of the hormones have genotoxic potential, but generally the potential is weak. ... MGA is negative in genotoxicity assays. Any genotoxic effects of the five hormones are likely to be minimized by good veterinary practice."[947]

7.824 We note that the European Communities argues that new studies have brought fresh evidence which depart from the majority view. At our request, the experts commented on the 17 studies commissioned by the European Communities. Regarding study 4, which is referred to in the 2002 Opinion, Dr. Boobis confirmed the negative results concerning mutagenicity and genotoxicity of melengestrol acetate:

> "[i]n study 4 (mutagenicity and genotoxicity of MGA), MGA was negative in studies of the induction of *hprt* mutations in V79 cells, the induction of micronuclei in V79 cells and the induction of *lac*I mutations in *E coli*. Pure MGA had no effect on apoptosis, which could potentially confound interpretation of studies using V79 cells."[948]

7.825 Dr. Boobis adds, with respect to DNA adducts, that:

> "[P]reliminary studies with rat liver slices, reported in an abstract but not yet published in the peer reviewed literature, suggested that MGA could produce unidentified adducts with DNA. As indicated above, there are mechanisms of adduct formation that do not involve direct interaction of the inducing compound with DNA. Overall, a report of putative covalent binding to DNA observed using 32P-post-labelling is not sufficient to over-ride the consistently negative results of MGA in a range of tests for mutagenicity. Hence, on the basis of the findings in study 5, there is no reasons to change the risk assessment or MGA."[949]

7.826 Regarding carcinogenicity of melengestrol acetate, we note that melengestrol acetate has not been evaluated by IARC, nor have the specific risks from the consumption of meat from cattle treated

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[946] Dr. Boobis cited to Metzler M and Pfeiffer E (2001). Genotoxic potential of xenobiotic growth promoters and their metabolites. APMIS, **109**:89-95, see Annex D, para. 198.

[947] Reply of Dr. Guttenplan to question 21 of the Panel, Annex D, para. 200. Dr. Guttenplan, referring to the 2002 Opinion, mentioned that his reply for the hormones at issue would not have been different in September 2003.

[948] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 486.

[949] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 486.

with this growth promotion hormone.[950] In reply to a question from the Panel on whether the carcinogenic effects of the hormones at issue were related to a mechanism other than hormonal activity, Dr. Boisseau replied that:

> "[i]n its 1999 report, SCVPH concluded, about the carcinogenicity of melengestrol, that: 'in view of the lack of data on mutagenicity/carcinogenicity and on DNA interactions and in consideration of carcinogenicity studies conducted only in one animal species, these data are inadequate to assess the carcinogenic potential of melengestrol.' Therefore, the scientific evidence relied upon in the SCVPH Opinions does not support the conclusion that the carcinogenic effects of melengestrol are related to a mechanism other than hormonal activity."[951]

7.827 The European Communities contests these comments, arguing that Dr. Boisseau interprets lack of data as lack of adverse effect.[952] We do not agree with the European Communities. The test to be met under Article 5.7 is that relevant scientific evidence be insufficient, and we have considered that, in this case, this implied that there be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. This is also the case for melengestrol acetate. We recall that JECFA evaluated this hormone on two occasions. This suggests that evidence has been at one point sufficient. Having regard to this context, we do not read the EC comment, nor any evidence presented in the course of these proceedings, as meeting the above-mentioned test.

Conclusion

7.828 Having regard to our specific conclusions above, we recall that the Appellate Body clarified in *Japan – Apples* that relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1. In this respect, we note that, at our request, the experts also expressed their views on the more general question whether the scientific evidence available at the time of the adoption of Directive 2003/74/EC and subsequently allowed the conduct of a risk assessment, in relation to meat from cattle treated, *inter alia,* with melengestrol acetate. Dr. Boobis replied that:

> "[T]here was sufficient information available to the EC to have enabled it to have conducted an assessment of the risks to human health arising from consumption of meat from cattle treated with any of the six hormones at issue."

7.829 We also note Dr. Guttenplan's comment with respect to JECFA's risk assessment that:

> "The assessment for melengestrol acetate seems sound. Thorough metabolic and estrogenic studies have been carried out."[953]

7.830 These general remarks support our conclusions on the specific elements discussed above. We therefore conclude that it is not established that the relevant scientific evidence is insufficient with respect to melengestrol acetate, within the meaning of Article 5.7 of the *SPS Agreement*.

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[950] IARC reply to question 25 of the Panel, Annex E-3, p. 129.
[951] Reply of Dr. Boisseau to question 16 of the Panel, Annex D, para. 162.
[952] EC's comments on the experts replies, question 16, Annex F-1, p. 13.
[953] Reply of Dr. Guttenplan to question 61 of the Panel, Annex D, para. 458.

(xii) Conclusion

7.831 We recall that we asked the scientific experts whether the scientific evidence relied upon by the European Communities supports the EC contention that the new scientific studies that have been initiated since 1997 have identified new important gaps, insufficiencies and contradictions in the scientific information and knowledge now available on these hormones such that more scientific studies are necessary before the risk to human health from the consumption of meat from cattle treated with these hormones for growth promotion purposes can be assessed.[954]

7.832 Three experts replied. In his written reply, Dr. Guttenplan saw several important gaps and gave examples. However, at the meeting with the Panel, he specified that, "on subsequent reading, [he] could not find anything to indicate adverse effect, and [he] now think[s] that risk assessment is alright."[955] He added that "the ability [to make a risk assessment] varies between compounds, but that does not mean you can't make a risk assessment, it just means the accuracy of the risk assessment is different."[956] The other two experts considered that "these new data [provided by the European Communities] [did] not demonstrate any important gaps, insufficiencies or contradictions in the scientific information used by JECFA for conducting its risk assessments" (Dr. Boisseau)[957], or that "[t]here was little information in the scientific studies initiated by the EC since 1997 that support the contention that they have identified important new gaps, insufficiencies and contradictions in the scientific information and knowledge on the hormones, and that additional studies are necessary before the risks to health of consumption of meat from treated animals can be assessed" (Dr. Boobis).[958] Dr. Boobis elaborated as follows:

> "Whilst additional information has been obtained on a number of aspects of the hormones in question, this was often not definitive, sometimes it was not relevant, in some instances it confirmed or expanded on previous knowledge. The evidence obtained did not indicate any additional concern regarding the risk from exposure to residues of the hormones in meat from cattle treated for growth promotion."

7.833 We also note that, at our meeting with experts, Dr. Cogliano and Dr. Boobis confirmed, in response to a question from the Panel, that the data were sufficient to perform a risk assessment based on ADI, as done by JECFA.[959]

7.834 We recall that the test we applied in this case was that there must be a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient. We note that the experts who expressed themselves in detail on this matter have confirmed, both in general and for each of the five hormones subject to a provisional ban, that such critical mass had not been reached.

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

7.836 We recall that all four of the requirements identified by the Appellate Body in *Japan – Agricultural Products II* with regard to the application of Article 5.7 of the *SPS Agreement* must be satisfied in order to adopt and maintain a provisional measure. The Appellate Body noted that the four

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[954] Panel question 62.
[955] Transcript of the Panel meeting with the experts, Annex G, para. 981.
[956] Transcript of the Panel meeting with the experts, Annex G, para. 983.
[957] Reply of Dr. Boisseau to question 62 of the Panel, Annex D, para. 460.
[958] Reply of Dr. Boobis to question 62 of the Panel, Annex D, para. 495.
[959] Transcript of the Panel meeting with the experts, Annex G, Dr. Cogliano, para. 871; Dr. Boobis, para. 873.

requirements are "clearly cumulative in nature". Since we found that the first requirement (the measure is imposed in respect to a situation where "relevant scientific evidence is insufficient") has not been satisfied, we do not find it necessary to address any of the three other requirements. We therefore conclude that the EC compliance measure does not meet the requirements of Article 5.7 of the *SPS Agreement* as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned.

7.837 Having reached that conclusion, we want to make clear that we only determined that it had not been established that the existing relevant scientific evidence was insufficient. This does not mean that no measure can be imposed by the European Communities under the *SPS Agreement* in relation to the five hormones at issue. Indeed, our determinations are without prejudice to the legality of any EC measure regarding these hormones, should the European Communities decide to complete its risk assessments pursuant to Article 5.1 of the *SPS Agreement*.

(g) Compatibility of the EC implementing measure with Article 3.3 of the *SPS Agreement* with respect to all hormones at issue with the exception of melengestrol acetate

Summary of the main arguments of the parties[960]

7.838 The **United States** argues that the European Communities' import ban is not "based on" international standards within the meaning of Article 3.3 as the relevant standards adopted by Codex permit trade in meat and meat products from cattle treated with hormones for growth promotion purposes by setting MRLs, as necessary, for residues of the hormones.[961]

7.839 The United States argues that, although Members may introduce or maintain sanitary 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, the European Communities is not permitted to do so because it does not satisfy the requirement in Article 3.3 that such stricter measures be in accordance with paragraphs 1 through 8 of Article 5. Specifically, the United States argues that because the European Communities measure is not based on a risk assessment within the meaning of Article 5.1, or otherwise satisfies the conditions for maintaining a provisional measure within the meaning of Article 5.7, the European Communities is acting contrary to Article 3.3.[962]

7.840 The United States contends that Article 3.3 of the *SPS Agreement* requires that Members base their measures on international standards where they exist and only permits Members to diverge from such standards if there is a scientific justification for doing so. For purposes of this dispute, the United States contends that such scientific justification could have taken the form of a properly conducted risk assessment for oestradiol. However, the United States believes it has demonstrated that the European Communities has failed to provide such a justification.[963]

7.841 The **European Communities** does not dispute that its ban on oestradiol-17β is not based on international standards, namely the Codex standard which requires no average daily intake or maximum residue levels for oestradiol-17β. Instead, the European Communities argues that it is permitted instead to prohibit the placing on the market, including a ban on imports, of meat and meat

[960] A more detailed account of the parties' arguments can be found in Section IV of the descriptive part of this Report. The order in which the respective arguments of the parties are presented does not reflect any allocation of the burden of proof by the Panel.
[961] US's first written submission, para. 163.
[962] US's first written submission, para. 164.
[963] US's replies to Panel questions after the second substantive meeting, Annex C-3, para. 27.

products treated with oestradiol-17β for growth promotion purposes because its decision is based on a comprehensive risk assessment, which is not in violation of Article 5.1 of the *SPS Agreement.*[964]

7.842 Additionally, the European Communities argues that it decided not to use the Codex standard on oestradiol-17β, because the Codex recommendations are not only old but also do not allow the European Communities to achieve the level of protection it considers appropriate in its territory.[965]

7.843 With respect to the other five hormones, the European Communities considers that it is possible, in the presence of an international standard, guideline or recommendation that is based on a risk assessment, to adopt a provisional sanitary measure on the grounds that the relevant scientific evidence is insufficient. A Member may disagree with the risk assessment for scientific reasons and, in particular, on the issue of whether the scientific evidence relied upon is sufficient. Such disagreement may stem from differences of views on scientific questions such as methodology, data interpretation etc. It may also result from the fact that in order to meet a higher level of protection, the Member concerned may require more information than what is provided in the risk assessment in question. As a concrete example, the JECFA study referred to by the defending parties did not take into account the data obtained in the seventeen studies which had been performed upon the initiative and with the funding of the European Communities.[966]

Reasoning of the Panel

7.844 Article 3.3 reads as follows:

> "Members may introduce or maintain sanitary ... 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 ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[967] Notwithstanding the above, all measures which result in a level of sanitary ... 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."

7.845 We concluded above that the European Communities did not comply with Article 5.1 and with Article 5.7 of the *SPS Agreement*. In light of our mandate and of our objectives in engaging in a review of the conformity of the EC implementing measure with the *SPS Agreement*, we see no reason to reach a conclusion on Article 3.3 of the *SPS Agreement*, to the extent that this conclusion depends on a violation of Article 5.

7.846 We therefore refrain from drawing any conclusion with respect to Article 3.3 of the *SPS Agreement*.

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[964] EC's second written submission, paras. 213-214.

[965] EC's second written submission, para. 119; EC's replies to Panel questions after the first substantive meeting, Annex B-1, para. 129.

[966] EC's replies to Panel questions after the first substantive meeting, question 72, Annex B-1.

[967] (*footnote original*) For the purpose 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 ... protection.

(h) Conclusion on Article 22.8 of the DSU

7.847 For the reasons stated above, we conclude that it has not been established that the European Communities has removed the measure found to be inconsistent with a covered agreement.

7.848 We also note that the European Communities does not claim that it has provided a solution to the nullification or impairment of benefits suffered by the United States within the meaning of Article 22.8 of the DSU.

7.849 None of the parties has claimed that a mutually satisfactory solution had been found in the context of the *EC – Hormones* case.

7.850 For these reasons and those developed above, we find that the European Communities did not demonstrate a breach of Article 22.8 of the DSU by the United States.

4. Violation of Articles 23.1 and 3.7 of the DSU

7.851 The Panel recalls its understanding that violations of Articles 23.1 and 3.7 were only claimed in relation to the violation of Article 22.8 of the DSU. To the extent that Article 22.8 has not been breached, the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU. The Panel concludes that there is no violation of Articles 23.1 and 3.7 of the DSU by the United States as a result of a breach of Article 22.8.

D. VIOLATION OF ARTICLE I.1 AND ARTICLE II OF THE GATT 1994

7.852 The European Communities has claimed that there is a violation of Articles I:1 and II of the GATT 1994 because the US continued suspension of obligations could not be justified anymore under Article 22 of the DSU.

7.853 In light of our conclusions above, we see no basis to make findings in relation to these claims.

E. CONDITIONAL CLAIM OF VIOLATION OF ARTICLE 22.8 OF THE DSU MADE IN THE ALTERNATIVE

7.854 We recall that the European Communities also raised a *conditional* claim of violation of Article 22.8 of the DSU *per se.* The European Communities specified in its first written submission that this claim was "made in the alternative and only on the condition that the Panel does not establish any violation under Articles 23.1, 23.2(a), 3.7, 22.8 and 21.5 of the DSU".[968]

7.855 We note that we have established a violation of Article 23.1 and 23.2(a). We also recall that we have already addressed the alleged violation of Article 22.8 of the DSU as part of our review of the EC claim of violation of Article 23.1 read together with Article 22.8 and Article 3.7 of the DSU. Under those circumstances, it is not necessary for the Panel to address the conditional claim of violation 22.8 of the DSU *per se* in the alternative.

F. CONCLUSION

7.856 For the reasons set forth in this report, the Panel concludes that, with respect to the claims of the European Communities concerning the violation of Article 23.2(a) read together with Articles 21.5 and 23.1 of the DSU, the United States made the following procedural violations:

[968] EC's first written submission, para. 132.

(a) by seeking, through the measure at issue – that is the suspension of concessions or other obligations subsequent to the notification of the EC implementing measure (Directive 2003/74/EC) – the redress of a violation of obligations under a covered agreement without having recourse to, and abiding by, the rules and procedures of the DSU, the United States has breached Article 23.1 of the DSU;

(b) by making a determination within the meaning of Article 23.2(a) of the DSU to the effect that a violation had occurred without having recourse to dispute settlement in accordance with the rules and procedures of the DSU, the United States has breached Article 23.2(a) of the DSU.

7.857 In addition, having addressed the claims raised by the European Communities concerning Article 23.1 read together with Articles 22.8 and 3.7 of the DSU based on the considerations mentioned above[969], the Panel concludes that:

(a) to the extent that the measure found to be inconsistent with the *SPS Agreement* in the *EC – Hormones* dispute (WT/DS26) has not been removed by the European Communities, the United States has not breached Article 22.8 of the DSU;

(b) to the extent that Article 22.8 has not been breached, the European Communities has not established a violation of Articles 23.1 and 3.7 of the DSU *as a result of a breach of Article 22.8*.

VIII. RECOMMENDATIONS

8.1 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The United States failed to rebut this presumption. Therefore, to the extent the United States has acted inconsistently with its obligations under the DSU, it must be presumed to have nullified or impaired benefits accruing to the European Communities under that Agreement.

8.2 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the United States to bring its measure into conformity with its obligations under the DSU.

8.3 Whereas it is for the Members to decide on the appropriate steps needed to bring measures found in breach of their WTO obligations into conformity, the Panel deems it important to recall its conclusion in paragraph 7.251 as the parties have apparently diverging opinions as to how this report should be implemented by the respondent. As already mentioned, while the Panel performed functions similar to that of an Article 21.5 panel, this was done only in order to determine whether Article 22.8 of the DSU had been breached. This Panel was not called upon, nor does it have jurisdiction, to determine the compatibility of Directive 2003/74/EC with the covered agreements. In that context, the Panel suggests that, in order to implement its findings under Article 23 and in order to ensure the prompt settlement of this dispute, the United States should have recourse to the rules and procedures of the DSU without delay.

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[969] See Section VII.C.2 and Section VII.C.3(a), (b) and (c) above.