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CANADA – CONTINUED SUSPENSION OF OBLIGATIONS IN THE EC – HORMONES DISPUTE

Report of the Panel

Addendum

This addendum contains Annex B to the Report of the Panel to be found in document WT/DS321/R. The other annexes can be found in the following addenda:

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ANNEX B

REPLIES OF THE PARTIES TO QUESTIONS POSED BY THE PANEL AND OTHER PARTIES AFTER THE FIRST SUBSTANTIVE MEETING

ANNEX B–1

REPLIES OF THE EUROPEAN COMMUNITIES TO QUESTIONS POSED BY THE PANEL AFTER THE FIRST SUBSTANTIVE MEETING

(3 October 2005)

TABLE OF CASES

Short Title	Full Case Title and Citation
Australia – Salmon	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
Brazil – Aircraft	Appellate Body Report, *Brazil – Export Financing Programme for Aircraft*, WT/DS46/AB/R, adopted 20 August 1999, DSR 1999:III, 1161
Canada – Aircraft (Article 21.5 – Brazil)	Panel Report, *Canada – Measures Affecting the Export of Civilian Aircraft – Recourse by Brazil to Article 21.5 of the DSU*, WT/DS70/RW, adopted 4 August 2000, as modified by the Appellate Body Report, WT/DS70/AB/RW, DSR 2000:IX, 4315
EC – Export Subsidies on Sugar	Appellate Body Report, *European Communities – Export Subsidies on Sugar*, WT/DS265/AB/R, WT/DS266/AB/R, WT/DS283/AB/R, adopted 19 May 2005
EC – Hormones	Appellate Body Report, EC *Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
EC – Sardines	Appellate Body Report, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, adopted 23 October 2002
India – Patents (US)	Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, adopted 16 January 1998, DSR 1998:I, 9
Japan – Apples (Article 21.5 – US)	Panel Report, *Japan – Measures Affecting the Importation of Apples, Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW, 23 June 2005
Korea – Procurement	Panel Report, *Korea – Measures Affecting Government Procurement*, WT/DS163/R, adopted 19 June 2000, DSR 2000:VIII, 3541
US – Certain EC *Products*	Appellate Body Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/AB/R, adopted 10 January 2001
US – FSC	Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations"*, WT/DS108/AB/R, adopted 20 March 2000, DSR 2000:III, 1619
US – FSC (Article 21.5 II – EC)	Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities*, WT/DS108/AB/RW2, not yet adopted
US – Hot-Rolled Steel	Appellate Body Report, *United States – Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan*, WT/DS184/AB/R, adopted 23 August 2001, DSR 2001:X, 4697
US – Offset Act (Byrd Amendment)	Appellate Body Report, *United States – Continued Dumping and Subsidy Offset Act of 2000*, WT/DS217/AB/R, WT/DS234/AB/R, adopted 27 January 2003
US – Shrimp	Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
US – Wool Shirts and Blouses	Panel Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/R, adopted 23 May 1997, as upheld by the Appellate Body Report, WT/DS33/AB/R, DSR 1997:I, 343

Q1. In their first submissions, Canada and the United States argue that the European Communities could have had recourse to Article 21.5 of the DSU. Could the EC explain why it did not have recourse to Article 21.5 of the DSU? Did the EC consider seeking a decision of the DSB abrogating the authorization to suspend concessions or other obligations granted to Canada and the United States by the DSB on 26 July 1999? If not, why?

1. The European Communities considers that an implementing Member cannot have recourse to Article 21.5 of the DSU in order to confirm the WTO-consistency of its compliance measure. The European Communities has already explained that the dispute settlement system is based on contradictory proceedings where a WTO Member claims the *inconsistency* of a measure of another WTO Member. On the other hand, the dispute settlement proceeding is not appropriate to request an abstract confirmation of the *consistency* of a measure.[1]

2. This understanding is confirmed by the very notion of the DSU as a "dispute" settlement system. Moreover, this basic logic is also reflected in Articles 1.1, 3.3, 3.12, 4.4, 4.7 and 6 of the DSU.

3. The WTO dispute settlement system is based on the "Understanding on Rules and Procedures Governing the Settlement of Disputes". The word "dispute" indicates that the WTO proceedings are designed to resolve differences between WTO members. Thus, the *New Shorter Oxford English Dictionary* defines a "dispute", *inter alia*, as "a disagreement in which opposing views are strongly held".[2]

4. Consequently, the DSU is not designed to seek an abstract confirmation of the WTO-consistency of a measure in the absence of a challenge by another Member. Unlike other legal systems, the DSU does not provide for an objective procedure whereby a WTO Member could ask a Panel for an opinion about its measure.

5. The structure and the definition of the scope of application of the DSU confirm this principle. Under Article 1.1, the DSU

> (…) shall apply to disputes brought pursuant to the consultation and dispute settlement provisions of the (…) [covered] agreements (…). The rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations under the provisions of (…) this Understanding.

6. Thus, it is clear that the assertion "there is WTO-consistency (notably with the *SPS Agreement*)" would not be a "dispute" related to rights and obligations under the DSU, but one related to rights and obligations under the *SPS Agreement*. It would also not be possible to consider this as a basis for a "dispute" under Article 11.1 of the *SPS Agreement* and Article XXIII:1(a), (b) or (c) of the GATT. Therefore, the European Communities does not even see how the DSU would apply to such a self-initiated procedure under Article 21.5 of the DSU.

7. Article 3.3 of the DSU further confirms that the dispute settlement system is based on contradictory proceedings. Article 3.3 provides that:

> The prompt settlement of situations in which a Member considers that *any benefits accruing to it directly or indirectly under the covered agreement are being impaired by measures taken by another Member* is essential to the effective functioning of the

[1] EC Oral Statement, para. 54.
[2] *The New Shorter Oxford English Dictionary*, Vol. 1, 1993, p. 701.

> WTO and the maintenance of a proper balance between the rights and obligations of Members. (Emphasis added)

8. Thus, Article 3.3 assumes a scenario where one Member challenges the measure of another Member because the complaining member considers its rights being affected. Conversely, Article 3.3 does not address the situation where a Member is complaining against its own measure. In fact, unless one assumes that WTO members act in a schizophrenic manner they would not consider that "any benefits accruing to it (…) are being impaired".

9. Furthermore, Articles 6, 3.12, 4.4 and 4.7 of the DSU have in common that they refer to a "complaining party" and/or "a complaint". The use of these terms demonstrates again that the DSU is based on contradictory proceedings.[3]

10. The term "complaining party" derives from the word "to complain" which is defined in the *New Shorter Oxford Dictionary* as "bewail, lament, express dissatisfaction, formal statement of a grievance, bring a charge".[4] The European Communities fails to see how a Member who seeks confirmation of the WTO-consistency of the measure could fall under this ordinary meaning of the word. Indeed, this WTO-Member would just do the opposite of "complaining" against its measure.

11. The European Communities would note that the notion of a "complaining party" logically also requires a "defending or responding party" (or in the words of the working procedures "the party complained against"). Even if one assumes for the sake of the argument that the European Communities could be a "complaining party" in a self-initiated Article 21.5 proceeding, the European Communities fails to see how the United States and Canada could be considered as "defending parties" or as "parties complained against". Certainly, the United States and Canada would not "defend" the EC's compliance measure. In the same vein, the European Communities would not consider the United States and Canada as parties against which it had brought a complaint against the EC compliance measure. Also, a self-initiated Article 21.5 dispute would not cover the retaliatory measures which the United States and Canada are applying against the European Communities, because these measures are not the "measures taken to comply" over whose existence or WTO-compatibility there is a disagreement.

12. In this context, the European Communities is also wondering whether the United States and Canada as "defending party" would be obliged to participate in such proceedings. Indeed, in the only ever self-initiated compliance proceeding (*EC – Bananas III – Article 21.5 (EC)*) the United States (and other original complainants) explicitly refused to do so and the panel stated that it was unable to force them to do so. Even in the current proceeding the United States did not explicitly confirm that it would participate in an Article 21.5 proceeding if self-initiated by the European Communities.

13. In similar vein, Articles 6, 3.12 and 4.4 refer to the term "*complaint*". This word is defined in the *New Shorter Oxford Dictionary* as "a lamentation, a plaint, a formal accusation or charge".[5] Yet, by requesting an Article 21.5 compliance Panel, the European Communities would not make "a plaint" or bring "a formal accusation or charge" against its own measure. Rather, the opposite is the case.

14. In this context, it is also relevant to consider the past practice of WTO members in Article 21.5 proceedings. Since the establishment of the WTO until August 2005 there have been sixteen Article 21.5-proceedings. Fifteen out of these sixteen proceedings had been initiated by the original complaining Party which disagreed with a compliance measure. All of these 15 proceedings

[3] *See* also Article 9 of the DSU on multiple complainants.
[4] *The New Shorter Oxford English Dictionary*, Vol. 1, 1993, p. 459.
[5] *The New Shorter Oxford English Dictionary*, Vol. 1, 1993, p. 459.

worked in that they resulted in violation findings or in findings that the compliance measure was not inconsistent with the invoked provisions. The only exception where the Article 21.5 proceeding has been initiated by the original respondent was the case *EC – Bananas III (Article 21.5 (EC))*. For the reasons already mentioned above, this proceeding did not work. Also, this report was never adopted and it has therefore no legal status. Rather the non-adoption of this report confirms that the WTO Members did not agree with the approach undertaken at the time by the European Communities. In the European Communities' view, this subsequent practice is relevant for the correct interpretation of Article 21.5 of the DSU in accordance with Article 31.3(b) of the Vienna Convention of the Law of the Treaties.

15. Finally, an Article 21.5 proceeding initiated by the European Communities would not affect the DSB authorization because an Article 21.5 panel only has jurisdiction to rule on the question of compliance. It would certainly not make sense to go through an Article 21.5 process in order to subsequently launch yet another case like the present one in order to challenge any continuing sanctions.

16. In respect of the second half of the question on whether the European Communities sought a DSB decision abrogating the DSB authorization, the answer is no. The DSU does not provide for a legal basis for the DSB to do so nor a decision-making procedure. For instance, Article 2 of the DSU (which defines the tasks of the DSB) only mentions the right of the DSB to authorize the suspension of concessions. But it does not address the withdrawal of the DSB authorization. Thus, as Article 2.4 of the DSU refers only to explicit provisions under which the DSB may take a decision and in the absence of such a provision regarding the withdrawal of the DSB authorization the European Communities did not pursue this road.

17. The European Communities would assume that the absence of any provision on the abrogation of a DSB authorization may be also one reason why in those cases where a DSB authorization has been granted this authorization has never been withdrawn.[6]

18. The only DSU provision dealing with an end of the sanctions is Article 22.8. Yet, as already explained this provision concerns the *application* of sanctions. Even Article 22.8 does not contain any indication regarding the fate of the DSB authorization once the conditions under Article 22.8 are fulfilled.

19. Finally, even if a DSB authorization could be terminated, positive consensus would apply, Article 2.4 of the DSU. Thus, any attempt would have been unlikely to work and certainly would not have worked in the current circumstances. Since the United States and Canada determinated that the EC compliance measure was WTO-inconsistent both WTO members would have blocked any positive consensus in the DSB.

Q2. Does the European Communities agree that, under the DSU as it currently stands, there is no restriction on any party to initiate Article 21.5 proceedings? if not, could the EC elaborate on the legal, procedural or technical reasons which make it impossible or ineffective for a given party to a dispute to have recourse to Article 21.5 of the DSU?

20. Article 21.5 of the DSU does not itself mention who is to initiate the compliance review. However, Article 21.5 expressly refers to the DSU procedures ("these dispute settlement procedures"), which includes, *inter alia*, Article 6, i.e. the legal basis for the DSB to establish panels

[6] The European Communities would refer in particular to the case *Brazil – Aircraft*, WT/DS46, where the DSB authorized the suspension of concessions. This authorization was not revoked despite the fact that the DSB adopted the second Article 21.5 compliance Panel Report and which found the Brazil' compliance measure as WTO consistent.

on the basis of a complaint. Thus, as pointed out under Question 1 it is clear from the context, the object and purpose of the DSU and subsequent practice by WTO Members that it is for a complaining Member to challenge the WTO-consistency of a compliance measure by initiating the proceedings under Article 21.5 of the DSU. Moreover, in our reply to Question 1 the European Communities has also explained why a recourse to Article 21.5 by an original responding party would be ineffective.[7]

Q3. Could the European Communities comment on the "endless loop of litigation" argument made by the United States in paragraph 9 of its first written submission?

21. In paragraph 9 of the US First Written Submission, the United States argues that the EC interpretation of Article 21.5 of the DSU an implementing Member can create an "endless loop of litigation".

22. The European Communities considers that such a scenario is misplaced. In fact, an "endless loop of litigation" due to a "mere declaration of compliance" presupposes that a complying Member adopts a sort of "sham measure" which consequently would be found inconsistent in an Article 21.5 proceeding. The complying Member would consequently enact a second "sham measure" which would then again be found to be WTO-inconsistent under an Article 21.5 proceeding. According to the United States this could go on forever.

23. One does not need a lot of imagination to realize that this scenario is pure science fiction. Indeed, it is based on the very hypothesis that a complying Member would constantly act in bad faith. Such an assumption is certainly not reflected in any past WTO experience. But in addition, the US' argument turns on its head the fundamental principle in the WTO that WTO Members should not be presumed to act in bad faith. Yet, WTO-Members should not be assumed lightly to take a risk of losing their credibility by making in bad faith "mere declarations of compliance". Indeed, under the same logic one could argue that the US' refusal to initiate an Article 21.5 proceeding would create an "endless loop of sanctions".

24. Moreover, as the European Communities has highlighted in its Closing Statement of the First Substantive meeting, Members do not engage in dispute settlement proceedings in order to lose them needlessly and ignominiously.

25. That said, the scenario described by the United States is also completely irrelevant in the present case. While the United States and Canada disagree with the EC compliance measure they have also clearly stated that they do not contest that the European Communities has acted in good faith. Thus, the very basis for the US' theory of an endless loop of litigation does not apply in the present circumstances.

Q4. In its first written submission, the European Communities claims that it should benefit from a presumption of good faith compliance. Canada and the United States have argued against such a presumption and have further argued that the EC compliance measure is in breach of Articles 3.3, 5.1 and 5.7 of the *SPS agreement.*

(a) Could the European Communities comment on the US statement in footnote 124 of the first US written submission?

26. In footnote 124 of its First Written Submission the United States is confused about the use of the terms "principle of good faith" and "presumption of good faith". Furthermore, the United States tries to limit the scope of the principle of good faith to the issue of "burden of proof".

[7] *See* also EC reply to Question 62 regarding the burden of proof under a self-initiated Article 21.5 proceeding.

27. In respect to the relationship between the "principle of good faith" and the "presumption of good faith" the European Communities would refer to its reply in Question 61.

28. As far as the issue of burden of proof is concerned, the European Communities considers that the US' view does not encompass the full scope of the principle of good faith. Indeed, this general principle is well recognized under public international law and the WTO Agreement.

29. The DSU refers in several instances to the principle of good faith, for instance in Articles 3.10 or 4.3 of the DSU. These provisions are unrelated to the issue of "burden of proof".

30. Moreover, the Appellate Body at several occasions expressed the broad nature of the principle of good faith under the WTO Agreement. In *United States – Hot Rolled Steel* from Japan the Appellate Body found

> We see this provision [under the Anti-Dumping Agreement] as another detailed expression of the principle of good faith, which is, at once a general principle of law and a principal of general international law, that informs the provisions of the *Anti-Dumping Agreement*, as well as the other covered agreements.[8]

31. Furthermore, in the case *United States – CDSOA (Byrd Amendment)* the Appellate Body decided that

> The performance of treaties is also governed by good faith.[9]

32. The European Communities would quote from the dispute *European Communities – Sugar*. In this case, the Appellate Body found that

> [The principle of good faith] covers, in our view, the entire spectrum of dispute settlement, from the point of initiation of a case through implementation.[10]

33. Finally, the European Communities would recall the Appellate Body decision in *European Communities – Sardines*:

> "We must assume that Members of the WTO will abide by their treaty obligations in good faith, as required by the principle of *pacta sunt servanda* articulated in Article 26 of the *Vienna Convention.* And, always in dispute settlement, every Member of the WTO must assume the good faith of every other Member."[11] (Footnote omitted)

34. All these cases were unrelated to the issue of "burden of proof".

35. Against this background the European Communities considers that the US' approach to limit the scope of the principle of good faith to the issue of burden of proof falls far short of its actual meaning under the DSU, public international law and the jurisprudence of the Appellate Body or other relevant international bodies.

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[8] Appellate Body Report, *United States – Hot Rolled Steel from Japan*, para. 101.
[9] Appellate Body Report, *United States – Offset Act (Byrd Amendment)*, para. 296.
[10] Appellate Body Report, *European Communities – Export Subsidies on Sugar*, para. 312.
[11] Appellate Body Report, *European Communities – Trade Description of Sardines*, para. 278. Article 26 of the Vienna Convention reads as follows: "Every treaty in force is binding upon the parties to it and must be performed by them in good faith".

(b) Does the European Communities consider that the presumption of good faith compliance it invokes is irrebutable? if not, does it agree that Canada and the United States could submit arguments to rebut that presumption and that it may in return have to provide evidence to support its claim that its compliance measure is compatible with the SPS agreement?

36. The presumption of good faith is rebuttable. However, such a rebuttal can only take place in the appropriate forum. In the present case, this means that the United States and Canada must challenge the EC measure under an Article 21.5 proceeding if they seek a determination that the EC compliance measure is WTO-inconsistent. Conversely, the United States and Canada cannot rebut the presumption of good faith in the present systematic proceedings under Article 22.8 in conjunction with Article 23.1 of the DSU.

37. As already explained, this dispute is about procedural and systemic issues under the DSU. More specifically, this case is about the US' and Canada's unilateral determination that the EC compliance measure is inconsistent, and based on this determination the US' and Canada's continued suspension of concessions and related obligations.

38. This violation by the United States and Canada is independent of the EC compliance measure. Even if the United States and Canada were able to rebut the presumption of good faith compliance, *quod non*, they would still be in violation of Articles 23, 21.5 and 22.8 of the DSU. This is so because they would still have made a unilateral determination of non-compliance and continued to apply sanctions contrary to relevant DSU provisions at the time of the establishment of the Panel. Conversely, the United States and Canada cannot mend this procedural and systematic failure to respect the dispute settlement rules by arguing now about the EC compliance measure.

39. In its Oral Statement the European Communities has asked a simple question which elucidates this point further: Can the United States and Canada contest that the inconsistency of the measure has been removed (Article 22.8) without violating Article 23 if they do not have recourse to WTO dispute settlement[12]? The simple answer is no. Indeed, by contesting that the inconsistency of the measure has not been removed, the United States and Canada are determining unilaterally that the EC measure is WTO-inconsistent. And since they apply sanctions on that basis they are in violation of Articles 23.1, 23.2(a), 21.5 and 22.8 of the DSU. Thus, whether or not the EC measure is *later* to be found WTO-consistent under the proper proceeding has no effect on the *current* violations by the United States and Canada.

(c) Could the European Communities explain whether the responding parties are entitled to the same presumption of good faith application of the retaliatory measures? If not, why?

40. The United States and Canada can also rely on the presumption of good faith for the application of sanctions. However, the principle of good faith requires the United Sates and Canada to apply the DSU in good faith and therefore to initiate Article 21.5 proceedings against the European Communities within a reasonable period of time if they disagree with the EC's view that it is now in compliance. Yet, the United States and Canada have not done this and they even refuse to consider bringing an Article 21.5 proceeding.

41. By bringing this case against the United States and Canada the European Communities has rebutted the presumption that the United States' and Canada's measures are adopted in good faith.

[12] EC Oral Statement, para. 57.

Indeed, the European Communities made a *prima facie* case on why the application of the sanctions by the United States and Canada is in violation of the DSU.

42. The European Communities would note that this situation is normal for every other WTO proceedings. A complaining Member challenging a measure of another Member has to present a *prima facie* case in order to rebut the presumption of good faith. Conversely, until the DSB makes a finding of WTO-inconsistency no Member can be considered to be in violation of its WTO obligations. Thus, every WTO Member enjoys the presumption of good faith or, in other words, the benefit of the doubts.

43. Yet, the problem in the present case is precisely that the United States and Canada are refusing to bring a dispute settlement case to complain against the EC compliance measure. Thus, due to this refusal they cannot rebut the presumption of good faith compliance in the current proceedings, which the European Communities has brought against the United States' and Canadian measures.

Q5. Could the European Communities specify whether it maintains its claim under Article 23.2(c), or whether it limits its claims under Article 23 to violations of Article 23.1 and 23.2(a)? Likewise, does the European Communities consider that it has "provided a solution to the nullification or impairment of benefits" to the United States (see US first written submission, para. 105)?

44. The European Communities does not maintain its claim under Article 23.2(c) because it does not add anything to the violation claims that are pursued.

45. The European Communities has "provided a solution to the nullification or impairment of benefits" to the United States. By removing the inconsistency of the old measure, the European Communities has removed any nullification or impairment of benefits to the United States that previously resulted from a violation (see Article 11.1 of the *SPS Agreement* and Article XXIII:1(a) of the GATT 1994).

46. Contrary to what the United States obviously believes, the United States has no right to see the import ban lifted. It has only a right to see that the EC measure fulfils the conditions set out under the *SPS Agreement*. Since the adoption of Directive 2003/74/EC this is the case. Consequently, the United States (and Canada) currently does not suffer any nullification or impairment as a result of a violation. All the more it is therefore illegal to continue to apply sanctions as if the US' and Canada's benefits were still being nullified or impaired, and as if, therefore, the United States and Canada were "rebalancing rights and obligations". Indeed, what we currently see is that two WTO Members assume an *additional* right under the DSU to apply sanctions against another WTO Member merely on the basis of a unilateral determination of non-compliance.

Q6. The United States argues in paragraph 200 of its first written submission that there is no basis for concluding that Article 21.5 of the DSU imposes on the original complaining Members a greater burden than on the Member already found to breach its WTO obligations and which has failed to implement the DSB recommendations and rulings by the conclusion of the reasonable period of time. Could the EC comment on this argument?

47. The European Communities can only speculate about what the United States has in mind when it pretends that the EC approach would impose under an Article 21.5 proceeding "a greater burden" on the original complaining Member than on the complying Member. The European Communities does not ask for more than what is the logic under Article 21.5 and what has been the constant practice by WTO Members (see our reply to question 1). If the United States considers this ordinary approach as a "greater burden" for the original complaining party so be it. The European

Communities has readily accepted such a "greater burden" for instance in the latest Article 21.5 proceedings concerning *FSC*. Similarly, any other WTO Member, including by the way the United States, has assumed such a "greater burden" in other proceedings. The burden is merely that of a complainant who challenges the WTO-compatibility of measures of other Members.

48. Furthermore, the European Communities would also recall that in the current circumstances the obligation to initiate an Article 21.5 proceeding results from Article 23.1, 23.2(a) of the DSU. Thus, if the United States were not presently applying sanctions as if nothing had happened, the European Communities would not ask this Panel to put the "burden" to initiate a compliance case on the United States.

49. That said, the European Communities would strongly object to the link the United States tries to establish between an Article 21.5 proceeding and the question on whether or not a WTO Member was able to implement the DSB recommendations and rulings within the reasonable period of time. Indeed, these are two completely different issues. Article 21.5 applies to "measures taken to comply". This provision does not make any reference to whether the measure was taken within or outside the reasonable period of time.

Q7. With regard to the European Communities claim of presumption of good faith compliance, how would the European Communities avoid the risk of not distinguishing between meritorious and purely illusory measures purportedly taken to comply as mentioned by Canada in paragraph 62 of its first written submission?

50. The European Communities has already addressed this issue under Question 3. As said above, WTO Members should not be presumed to adopt in bad faith meritorious and purely illusory measures.

51. Moreover, in the present case, all parties and third parties agree that the EC compliance measure is neither meritorious nor purely illusory. Therefore, even though this question may be of certain academic interest it is not necessary to answer to this question in order to resolve the present dispute.

Q8. If the Panel were to address the EC's alternative claim of violation of Article 22.8 of the DSU, do you think it may rely on the presumption of good faith compliance to consider *how* the burden of proof is to be discharged by each party in its examination of the Article 22.8 claim?

52. Yes. The presumption of good faith also applies to the question on how the burden of proof is to be discharged. Since the United States and Canada are contesting the removal of the inconsistency of the measure, they would have to make a *prima facie* case on the WTO-inconsistency of the EC compliance measure. This is the normal procedural rule in WTO proceedings where it is for a Member which contests the WTO-consistency of another Member's measure to bear the burden of proof.

53. The European Communities would add that it has, in its conditional claims, not only invoked Article 22.8 of the DSU, but also Article I:1 and II:1 of the GATT 1994, for which the *prima facie* case of a violation cannot be denied by the United States and Canada. The consequence is that the United States and Canada must invoke a defence and establish and prove that all conditions of that defence are satisfied. Because of Article 22.8, these conditions notably include that there is an ongoing violation of WTO law by the European Communities.

Q9. Could the European Communities comment on the statement of the United States in paragraphs 97-98 of the first US written submission? In particular, could the European

Communities explain why, in the *US – FSC* case, it apparently did not suspend or terminate its suspension of concessions retroactively on 24 November 2004?

54. On 24 November 2004, the United States announced in the DSB that the President had signed into law the American Jobs Creation Act of 2004. At this occasion the US' representative declared that "the repeal of the ETI provision was effective for transactions occurring after 31 December 2004."[13]

55. Thus, on 24 November 2004 the United States declared in the DSB that its compliance measure would only be effective as from 1 January 2005. Conversely, the United States did not argue that it was in compliance as from 24 November 2004. Therefore, the European Communities suspended the application of the sanctions against the United States as from 1 January 2005, the date when the US' compliance measure came into effect.

Q10. Could the European Communities comment on the statement of Canada in paragraphs 40-41 and 61 of Canada's first written submission?

56. In paragraph 40 Canada submits that the European Communities is under an ongoing obligation to comply subject to the surveillance by the DSB. In paragraph 41, Canada argues that its sanctions are due to the DSB authorization by definition WTO-consistent. In order to ensure the security and predictability of the DSU only the DSB can terminate the authorization. Finally, in paragraph 61, Canada maintains that the European Communities could enjoy the presumption of compliance before the adoption of the DSB authorization. Yet, this presumption yields to the DSB authorization.

57. As to the first point, the European Communities does not agree that it is still under an ongoing obligation to comply since the European Communities has already complied. Of course, the European Communities understands that Canada is in disagreement on this point but Canada should then have launched an Article 21.5 proceeding. The failure to do so amounts in the present circumstances to a unilateral determination of non-compliance which is inconsistent with Articles 23.1, 23.2(a) and Article 21.5 of the DSU.

58. Regarding the second point, the European Communities has explained in detail that the DSB authorization does not make the application of sanctions "by definition" WTO-consistent: Article 22.8 of the DSU clearly provides that the application of sanctions is conditional upon, *inter alia*, the continued existence of inconsistency. Once the inconsistency has been removed the application of sanctions shall be terminated. This obligation is self-executing. That is, it must be applied spontaneously and does not require any further determination by the DSB.[14] In this respect, the European Communities has also submitted that the DSB authorization cannot be seen in an isolated way. Rather, the DSB authorization needs to be put into its proper context, in particular it cannot be possible to allow the application the DSB authorization irrespective whether the underlying reason, i.e. the WTO-inconsistency of the old measure, still exists.[15]

59. Furthermore, if Canada's (and the US') approach were correct a panel could never find a violation of Article 22.8 precisely because the defending parties claim that the application of the sanctions is "by definition" WTO-consistent. A panel could never come to a recommendation that the sanctions should not be applied any longer, if at the same time the DSB authorization would make the application of the sanctions "by definition" WTO-consistent. The only way for a panel to overcome this barrier and to reach a recommendation that sanctions should not be applied any longer would be

[13] WT/DSB/M/178.
[14] EC First Written Submission (WT/DS321), para. 93. EC Oral Statement, para. 118.
[15] EC First Written Submission (WT/DS321), paras. 104 *et seq.*; EC Oral Statement, paras. 110 *et seq.*

therefore to conclude that the DSB authorization cannot justify "by definition" the application of sanctions.

60. The European Communities would note that the United States and Canada are rather illogical on this point: On the one hand, when it comes to the violation claim under Article 21.5, 23.1, the defending parties have argued during the First Substantive meeting that the European Communities could bring an Article 22.8 case in order to get the sanctions lifted. On the other hand, when it comes to the violation claim under Articles 22.8 (23.1) the defending parties argue that there can not be any violation because of the DSB authorization. However, if the latter were true, the former would not work.

61. The inherent flaws of the US' and Canada's logic come from the fact that they do not properly distinguish between the existence of the DSB authorization and the application of the sanctions. As explained above, the DSU does not provide for any mechanism for the formal revocation of the DSB authorization. It does, however, provide for a self-executing provision on the application of the suspension of obligations pursuant to a DSB authorization. And this application is not "by definition" WTO-consistent but subject to certain conditions, i.e. the continued inconsistency of the measure.

62. Finally, in respect to para. 61 of Canada's First Written Submission the European Communities has also already explained that the presumption of compliance is in no way affected by the existence of a DSB authorization.[16]

Q11. Could the European Communities comment on the statement of the United States in paragraph 187 of the first US written submission?

63. In paragraph 187 of the US First Written Submission, the United States argues that the European Communities' interpretation of Article 23.2(a) would force a complaining Member into a breach of this provision if it does not immediately agree with the measure or launch an Article 21.5 proceeding.

64. The European Communities replied to this argument in paras. 47 and 48 of its Oral Statement. In fact, the United States seems to get carried away by referring to an alleged need to make an "immediate" determination regarding the WTO-consistency of a compliance measure. Yet, this is not the case before us. Almost two years have passed since the European Communities has adopted its measure in October 2003. Moreover, this measure did not come out of the blue. In November 2000, the European Communities had already notified the legislative proposal to the WTO SPS Committee.[17] Thus, until today the United States and Canada had almost five years to make up their mind on the WTO-consistency of the (proposed) measure. And still they pretend not to have made any determination to this effect and to be unable to do so. Moreover, the United States even denies that there is a "disagreement" with the European Communities on the consistency of the measure within the meaning of Article 21.5.[18]

65. What the United States conveniently overlooks is the fact that since all that time it applies sanctions against EC products. This is indeed a special situation. If the United States were not applying sanctions the European Communities would certainly not be concerned about whether the

[16] EC First Written Submission (WT/DS321), paras. 104 *et seq.*

[17] G/SPS/N/EEC/102 and G/SPS/N/EEC/102 Rev. 1.

[18] Surprisingly, this does not prevent the United States to argue that the European Communities could have brought an Article 21.5 case. But if it were true that there is no disagreement between the United States and the European Communities on what basis could the European Communities then have initiated an Article 21.5 proceeding?

United States needs another five years to come to a conclusion about the WTO-consistency of the EC compliance measure.

66. A retaliating Member has at a minimum a good faith obligation to assess within a reasonable delay the compliance measure. And if it is unable to do so it should suspend the sanctions. If this had been the case the European Communities would certainly not have initiated these proceedings. But the sluggishness of a retaliating Member cannot be at the expense of an implementing Member that has made every effort to comply with its obligations.

Q12. Could the European Communities comment on the US interpretation of "these dispute settlement proceedings" in Article 21.5 of the DSU (see first US written submission, paras. 193 and 199-201)?

67. The European Communities has a different understanding of Article 21.5. In its view Article 21.5 provides for a proper compliance proceeding. The term "these dispute settlement proceedings" encompass the normal rules that apply for dispute settlement proceedings in general such as for instance Article 4 or 6.[19]

68. That said, the European Communities does not disagree that the DSU also provides for other proceedings other than Article 21.5. This could be, for instance, Article 25. However, as explained in response to Question 50, the United States and Canada refused the European Communities' offer to resolve this dispute through an agreed procedure, including recourse to arbitration under Article 25 DSU.

Q13. Having regard to the first claim of the EC, does the European Communities consider that there could be a breach of Articles 21.5 and 23.2(a) of the DSU by Canada and the United States even if the presumed compliance has not actually translated into actual compliance?

69. Yes, as already indicated in our reply to question 4(b), the procedural violations committed by the United States and Canada are independent of whether or not the European Communities has actually complied. The European Communities claims that the United States and Canada are violating Article 21.5 in conjunction with Articles 23.1 and 23.2(a) because they have made a unilateral determination of non-compliance and because they continue to apply sanctions on that basis. Since the United States and Canada have already made such an illegal unilateral determination it does not matter whether the EC compliance measure is WTO-consistent or not. It suffices to state that the United States and Canada have made a unilateral determination they were not allowed to make under the DSU.

70. The European Communities of course understands the defending parties' strategy to distract the Panel from this procedural violation of the DSU by discussing the substantive compliance by the EC measure. However, this discussion cannot mend the violation that has already occurred. Indeed, it would be ironic if the United States and Canada were allowed to justify their illegal unilateral determination of non-compliance under Article 21.5 in conjunction with Article 23.2(a) if they could use these proceedings to discuss the substance of the EC compliance measure. As the European Communities has repeatedly made clear, the present proceedings are not the appropriate forum for such a discussion.

[19] That said, Article 21.5 is not an ordinary panel procedure in that the terms of reference are defined as consisting of the existence or WTO-consistency of the measure taken to comply and in relation to the recommendations which Article 21.5 panels (do not) make.

Q14. Could the European Communities comment on the US statement and its reference to the Appellate Body Report in *US – Certain EC Products* (first US written submission, para. 207 and related footnote)?

71. In paragraph 207 of the US' First Written Submission the United States refers to the Appellate Body statement whereby Article 3.7 of the DSU does not contain an explicit obligation not to apply sanctions without prior authorization. The United States interprets this sentence so as to mean that Article 3.7 does not contain any obligation at all.

72. The United States obviously misinterprets the Appellate Body statement. There is a difference between the Appellate Body statement whereby Article 3.7 does not set out an *explicit* obligation, on the one hand, and the US' interpretation that Article 3.7 does not contain an obligation at all. Rightly so, the United States also quotes the last sentence of the Appellate Body statement in paragraph 120 which reads as follows:

> We consider, however, that if a Member has acted in breach of Article 22.6 and 23.2(c) of the DSU, that member has also, in view of the nature and content of Article 3.7, last sentence, necessarily acted contrary to the latter provision.[20]

73. In the present case, the European Communities applied this Appellate Body' interpretation of Article 3.7. Indeed, if a WTO-Member can act "contrary to Article 3.7" it is clear that this provision also contains a specific obligation.

Q15. Can the presumption of good faith implementation/consistency of the compliance measure override the DSU authorization for suspension of obligations? Please elaborate.

74. The European Communities has difficulties to understand what the Panel means by the word "override" and this word seems rather inappropriate. The European Communities bases its claim, *inter alia*, on Article 22.8 which provides that under certain conditions sanctions may not be "applied" any more. It is true that within the Articles 22.8, 23 claim the European Communities relies on the presumption of good faith. But as explained in our reply to question 4(b) the defending parties cannot escape this presumption in the absence of any challenge of their own under Article 21.5 of the DSU.

75. On the other hand, if the Panel's question implies whether the presumption of good faith terminates the DSB authorization the European Communities would recall that it has never argued this.

Q16. Could the European Communities identify: (i) the document(s) that encompass the risk assessment for the ban on imports of beef from cattle treated with oestradiol 17β for growth promotion purpose, and (ii) the information that served as basis for the provisional measure on imports of beef from cattle treated with the other five hormones for growth promotion purpose? Could the EC also indicate whether this information is publicly available? If yes, since when? If not, has it been made available to the United States and Canada at any point of time?

76. In answering this question, the European Communities refers to the assessment of risk performed by the relevant scientific committee which the applicable Community law defined as the committee competent to perform the risk assessment for this kind of substances in the EC legal system. This is the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) (see 1st EC Written Submission, para. 143). This is also explained in the recitals of Directive 2003/74. Although the Panel's question does not clarify what it means by "risk assessment", the European

[20] Appellate Body Report, *US – Certain EC Products*, para. 120.

Communities uses here the term "risk assessment" to refer to a risk assessment in a strict (narrow) sense.[21] But as the Panel knows, the Appellate Body in the *Hormones* case has clarified that the term "risk assessment" in the *SPS Agreement* is wider in scope because it covers also evidence, considerations, objectives and factors that are also taken into account at the "risk management" phase.[22] The European Communities will indicate separately the basis of its "risk management" that led to the adoption of the new Directive 2003/74.

77. The main documents and information that encompass the risk assessment for the restriction on imports of beef from cattle treated with oestradiol 17β for growth promotion purposes as well as for the provisional restriction of imports of beef from cattle treated with the other five hormones for growth promotion purposes, are the three opinions of the SCVPH of 30 April 1999, of 2 May 2000, and of 10 April 2002.[23] These three scientific opinions explain in detail the scientific information, data and other evidence upon which they are based, and each one of them provides at the end a list of references. In particular, they explain the procedures that were followed and also provide in detail the data and evidence resulting from the 17 specific scientific studies that were initiated by the Commission to obtain as much as possible of the missing scientific information that was identified by the WTO Panel and Appellate Body reports in the *Hormones* case.

78. It should also be clarified that these three scientific opinions of the SCVPH took into account and analysed the scientific evidence and data from any relevant source available at the time, including the opinions from the 1999 United Kingdom's Veterinary Products Committee, the 1999 Committee on Veterinary Medicinal Products of the European Community (CMVP),[24] and the 1999 and 2000 re-evaluations from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of some of these hormones.

79. The three SCVPH opinions (as well as the other opinions on which they are based) are all public. They were made available to all concerned a few days after their adoption, and were also put on the internet site of the European Commission soon thereafter. Moreover, the results of the 17 scientific studies, after being peer reviewed, led to a number of publications in international scientific journal and reviews and were presented also at international scientific conferences.[25] This is explained in more detail below.

80. The three scientific opinions of the SCVPH were published as follows:

– Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health: Assessment of potential risks to human health from hormone residues in bovine meat and meat products (of 30 April 1999), is on the European Commission's website since April 1999 at:

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[21] That is as it is defined in the Codex Alimentarius Commission Procedural Manual, 14th ed., pages 46-47, available at http://www.codexalimentarius.net/web/procedural_manual.jsp.

[22] *See* Appellate Body Report in *EC – Hormones*, at paras. 181 and 206.

[23] They have already been provided to the Panel by both the USA and Canada. *See*: USA list of exhibits nos 4, 17 and 1, respectively; and Canada's list of exhibits nos 2, 4, and 7, respectively. For this reason, the European communities will not submit them again to the Panel.

[24] It should be clarified that both the USA and Canada misinterpret in their first written submission the role of the CVMP and the relevance of its opinion in the Community legal system. The European Communities will explain in greater detail with its rebuttal this important misunderstanding by the defending parties and the erroneous arguments this has lead them to advance.

[25] *See*, e.g., Andersson, Grigor, Rajpert-De Meyts, Leffers and Skakkebaek (eds.): Hormones and Endocrine Disrupters in Food and Water - Possible Impact on Human Health, published by Munksgaard, Copenhagen, 2001 (ISBN 87-16-16462-8). This book contains 43 peer-reviewed papers and discussions from an international workshop held at the University Hospital Rigshospitalet, Copenhagen, Denmark, May 27-30, 2000.

http://web.archive.org/web/20000417013041/europa.eu.int/comm/dg24/health/sc/scv/out21_en.html.

– Review of specific documents relating to the SCVPH opinion of 30 April 1999 on the potential risks to human health from hormone residues in bovine meat and meat products (adopted on 03 May 2000), is on the website since August 2000 at:

http://web.archive.org/web/*/http://europa.eu.int/comm/food/fs/sc/scv/out33_en.pdf

– Opinion on review of previous SCVPH opinions of 30 April 1999 and 3 May 2000 on the potential risks to human health from hormone residues in bovine meat and meat products (adopted on 10 April 2002), is on the website since August 2002 at:

http://web.archive.org/web/*/http://europa.eu.int/comm/food/fs/sc/scv/out50_en.pdf.

81. These three scientific opinions of the SCVPH were made available to every person concerned, including of course the USA and Canada. In particular, both the USA and Canada do not deny that they have received these there scientific opinions in time. The USA only claimed, for the first time during the oral hearing on 13 September 2005, that it has not received the details of the 17 studies initiated by the European Commission. Canada has never made such a claim. It should be noted that Canada, Australia and the United Kingdom have made a review of these three opinions of the SCVPH and of the results of the 17 studies mentioned above, and issued their own reviews of these studies. The reviews of these three countries are also publicly available (and actually provided to the panel with the parties submissions).[26] This means that these three countries have had no problem whatsoever to obtain access to all relevant documentation pertaining to the European Communities' risk assessment.

82. The European Communities will also explain in more detail with its rebuttal that the defending members not only received the three scientific opinions but that the European Communities has been in contact with their competent authorities and scientists several times, where the results of the risk assessment have been explained and discussed.

83. As already indicated above, the European Communities took also into account the evidence relating to the factors mentioned in Article 5.2 and 5.3 of the *SPS Agreement*. This is in accordance with the Appellate body findings in paragraphs 205-208 of the Appellate Body report in the hormones case. They are documented in particular in the 1999[27] and 2002[28] opinions of the SCVPH, where specific references to the scientific evidence upon which they are based are explained. These factors and other considerations and the evidence upon which they are based are also explained in recitals 10-

[26] *See* the 1st written submission of the USA, list of exhibits, nos 12 and 16. *See* also 1st written submission of Canada, list of exhibits, no 6. Moreover, the following is an excerpt from the web-site of Health Canada: "How is Health Canada addressing results of the EU commissioned studies on hormonal growth promoters? It is imperative that any decisions taken by the Government of Canada regarding the use of hormonal growth promoters be based on the most accurate interpretation of scientific evidence available. To this end, Health Canada's Veterinary Drugs Directorate (VDD) undertook an intensive review of seventeen studies commissioned by the EU to assess scientific information on the toxicity and safety of hormone-treated beef. VDD's scientific review of the EU studies concluded that residues in meat from animals treated with hormonal growth promoters (when administered according to good veterinary practices) pose **no undue** risk to human health." (Emphasis added). Available at http://www.hc-sc.gc.ca/dhp-mps/vet/faq/growth_hormones_promoters_ croissance_hormonaux_stimulateurs_e.html. (visited on 1 October 2005).

[27] *See* section 3 of the 1999 SCVPH opinion.

[28] *See* section 4.1.4, section 6 and Annex 1 of the 2002 SCVPH opinion.

12 of the new Directive 2003/74. The European communities will provide more details of the evidence and the data upon which its "risk management" phase was based with its rebuttal in this case.

84. The European Communities provides as an exhibit to this submission the results of all the 17 studies initiated by the European Commission and the numerous publications they have given rise to in various peer reviewed scientific journals. When a couple of these studies are not published in peer reviewed scientific journals, a copy of the original of the study is provided.[29]

Q17. Has the European Communities assessed the specific risk associated with residues in meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice? Please provide the risk assessment, as well as the scientific studies on which it relies.

85. Yes, the EC has assessed the specific risk associated with residues in meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice (GVP). As explained above with the reply to question 16, the European Communities' assessed in the specific case of the six hormones the potential adverse effects of the factors mentioned in Articles 5.2. and 5.3. of the *SPS Agreement*.

86. The studies that assessed the specific risk associated with residues in meat from cattle treated with hormones for growth promotion according to GVP are, in particular, the following:[30]

- Study concerning an analysis of 500 samples for the presence of growth promoters, published as "Hormones found in meat samples from regular controls within the EU and from US imports", in Chemical Awareness; issue 9, July 5th, 2000.

- Study concerning an analysis of 500 samples for the presence of growth promoters steroids in meat by gas chromatography coupled to mass spectrometry, published in Journal of Chromatography A, 867: 219-233, 2000.

- Study concerning a survey of anabolic agents in meat, published as "Le contrôle des anabolisants dans la viande", in Annales de Toxicologie Analytique, vol.XII, no.1, 2000.

- Study concerning the long term effects in children to estrogenized meat, published as "Accidental gynecomastia in children", in APMIS 109, suppl. 103: 203-209, 2001.

- Study concerning the use of hormones as growth promoters: genotoxicity and mutagenicity of Zeranol &Trenbolone, published as "Genotoxic potential of xenobiotic growth promoters and their metabolites", in APMIS 109:89-95, 2001.

- Study concerning the metabolic pathways of estrogens as steroidal growth promoting agents, published as "Estrogenic activity of estradiol and its metabolites in the ER-CALUX assay with human T47D breast cells", in APMIS 109: 101-107, 2001.

87. It should also be recalled that one of the critical issues in the assessment of the risk at stake, as identified by the Appellate Body in the hormone case, is to take into account in this specific instance the lack of an harmonised GVP, as well as the conditions of implementation and control of such GVP.

[29] Exhibit EC – 6 (US), Exhibit EC – 4 (CAN).

[30] Copies of the original of these studies as well as their published version, when available, have been provided with the exhibits attached to Question 16.

And as the Appellate Body pointed out, it is possible to deduce that, if a product is said to be safe if GVP is followed, then it **may or may not be safe if GVP is not implemented.** The GVP - or rather *Good Practice in the Use of Veterinary Drugs (GPVD)* as it is called in the Codex Alimentarius Commission (Manual, page 45) - is defined as follows:

> Good Practice in the Use of Veterinary Drugs (GPVD) [ ] is the officially recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.

88. The GPVD is, therefore, dependant on what national governments consider appropriate, and is indeed different in each country, as it is dependant on each national authorisation.[31] The definition is, therefore, somewhat circular and hence problematic.[32]

89. The European Communities has evaluated also the specific risks to human, animal and environmental adverse effects associated from the misuse or abuse of these hormones for animal growth promotion purposes. The studies that carried these evaluations are the following:[33]

- The study concerning the application of anabolic agents to food producing animals - health risks through disregard of requirements of good veterinary practice. This multifaceted study has given rise to a number of scientific publication in peer reviewed journals. They are the following:

  1) "Detection of melengestrol acetate residues in plasma and edible tissues of heifers", The Veterinary Quarterly 21: 154-158, 1999.

  2) "Detection of anabolic residues in misplaced implantation sites in cattle", Journal of AOAC International 83(4); 809-819, 2000.

  3) "Suppression of androstenone in entire male pigs by anabolic preparations", Livestock Production Science- 69: 139-144, 2001.

  4) "A sensitive enzyme immunoassay (EIA) for the determination of Melengestrol acetate (MGA) in adipose and muscle tissues", Food Additives and Contaminants 18(4):285-291, 2001.

  5) "Characterisation of the affinity of different anabolics and synthetic hormones to the human androgen receptor, human sex hormone binding globulin and to the bovine progestin receptor", APMIS 108: 838-846, 2000.

  6) "Dose-dependent effects of melengestrol acetate (MGA) on plasma levels of estradiol, progesterone and luteinizing hormone in cycling heifers and influences on oestrogen residues in edible tissues", APMIS 108: 847-854, 2000.

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[31] For instance, the latest 2005 United Kingdom report on hormones, provided by the USA with its oral statement during the first oral hearing, which is cited very selectively by the USA, states on page 6 that: it is "more likely to have abuses in a context where these hormones are authorised".

[32] For instance, JECFA stated that: "[B]ecause the use pattern of veterinary drugs varies considerably form one country to another and because information on such use generally is not available to JECFA, it is very difficult to estimate the percentage of national herds that are likely to be treated with a substance at any time and consumer consumption patterns from national surveys to a precision that would be sufficient to estimate the intake" (*See* page 7 of the response from the 60th meeting of JECFA to questions raised by the 13th CCRVDF).

[33] Copies of the original of these studies as well as their published version, when available, have been provided with the exhibits attached to Question 16.

7) "Hormone contents in peripheral tissues after correct and off-label use of growth promoting hormones in cattle: Effect of the implant preparations Finaplix-H®, Ralgro®, Synovex-H® and Synovex Plus®", APMIS 109: 53-65, 2001.

8) "Tissue-specific expression pattern of estrogen receptors (ER): Quantification of ER_ and ER_ mRNA with real-time RT-PCR", APMIS 109: 345-355, 2001.

- The study concerning screening water samples for estrogenic &androgenic anabolic chemicals scientist has not yet indicated name of journal and publication date, partly published in APMIS 109, suppl.103: 551-556, 2001.

- The study concerning endocrine disrupting effects of cattle farm effluent on environmental sentinel species, published as "A re-examination of variation associated with environmentally stressed organisms", in Human Reproduction, update vol. 7, no. 3: 265-272, 2001.

90. Moreover, concerning the assessment of the risk associated with residues in meat from cattle treated with hormones for growth promotion purposes and the scientific studies on which it relies, the 1999 SCVPH opinion already refers to this issue, in particular at :

- Discussion on Susceptible populations (page 27)

- Exposure considerations upon misuse (at page 30)

- Exposure in relation to endogenous hormone production in humans at different stages of life (page 34)

- Assessment of excess exposure to oestrogens from consumption of hormone-treated beef (at page 36)

- Assessment of excess exposure to testosterone from consumption of hormone-treated beef (at page 47)

- Assessment of excess exposure to progesterone from consumption of hormone-treated beef (at page 52)

- Assessment of exposure to trenbolone from consumption of hormone-treated beef (at page 57)

- Assessment of exposure to zeranol from consumption of hormone-treated beef (at page 63)

- Assessment of exposure to melengestrol from consumption of hormone-treated beef (at page 67)

- Executive summary (at pages 69 – 73) in particular second paragraph (at page 72).

91. The European Communities reserves the right to develop further with its rebuttal these important issues and it will provide in particular specific evidence from misuse of these hormones that has recently arisen in the territory of the defending Members.

Q18. What is the EC's response to the comments in paragraphs 155 and 156 of the US first written submission on the EC's study of the carcinogenic effect of the oestradiol – 17β to human health? Does the European Communities agree that what is relevant is the risk resulting from human consumption of meat from cattle treated with oestradiol – 17 β for growth promotion purpose according to good veterinary practice?

92. Yes, 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 relevant. But there are a number of very important qualifications.

93. First, this kind of risk, if this was a "real life" situation, then as JECFA has already pointed out in its answer to the CCRDVF, it is very difficult to estimate the GVP and the hormone uses "*to a precision that would be sufficient to estimate the intake*".

94. In reality, however, human beings, including the populations at risks, are exposed to cumulative and synergistic effects, as they may be exposed to multiple sources of hormone and hormone residues, via several intake routes, as well as from endogenous production of some of these hormones. Not only is it 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. Therefore, 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.

95. Secondly, another important qualification comes from the proper implementation of GVP and the possibilities available to control good veterinary practice, as discussed in the answer to the previous question.

96. In summary, for the European Communities 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, may be particularly vulnerable segments of the population (e.g. like prepubertal children), etc.

97. More specifically, in paragraphs 155 and 156 of its first written submission the United States claims that the European Communities assessment of the risk in relation to a carcinogenic hazard of oestradiol - 17β is based on studies on the use of oestrogens in contraceptives and hormone replacement studies. This is partly correct. It should be added, however, something the USA does not explain in para. 155 of its 1st written submission, that even JECFA for the first time in its 1999 re-evaluation of oestradiol 17β came to the conclusion that: "*The Committee concluded that oestradiol 17β* ***has genotoxic potential"***. As said above, this was the first time JECFA made this finding – compared to its previous 1988 evaluation – and this has *inter alia* led now, again for the first time, to propose the definition of an Acceptable Daily Intake (ADI) for oestradiol 17β, which was not the situation before.

98. Moreover, what the USA also does not explain is that its own responsible health authorities have, for the first time since 2002, declared that oestradiol 17β is proven to be a human carcinogen and it is now listed as such, since 2002, in the USA Annual Report on Carcinogenesis. This latest report for instance states the following:

> "Steroidal estrogens also occur naturally in plants. Currently, more than 360 plants have been identified that have estrogenic activity. A few plants contain the principal estrogens found in mammals, estradiol and estrone (Setchell 1985). Meat and milk also may contain estrogens (Collins and Musey 1985). Veterinary use of steroidal estrogens (to promote growth and treat illnesses) can increase estrogens in tissues of food producing animals to above their normal levels."[34]

99. On the basis of the most recent evidence from all sources, the USA authorities concluded that "steroidal estrogens are *known to be human carcinogens* based on sufficient evidence of carcinogenicity in humans, which indicates a causal relationship between exposure to steroidal estrogens and human cancer." For this reason, the 2002 listing of steroidal estrogens as known to be human carcinogens now "supersedes the previous listing of specific estrogens in the Report on Carcinogens (RoC) and applies to all chemicals of this steroid class."

100. Equally, the United States argues against the European Communities assessment of risks by stating inaccurate generalities on the comparison of doses and bioavailability/biological activity, for different mode of intake and uses of the hormone. What is most importantly missing in the United States reasoning is the intrinsic and significant variability of the biological activities of this hormone, and its potential pathological consequences, according to individual sensitivity, stage of development, etc. Furthermore, it claims that "*oestradiol - 17β is **generally** inactive when given orally*" (emphasis added), while this argument is well known to be still controversial and not consensually accepted by the scientific community. It also claims, in footnote 167, without providing any relevant and peer reviewed scientific evidence to support its claim, how the results of some of the studies cited by the European Communities should be interpreted.

101. Most importantly, carcinogenic activities of molecules can not be assessed with the reasoning and the biological thresholds available to assess their acute or chronic toxicity, as does the United States. This is particularly the case when compounds have genotoxic activity. The carcinogenic activity of biologically active molecules, especially when their normal (as opposed to pathological) activity is related to radical modifications of developmental phenotypes and of cellular growth and development, indeed may often manifest itself at sub chronic level, with low doses under permanent exposure or with delayed potential effect. This carcinogenic activity may only manifest itself after a long period of time and it may even go unnoticed in classical acute, chronic or even sub chronic studies. Finally, as noted by the United States itself, synthetic or naturally occurring molecules bear different hazards, and contrary to the United States claim, results obtained from studies on one or the other are difficult to extrapolate to one another.

102. The European communities will provide more detailed information and specific data on this important issue with its rebuttal in this case.

Q19. Could the European Communities explain why the ban on testosterone, progesterone, MGA, TBA and zeranol is now only provisional?

103. The reason, in summary, is that the most thorough and recent information obtained in the latest assessments of the risk for each of these five hormones has been found to be insufficient, inconclusive and contradictory. Even if the insufficiencies and contradictions amount to different extents for each of the five hormones, they do not permit to reach firm conclusions and to perform a definitive risk assessment. For instance, it is not possible to set acceptable thresholds for these hormones as used in growth promotion or acceptable thresholds for their residues.

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[34] Available at http://ntp.niehs.nih.gov/index.cfm?objectid=72016262-BDB7-CEBA-FA60E922B18C2540.

104. This is explained more specifically and in detail in the assessment of risks performed by the SCVPH, in particular in its opinion of 1999 (see also replies to questions 67 and 73), as well as in the subsequent European Communities' new Directive 2003/74, in particular in its 7th, 10th and 13th recitals, as well as in its operative provisions. Recital 7 explains:

> "As regards the other 5 hormones, the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) assessment is that, in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers".

105. Consequently, as explained in the recital 10 of the said Directive:

> "taking into account the results of the risk assessment and all other available pertinent information, it has to be concluded that, in order to achieve the chosen level of protection in the Community from the risks posed, in particular for 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, it is necessary to continue provisionally to apply the prohibition to [these] five hormones. Furthermore, [ ] the provisional prohibition of these five hormones should apply while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge of these substances"

106. Finally, recital 13 concludes:

> "The proposed amendments to Directive 96/22/EC are necessary to achieve the chosen level of health protection from the residues in meat of farm animals treated with these hormones for growth promotion purposes, whilst respecting the general principles of food law set out in Regulation (EC) No 178/2002 and the international obligations of the Community. Moreover, there is no other means that is reasonably available at present, taking into account technical and economic feasibility, which is significantly less restrictive of trade and can achieve equally effectively the chosen level of health protection. [ ] "

107. Furthermore, the operative provisions of the said Directive require that the ban on these 5 hormones be provisional (Article 3.1 of the amended Directive), and Article 9 of Directive 2003/74/EC (article 11a of the amended former Directive) requires that additional information is sought and that the measures applied be kept under regular review, with a view to timely present any necessary amendments.

108. The prohibition on the use of these five hormone for animal growth promotion is *now* provisional, while it was not so in the Directive 96/22/EC, for a number of reasons. First, the new scientific studies that have been initiated since the DSB recommendation in the hormone case, in order to address the scientific information that was found by the panel and the Appellate Body to be missing, have now identified new important gaps, insufficiencies and contradictions in the scientific information and knowledge now available on these hormones, which have together reinforced the need for even more studies. Second, the previous Directive 96/22/EC was drafted in 1995 and adopted in 1996 as a codification of the pre-existing European Community measures in this area. This happened at a time where international guidance on how to perform a risk assessment was not yet available to tackle situations where scientific information was insufficient to conclusively assess a particular risk, in accordance with a member's chosen level of health protection. For example, at that time there did not exist standards nor guidelines from the Codex Alimentarius Commission on how to

perform a risk assessment and risk analysis. Moreover, the provisions of Article 5.7 have now been clarified in a number of panel and Appellate Body reports, starting with their reports in the *hormones* case, which was not the legal situation before 1996.

109. Substantive international discussions have lead to the development of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius Commission[35] after 1996. This has only been adopted by the Codex Alimentarius Commission at the 26th Codex Alimentarius Commission meeting at Rome in July 2003. The relevant concepts developed there have been taken into account by the European Communities and have now influenced the drafting of its framework Food Law, namely Regulation 2002/178/EC. In the context of temporary measures, articles 6 and 7 thereof are particularly relevant, and they read :

> Article 6 - Risk analysis
>
> 1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
>
> 2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
>
> 3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.
>
> Article 7 - Precautionary principle
>
> 1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.
>
> 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Q20. Could the European Communities explain why it has banned oestradiol 17β treatments of animals for growth promotion, and the meat derived from those animals, while allowing its continued use for therapeutic and zootechnical purposes (Canada's first written submission, para. 104)?

110. The European Communities would like to recall that the Appellate Body has reversed the panel's findings on the issue concerning the occasional use of the hormones for therapeutic or

[35] *See* at ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_14e.pdf

zootechnical purposes.[36] Therefore, arguments of this kind by the defending parties in the context of these proceedings attempt to reintroduce a debate that they have lost at the Appellate Body level. A short reply to this question, therefore, is that this issue is now irrelevant.

111. Nevertheless, the European Communities will provide again some information and reserves the right to further develop its views on this issue in the remaining stages of these proceedings. First, the new Directive 2003/74 does not allow all uses for therapeutic and zootechnical purposes, but only a very few (Article 5a.1 and 5a.2 of the new Directive), for which no viable effective medicinal alternatives exist, and on a defined temporary basis, pending availability of alternative treatment methods, as follows :

Treatments:

– the treatment of foetus maceration or mummification in cattle, or

– the treatment of pyometra in cattle,

Zoo technical:

– oestrus induction in cattle, horses, sheep or goats, until 14 October 2006.

112. Secondly, these treatments must be carried out under strict veterinary oversight, by the veterinarian himself, on farm animals which have been clearly identified and documented, and under strict conditions of control and holding of the hormone (article 5a.3 of the new Directive). This is in striking contrast to the availability of this hormone in the United States and Canada, as an "over the counter product" (OTCs) which are freely available to every lay person.

113. Why were these uses authorised, and how do they meet the chosen level of protection of the European Communities? The difference between the risks from the use of this and the other hormones as growth promoters and of other uses arises from their differential impact on consumer exposure to the hormone, as well as from the different level of oversight of these different uses. Contrary to Canada's view, the European Communities has based its new measure precisely on available risk assessments, in particular the SCVPH opinion which has considered the use of hormones as growth promoters. Here it is used systematically and freely in almost every animal produced, whereas the treatments for therapeutic and zoo technical purposes allowed in the European Communities, are only allowed in few animals and rare occasions, in order to treat particular conditions, and on animals under strict veterinary control.

114. These temporary exemptions, based amongst others on animal health and welfare, are still under consideration. Besides, these therapeutic or zootechnical treatments pose no risk because the animals are intended to be slaughtered in the near future. In practice, therefore, there is a huge difference between the systematic use of growth promoting hormones in animals intended for beef, compared with the occasional use by a veterinarian for treating a sick animal. If at all, the consumer exposure from this kind of use cannot be compared to that resulting from the systematic use of growth promoting hormones in all beef producing cattle. If all hormonal growth promoters are used in the same manner as they are in the United States, 96% of all beef cattle in feedlots are implanted at least once[37], leading to a much higher exposure.

115. The other two treatments allowed by the European Communities are rare occasions. Specialist veterinary practitioners have generally not more than one case per year. It is moreover highly unlikely

[36] *See* Appellate Body Report, *EC – Hormones*, at paras. 221-225.
[37] *See* NAHMS, 2000, cited by Scheffler *et al*., 2003.

that animals treated with these are slaughtered. In must be reiterated that the use for these purposes is supported by the report of the Veterinary Medicinal Products of the European Community (CVMP) in December 1999. It must be stressed that the purpose of the CVMP evaluation was strictly limited to this kind of use only and did not consider the use of the hormones for growth promotion purposes, as both the USA and Canada wrongly argue.

116. Moreover, as laid out in Directive 2003/74, the uses for therapeutic and zootechnical purposes are authorised under conditional and provisional terms, and the reasons for it are explained in Recitals 11 and 12, and in the operative provisions of article 5a of the new Directive. Recital 11 states :

> "However, the use of certain of the above substances, where this is necessary, for therapeutic purposes or zootechnical treatment may continue to be authorised as it is not likely to constitute a hazard for public health owing to the nature and the limited duration of the treatments, the limited quantities administered and the strict conditions laid down in Directive 96/22/EC in order to prevent any possible misuse."

117. Recital 12 states :

> "However, in the light of the existing information it is appropriate to limit as far the exposure to oestradiol 17β and only authorise those treatments for which no viable effective alternatives exist. In general, there are alternative treatments or strategies available to replace most of the uses of oestradiol 17β for therapeutic or zootechnical purposes. Nonetheless, studies appear to show that at present no viable effective alternatives exist in all the Member States for certain treatments which are currently authorised. In order to allow for the necessary adjustments and in particular for the authorisation or the mutual recognition of the pharmaceutical products needed, it is appropriate to phase out the use of oestradiol 17β for oestrus induction over a given period. It is also appropriate to maintain the possibility of authorising, under strict and verifiable conditions so as to prevent any possible misuse and any unacceptable risk for public health, its use for the treatment of certain conditions (foetus maceration or mummification and pyometra in cattle) which have serious consequences for animal health and welfare. It is necessary to review this possibility within a given time."

118. According to the amended Directive, the zootechnical treatment temporarily authorised will be phased out in October 2006. The two other therapeutic treatments authorised will be phased out in relation to the outcome of a report on alternative methods, which is to be presented in October 2005.

Q21. Is there a regulation restricting the residue levels of the relevant six hormones in meat in the EC's health regulations or in any other countries' health regulations? If not, why would such a regulation not be a reasonable alternative to the EC's current definite ban on the use of oestradiol – 17 β for growth promotion purposes and to the provisional ban of the use of the other five hormones for the same purpose? Does the present EC measure eliminate similar risks to human health arising from these hormones when used for other purposes?

119. No, the European Communities' legislation does not lay down maximum residue limits (MRL) or other thresholds of unacceptable residue levels for the relevant six hormones in meat. The Member States of the European Communities do not have their own legislation on these matters because they are pre-empted by Community law.

120. There are several reasons why it is neither a reasonable nor a sustainable alternative to the current Community measure prohibiting permanently oestradiol 17 B and the other five hormones provisionally for growth promotion. First, as cited in our reply to question 17, the JECFA itself

indicates that it is not possible to estimate the hormone intake from meat, which would be a prerequisite for the design of such thresholds. The European Communities' scientists and experts concur with that view, and are of the opinion that one can not set thresholds in this instance. Second, one other important reason why residues limits are not fixed is that these hormones are also produced endogenously both by the animals and humans at different levels which vary considerably, which also impairs the setting of fixed threshold values. Third, different values might have to be set for different populations, according to their varying susceptibility to these hormones and hormone residues, or whether they would be populations at risk or not. It is well established that variable limits of residue levels for different populations would be practically impossible to implement.

121. Accordingly, and with the main objective of limiting the risks imbedded with additive intakes from cumulative and uncontrolled sources, the European Communities has adopted its new implementing measure as it now stands, namely a provisional or definitive ban, depending on the hormone, with a very limited number of highly controlled exceptions, pending further assessment. As a consequence, and for the reasons explained above, thresholds of residues from the banned hormones could not and have not been set.

122. As regards the second part of the question (that is does the present EC measure eliminate similar risks to human health arising from these hormones when used for other purposes), the short answer is yes.

123. The relevant Community legislation allows, where appropriate, to take into account and to provide for measures adapted to the different levels of risks presented by different uses. However, a proper answer to this last part of the question should also clarify that the risks arising from the uses authorised for other purposes, such as therapeutic and zootechnical purposes, are in fact either not present or are not similar, but distinctly lower in magnitude, as explained in detail in our answer to question 20. This is precisely referred to in recital 11 of Directive 2003/74 cited above.[38]

Q22. Does the European Communities agree that JECFA conducted new safety assessments for two of the five hormones (progesterone and testosterone) in 1999 and reaffirmed their safeness when used according to good veterinary practice? JECFA also conducted risk assessments with respect to three hormones since the 1980s and concluded that they are safe within the recommended ADIs. Do the conclusions of JECFA constitute "available pertinent information" that shall be taken into account by the EC in its risk assessment and in the context of Article 5.7 of the *SPS Agreement*? What are the EC's comments to the conclusions of the risk assessments by JECFA? (US first written submission, para. 127)?

124. The European Communities agrees that JECFA has conducted, incidentally without being asked, a new safety assessment on the use of progesterone and testosterone for growth promotion in 1999. The European Communities has asked JECFA to provide it with the underlying scientific evidence that claims to have considered but it never saw the basic information and raw data on which it is based. This information appears to have been provided directly only to JECFA, probably pursuant to exchanges with the industry, but it was not accessible to the European Communities, as was not accessible the detailed safety assessment of the United States and Canada, and in particular the detailed data on which it might have based its assessment. The European communities would welcome any further attempts this Panel may like to undertake in order to obtain this underlying information and make it available to it and the other parties to this dispute.

[38] Moreover, an example is provided by Commission Regulation (EC) No 1873/2003, amending Annex II to Regulation (EEC) No 2377/90, OJ L 275, page 9, 2003, regarding the use of progesterone for therapeutic or zootechnical uses, the recitals of which explain in detail the conditions under which such used is authorised.

125. Do the conclusions of JECFA constitute "available pertinent information" that shall be taken into account by the European Communities in its risk assessment? Yes, the conclusions of JECFA do constitute part of the pertinent information, and they were actually taken into account both by the SCVPH that has issued the three scientific opinions on the same hormone and the same uses, and by the European Communities authorities that have drafted the new Directive 2003/74.

126. To comment more specifically on the conclusions of the JECFA's risk assessments, the European Communities would like to refer first to extracts from its own SCVPH opinions which specifically addressed the JECFA assessment. For example, the 1999 opinion of the SCVPH discussed at several places the re-evaluation made by JECFA, as follows:

- **1999 SCVPH opinion (page 9).** In a three generation study of rats receiving zeranol at levels up to 0.20 ppm throughout gestation, it has been concluded that the fertility of the offspring is not affected (JECFA, 1988). However, male mice exposed *in utero* to zeranol (150 μg/kg of body weight injected on days 9 and 10 of gestation) show testicular abnormalities (regressive changes in the germinal epithelium and Sertoli cells, and immature morphology of Leydig cells) when testes are examined at 45 days of postnatal life (Perez-Martinez et al., 1997). Moreover, in a multi-generational study, it has been shown that trenbolone acetate, administered to female rats at dietary concentrations of 3 and 18 ppb between 2 weeks before mating and 3 weeks delivery, exert effects on reproductive performance which are more marked in F2 pups than in F1 pups of a comparable age. Indeed, female F1 pups from F1-treated parents show signs of virilization, a delay in the mean vaginal opening and the presence of occlusive strands in the vagina or incomplete vaginal opening. Male pups show a delay in the occurrence of testicular descent and a decrease in weights of seminal vesicle, prostate, testes an epididymis. In addition, in F2 pups from both sexes the adrenal weight was also decreased (JECFA, 1988).

- **1999 SCVPH opinion (page 15).** Experiments in rats, mice, hamsters, dogs, pigs, cattle, sheep or monkeys have shown that exogenous sex hormones, including natural steroids as well as growth promoters (such as trenbolone acetate, zeranol or melengestrol acetate), administered by ingestion, injections or implants, induce dosedependent deleterious effects on reproduction in males and females (JECFA, 1988).

- **1999 SCVPH opinion (pages 20, 27/28).** Since the years when preceeding reports were written, such as the FAO/WHO or JECFA monographs knowledge has greatly increased, in particular on oestrogens. Different types of hormonal receptors (α and β) have been identified and their functions better defined. Also, steroid metabolism has been better studied. Genotoxic effects, independent from the presence of hormonal receptors, have been recognized for metabolites of the parent compounds. These concern essentially catechol-oestrogens and corresponding quinones, in particular 4 hydroxylated derivatives (Service, 1998). In addition, activation reactions during oestrogen metabolism contribute by oxidative stress to genotoxic effects. The possibility of synergism between the genotoxic activity of selected oestrogen derivatives and the classical promotional effect of steroïds cannot be excluded. A crucial question is whether consumption of meat from cattle treated with hormones under conditions approved in the USA *vs* non hormone-treated cattle, causes increased exposure to these hormones. The first step in this determination is a calculation of the theoretical increased daily hormone intake when consuming beef from treated as opposed to untreated animals. The recent JECFA report (of February, 1999) presented calculations of a theoretical excess maximum intake (μg/person/day)

of oestrogen (E2 +oestrone [E1]), testosterone and progesterone (see table A3). From this overview, referring to products presently licensed in the USA, it is obvious that, with the exception of pregnant heifers, the use of these growth promoting hormones will result in an additional excess daily intake of oestrogens of 1.1 to 83.9 ng/person (E2 + E1), of progesterone of 64-467 ng/person, and of testosterone of 5-189 ng/person. It is worthwhile to indicate that these data refer to the parent compounds only and do not include contributions from metabolites. It should also be noted that these hormone implant-induced increases in hormone levels result in oestrogen and testosterone exposures below that which would occur upon consumption of beef from pregnant heifers. However, meat from pregnant heifers accounts for only a relatively small amount of the beef consumed, as these animals are slaughtered only incidentally.

- **1999 SCVPH opinion (page 28/29).** The data show that premenopausal women have the highest levels of endogenous oestrogen (oestradiol and estrone) and progesterone. Oestradiol and progesterone production rates in premenopausal women during the follicular phase have been determined to be approximately 445 μg/day and 418 μg/day, respectively (JECFA, 1987). During pregnancy, oestradiol levels rise dramatically to approximate values of 18,000 pg/ml (Goodman, 1996). Oestradiol and progesterone production rates during late pregnancy have been determined to be approximately 13,800 μg/day and 94,000 μg/day, respectively (JECFA, 1987). In men, daily production rates for oestradiol and progesterone are approximately 48 μg/day and 416 μg/day, respectively (JECFA, 1987). In prepubertal boys, oestradiol and progesterone production rates have been reported as being 6 μg/day and 150 μg/day, respectively (JECFA, 1987). Thus, prepubertal and postmenopausal women and prepubertal and adult men have the lowest levels of endogenous oestrogens and progesterone and thus would represent the individuals most likely to be at increased risk for adverse health effects that might be associated with exposure to exogenous sources of oestrogens. As expected, men have the highest levels of blood testosterone and the daily production rate has been determined to be approximately 6,500 μg/day (JECFA, 1987). Testosterone levels are much lower and similar in women and prepubertal men. It has been reported that daily production rates of testosterone are between 140 to 240 μg/day in adult women and 32 and 65 μg/day in prepubescent girls and boys, respectively (JECFA, 1987). These data suggest 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.

- **1999 SCVPH opinion (page 33/34).** 4.1. 17 β-oestradiol. 17β-Oestradiol (E2), estra-1,3,5 (10)-triene-3,17β-diol, is an 18-carbon steroid hormone and the most potent of the naturally occurring oestrogens. This hormone is produced primarily by the developing follicle of the ovary in adult females. E2 exerts its pleotropic biological effects on cell growth and differentiation largely through receptor-mediated mechanisms. E2 binds with high affinity and high specificity to intracellular proteins know as oestrogen receptors (JECFA, 1988; JECFA, 1999; Anstead et a., 1997). Two subtypes of oestrogen receptor (ER) are known, ER-α and ER-β. It is known that these proteins can form both homo- and heterodimer complexes, yet current information about the ER-β subtype is limited. The value of the dissociation constant of E2 for the ER-α is in the 0.1-1.0 nM range (Anstead et al., 1997; Giguere et al., 1998). The aromatic A-ring and 3-OH group of E2 are known to be important components of the ligand binding activity and receptor activation activities of E2.

- **1999 SCVPH opinion (pages 34, 37).** *4.1.2. Oestradiol disposition in the target animal.* After administration of oestradiol benzoate, the major metabolites found in muscle were 17α-oestradiol (38-70% of extracted radioactivity) and E1 (17-45%). The pattern of metabolites in fat was similar to that in muscle. The highest residues were found in kidney and liver. The major oestrogenic metabolites in kidney were 17α-oestradiol, 17α-oestradiol-glucuronide, E2 and E1. In liver, the major metabolite could not be identified (40% of the extracted radioactivity). E2, E1, estriol, and glucuronides accounted for the remaining radioactivity (JECFA, 1988; Dunn et al., 1977). The nature of the unidentified polar metabolites from livers of steers was investigated in another study using radiolabeled E2. The major polar metabolite was the β-Dglucopyranoside of 17α-oestradiol. The 3-β-D-glucuronate of 17α-oestradiol, and other 17-glycosides of oestradiol were also characterized (JECFA, 1988; Rao et al., 1979). Recent studies have begun to consider the formation in cattle of the major oestrogen metabolites found in humans, i.e. the 2-OH, 4-OH and 16α-OH-oestrogens. While it is likely that these routes of metabolism are present in cattle, quantitative measures are not yet published. At its February, 1999 meeting, JECFA established the ADI for 17β-oestradiol as 0-50 ng/kg bw/day. This value is based on a study in postmenopausal women where conjugated equine oestrogens at doses of 0.3, 0.62. 1.2 and 2.5 mg were administered for two weeks followed by no treatment for three weeks. This regimen was repeated four times after which serum levels of corticosteroid binding protein (CBG) were determined. No increase in CBG levels was detected at the 0.3 mg dose (equivalent to 5 μg/kg bw/day) which was thus considered to represent the no-observed-effect level (NOEL). In another analysis (it is not clear if this was part of the same study or a different one), the dose of 0.3 mg of conjugated equine oestrogen was determined to be the NOEL for induction of serum concentrations of follicle-stimulating hormone, angiotensinogen, SHBG and CBG. It was stated that fine-particle 17ß-oestradiol and the conjugated equine oestrogens were equipotent for all four hormone-dependent end points. In a separate study, the bioavailability of fine-particle 17β-oestradiol administered orally was determined to be 5% compared to a dose administered intravenously. Sixty percent of the fineparticle 17β-oestradiol dose was determined to appear in the serum as estrone and estrone sulfate. While the results of these studies would appear to indicate that the maximum excess exposure level (84 ng/person/day) for oestrogen derived from hormone-treated beef is below the NOEL, there are several concerns. First, neither the actual data nor references to peerreviewed publication of this data were available. Second, it is uncertain whether the use of fine-particle 17β-oestradiol, and in particular conjugated equine oestrogens, represents appropriate surrogates for consumption of oestrogens in association with beef. The equine oestrogens consist predominately of equilin and equilenin, which are chemically different from oestradiol. In the USA, the FDA has established an acceptable level of exposure for oestradiol (Table 3). These values represent parent hormone residue levels in uncooked meat that are considered unlikely to produce any physiological effects in individuals chronically ingesting animal tissues.

Table 3: Acceptable levels of oestradiol levels in beef (Ref.: Code of Federal Regulations (CFR) 21, Part 556, Tolerances for residues of new animals drugs in food)

Tissues	Oestradiol (ng/kg)
Muscle	120
Liver	240
Kidney	360
Fat	480

The FDA guidelines state that: "… no physiological effect will occur in individuals chronically ingesting animal tissues that contain an increase of endogenous steroid equal to 1% or less of the amount in micrograms produced by daily synthesis in the segment of the population with the lowest daily production. In the case of oestradiol and progesterone, prepubertal boys synthesize the least, in the case of testosterone, prepubertal girls synthesize the least" (taken from Andersson and Skakkebaek, 1999).

- **1999 SCVPH opinion (page 46).** *4.2.1. Pharmacokinetics and Biotransformation of Testosterone in animals.* Testosterone or testosterone propionate is administered by subcutaneous implantation in the ear. The ear, along with any residual drug, is discarded at slaughter. The dosage of testosterone varies with the manufacturer of the implant, but is most often 200 mg per animal (JECFA, 1988). In the circulatory system of the animal, testosterone derived from the implant is indistinguishable from endogenous testosterone, i.e. enzymatic transformation of the biologically active molecule into less active metabolites. Excretion is predominately via the biliary route, and to a lesser extent via the urine. In general, the fraction of the hormone eliminated in the urine is in the conjugated form, while the fraction found in the feces is in the free form. For testosterone propionate, enzymatic cleavage of the ester produces testosterone which, is again metabolized as the endogenous compound (Hoffmann and Karg, 1976; Hoffmann and Evers, 1986).

- **1999 SCVPH opinion (page 47/48).** At its February 1999 Meeting, the JECFA established for testosterone an ADI of 0.2 ug/kg bw (14 µg/70 kg person) on the basis of a study in eunuchs. This value includes a safety factor of 1000 to protect more sensitive populations and because of the small number of subjects in the study used to determine the NOEL. In that study, oral administration of a dose of 100 mg/day (equivalent to 1.7 mg/*kg* bw/day) of fine-particle testosterone to five eunuchs had no effect on sexual function indexes while a dose of 400 mg/day restored full sexual function. The dose of 100 mg/day was taken as the NOEL in this study. In another study in postmenopausal women, treatment with 10mg/day methyltestosterone was found to induce signs of virilisation. The ADI for testosterone established by the JECFA (14 µg/person) is greater than the highest excess exposure to testosterone (189 ng/person) that could occur from ingesting hormone-treated beef. However, there are concerns regarding the strength of the study that provided the data for determination of the ADI. First, neither the actual data nor reference to a peer-reviewed publication was provided. Second, 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. The tolerance levels for testosterone levels in uncooked tissues of steers and calves established by the FDA (Ref.: Code of Federal Regulations (CFR) 21, Part 556, Tolerances for residues of new animals drugs in food) are:

Tissue	Testosterone (μg/kg)
Muscle	0.64
Liver	1.3
Kidney	1.9
Fat	2.6

Based on these levels, consumption of 500 g/day of beef (300 g muscle, 100 g liver, 50 g each of kidney and fat) would result in exposure to approximately 0.6 μg/person/day. The maximum excess exposure to testosterone estimated to occur upon consumption of meat from hormone treated cattle, 189 ng/person/day (Table A3, Annex) represents 33% of the acceptable level established by the FDA (0.6 μg/person/day) which also represents approximately 1-2% of the daily production rate for testosterone of 32 μg/day estimated for prepubertal girls. However, there is considerable uncertainty associated with the validity of the daily production rate data. It is possible that this value has been over estimated by one to two orders of magnitude, in which case excess testosterone intake from hormone-treated beef could at best exceed the 1% FDA safety margin and at worst be greater than that naturally present.

- **1999 SCVPH opinion.** *Testosterone Levels in Human Blood.* As expected, men have the highest levels of blood testosterone (Table 1, section 4.1) and the daily production rate has been determined to be approximately 6,500 μg/day (JECFA, 1987). Testosterone levels are much lower and similar in females and prepubertal males. It has been reported that daily production rates of testosterone are between 140 to 240 μg/day in adult women and 32 and 65 μg/day in prepubescent girls and boys, respectively (JECFA, 1987). These data suggest that all females and prepubertal males represent the individuals are greatest risk for adverse health effects that might be associated with exposure to exogenous sources of testosterone.

- **1999 SCVPH opinion (page 51) 4.3. Progesterone.** Progesterone, pregn-4-ene-3, 20-dione, is a C-21 steroid hormone and the most potent endogenous progestogen. This hormone is present in all steroid producing organs, and its production rate varies widely as a function of the phase of a woman's menstrual cycle and pregnancy. The major physiologic function of progesterone is to prepare the uterus for implantation and to maintain pregnancy. The production of progesterone in the corpus luteum of the ovary in adult females is controlled by pituitary luteinizing hormone. Progesterone is essential for uterine development, implantation, blastocyst development and maintenance of the fetus and the uterus during pregnancy. Progesterone opposes some of the effects of oestrogens, and in non-pregnant females, this hormone inhibits the cyclic release of luteinizing hormone and follicle stimulating hormone. The actions of progesterone require prior stimulation with oestrogens, perhaps to increase expression of progesterone receptor (PR). The PR is a member of the steroid hormone superfamily of receptor proteins and mediates the biologic activity of progesterone through gene regulatory mechanisms (Mahesh et al., 1996; Katzenellenbogen, 1996). In animals, progesterone is used primarily in combination with oestrogenic compounds in order to improve their rate of weight gain and feed efficiency, and to suppress oestrus in feedlot heifers.

- **1999 SCVPH opinion (page 51).** Progesterone is administered by subcutaneous implantation in the ear. The ear, along with any residual drug, is discarded at slaughter. The dosage of progesterone is 200 mg per animal (JECFA, 1988). In the circulatory system of the animal, progesterone derived from the implant is

indistinguishable from endogenous progesterone (Baird et al., 1969). The metabolism of progesterone in cattle has been investigated using radiolabeled compound (Estergreen et al., 1977; Purdy et al., 1980; Lin et al., 1978). Animals were administered progesterone, 50μg/kg twice daily for 15 days. Each of the last three injections contained 0.9 mCi [14C]-progesterone and the animals were killed 2-3 hours after the final treatment. Most of the radioactivity in all extracts corresponded to the parent compound (54% of the free radioactivity in muscle and 69 and 73% of the free and conjugated radioactivity, respectively in fat), (Lin et al., 1978). The major metabolites detected in muscle (16% of total radioactivity) included: 5α-pregnane-3, 20-dione (9%); 20-β-hydroxy-4-pregnen-3-one (8%); 3α-hydroxy-5β-pregnan-20-one (13%); and 3α-hydroxy-5α-pregnan-20-one (3%). The major metabolite detected in fat (62% of the total radioactivity) was 20-β-hydroxy-4-pregnen- 3-one (11%), (Estergreen et al., 1977). Little is known about the specific enzymes in cattle that metabolize progesterone, although hepatic cytochrome P450 enzymes are likely involved in the metabolic clearance of this hormone.

- **1999 SCVPH opinion (page 52/53/54).** *4.3.4. Assessment of excess exposure to progesterone from consumption of hormone-treated beef.* Table A3 (Annex) shows that consumption of beef from hormone treated vs non-treated non-pregnant cattle results in exposure to excess levels of progesterone ranging from 64 to 467 ng/person/day, depending upon the implant used. At its February 1999 Meeting, the JECFA established for progesterone an ADI of 0-30 μg/kg bw (0-2,100 μg/70 kg person). This value was based on studies where a lowest-observed-effect level (LOEL) of 200 mg fine-particle progesterone (equivalent to 3.3 mg/kg bw) was determined and includes a safety factor of 100 to allow for extrapolation from the LOEL to a NOEL. In one study, designed to explore anti-proliferative and secretory endpoints in the endometrium, women were treated with 300 or 600 mg/day of fine particle progesterone for two weeks following a thirty day pretreatment with oestrogen. The group treated with the 300 mg dose showed incomplete conversion of the uterus to full secretory activity whilst the group receiving the 600 mg dose did. In an additional studies using 200 or 300 mg oral doses of progesterone for one or five years, there was no evidence of endometrial hyperplasia or carcinoma. In addition, it was stated that a single oral dose of 200 mg fine-particle progesterone produced concentrations of progesterone in blood similar to those found during the luteal phase of the ovulatory cycle. While these data indicate that the daily exposure from consuming hormonetreated beef is well below the ADI, there is some concern regarding determination of the ADI. First, neither the actual data nor reference to a peer-reviewed publication was provided. Second, 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. The tolerance levels for progesterone levels in uncooked tissues of steers and calves established by the FDA (Ref.: *Code of Federal Regulations (CFR) 21, Part 556, Tolerances for residues of new animals drugs in food*) are:

Tissue	Progesterone (μg/kg)
Muscle	3
Liver	6
Kidney	9
Fat	12

Based on these levels, consumption of 500 g/day of beef (300g muscle, 100g liver, 50g each of kidney and fat) would result in exposure to approximately

2.6 µg/person/day. This amount represents approximately 1-2% of the daily production rate for progesterone of 150 µg/day estimated for prepubertal boys, and approximately 0.3% of the maximum excess exposure to progesterone estimated to occur upon consumption of meat from hormonetreated cattle (Table A3, Annex). However, there is considerable uncertainty associated with the validity of the daily production rate data. It is possible that this value has been over estimated by one to two orders of magnitude, in which case excess progesterone intake from hormone-treated beef could at best exceed the 1% FDA safety margin and at worst be greater than that naturally present.

- **1999 SCVPH opinion.** *Progesterone Levels in Human Blood:* The data show that premenopausal women have the highest levels of endogenous progesterone (Table 1, section 3.1). Progesterone production rates in premenopausal women during the follicular phase have been determined to be approximately 418 µg/day (JECFA, 1987 monograph). During pregnancy, progesterone production rates during late pregnancy have been determined to be approximately 94,000 ug/day (JECFA, 1987 monograph). In men, the daily production rate for progesterone is approximately 416 µg/day, respectively (JECFA, 1987). In prepubertal boys, the progesterone production rate has been reported to be 150 µg/day (JECFA, 1987). Thus, prepubertal and postmenopausal females and prepubertal and adult males have the lowest levels of endogenous progesterone and thus would represent the individuals most likely to be at increased risk for adverse health effects that might be associated with exposure to exogenous sources of oestrogens.

- **1999 SCVPH opinion (page 55-56).** 4.4. Trenbolone. Trenbolone acetate (TBA), 17β-hydroxyestra-4,9,11-triene-3-one, is a synthetic steroid with anabolic properties. It is 8 to 10 times as potent as testosterone (Bouffault and Willemart, 1983). In animals, TBA, alone or in combination with 17ß-ooestradiol, is used to improbe weight gain and feed efficiency. This effect is most likely a consequence of the anabolic acion of this androgen. The various TBA-containing implants, their composition, and target animal are shown in Tables A1 and A2.

  4.4.1. Pharmacokinetics and biotransformation of trenbolone in animals. TBA is administered by subcutaneous implantation in the ear. The ear, along with any residual drug, is discarded after slaughter. The dosage of TBA varies with manufacturer of the implant, ranging between 40 and 300 mg per animal (JECFA, 1988). TBA upon entering the circulatory system is rapidly hydrolyzed to its active free form, 17β-trenbolone (TBOH). In the bovine species, the 17α-epimer is the major metabolite occurring in the excreta, bile and liver; the 17β-epimer is the major metabolite occurring in muscle (Jouquey et al., 1983). Elimination in the bile and urine occurs following conjugation, predominately to glucuronic acid (Pottier et al., 1979; Pottier et al., 1981). Also in blood plasma, conjugated TBOH has been determined; 56 concentrations were 13% of those of free TBOH. In addition a number of other metabolites have been identified in bile. However, only trendion seems to occur in some qualitative amounts. In 1978, Ryan and Hoffman (Ryan and Hoffman, 1978) reported remarkable discrepancies in residue concentrations as determined by radiotracer studies and RIA; they concluded that the much lower values obtained by RIA were due to the formation of covalently bound nonextractable residues. This observation was further substantiated (Evrard and Maghuin-Rogister, 1988), and in vitro studies (43) have demonstrated the involvement of hepatic cytochromes P450 in the formation of these type of residues. The metabolism of TBA appears complex and species dependent. Further investigations of both the metabolic

fate and the chemical nature of the covalently bound residues is warranted (Metzler, 1999).

- **1999 SCVPH opinion.** *4.4.2. Trenbolone disposition in the target animal.* TBA is rapidly metabolised to its free active form, alpha and beta TBOH. In cattle, the β-epimer is the major metabolites in muscle. The concentrations of α- and β-TBOH, free and conjugated have been measured in muscle, liver, kidney and fat of treated cattle at various times after implantation. Table 8 shows the residue values for these tissues at the time after implantation where the highest level of ß-TBOH was detected in muscle. (*Table 8: Residue Levels (ng/kg) of α- and β-TBOH (free + conjugated) in tissues of treated cattle *30 days post implant; + free + conjugate; Data from JECFA, 1987)*.

- **1999 SCVPH opinion.** *4.4.3. Pharmacokinetics and biotransformation of trenbolone in humans* The metabolism of trenbolone in humans has not been extensively studied. In one study, Spranger and Metzler (Spranger and Metzler, 1991) examined the disposition of 17-β-trenbolone in a single human subject administered 0.04 mg/kg body weight. Urine was collected in fractions for 72 hours after ingestion. The fraction of the first 3-h urine contained the highest concentration of radioactivity and was used for the analysis of metabolites. Of the urinary material, 54 % was present as glucuronides, which contained mostly 17α-trenbolone, 17β-trenbolone and trendione. At least five other polar metabolites, presumably hydroxylated products, were detected in smaller amounts. A total of 54% of the administered radioactivity was found in the urine after 26 hours, and 63% after 72 hours (Spranger and Metzler, 57 1991). Further analyses of the formation of polar metabolites of trenbolone is essential to the assessment of the risk of repeated dietary exposure of humans to this compound.

- **1999 SCVPH opinion.** *4.4.4. Assessment of exposure to trenbolone from consumption of hormone-treated beef.* Since TBA does not occur naturally, by definition endogenous levels in humans should be zero. Thus, any residues detected in the meat of treated cattle represent excess exposure to individuals consuming the meat. The ADI for trenbolone acetate recommended by the JECFA(1987) for humans was 0-0.1 µg/kg body weight based on a non-hormonal effect level of 2 µg TBA/kg in a study in pigs. In 1988 the Expert Committee on Food Additives (JECFA), using this same non-effect level established a temporary ADI of 0.01 µg TBA/kg body weight (0.7 µg/70 kg person), and recommended a temporary Acceptable Residue Level of 1.4 µg/kg bovine meat for β-TBOH on the basis of consumption of 500 g meat by a 70 kg person. The FDA (*CFR 21, Part 556, Tolerances for residues of new animals drugs in food*) has set tolerance limits for TBA levels in uncooked tissues of cattle.

Tissue	TBA (µg/kg)
Muscle	50
Liver	100
Kidney	150
Fat	200

Based on these levels, consumption of 500g of meat/person/day (comprised of 300g muscle, 100g liver, 50g kidney and 50g fat) the acceptable daily consumption of TBA could reach 43 µg/person/day, an amount considerably greater than recommended by the JECFA. This value greatly exceeds the recommended ADI. The toxicological

issues of concern include endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects. Specific hazardous effects are detailed below.

- **1999 SCVPH opinion.** *4.4.5. Mutagenicity and genotoxicity* 17β-Trenbolone (β-TBOH) is a synthetic androgen. 17α-trenbolone (α-TBOH) is a metabolite formed in cattle. Both, the parent compound and its metabolite (α-TBOH), have been extensively tested for their mutagenic/genotoxic potential. The results are summarized as follows (table 9).

- **1999 SCVPH opinion. (***Table 9: Mutagenicity testing of trenbolone and its metabolite)*. Both 17α- and 17β- TBOH gave the same results. As the 17α-metabolite is more weakly androgenic, it might be concluded that the genotoxic effects of TBOH are not related to their hormonal activity. The ability of 17β-TBOH to transform Syrian hamster embryo cells has to be noted (Lasne, et al., 1990), although another laboratory found negative results at all concentrations tested (Tsutsui, et al., 1995).

- **1999 SCVPH opinion.** *4.4.6. DNA adducts and DNA damage.* Covalent binding of [3H]17β-TBOH to DNA was observed after incubation with rat liver postmitochondrial supernatant *in vitro* and in rats *in vivo* after oral or i.p. administration (Lutz et al., 1988). Binding of TBOH to rat liver DNA was also observed by Barraud et al. (1984) and Petit et al. (1989). Formation of DNA adducts is also observed in rat hepatocytes cultured with 30 μM β-TBOH (Metzler, 1999).

- **1999 SCVPH opinion.** *4.4.7. Carcinogenicity.* Feeding of high doses of Trenbolone acetate (TBA) to mice induced a significant amount of liver hyperplasia and tumors; in rats a slight increase in islet-cell tumors of the pancreas was observed (WHO Technical Report No. 696, 1983). A 2-year carcinogenesis bioassay in male and female rats and mice did not provide definitive results on the carcinogenicity of β-TBOH (mentioned in Schiffman et al., 1988). In humans, no data are currently available to assess the carcinogenicity of trenbolone. In conclusion, in consideration of the lack of in vitro short-term assays on mutagenicity and genotoxicity of other TBOH metabolites other than α-TBOH, 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. It has also to be noted that a considerable fraction of TBOH residues seems to be covalently bound to tissues.

- **1999 SCVPH opinion.** *4.4.8. Effect of trenbolone on growth and reproduction.* Deleterious effects of trenbolone acetate exposure were reported in the reproduction of both male and female mammals of various species (JECFA, 1988). In the adult male, trenbolone acetate administered by ingestion, injections or implants induces a decrease in testis, seminal vesicle and prostate weights and alterations in spermatogenesis. In the adult female, such treatments induce virilization and alteration or suppression of ovarian cycles. In a study involving women volunteers given i.m. doses of 10 mg trenbolone acetate every-other-day during 14 days, disturbances of the menstruation cycle have been reported. Some data in rodents indicate that administration of trenbolone acetate during the intrauterine or/and perinatal period alters the reproductive function in adults. In a multi-generation study, it has been shown that trenbolone acetate, administered to female rats at dietary concentrations of 3 and 18 ppm between 2 weeks before mating and 3 weeks after birth of youngs exerts effects on reproductive performance which are more marked in F2 pups than in F1 pups of a comparable age. Indeed, female F1 pups from F1-treated

parents show signs of virilization, a delay in the mean vaginal opening and the presence of occlusive strands in the vagina or incomplete vaginal opening. Male pups show a delay in the occurrence of testicular descent and a decrease in weights of seminal vesicles, prostate, testes and epididymis. In addition in F2 from both sexes, the adrenal weight is also decreased (JECFA, 1988). These data do not allow a realistic assessment of a dose response relationship.

- **1999 SCVPH opinion.** *4.4.9. Effects of trenbolone on the immune system.* Investigations on the effects of trenbolone on the immune system are very limited. A slight, but non statistically significant, immuno depression was seen in male calves given SC implants of trenbolone acetate (140 mg). A statistically significant change was observed when a combination of trenbolone acetate and oestradiol (20 mg) was used. No such change was seen with oestradiol alone. In female calves no such effects were observed (Gropp et al., 1975). In conclusion, this information is insufficient to assess the possible impacts of low levels of trenbolone in meat and meat products on consumers.

- **1999 SCVPH opinion.** 4.5. Zeranol. Zeranol (α-zearalanol) is an oestrogenic derivative of the mycooestrogen zearalenone. This oestrogen depresses the endogenous gonadotropins, luteinizing hormone and follicle stimulating hormone. Zeranol binds to the oestrogen receptor in swine, rats and chickens with a binding affinity similar to that of DES, which is much greater than that of oestradiol (Fitzpatrick, et al., 1989). In rat liver, zeranol was shown to bind to the oestrogen receptor and to DNA in a manner similar to that of oestradiol (Mastri, et al., 1986). Dietary administration of castrate female Rhesus monkeys for two consecutive days provided a no-effect level of 1 mg/kg/day (Fuller, et al., 1982). The zeranol-containing implants and target animals are summarised in Table A2 of the Annex.

- **1999 SCVPH opinion.** *4.5.1. Pharmacokinetics and biotransformation of zeranol in animals.* The half-life of zeranol plus its metabolites in the blood was 26 h in New Zealand rabbits and 18 h in Rhesus monkeys (Migdalof, et al., 1983). Glucuronide and sulfate conjugates were found in the urine. Both zearalenone and taleranol (isomeric β-zearalanol) have been found as metabolites of zeranol in cattle (Sharp and Dyer, 1972; Duchatel and Maghuin-Rogister, 1985; Jansen, et al., 1986; Kim, et al., 1986). When zeranol was metabolized by uninduced or Arochlor-induced rat liver microsomes, five new metabolites, tentatively identified as monohydroxylated derivatives, and small amounts of taleranol and zearalenone were observed (Metzler, 1999). Three of the five monohydroxylated derivatives of zeranol were also observed with bovine liver microsomes.

- **1999 SCVPH opinion.** *4.5.2. Zeranol disposition in the target animal.* In a study of cattle implanted in the ear with 30 mg of tritium-labeled zeranol, the tissue residues peaked at 5-15 days and then slowly decreased (Tarr, et al., 1984). At 65 days, approximately 60% of the initial dose remained at the implant site. The maximum residue level occurred in the liver and never exceeded 10 μg/kg, whereas the residue level in muscle did not exceed 0.13 μg/kg. In cows implanted with Ralgro (36 mg) and slaughtered 70 days later, the average values of zeranol determined by a radioimmunoassay were 0.127 μg/kg in muscle, 0.184 μg/kg in fat, 0.299 μg/kg in liver and 0.157 μg/kg in kidney (Dixon and Mallinson, 1986). In steers implanted with Ralgro (36 mg) and slaughtered 70 days later, the levels of zeranol in liver, kidney, muscle and fat were 0.200, 0.126, 0.725 and 0.073 μg/kg (Dixon, et al., 1986).

- **1999 SCVPH opinion (page 60).** Male pups show a delay in the occurrence of testicular descent and a decrease in weights of seminal vesicles, prostate, testes and epididymis. In addition in F2 from both sexes, the adrenal weight is also decreased (JECFA, 1988). These data do not allow a realistic assessment of a dose response relationship.

- **1999 SCVPH opinion.** The convention used by JECFA as the basis for determination of daily consumption of hormones is based on eating 500 g of meat per day (300g muscle, 100g liver, 50g kidney and 50 g fat). Based on this and the acceptable oestradiol levels in beef shown in Table 3, total daily consumption of currently acceptable levels of oestradiol would be 102 ng. This value represents approximately 1-2% of the currently used calculated daily production rates for oestradiol in prepubescent children. As mentioned previously in the *Exposure Considerations Section*, the daily production rate for oestradiol was estimated to be 6 µg/day oestradiol in boys. These daily production rate (PR) values are determined by the formula: PR (µg/day) = plasma concentration (µg/ml) x metabolic clearance rate (MCR, ml/day). However, there are two potential problems with these values. First, as mentioned previously (*Exposure Considerations Section)*, determination of plasma concentrations of oestradiol is subject to considerable variability, relative insensitivity given its low levels in children, and interference. A new, highly specific, more sensitive assay for oestradiol indicated that blood oestradiol levels in girls may be as much a 13 fold less and in boys 100 fold less than previous determinations using RIAs indicate. Second, it does not appear that MCRs have ever been determined directly in children. Rather, it appears as if MCR values from adult women were used in the calculations of the PRs for children (Andersson and Skakkebaek, 1999). This approach may or may not be valid given the known differences in levels of SHBG (higher in children, which would reduce clearance), and likely differences in uptake and metabolism, etc. Given these issues, it is possible that the safety margin for oestradiol exposure used by the FDA may be in error and that acceptable levels of hormone residues in beef could be much lower. (Similar concerns apply to progesterone and testosterone). The median level of excess exposure to oestradiol from consuming meat from hormone-treated cattle is 6.8 ng/person/day (calculated from Table A3, Annex, range 1 to 84 ng/person/day). For comparative purposes, assuming 100% absorption and a whole blood volume of 78ml/kg body weight, for a 40 kg child, based on the median value for excess oestrogen exposure, the blood concentration calculates to be 2.2 pg/ml (1 to 26 pg/ml). If the blood oestrogen levels are 100 fold lower than previously determined and the MCR too high by a factor of 10, the oestradiol daily production rate could be as low as 6 ng, and 1% of this would be 60pg. Thus, the FDAs acceptable daily intake (102 ng/person/day, see above) could exceed the daily production rate of oestradiol by 1,700 fold. While there is some experimental evidence in support of the currently used blood levels of oestradiol being 100 fold too high (Klein et al., 1994), the other assumptions used in coming to this conclusion may be too conservative. Thus, if absorption is reduced to 10% and the MCR for children is only 1/2 that of adults, the FDA acceptable daily intake could still be 85 fold too high. Given all of the uncertainties in these estimates, it appears that the data are insufficient to form the basis of a sound risk assessment. Clearly, this is an important area for additional research.

- The question is whether the risk assessments of the five hormones by JECFA in 1987/1989 and of MGA by the US and Canadian authorities were based on evidence focusing specifically on the lack of carcinogenic, genotoxic, or endocrine effects of

> the residues of these hormones in bovine meat and meat products? The risk assessment by JECFA in 1987/1989 was based on hormonal effects only and no excess exposure was envisaged, the genotoxic and carcinogenic potential of residues in meat and meat products was not considered. More recent work on biotransformation mediated genotoxicity (cited also in the JECFA 199 report) shows that no threshold can be defined either for the endocrine, developmental, immunological and neurobiological effects or for their potential immunotoxicity and carcinogenicity. This statement is also made in the light of the emerging concerns of the effects of hormones at different stages of life and the accumulating epidemiological findings on tumor incidence as summarized by IARC. The SC also acknowledged that recent findings on the metabolism based genotoxicity of 17-ß oestradiol (see chapter 2.5 of the 1999 report) it has to be stated that the assumption that the carcinogenic potential is exclusively related to the hormonal activity is no longer valid. In addition it is worthwhile mentioning recent improvements in analytical techniques applied in the measurement of physiological hormone levels. The introduction of more sensitive and specific bioassays/oestrogen receptor assays (as outlined in detail in the text of the report) indicated that a critical reappraisal of the endogenous hormone levels in certain segments of the human population, such as prepubertal boys and girls is required.

127. The 2002 opinion of the SCVPH moreover considered the report on melengestrol acetate prepared by the 54th meeting of JECFA.

128. In summary, the European Communities considers that the assessments of JECFA mentioned above have suggested that it is unnecessary to set maximum residue limits (MRLs) for oestradiol 17ß, testosterone and progesterone because they considered that residues resulting from the use of these substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health. But for zeranol and trenbolone acetate MRLs have been proposed by JECFA.

129. However, as already explained the above-mentioned JECFA reports found that oestradiol 17ß "*has genotoxic potential*" and that the evidence for progesterone was interpreted "*on balance*" as not having genotoxic potential. On the basis of these findings, JECFA did consider for the first time that ADIs were necessary to be fixed but not MRLs, because of the endogenous production of these natural hormones and the difficulties in applying the available detection methods in order to determine the origin of any residues in meat. But the European Communities could not adopt the risk management options proposed by JECFA, because the scientific risk assessment of the SCVPH did not come to the same conclusions as those of JECFA (see the passages from the SCVPH opinion listed above). One of the difficulties of the JECFA reports, for instance, is that JECFA's traditional mandate does not allow it to examine all risk management options but restricts it to either propose MRLs or not. Therefore, after the examination of the full range of risk management options and taking into account the potential advantages and disadvantages as well as consequences and feasibility of risk management options (in particular that of control), the European Communities regulatory authorities concluded that the prohibition of the use of hormones for growth promotion within the European Communities and the exclusion of import of meat derived from animals treated with hormonal growth promoters was the most appropriate measure in order to protect its consumers from the risks identified from excess intake of hormone residues and their metabolites and the potential for abuse, *inter alia*, through non-observance of good husbandry practices. In other words, the European Communities came to the conclusion that the JECFA's recommendations could not achieve the level of health protection considered appropriate by the European Communities in its territory from residues of these hormones under realistic conditions of use for animal growth promotion.

Q23. Does the European Communities agree that the re-evaluation of the risks of progesterone by the Committee for Veterinary Medical Products in 1999 concluded that this hormone is safe when used according to good veterinary practice? If so, has the European Communities taken this conclusion into account in its overall risk assessment process? If not, why has this conclusion not been considered? What are the arguments that have precluded this conclusion from being used as the basis of the EC's measure for progesterone (US first written submission, para. 128)?

130. The European Communities would like to recall that the Appellate Body has reversed the panel's findings on the issue concerning the occasional use of the naturally occurring hormones for therapeutic or zootechnical purposes.[39] Therefore, arguments of this kind by the defending parties in the context of these proceedings attempt to reintroduce a debate that they have lost at the Appellate Body level. A short reply to this question, therefore, is that this issue is now irrelevant.

131. However, the European Communities will provide some information on this question. Indeed, the SCVPH opinions, and in particular the opinion of April 2002, have indeed taken the CVMP's 1999 assessment on progesterone into account, notably in the light of the new scientific studies available by 2002. Hence, the European Communities' overall risk assessment of progesterone use as growth promoter in cattle has duly taken this opinion into account, as evidenced in recital 7 of the new regulation on progesterone (Commission Regulation (EC) no 1873/2003/EC mentioned above),[40] which explicitly cites the CVMP conclusions and explains how they are taken into account, as a basis for the new provisional ban on progesterone.

132. The arguments that have precluded the conclusion of the CVMP's from being used as the only basis of the EC's measure for progesterone as a growth promoter are the following : First, new scientific evidence had appeared since, and the SCVPH opinions, within their own assessment for its use as a growth promoter, had identified risks, which were incompatible with the level of health protection which the European Communities applies to these hormones when intended to be used for animal growth promotion purposes.

133. Secondly, it would be more correct to states that the "qualifier" of the CVMP conclusion would rather be when progesterone is used in veterinary *medicinal* products authorised in accordance with the relevant Community legislation, which would exclude "over the counter" products freely available to a layman, outside any veterinary control. In reality, the CVMP risk assessment on the possible need to establish MRLs for progesterone was evaluated only for therapeutic or zootechnical purposes and *not* for animal growth promotion purposes, as the defending parties wrongly argue. The assessments of the risks from the CVMP and from the SCVPH were, therefore, for different purposes and it is not possible to extrapolate the conclusion of one Committee made for one specific use, as explained above.

Q24. Does the European Communities agree with the United States that a risk assessment includes four steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization? What is the EC's response to the US argument that the EC failed to proceed from identifying hazards to characterizing hazards and to assessing the exposure in order to demonstrate a specific risk to consumers (first US written submission, para. 42)?

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[39] *See* Appellate Body Report, *EC – Hormones*, at paras. 221-225.

[40] Commission Regulation (EC) No 1873/2003 of 24 October 2003 amending Annex II to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

134. The European Communities does not agree with the United States unfounded claim that the EC would not have followed internationally recognized standards of risk assessment (in the narrow or strict sense mentioned in the Codex Alimentarius Commission principles on risk analysis, as explained with the reply to Question No 16 above), and find this kind of criticism unfounded and irrelevant.

135. First, it has to be clarified that, as defined by the Codex Alimentarius Commission, risk assessment is normally considered to be only the first component of a three part process, known as risk analysis. It is the scientific process which is intended to provide the competent regulatory authority with the information required to allow it to decide on the measures necessary to reduce the risk from a particular hazard to a level that is considered acceptable in its territory and under the conditions prevailing therein.

136. The United States and Canada make little or no reference to risk management, which is the second component and an integral part of the internationally agreed process of risk analysis, which has to be completed *after* the completion of the four steps of risk assessment.

137. This second part of risk management is 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". And as the Appellate Body indicated in its report, in agreeing with the European Communities, setting the level of health protection is the autonomous right of the authority responsible for risk management.

138. For instance, as regards the use of these hormones for animal growth promotion in the circumstances prevailing in the European Communities, its authorities have determined at the risk management stage of the risk analysis, on the basis of the scientific risk assessments that the SCVPH had performed on its behalf, that the addition to the food chain, whether of naturally occurring or synthetic hormones, is an avoidable risk, which needs to be prevented in order to meet the chosen level of health protection.

139. But to come back to the scientific assessment of the risks itself, as the first component of risk analysis, it is performed in the European Communities by advisory bodies composed of independent experts, such as the SCVPH, as it is laid down in the relevant legislation that is generally applicable. The United States cites four general steps which are identified internationally (albeit not always with the name cited by the United States), as being relevant for the risk assessment (at the first stage in risk analysis), but not the risk analysis itself.

140. The European Communities of course follows these four components or steps, as does all advisory bodies performing internationally recognised assessments of risks.[41] It has to be noted, however, that which ever approach is followed, they are all based on a deterministic approach to risk characterisation (the level of exposure amounts proportionally to the level of risk for a given hazard), have serious limitations in non-linear situations, such as in the current case regarding these hormones. Here, the risks are embedded in changes in exposure to biologically active molecules which may, within minute differences in their bioavailability, have dramatic effects, such as turning on or off complete developmental programs of the human genome, or inducing pathological conditions. This is a classical non linear situation, which is poorly addressed by the risk assessment guidance currently available from the Codex Alimentarius Commission.

[41] For instance, another internationally recognised approach for risk assessment is made of three steps: hazard characterisation (in fact the severity of each identified hazard), probability of occurrence, and the risk being then conceptually characterised as the product of the hazard (danger) by its probability of occurrence.

141. The United States also fails to identify that, for instance, the recommendation to perform an exposure assessment is to be formalised to an actual identification of exposure, only when such exposure assessments can be made because the data are available, which, in this case, as largely demonstrated by the opinions of the SCVPH and the available scientific evidence, is often not the case in the current state of available pertinent information.

142. The USA criticism is also irrelevant in the present context, where the risk assessment at the basis of the new Directive precisely follows these four steps, enabling it to identify different levels of risks presented by different uses, and the new Directive then adapts the management of these risks accordingly, which incidentally is not the case in the defending members.

143. In addition to the above rather general considerations, in order to confirm that the European Communities has addressed in its risk assessment the four steps mentioned by the United States, it would suffice to draw the attention of the Panel to the table of contents (Index) of the SCVPH 1999 opinion, which is reproduced below and identifies all these steps, one after the other for all the six hormones, each of which then being explored in detail and in substance in the body of the SCVPH report: the title for each entry speaks for itself.

144. Indeed, the whole of section 2 identifies and characterizes more than twelve serious hazards due to these hormones, and section 3 addresses thoroughly exposure assessment, as indicated explicitly in its title. Section 4 then addresses individually each of the six hormones, and goes into the characterisation of each risk, with the relevant exposure assessment for each of the hazard previously identified and characterised and which is relevant for that hormone. Section 5 summarizes the overall risk characterization of the opinion.

Q25. Could the European Communities explain the hazard characterization in terms of the Opinions. Is dose-response assessment a necessary approach of hazard characterization in the EC's view? Or, is there an alternative approach which replaces the dose-response assessment? What have the Opinions done in this respect?

145. Hazard characterisation, as the words denote, is the step whereby a generally identified hazard (death, spontaneous abortion, carcinoma, breast cancer, autoimmune disease, developmental pathology of reproductive organs, DNA adduct formation, etc.) may be characterised in connection with the uses of the six hormones.

146. The short answer to the second part of the question is that a dose-response assessment is a recommended approach to characterise specific hazards **when one can do it**, but is by no means a compulsory nor a necessary approach. In fact, the Appellate Body has clearly judged that a risk assessment can be either qualitative or quantitative and has rejected the contention that a minimum magnitude of risk was necessary (at para 186 of the Appellate Body report).

147. But in any case, as regards the six hormones in question, the scientific opinions of the SCVPH have made a hazard characterisation for each of these hormones, as it can easily be verified by reading its 1999 opinion. In particular, it has identified a number of hazards and has characterised for the bioactive molecules at stake in these hormones that the hazards, such as for example genotoxic effects, may manifest themselves with very long time lapses between dose exposure and response, and it may often not be possible to measure properly the relevant dose-response impacts of the hormone or hormone residues. The 1999 SCVPH states*, inter alia*, on this issue:

> "The potential adverse effects on human health from residues in bovine meat and meat products include endocrine, developmental and neurobiological, immunological as well as carcinogenic, genotoxic and immunotoxicological effects as described in the report and addressed in the executive summary. These effects can be attributed to

> either the parent compound or the metabolites. Residue analysis has focussed in the past on the quantification of the amounts of residues of the parent compounds and those metabolites exerting hormonal activity. Recent data indicate that other metabolites occur additionally which have genotoxic activity. For example, 17-ß oestradiol can be metabolized to 2-OH, 4-OH and 16α-OH oestrogens. Particular the 2-OH, and 4-OH oestrogens have been found to be directly or indirectly genotoxic. This implies that 17-ß oestradiol may act as tumor initiator as well as tumor promoter. These findings are in agreement with epidemiological data and resulted in the classification of 17-ß oestradiol as human carcinogen (Group 1 according to the IARC classification). This implies that any excess exposure towards 17-ß 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. It should be noted that for these genotoxic metabolites in bovine tissues, no threshold level can be established. In addition, no threshold level can be established for any of the hormonally active compounds and metabolites which might exert endocrinal, developmental and neurobiological, immunological or immunotoxicological effects.
>
> With the exception of 17-ß oestradiol, the currently available information for testosterone, progesterone and the synthetic hormones zeranol, trenbolone and particularly MGA has been considered inadequate to complete an assessment.
>
> This conclusion is based upon:
>
> – incomplete data on the biotranformation pathways of these compounds and the possible biological activity of the metabolites formed in bovine tissues as, for example, testosterone might be aromatized to oestradiol.
>
> – lack of data on the potential genotoxicity of these metabolites in consideration of the current state of the art for genotoxicity testing as indicated in the answer to question 2 (a).
>
> – insufficient data on immunological and immunotoxical effects.
>
> Based on experimental and epidemiological data, testosterone and progesterone have been classified by IARC as Group 2 substances - probable/possible carcinogens in humans. No epidemiological data are available for zeranol, trenbolone and MGA (melengesterol acetate) although residues of hormonally active compounds in (poultry) meat have been shown to exert an oestrogenic response in prepubertal children in certain countries.
>
> Thus, no final conclusions can be drawn with respect to the safety of at least five out of the six substances under consideration, until the above described issues have been clarified. For oestradiol genotoxicity has already been demonstrated explicitly."

148. Moreover, it has done this hazard characterisation as regards also the particularly vulnerable segments of the population that may be exposed to these identified hazards, that is prepubertal children. The 1999 SCVPH states, inter alia, on this issue:

> "In acknowledging the recent findings on the metabolism based genotoxicity of 17-ß oestradiol (see chapter 2.5 of the report) it has to be stated that the assumption that the carcinogenic potential is exclusively related to the hormonal activity is no longer

valid. In addition it is worthwhile mentioning recent improvements in analytical techniques applied in the measurement of physiological hormone levels. The introduction of more sensitive and specific bioassays/oestrogen receptor assays (as outlined in detail in the text of the report) indicated that a critical reappraisal of the endogenous hormone levels in certain segments of the human population, such as prepubertal boys and girls is required."

Q26. Is "exposure assessment" a necessary element of the risk assessment? Please explain the EC exposure assessment in terms of the Opinions? Has the European Communities conducted an analysis comparing the actual residues of the hormones in meat from cattle not treated with growth-promoting hormones with those in meat from cattle treated with hormones according to good veterinary practice? What is the health risk to humans associated with the pathway of oestradiol 17 β used in animals for therapeutic and zootechnical purpose?

149. The last part of the question on therapeutic and zootechnical purposes, apart from being legally irrelevant in view of the Appellate Body findings mentioned above, has been largely addressed in the replies to the previous questions, in particular question 20, and will not be addressed here anymore.

150. This being said, in the case of the six hormones, the European Communities has performed exposure assessments systematically when it was able to do so, as detailed in the three SCVPH opinions.

151. As regards the question whether the European Communities has performed an "analysis of comparing the actual residues of the hormones in meat from cattle not treated with growth-promoting hormones with those in meat from cattle treated with hormones according to good GVP", the European Communities has already explained with its reply to Question 17 above, 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 could not achieve the level of protection it has considered appropriate in its territory. As discussed before, for the purposes of exposure assessment from the residues of these hormones, it is not so much necessary to compare (if it were only possible!) 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 human to multiple hazards, in addition to the endogenous production of some of these hormones by the animals and the human beings. For those reasons, the European Communities has determined, at the risk management stage of the risk analysis, on the basis of the scientific risk assessment that the SCVPH had performed on its behalf, that the addition to the food chain of any level of residues from the exogenous administration of these hormones to animals for animal growth promotion purposes is an avoidable risk, which needs to be prevented in order to meet its chosen level of protection.

152. Furthermore, one would also like to know what exactly the defending members have done in this respect, since the risk assessments they claim to have performed are very old by today's standards (dating from the 70's in most cases). Have the United States and Canada, or any other WTO member, actually done this kind of exposure assessment, when they decided to authorise these hormones for animal growth promotion purposes? Could they communicate the results of their assessment on this specific point to the Panel and other parties to this dispute?

153. Finally, it should again be clarified that whereas the original Panel concluded that "potential" means "probable", the Appellate Body concluded (at para. 184) that the use of this term gave cause for concern, noting that this introduces a quantitative dimension to the notion of risk, also noting that

the ordinary use of "potential" relates more to the word "possible". Otherwise, it argued, there would be an implied need for a quantitative assessment of risk. The Appellate Body clearly judged that a risk assessment can be either qualitative or quantitative. Thus, the panel implication in the hormones case that there must be a minimum magnitude of risk was rejected by the AB (at para. 186). The submissions from US and CAN in the context of the present dispute, however, seek again to impose the need for a quantitative assessment and a minimum level of risk. This has failed once and should fail again. The US and CAN submissions misrepresent certain other elements of a risk assessment. For example, the US 1st written submission (at para. 143) equates hazard characterisation with dose response. Although the Codex Alimentarius recommendations on risk analysis urge that a dose response assessment should be carried out where possible, this is not the central issue in hazard characterisation. According to Codex Alimentarius, the central element is "---a qualitative or quantitative description of the severity and duration of adverse effects ---". The EU has demonstrated the potential adverse effect, but has been unable to quantify it in a precise manner. No one, on the other hand, can doubt the severity of a carcinogenic effect, both pathologically and psychologically. It is quite clear that the potential effect of a carcinogenic substance is substantially greater than, for example, the effects of most microbiological agents. It is clear that this risk can be avoided or at least not added to the burden resulting from the naturally-occurring hormones and residues from other sources. There is no good reason to deny the consumer in the European Communities this higher level of protection.

Q27. Could the European Communities provide the Panel with the relevant data and analysis leading to the conclusion that "misplaced implants and repeated implanting seem to occur frequently, represent a considerable risk that highly contaminated meat could enter the food chain" in the SCVPH's 2002 review Opinions (US first written submission, para. 145)?

154. There was indeed a specific study taken into account in the SCVPH 2002 opinion that has addressed this issue. The European Communities provided it to the Panel with the exhibits attached with its reply to question no 16 (as Exhibit EC-6 (US) and Exhibit – EC 4 (CAN)). It is the study concerning the application of anabolic agents to food producing animals - health risks through disregard of requirements of good veterinary practice. This multifaceted study has given rise to a number of scientific publication in peer reviewed journals. They are the following:

(1) "Detection of melengestrol acetate residues in plasma and edible tissues of heifers", The Veterinary Quarterly 21: 154-158, 1999.

(2) "Detection of anabolic residues in misplaced implantation sites in cattle", Journal of AOAC International 83(4); 809-819, 2000.

(3) "Suppression of androstenone in entire male pigs by anabolic preparations", Livestock Production Science- 69: 139-144, 2001.

(4) "A sensitive enzyme immunoassay (EIA) for the determination of Melengestrol acetate (MGA) in adipose and muscle tissues", Food Additives and Contaminants 18(4):285-291, 2001.

(5) "Characterisation of the affinity of different anabolics and synthetic hormones to the human androgen receptor, human sex hormone binding globulin and to the bovine progestin receptor", APMIS 108: 838-846, 2000.

(6) "Dose-dependent effects of melengestrol acetate (MGA) on plasma levels of estradiol, progesterone and luteinizing hormone in cycling heifers and influences on oestrogen residues in edible tissues", APMIS 108: 847-854, 2000.

(7) "Hormone contents in peripheral tissues after correct and off-label use of growth promoting hormones in cattle: Effect of the implant preparations Finaplix-H®, Ralgro®, Synovex-H® and Synovex Plus®", APMIS 109: 53-65, 2001.

(8) "Tissue-specific expression pattern of estrogen receptors (ER): Quantification of ER_ and ER_ mRNA with real-time RT-PCR", APMIS 109: 345-355, 2001.

Q28. Has the European Communities considered the general low bioavailability of the six hormones at issue in its risk assessment? What is the EC's response to the US argument that JEFCA's risk assessment has indicated that oestradiol is generally inactive when given orally to humans (5% bioavailability)? In what way does this factor of low bioavailability affect the exposure assessment? Could the European Communities point out its analysis concerning the occurrence of health risk to consumers via the specific pathways at issue?

155. Yes, the general bioavailability of the six hormones at issue was considered in the risk assessment of the European Communities. The 1999 opinion of the SCVPH explains for each of the six hormones the evidence relating to their bioavailability. For instance, as regards oestradiol, the 1999 opinion states (on page 36) that:

> "4.1.4. Pharmacokinetics and biotransformation of 17β-oestradiol in humans.
>
> The oxidative metabolism of endogenous oestrogens is known to occur at several positions including carbons C-1, C-2, C-4, C-6, C-7, C-11, C-14, C- 15, C-16, and C-18. The major oestrogens detected in serum and urine are the 2-hydroxylated metabolites. The liver is the primary site of oestrogen metabolism, where rates of 2- and 16α-hydroxylation, catalysed by P4501A2, P4503A3 and P4503A4, greatly exceed that of 4-hydroxylation. Because 4- hydroxylated metabolites represent only a small percentage of the total amount of oestrogens detected in the urine, 4-hydroxylation has been considered a minor metabolic route of metabolism. However, it is now understood that extrahepatic tissue 4-hydroxylation of E2 may play a significant role in oestrogen homeostasis. In several organs which are sites of oestrogen-induced tumours, the rate of E2 4-hydroxylation equals or exceed the rate of 2-hydroxylation, and in comparison to normal tissue, elevated E2 4-hydroxylase activity has been observed in samples prepared from breast and uterine tumours. In humans, cytochrome P4501B1 has been identified as the most significant E2 4-hydroxylase. This enzyme is expressed primarily in extra-hepatic tissues (reviewed in Zhu and Conney, 1998, Martucci and Fishman, 1993).
>
> Specific information about the absorption, biotransformation and elimination of E2, E1 and 17α-oestradiol from meat and meat-product is not available. The effects of cooking and other processing on the bioavailability of such compounds is also lacking. Based on the lipophilicity of oestradiol, there is no reason to assume that such compounds will be poorly absorbed. Metabolic studies of orally administered 17ß-oestradiol indicate that as much as 20 percent of a 2 mg dose of micronized E2 is absorbed, with a serum half-life in the range of 2 to 16 hours (Zimmermann et al., 1998; Vree and Timmer, 1988: Ginsburg et al., 1998). In a 1998 study (Lippert et al., 1998) of oestradiol metabolism in postmenopausal woman orally administered oestradiol valeriate, 2 mg/day for 2 weeks, it was shown that along with the increased serum concentrations of oestradiol, there was a proportionate increase in the level of estrone, 2-hydroxyestrone and 16α-hydroxyestrone. Thus exposure to exogenous

> oestrogens leads to increased levels of the parent oestrogen compounds and their metabolites."

156. Moreover, as regards the young children – which is most vulnerable segment of the population - the 1999 opinion states (on pages 38-39) on this point the following:

> "However, there are two potential problems with these values. First, as mentioned previously (*Exposure Considerations Section)*, determination of plasma concentrations of oestradiol is subject to considerable variability, relative insensitivity given its low levels in children, and interference. A new, highly specific, more sensitive assay for oestradiol indicated that blood oestradiol levels in girls may be as much a 13 fold less and in boys 100 fold less than previous determinations using RIAs indicate. Second, it does not appear that MCRs have ever been determined directly in children. Rather, it appears as if MCR values from adult women were used in the calculations of the PRs for children (Andersson and Skakkebaek, 1999). This approach may or may not be valid given the known differences in levels of SHBG (higher in children, which would reduce clearance), and likely differences in uptake and metabolism, etc. Given these issues, it is possible that the safety margin for oestradiol exposure used by the FDA may be in error and that acceptable levels of hormone residues in beef could be much lower. (Similar concerns apply to progesterone and testosterone). The median level of excess exposure to oestradiol from consuming meat from hormone-treated cattle is 6.8 ng/person/day (calculated from Table A3, Annex, range 1 to 84 ng/person/day). For comparative purposes, assuming 100% absorption and a whole blood volume of 78ml/kg body weight, for a 40 kg child, based on the median value for excess oestrogen exposure, the blood concentration calculates to be 2.2 pg/ml (1 to 26 pg/ml). If the blood oestrogen levels are 100 fold lower than previously determined and the MCR too high by a factor of 10, the oestradiol daily production rate could be as low as 6 ng, and 1% of this would be 60pg. Thus, the FDAs acceptable daily intake (102 ng/person/day, see above) could exceed the daily production rate of oestradiol by 1,700 fold. While there is some experimental evidence in support of the currently used blood levels of oestradiol being 100 fold too high (Klein et al., 1994), the other assumptions used in coming to this conclusion may be too conservative. Thus, if absorption is reduced to 10% and the MCR for children is only 1/2 that of adults, the FDA acceptable daily intake could still be 85 fold too high. Given all of the uncertainties in these estimates, it appears that the data are insufficient to form the basis of a sound risk assessment. Clearly, this is an important area for additional research."

157. It has to be pointed out, however, that there is significant disagreement among scientists on the bioavailability of oestradiol in the specific oral pathway considered here, where the level of bioavailability cited in peer reviewed scientific literature ranges from 5% to 20%.

158. Moreover, similar finding are made for all the other five hormones. In addition, the 2002 opinion of the SCVPH further explained that the aim of one study (**study no 10 by Dr. Florence Le GAc**) was in particular to determine whether anabolics and their metabolites compete with natural sex hormones for binding to sex hormone binding globulin (SHBG / SBP). Theoretically, if this were indeed the case, tissues would be deprived of natural hormones that affect the development of sex hormone target organs during diverse stages of development. The data collected, shows a pattern of binding to SHBP and competition with ^{3}H-testosterone by ethynyl oestradiol, zearanolol alpha and beta, 19-nortestosterone, trenbolone acetate and 17β - trenbolone, and other natural androgens, not much different from those reported by others. The synthetic compounds did not bind to SHBG in blood plasma with high affinity. This study concluded that the lack of significant binding of zeranol

and its metabolites to SHBG suggest that when present in plasma their effect in brain and other oestrogen target organs is not neutralized by their weak binding to this plasma-borne protein.

159. Furthermore, the 2002 opinion considered (on page 12, section 4.1.5) the results of one more study (**the study no 3)** which found *inter alia* that:

> "The obtained results indicate that the potency of 17α-E2 is approximately 10% of 17β-E2. However, the potency of the lipoidal esters exceeded the effect of 17β-E2 in the in vivo assay by approximately a factor of 10 (Paris et al., 2001). Furthermore, lipoidal esters appear to have an even higher effect on the mammary gland in experimental animals (Mills et al., 2001). The high potency of lipoidal esters after oral applications might be explained by the fact that they reach systemic circulation via the lymphatic system, as suggested by preliminary data. These findings warrant further investigation, as a high bioavailability of biologically active lipoidal esters and the possibility of accumulation (Zarner et al., 1985) might contribute significantly to an undesirable exposure to oestrogenic substances. The impact of residual protein bound non-extractable oestrogen remains to be elucidated. In conclusion, it has to be stated that lipoidal esters of oestradiol add to the oestrogen exposure, as mentioned above. While the oral bioavailability of these metabolites was high in animal experiments, no information is available on the oral bioavailability in humans following dietary exposure via contaminated meat products."

Q29. Is the relatively low dose used for animal growth promotion purposes relevant for the risk assessment at issue? In what manner has this factor affected the result of the EC's risk assessment?

160. It should be clarified first that it is generally recognised that for substances which have genotoxic potential (as is the case with oestradiol 17β) the low dose used in animal growth promotion is not relevant, precisely because the possible genotoxic risks may arise at any dose. This being said, generally speaking, yes it is a relevant factor and the relative doses of hormones used for animal growth promotion purposes and the level of residues they give rise to in the different animal tissues has been taken into account in the European Communities' risk assessment. This is explained in detail for each of the six hormones in particular in the 1999 opinion of the SCVPH, which discusses this issue in several places. See, for example, table 2 on page 35 as regards oestradiol and the ensuing discussion; table 5 on page 47 as regards testosterone and the ensuing discussion; table 7 on page 52 as regards progesterone and the ensuing discussion; table 8 on page 56 as regards trenbolone acetate and the ensuing discussion; tables 10a and 10b on page 63 as regards zeranol and the ensuing discussion; and pages 66-68 as regards melengestrol acetate. As regards melegenstrol acetate, the 2002 opinion also analysed the more recent data resulting from the studies nos 5 and 10 (see section 4.5.2, pages 17-18 of the 2002 opinion).

161. The 1999 opinion concluded on this point that:

> "Endogenous hormones and their metabolites are present in measurable amounts in various animal tissues including meat (Section 3.1. and 4.1.5., 4.2.4., 4.3.4., 4.4.4., 4.5.4., 4.6.4.). The concentrations found, reflect different stages of the animals life cycle as exemplified by the high levels of testosterone in tissues of male cattle (bulls) or oestrogen and progesterone levels in tissues of young females (heifers) at a late stage of pregnancy (240 days gestation). Heifers are slaughtered and enter the food chain only exceptionally. It is therefore questionable whether levels in such animals should be included in estimates of the upper range of hormonal levels in meat and edible tissues. In contrast, for pharmaceutical products containing one or more of the

> three natural hormones, it is estimated that the use of these growth promoting agents will result in an additional excess daily intake of oestrogens in the range of 1 to 84 ng/person (17-β oestradiol + estrone), of progesterone of 64 to 467 ng/person, and of testosterone of 5 to 189 ng/person. As the levels of the synthetic compounds used as growth promoting agents are virtually zero in untreated animals, any residual amount in edible tissues must be regarded as excess exposure (see section 3.1). No validated data exists on the bioavailability of hormones and their metabolites after oral ingestion with meat."

Q30. Regarding the potential risks to consumers from the consumption of beef from cattle treated with testosterone, progesterone, zeranol, TBA and MGA, could the European Communities explain why, in the light of the available evidence, the European Communities has determined that the relevant scientific evidence is insufficient to permit the assessment of risks in a manner consistent with Article 5.1 and Annex A(4) of the *SPS Agreement*? With respect to what elements of risks does the European Communities believe that the available scientific evidence is insufficient?

162. As explained in the Recital 7 of Directive 2003/74 EC:

> "the SCVPH assessment [of 1999] is that, in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers."

163. This assessment has not been reversed by the new scientific evidence available after 1999 and later assessed by the SCVPH, as explained in the Recital 10 of the said Directive (see reply to question 19).

164. Specific assessments have been conducted regarding the potential risks to consumers from the consumption of beef from cattle treated with each of these five hormones for growth promotion purposes. These assessments have identified that, for each hormone, the level of information missing or contradictory was variable, at each individual step of the risk assessment.

165. The SCVPH has itself, in answering the questions of its mandate to perform the assessment of risks at stake, identified clearly where the information was felt insufficient. Question 1 (b) of SCVPH's mandate was formulated as follows:

> To what extent is the currently available information (clinical and epidemiological evidence included) sufficient to allow the SCVPH to complete its assessment, in particular for melengestrol acetate (MGA)?

166. In its reply, the SCVPH stated for all the six hormones the following:

> *ad 1 (b):* With the exception of 17-ß oestradiol, the currently available information for testosterone, progesterone and the synthetic hormones zeranol, trenbolone and particularly MGA has been considered inadequate to complete an assessment. This conclusion is based upon:
>
> – incomplete data on the biotranformation pathways of these compounds and the possible biological activity of the metabolites formed in bovine tissues as, for example, testosterone might be aromatized to oestradiol.

– lack of data on the potential genotoxicity of these metabolites in consideration of the current state of the art for genotoxicity testing as indicated in the answer to question 2 (a).

– insufficient data on immunological and immunotoxical effects.

Based on experimental and epidemiological data, testosterone and progesterone have been classified by IARC as Group 2 substances - probable/possible carcinogens in humans. No epidemiological data are available for zeranol, trenbolone and MGA (melengesterol acetate) although residues of hormonally active compounds in (poultry) meat have been shown to exert an oestrogenic response in prepubertal children in certain countries. **Thus, no final conclusions can be drawn with respect to the safety of at least five out of the six substances under consideration, until the above described issues have been clarified. For oestradiol genotoxicity has already been demonstrated explicitly.** (emphasis added)

Q31. The Panel is aware that the FAO/WHO *Codex Alimentarius* Commission has adopted standards with respect to five of the hormones at issue. For TBA and zeranol, the Codex has established MRLs; for oestradiol, testosterone and progesterone, the Codex decided that no MRLs were necessary. Please explain whether the European Communities believes that the Codex standards have been developed without "sufficient scientific evidence". With respect to what elements of risks do you believe that the available scientific evidence is insufficient?

167. For the reasons explained with its reply to question no 22, the European Communities considers that the standards adopted by the Codex Alimentarius Commission cannot achieve its chosen level of protection. The Codex Alimentarius standards are based on the assessments of JECFA mentioned above, which have suggested that it is unnecessary to set maximum residue limits (MRLs) for oestradiol 17ß, testosterone and progesterone because they considered that residues resulting from the use of these substances as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health and also because it is impossible to identify the real origin of any residues in meat (i.e. whether it is from endogenous production or exogenous administration), since the available detection methods are not capable of performing this kind of analysis. But for zeranol and trenbolone acetate MRLs have been proposed by JECFA.

168. However, as already explained the above-mentioned JECFA reports found that oestradiol 17ß "*has genotoxic potential*" and that the evidence for progesterone was interpreted "*on balance*" as not having genotoxic potential. On the basis of these findings, JECFA did consider for the first time that ADIs were necessary to be fixed but not MRLs, because of the endogenous production of these natural hormones and the difficulties in applying the available detection methods in order to determine the origin of any residues in meat. But the European Communities could not adopt the risk management options proposed by JECFA, because the scientific risk assessment of the SCVPH did not come to the same conclusions as those of JECFA (see the passages from the SCVPH opinion listed above). One of the difficulties of the JECFA reports, for instance, is that JECFA's traditional mandate does not allow it to examine all risk management options but restricts it to either propose MRLs or not. Therefore, after the examination of the full range of risk management options and taking into account the potential advantages and disadvantages as well as consequences and feasibility of risk management options (in particular that of control), the European Communities regulatory authorities concluded that the prohibition of the use of hormones for growth promotion within the European Communities and the exclusion of import of meat derived from animals treated with hormonal growth promoters was the most appropriate measure in order to protect its consumers from the risks identified from excess intake of hormone residues and their metabolites and the potential for abuse, *inter alia*, through non-observance of good husbandry practices. In other words, the European

Communities came to the conclusion that the JECFA's recommendations could not achieve the level of health protection considered appropriate by the European Communities in its territory from residues of these hormones under realistic conditions of use for animal growth promotion.

169. Moreover, the JECFA evaluations date of 1999 for the three natural hormones. It follows that they did not take into account the most recent data generated by the 17 studies initiated by the European Communities, upon which the three opinions of the SCVPH are also based. Consequently, it appears that the Codex Alimentarius standards have indeed been adopted on previous evidence, which by today's standards must be considered to be old. It is also generally accepted that evidence which is old becomes scientifically and legally "insufficient" when more recent information and data put into question its evidentiary value for the purposes of a risk assessment. Moreover, to the extent both JECFA and the relevant scientific committees of the European Communities considered partly the same evidence, they arrived at different results.

170. Finally, the elements of risks for which the JECFA assessment must be considered to be "insufficient" are explained, *inter alia*, with the reply to Question No 30 above.

171. Moreover, the European Communities has carried over a number of years several inspection mission in the USA and Canada in order to review and verify the respect of GVP and the extent of residue monitoring and control by the defending members. From these reports it is clear that there were a number of serious irregularities in the residue monitoring both in the USA and Canada (farm level as well as the laboratory testing itself). For instance, the results from the 2000 mission reports to USA and Canada can be found at the following website of the European Commission:

- http://europa.eu.int/comm/food/fs/inspections/vi/reports/usa/index_en.html.

and

- http://europa.eu.int/comm/food/fs/inspections/vi/reports/canada/index_en.html.

172. The above were further considerations that have led the responsible risk management authorities of the European Communities to conclude that under the realistic conditions of use, the standards recommended by Codex Alimentarius are not capable of achieving the chosen high level of protection by the European Communities from residues resulting from the consumption of meat from animals to which these hormones have been administered for growth promotion purposes.

Q32. Can the European Communities provide the Panel with a copy of the requests for information made to the United States, Canada and New Zealand in relation to scientific studies?

173. The European Communities will provide the Panel with the requested copies of these letters, which date back to April 1998. In fact, they have been archived in storage facilities outside the headquarters of the European Commission and are therefore difficult to retrieve. The European Communities apologizes for the delay. It will submit the copies as soon as it has retrieved them from the archives.

Q33. With respect to the written request made by the United States to the European Communities under Article 5.8 of the *SPS Agreement* for an explanation on the consistency of the EC's implementing measure, could the European Communities provide the Panel with a copy of its written response of 19 May 2005 (US first written submission, para. 194)? Could the EC explain why it replied to the US request for information pursuant to Article 5.8 of the *SPS Agreement* only after having requested the establishment of a panel?

174. The European Communities provides its written responses to the United States request under Article 5.8 of the *SPS Agreement* as Exhibit EC-7 (US) and Exhibit EC-5 (CAN)

175. Regarding the second part of the question, the United States, after not requesting anything for one and a half year since the notification of the new Directive to the WTO, or even having not commented to any of the earlier European Communities' calls for scientific input in its risk assessment, sent this request some time after the European Communities requested consultations in the present case: its request came on 13 December 2004, at the same time the consultations under these proceedings were held (16 December), which means more than one month after these consultations were requested by the EC.

176. It is a fact, therefore, that the United States' request came after these proceedings have started by the European Communities. The European Communities believes that the United States' request was in fact stemmed by our request for consultations, when they realised that the European Communities was serious about this issue and would certainly request the establishment of a Panel, as they had already then no intention to suspend their sanctions against us.

177. Their request was, therefore, part of the preparation of their defence strategy in this case, namely that they are now claiming to still "consider" our measure to comply, despite the many bilateral exchanges and requests for information which they had systematically denied before.

178. The exact date of the United States' request was 13 December 2004 and the European Communities requested the establishment of this Panel in 13 January 2005. With the standard administrative procedure to handle such requests, the European Communities took approximately 5 months to reply to the United States' request on 19 May 2005, a perfectly reasonable period of time, which should not come as a surprise, in the light of the internal institutional consultations required within the European Communities on issues of such a nature, and taking into account that Christmas and Eastern breaks had intervened in the meantime.

179. It would certainly be absurd to assume that such a reply could have been ready right after the Christmas break, before the request to establish the Panel, which had to follow naturally in the light of the lack of willingness of the United States to consider interrupting their sanctions in the preceding consultations.

180. Nevertheless, already at the time of its notification according to the *SPS Agreement*, the new Directive, and the risk assessments requested by the United States and which are provided for by the opinions of the SCVPH, were all publicly available through internet, as well as the scientific studies on which these assessments were based.

181. Finally, the European Communities would note that Canada never made any similar request under Article 5.8 of the *SPS Agreement*.

Q34. With reference to the EC statement in paragraph 102 of the EC's oral presentation that the European Communities "would have lifted the ban for these hormones if their use for growth promotion purposes were proven to be safe for the public health and would have met its chosen level of protection", please explain how the *safety* of the hormones could be proven?

182. The safety would have to be proven to the requisite legal standard by a state-of-the-art risk assessment taking into account the latest scientific information and data available. More importantly, the information and data gaps identified in the recent risk assessments and in particular those identified in the three opinions of the SCVPH would have to be clarified and properly addressed. This would require a lot of new information to be brought forward on all the crucial questions identified in the 1999 SCVPH opinion. It would in particular have to be shown that human exposure to residues of

hormonally-active substances contained in growth promoters used for meat production does not exert or has not the potential of exerting the harmful biological effects identified in the 1999 SCVPH opinion (e.g. cancer, on prepubertal children, etc.). This assessment would have to be performed on the basis of real situations of use, if authorised, so as to avoid the potential problems of misuse or abuse in order to achieve the high level of protection of no additional risk from the residues in meat of animals to which these hormones have been administered for growth promotion purposes. For instance, a group of independent USA scientists has recently published in a peer reviewed scientific journal that:

> "Zeranol (Ralgro) is a nonsteroidal agent with estrogenic activity that is used as a growth promoter in the US beef and veal industry. Thus zeranol is not an environmental contaminant per se. Rather, people are exposed to zeranol as a result of introduction of the compound into food animals by veterinary professionals on behalf of beef industry farmers. We have shown that 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 (6-8). Evidence indicates potential tumorigenic mechanisms for estrogen, such as direct genotoxic effects of estrogen metabolites and estrogen-induced expression of genes encoding growth and transcription factors. However, despite the clear importance of estrogens in the etiology of breast cancer, the mechanisms responsible for estrogenstimulated carcinogenesis remain undefined."[42]

183. The research for this study was supported by Ohio State University, the US National Cancer Institute and the US Department of Defence Breast Cancer Research program. This paper is appended as Exhibit EC-6 (US) and EC-8 (CAN). The European Communities would expect that the USA competent authorities will take the necessary steps to try and clarify the issues raised in this study and that other cautious WTO members would be entitled to take into account this kind of evidence, and many more which the European Communities will provide with its rebuttal, when assessing the safety of these substances.

[Questions 35 through 49 – Questions to US and Canada]

Q50. Could each party provide the Panel with a detailed account of the efforts it has made to solve this dispute since the notification by the European Communities of its implementing measure in 2003?

184. The European Communities undertook repeated efforts with the United States and Canada with the aim of agreeing on a procedure through which the existing disagreement over compliance could be resolved in accordance with the DSU, i.e. multilaterally. To this effect, discussions were held at the technical level from fall 2003 on the following possibilities: (i) a compliance review under Article 21.5 of the DSU, possibly with agreed terms of reference, or (ii) an agreed arbitration under Article 25 of the DSU, also with agreed terms of reference. The European Communities also made clear that, in the absence of the United States' and Canada's action according to options (i) or (ii), it would have no other choice than to launch an independent dispute against the continuation of the United States' and Canadian suspension of obligations. These discussions continued at the technical level into the beginning of the year 2004 and covered specific aspects of the terms of reference that could be agreed, in particular for an arbitration under Article 25 of the DSU.

[42] Suling Liu, and Young C. Lin: Transformation of MCF-10A Human Breast Epithelial Cells by Zeranol and Estradiol-1 7ß, *The Breast Journal, Volume 10, Number 6, 2004 514-521 (*2004). Exhibit EC-8 (US), 6 (CAN).

185. In January and February 2004, the issue of an agreed procedure for the review of the new Hormones Directive's WTO-compliance was also on the agenda of several meetings and phone calls which Commissioner Pascal Lamy had with Trade Representative Robert Zoellick and with Minister Jim Peterson. The last contact at ministerial level was a discussion between Commissioner Pascal Lamy and Ambassador Robert Zoellick in October 2004 shortly after the adoption by Congress of the American Jobs Creation Act of 2004. Mr. Lamy conveyed the European Communities' intention to initiate a procedure under Article 21.5 of the DSU against the WTO-inconsistent implementation in *US – FSC*. He also indicated the intention to propose to the Council of the European Union that the European Communities' countermeasures against the United States in *FSC* be suspended during the Article 21.5 review. He added that the European Communities expected the United States to proceed in the same manner as regards its suspension of obligations in *EC – Hormones*. Unfortunately, all these efforts have not borne fruit. In the absence of a positive reply, the European Communities decided to initiate the present dispute against the United States' and Canada's ongoing suspension of obligations. During the consultations in this dispute, the European Communities reiterated to the United States and Canada its offer not to pursue this case if the United States and Canada suspended their sanctions and initiated Article 21.5 proceedings.

Q51. Having regard to the first claim of the European Communities, in a post-retaliation phase, if a suspension of concessions is consistent with Article 22.8, can it nevertheless be inconsistent with Article 23 of the DSU? Under what circumstances? Please elaborate.

186. Yes, it can be inconsistent with Article 23 while being consistent with Article 22.8. The difference lies in who determines whether the measure has been "removed" within the meaning of Article 22.8. A Member who unilaterally determines that the inconsistency of the measure has not been removed and continues to apply sanctions on that basis, is in violation of Article 23, even if later it is multilaterally established that the measure had indeed not been removed and, therefore, that there is no violation of Article 22.8. The European Communities refers also to its answer to Question 13.

Q52. In the *US – FSC* case, the European Communities suspended the application of its suspension of concessions and then initiated an Article 21.5 procedure because it considered that the US implementing legislation was inconsistent, *inter alia*, with the SCM Agreement. Please give your views on whether it would also be possible to request the establishment of an Article 21.5 panel while continuing to apply the suspension of concessions pending the outcome of the Article 21.5 procedure?

187. The European Communities understands this question to inquire whether the suspension of concessions may continue while an Article 21.5 procedure is ongoing. In the European Communities' view there is no need for the Panel to give a general response to this question in the present proceeding. In the present case, the United States and Canada have violated Article 23 read together with Article 21.5 because they failed to initiate a compliance review for nearly one and a half years when this panel was established while continuing to apply sanctions. Accordingly, if the Panel agrees with this proposition, the United States and Canada will have to end their sanctions once the DSB has adopted the recommendations and rulings in this case. They cannot then initiate a compliance review and maintain the sanctions because this would defy the logic of the finding of a violation that consists of the application of sanctions and the non-initiation of the compliance review over a protracted period of time. Under these circumstances, there is no need to decide on the principle of whether the sanctions must be lifted (suspended) in a different case, where the original complainant initiates an Article 21.5 procedure in a timely fashion.

Q53. Are the parties of the view that, in the absence of a challenge by the implementing party against the continued suspension of concessions, such suspension can continue for an indefinite period of time, even though they are supposed to be only temporary. If not, what provision of

the DSU can serve as a legal basis for *preventing* the suspension of concessions for an indefinite period of time?

188. In the European Communities' view, where an implementing measure has been adopted, Members are prevented from suspending concessions for an indefinite period of time through Article 23 in conjunction with Article 22.8. These provisions read together require Members to challenge another Member's implementing measure if they consider it to be WTO inconsistent and thus prohibits them to simply continue to apply sanctions.

189. By contrast, while it is true that the suspension of concessions, according to Article 22.8 is only temporary, a Member would not be prevented from continuing to suspend concessions for an indefinite period of time in the absence of any implementing measure, i.e. where another Member would simply refuse to remove the measure that has been found to be inconsistent with a covered agreement.

Q54. Could the parties provide the Panel with their understanding of the meaning of the term "measure" in Article 19.1 of the DSU and of the term "measures taken to comply with the recommendations and rulings [of the DSB]" in Article 21.5 of the DSU? More particularly, do the parties consider that a measure taking, e.g., the form of a ban remains the same measure, irrespective of the change in supporting legislation, as long as it is a ban? If not, what makes a "measure taken to comply" different from the measure which had to be brought into conformity?

190. The "measure" within the meaning of Article 19.1 of the DSU is the measure that has been found to be inconsistent with a covered agreement. The findings identify the reasons for the inconsistency. The recommendation to bring the measure into conformity, in turn, must be read in light of these findings.

191. The "measure taken to comply" within the meaning of Article 21.5 of the DSU, is the measure that has been (or should be) taken to bring about compliance with the above recommendation.[43] Compliance depends on the reasons for inconsistency as they have been identified in the findings.

192. How to distinguish the two measures is a question that can be asked on two levels: on a formal/procedural level (has a Member adopted a new measure in order to bring about compliance?) and on a substantive level (has the Member actually achieved compliance?). The assessment on the latter level is clearly the task of a compliance panel.

193. In the present case, a new measure has been adopted to bring about compliance (a new Directive adopted by the Council and the European Parliament). Formally, therefore, there is a measure distinct from the original measure. Whether that measure is distinct also on a level of substance is a question of what compliance is about in this case. The reasons of inconsistency of the old *Hormones* legislation have been identified by the Panel and Appellate Body in their respective findings. They all relate to the risk assessment underlying the import prohibition. That risk assessment was essentially found not to sufficiently warrant a measure consisting in an import prohibition. Thus, it was not an import prohibition *as such*, that was found to be inconsistent with the *SPS Agreement*, but the particular import prohibition as based on the (deficient) risk assessment in question.

194. The new measure addresses these reasons for inconsistency in that it is based on a new risk assessment. The new risk assessment fully warrants a (definitive) import prohibition on one hormonal

[43] *See* also Appellate Body Report, *Canada – Aircraft (21.5 – Brazil),* at para. 36.

substance in question and yields enough available pertinent information to support a provisional import prohibition on the other five substances. Therefore, also on the level of substance, the measure taken to comply is a different one from the original measure found to be inconsistent irrespective of the fact that, in form, it remains an import prohibition.[44]

Q55. When does the legal effect of the DSB authorization lapse and by what procedures? Where parties disagree on the consistency of a notified implementing measure effected after the DSU retaliation authorization, does the DSU authorization lapse at the time when (i) the DSB makes a decision of compliance with respect to the implementing measure, or (ii) the implementing measure is in actual compliance regardless of whether the DSB has made a determination of compliance or not, or (iii) the Member concerned notifies its implementing measure to the DSB and declares its compliance, or (iv) the DSB makes a specific determination to terminate its previous retaliation authorization?

195. The European Communities expresses no view as regards whether and when the DSB authorization "lapses" in the sense of "ceases to exist". Where the European Communities has a clear view is the question of until when the suspension of obligations may be "applied".

196. As regards the possible answers which the Panel is presenting in this question, one has to distinguish: The answer is (ii) under Article 22.8 of the DSU, i.e. when the implementing measure is in actual compliance regardless of whether the DSB has made a determination of compliance or not. The reason is that Article 22.8 contains an obligation to cease the suspension of concessions if the measure has been removed. That obligation directly applies to the Member imposing retaliation. The DSB authorization cannot overrule this obligation. To the contrary, its legal effects are dependent on it. That is why a Member is no longer entitled to suspend obligations if the conditions of Article 22.8 are fulfilled.

197. Under Article 23 in conjunction with Article 22.8, however, a Member is not entitled to continue the suspension of obligations if this is based on a unilateral determination and accompanied by the failure to have recourse to the rules and procedures of the DSU.

Q56. Article 21.5 of the DSU provides that where there is a "*disagreement* as to the existence or consistency with a covered agreement of measures taken to comply with ... such dispute shall be decided through recourse to these dispute settlement procedures." Since Article 21.5 provides that "such dispute *shall* be decided"[45] through recourse to [the DSU]", would the parties consider that either of them has an obligation to refer the matter to the DSB under Article 21.5? If yes, why?

198. In the European Communities' view the "shall" refers to the obligation to resort to the dispute settlement procedures under the DSU, and more particularly to the one under Article 21.5, *if and when* it is envisaged to seek redress because of a disagreement on compliance. By contrast, it does not imply an obligation to *initiate* such a dispute in the absence of any desire to take action based on a

[44] *See* also the case *Japan – Apples* where the implementing measure maintained elements of the original measure. The Panel, in the case, found: "In its implementation process, Japan has made some changes to the original measure [footnote omitted] and has produced new studies to support its view that (a) mature, symptomless apples can be "latently" infected and (b) infected apples could, once on the Japanese territory, contaminate host plants. On the basis of these studies, Japan has maintained many elements of the original measure in the measure taken to comply. For this reason, we consider that all the elements of the measure currently in place should be treated as the "measures taken to comply", even though many of those elements were already found in the original measure [footnote omitted], *See* Panel report *Japan – Apples (21.5)*, at para. 8.32.

[45] Emphasis added by the Panel.

belief that there is non compliance. Article 21.5 makes clear ("shall be decided") that Members are not entitled to decide such disagreements through other means, as the United States and Canada have done by unilaterally deciding that there is no compliance and thus continuing their sanctions. This is confirmed by Article 23.

Q57. How would you distinguish between expressing "disagreement" over the WTO compatibility of a measure taken to comply with recommendations and rulings adopted by the DSB for the purpose of deciding whether or not to start an Article 21.5 procedure and a unilateral "determination" of WTO compatibility of such a measure?

199. The "disagreement" is less than a "determination." If a Member has made a determination within the meaning of Article 23.2(a) that there is no compliance, this will imply that there exists also a disagreement within the meaning of Article 21.5 (unless, of course, the original respondent agrees that there is no compliance). On the other hand, such a disagreement may exist without a Member having yet made a determination. The difference is that a determination is linked to the action of seeking redress implying that a Member takes steps to address what it perceives to be a case of non compliance. A disagreement, by contrast, does not (necessarily) imply taking any steps.

200. To illustrate the difference: If the defending parties had suspended the application of retaliatory measures, but had otherwise reacted in the same way as they have, i.e. making statements to the effect that they fail to see how the new measure could be compliant etc., there would be a disagreement, but no determination.

Q58. In a situation where an Article 21.5 panel, requested to examine the compatibility of an implementing measure, finds that only partial compliance has been achieved, what is the procedure available to the original complainant: (a) Can it continue to apply the suspension of concessions initially authorized by the DSB?; (b) Does it need to request a new authorization?(c) Can the implementing party object to the level of suspension and request an Article 22.6 arbitration to determine a new level of suspension of concessions?

201. If a 21.5 panel is called upon to rule on nullification and impairment it can rule that the level is less following partial implementation. Furthermore, the European Communities notes that in the case *US – FSC (second Article 21.5)* (report not adopted yet) the panel was confronted with partial compliance and opined that

> Although the phased reduction in amount of subsidy available in 2005 and 2006 may be relevant in another type of proceeding, such as an arbitration under Article 22.6 of the DSU or Article 4.10 and 4.11 of the SCM Agreement, the fact that, in 2005 and 2006, the percentage of subsidy available is less than the entire amount that was available under the ETI Act before 2005 is not material to our inquiry under the Article 21.5 DSU proceeding. 46

202. Thus, that panel seems to imply that an arbitration procedure under Article 22.6 would be possible. It is unclear, whether the Panel was suggesting that a new request for an authorization is required and whether there could be a suspension of concessions pending the outcome of the arbitration procedure. The European Communities is still considering the correctness of this statement and its implications, which may be subject to review by the Appellate Body.

[46] Panel Report, *US – FSC (second Article 21.5)*, not yet adopted, at para. 7.60, Footnote 78.

Q59. Is Article 23 of the DSU applicable to a suspension of concessions under a previous authorization of the DSB and in the absence of a new DSB decision of termination of the previous authorization?

203. Yes, Article 23 is applicable to such a situation, since it applies always when Members are "seeking redress". Indeed, it is difficult to see why it would not be applicable, i.e. which condition of its application would be lacking. The defending parties pretend that the element "seeking redress of a violation" is missing, because they would already have "sought and obtained" redress under the previous authorization.[47] In the European Communities' view this statement not only relies on a different meaning of the word "to seek" – one which does not make sense in the context of Article 23[48] – but it also lacks logic as the defending parties themselves admit that suspending concessions is a form of seeking redress.[49]

204. Also, the European Communities would reiterate that both legally and practically speaking there is, under the present rules, no such thing as a "new DSB decision of termination of the previous authorization".

Q60. Having regard to the US reference to the DSU negotiations in footnote 202 of its first written submission, could the parties indicate which proposals have been made in that context that would represent *amendments* to the current text of Articles 21.5, 22.8, 23.1 and 23.2(a) of the DSU?

205. As the European Communities has pointed out, this Panel is asked to interpret and clarify, in accordance with its mandate under the DSU, the existing provisions of that understanding. The fact that related questions are under discussions in the negotiations on improvements and clarifications of the DSU and whether or not there is consensus among Members on how the rules should be improved in that regard is therefore without direct relevance to this dispute. The Panel must apply the existing procedural rules of the DSU to this case, and the rights and obligations of Members under the existing rules cannot be altered by whatever Members may be discussing in the special session of the DSB as regards future DSU rules – whether improved or merely clarified.

206. Given that the Panel has stressed "amendments" in its question, the European Communities would once more point out that what does not exist in the current DSU rules is an explicit and streamlined mechanism for a formal removal of a previously granted DSB authorization to suspend obligations. Such a mechanism has indeed been the subject of the negotiations on a review of the DSU. The present absence of such a formal mechanism, however, in no way implies nor can the European Communities accept (contrary to the United States' stated belief at the first substantive meeting), that the current DSU rules contain no rules that regulate until what point a Member may suspend obligations pursuant to a once obtained DSB authorization. Also, there is no gap in the present rules since Article 21.5 of the DSU can serve to resolve a disagreement over compliance, which presupposes the complainant's initiative. Further, if like in the present case, the original complainant refuses to initiate a compliance review, the Member facing the suspension of obligations can challenge the legality of these sanctions in an ordinary panel procedure, as it has been done in the

[47] US First Written Submission, para. 175 ; Canada, First Written Submission, para. 68.

[48] There are the meanings of "seek" which have been identified by previous panels (*US – Certain* EC *Products,* at para 6.22) and which are "to resort to…to make an attempt, to try" (meanings which also the US identified, *see* US First Written Submission, at para. 172); and there is the other meaning which is "to ask for, to demand, to request" which is the one replied upon in the statement "sought and obtained" and authorization.

[49] Note also, and as pointed out in the EC First Written Submission, the Panel in *US – Certain* EC *Products* also found that suspension concessions (in order to seek redress of a violation) necessarily implies a determination, *see* Panel Report, *US – Certain* EC *Products,* at para. 6.100; *see* also EC First Written Submission, at para. 59.

present case. This is a long and complex recourse, but a possible one and the Panel may not refuse a ruling on this matter, lest a gap should be *created* in the current DSU and rights and obligations of Members diminished.

207. Ever since the DSU negotiations have started, the question of adding a more streamlined mechanism to bring sanctions to an end, notably by formally removing a previously granted DSB authorization to suspend obligations, has been on the table. Notably, in November 1999, several Members[50] co-sponsored a proposed amendment, the so-called Suzuki Text, which provided for such a specific remedy (WT/MIN(99)/8). The same proposed amendment was also contained in an amendment proposal of October 2001.[51] The Chairman's text of 2003 (which is 17 pages long, see TN/DS/9, and to this date the most recent draft text of proposed amendments authored by a Chairman of the DSB special session), maintained this remedy. It provides in essence that it is for the original complainant to challenge the WTO compatibility of the implementing measure, and if it does not do so within a specified time-period, the DSB formally withdraws the authorization by negative consensus. The start of that deadline is triggered through the implementing Member's qualified notification of its measure taken to comply. If a compliance review takes place and results in no findings of inconsistency, the DSB also withdraws the authorization to suspend obligations. If there is no full implementation, a new arbitration on the level of nullification or impairment may be requested and the DSB would subsequently modify the previous authorization accordingly.

208. It is worth recalling that the Chairman's text of May 2003 included only a select number of proposed elements of possible improvements and clarifications of the DSU. The Chairman's criterion for that selection was the degree of consensus among WTO Members in those negotiations.[52] Thus, while the Chairman's text was based on proposals made by individual or groups of Members, it omitted a large number of such proposals in view of the insufficient support which these had attracted in the course of the negotiations.[53] This is also evidenced in the Chairman's report of 6 June 2003 to the Trade Negotiations Committee: "A number of other proposals by Members could not be included in the Chair's proposal in the absence of a sufficiently high level of support, including, *inter alia*, …"[54] In some cases, the Chairman's text contained proposed amendments in square brackets to indicate a lower degree of consensus on the issue in question. It is worth noting that the proposed Article 22.9 of the DSU was part of the Chairman's text without square brackets.

209. In May 2004, Canada, who had been among the co-sponsors of the Suzuki Text, changed direction and, together with Argentina, Brazil, India, New Zealand and Norway, most of which are also third parties in this dispute, made a proposal under which it is solely for the original respondent to launch the compliance review in the post-retaliation phase (JOB(04)/52). The proposal specifies that the original complainant can submit new claims of violation after the original respondent has requested the establishment of the compliance panel and that the panel's terms of reference cover these as well. Listening to Canada at the first substantive meeting, the European Communities had the impression that Canada confuses the current rules with the procedures it has proposed to create. The joint proposal of Argentina, Brazil, Canada, India, New Zealand and Norway was substantially discussed in the special session of the DSB, where [confidential] that, despite the proposed initiation

[50] Canada, Costa Rica, Czech Republic, Ecuador, the European Communities and its member States, Hungary, Japan, Korea, New Zealand, Norway, Peru, Slovenia, Switzerland, Thailand and Venezuela.

[51] By Bolivia, Canada, Chile, Colombia, Costa Rica, Ecuador, Japan, Korea, New Zealand, Norway, Peru, Switzerland, Uruguay and Venezuela.

[52] See TN/DS/M/12, para. 1: "The Chairman said that the draft text reflected proposals on which there was a high level of convergence among Members."

[53] The totality of the draft text proposals submitted in those negotiations has been collected in a Compilation, *see* JOB(03)/10/Rev.3 and JOB(03)/10/Rev.4 (the version of spring 2003 and equally the further revision of October 2004 are each 102 pages long).

[54] TN/DS/9, page 1, para. 6.

of the compliance review by the original respondent, the respondent would not bear the burden of proof for its WTO compliance, given that established WTO jurisprudence makes clear that the party which asserts the *affirmative* of a claim or defence, not the *negative* thereof, bears the burden of proof.

210. Based on the discussion that had taken place in the special session of the DSB, the European Communities and Japan submitted an alternative text in March 2005 (JOB(05)/47). This proposal maintained (and further refined) the approach contained in the above-mentioned Chairman's text of May 2003 and thus also preserves the basic structure of WTO dispute settlement, namely that it is for complainants to initiate WTO disputes and to request the establishment of panels pursuant to Article 21.5 in conjunction with Article 6 of the DSU. That proposal was well received by a large number of Members, but some technical work remains and also the gap between the two recent texts in question.

211. Finally, the European Communities would like to point to an interesting proposal on dispute settlement which Canada has submitted in the negotiations on rules.[55] In that proposal, Canada proposes that an implementation measure would be considered WTO-compliant after a declaration of compliance to the DSB by the implementing Member and without the initiation of Article 21.5 proceedings within a prescribed period of time that is sufficient for the complaining Member to assess the adequacy of the compliance action (e.g. 60 days). Despite the different context (anti-dumping and countervailing duty enforcement action), the contrast between the position expressed in that proposal and Canada's position in the present dispute is quite striking.

Q61. How does the principle of good faith affect the allocation of burden of proof in these two disputes? What kind of presumption should be made by the Panel if/when applying this principle? Does the application of this principle under the circumstances of the present disputes lead to the conclusion that the EC's implementing measure shall not be presumed WTO-inconsistent? Or, should the conclusion be that the US and Canadian measures of suspension of obligations shall not be presumed to be inconsistent with the DSU? Please elaborate on why one specific conclusion is preferable than the other in your view.

212. It seems important to recall what the principle of good faith is about: To paraphrase the Appellate Body, the principle of good faith controls the exercise of rights [and the fulfilment of obligations][56] by states.[57] WTO Members are required to exercise their rights and comply with their obligations in good faith.[58] The principle of good faith has a number of "applications" (Appellate Body, *US – Shrimp*), which prohibit or prescribe a certain conduct on States (example of *US – Shrimp*: doctrine of *abus de droit*). Thus, the *principle* of good faith is about certain obligations of conduct that WTO Members have as contracting parties of the WTO agreements.[59]

213. The debate in the present case is about the *presumption* of good faith, which can be seen to be derived from the *principle* of good faith. Thus, it is not the obligation to act in good faith, but the presumption that that obligation has not been breached, which is of relevance in this case. That presumption, in turn, is but one aspect of the more general presumption that Members are acting in a manner consistent with their obligations under the WTO agreements.

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[55] TN/RL/GEN/37 and [confidential].

[56] The Appellate Body, in the specific context of the case *US – Shrimp*, was discussing a right, namely the right to rely on the exception of Article XX of the GATT. Other case law shows clearly that the principle applies equally to the fulfilment of obligations, *see* for example *US – FSC*, Report of the Appellate Body, at para. 66.

[57] Appellate Body Report, *US – Shrimp,* at para. 158.

[58] For the DSU this is explicitly stated in Article 3.10.

[59] *See* also Article 26 of the Vienna Convention.

214. The presumption that Members are acting in a manner consistent with their obligations under the WTO agreements is the very basis of the dispute settlement system (as it is essentially for any dispute settlement or court system that is there to solve disputes about contractual obligations). Disputes are brought to establish that a Member has acted in a manner inconsistent with its WTO obligations. In bringing the case and making the assertion that there is a violation the presumption of compliance is rebutted. It is then, in turn, for the defending party to rebut the assertion. The burden of proof rules flow naturally from this logic.

215. On the basis of that logic the European Communities has brought the present cases in order to have established that the United States and Canada are acting in a manner inconsistent with their obligations (under the DSU). In accordance with the burden of proof rules the European Communities has made a *prima facie* case that there is a violation and the defending parties have come back with arguments to rebut that assertion. Had the European Communities (or anybody else) not brought any case against the defending parties, they would have had to be presumed to be acting consistently with their WTO obligations. Neither the European Communities nor anybody else would have the right to claim otherwise, by, for example applying retaliation (Article 23).[60]

216. The same logic should apply, in turn, to the European Communities' implementing measure in the *Hormones* dispute. In order to rebut the presumption that the European Communities, in adopting that measure, has acted in a manner consistent with its WTO obligations, the defending parties have to bring a case. The normal burden of proof rules would apply. The fact that they have precisely not brought such a case is (1) the reason why the European Communities is claiming that there is a violation of Article 23.1, 23.2(a) in conjunction with 21.5 and (2) the reason why the European Communities relies on the presumption of compliance in the context of its claim under Article 23 in conjunction with Article 22.8.

Q62. Do you agree with the view that (i) if an original complaining party initiates an Article 21.5 dispute challenging the consistency of an implementing measure, that party shall bear the burden to prove that the implementing measure is WTO-inconsistent during the compliance procedure, and that (ii) if an original defending party initiates an Article 21.5 dispute claiming the WTO-consistency of its measure, that original defending party shall bear the burden of establishing the consistency of its implementing measure as a complaining party to the Article 21.5 dispute? Please elaborate on your response.

217. The question illustrates well the systemic incoherencies that arise in bringing a case against oneself in order to establish that there is compliance.

218. Scenario (i) is the standard scenario, to which the burden of proof rules apply without any problem. Indeed, the (original) complaining parties would have the burden of proving that the implementing measure is WTO-inconsistent.

219. Scenario (ii), on the other hand, is no standard scenario. The following remarks apply to this case: Burden of proof rules do not depend on a particular procedural constellation, i.e. on who is the complaining and who is the defending party, but on who asserts the affirmative of a particular claim or defence.[61] Therefore, even in the role of the "defending party" in a 21.5 procedure initiated by the implementing Member, it is the original complaining party that would assert – and therefore have to prove – that there is WTO inconsistency. This much seems implied in the above question.

220. The difficulty lies in the assumption that, when initiating a case itself, the implementing Member would have to assert – and therefore prove – that there is WTO consistency. The above

[60] *See* also EC reply to Question 4.
[61] Appellate Body Report, *US – Wool Shirts and Blouses*, p. 16

burden of proof rules do not envisage such a case as they apply either to violation claims or to defences (i.e. claims of inconsistency or rebuttals to such claims), but not to a free-standing assertion that there is WTO consistency. The assertion that "there is WTO-consistency" is not a claim in the sense of DSU and not a basis for a dispute under Article 1.1 of the DSU, Article 11.1 of the *SPS Agreement* and Article XXIII of the GATT. Indeed, to the extent such an assertion would be about establishing that there is no violation of a WTO provision, a Member would have to assert, not the *affirmative*, but the *negative* of a claim (e.g. "no violation of Article 5.1"). This, however, is impossible, both in scope and substance: First in scope, because it would effectively mean going through every single provision of the WTO agreements in order to rule out any possible violation (compliance under Article 21.5, after all, means "consistency with *a* (i.e. any) covered agreement."). Second, in substance, because it would require anticipating what the possible problem could be under any particular provision.

221. The very case of the *Hormones* Directive demonstrates this impossibility. Not only is it impossible for the European Communities to rule out any possible violation there might be under the covered agreements, but it is even impossible to do so with regard to the specific violations that had been found by the DSB to exist under the old measure. Take the case of Article 5.1 of the *SPS Agreement*. The Appellate Body had found that the risk assessment presented by the European Communities at the time did not sufficiently warrant the prohibition laid down in the legislation. While it might still be conceivable to address the specific reasons why this had been the case at the time (e.g. specificity of the evidence relating to hormones generally but not to hormone residues in meat consumed by humans and arising from use for growth promotion purposes), it is virtually excluded to address all other possible reasons why the new risk assessment may not sufficiently warrant the new measure. Indeed, Canada and the United States might find a multitude of other reasons why the risk assessment might be flawed according to their belief. Thus, they might contest the methodology used, disagree with the results obtained, dismiss the quality of the scientists employed, reject the conclusions drawn etc. Such potential criticisms cannot be anticipated. What's more, putting the burden of anticipating them on the implementing Member would effectively lift the burden of the original complaining parties to assert and demonstrate inconsistency.

222. One could think of solving such problems by "tailoring" the burden of proving consistency to something "feasible" (no new violations? only those identified by rulings and recommendations? only those reasons identified by Appellate Body?). However, assuming for the moment that this were legally conceivable, which it is not, the burden of proof issue would then become even more of a moving target (opening up a battlefield of arguments of what is new/old) creating further procedural complexities.

223. These issues demonstrate well that it is against the very nature of the dispute settlement and its rules of burden of proof to assume that there exists a burden of proving consistency if such a burden is supposed to consist in anything else but the mere presentation of the implementing measure.

Q63. Would the parties consider that the principle *rebus sic stantibus*, could apply to a decision of the DSB (see, *inter alia*, para. 26 of Canada's oral presentation regarding the legal status of DSB decisions)? In its oral comments on Canada's oral presentation, the EC stated that there is no hierarchy in customary international law, the principle of good faith in this case, and a treaty language, the DSB authorization in the current dispute. Could the parties provide evidence that the EC statement is or is not supported by international jurisprudence?

224. This question requires first of all a few general remarks about the relationship between WTO agreements and customary international law (or other sources of international law).

225. As stated at the substantive meeting, a concept of hierarchy of norms comparable to what exists in domestic law does not exist in public international law. As the International Law Commission pointed out most recently, such a "concept [of hierarchy] […] was not present on the international legal plane and should not be superimposed."[62]

226. There are, however, different sources of public international law and these are enumerated in Article 38 of the ICJ Statute. As explained by *Brownlie*

> They are not stated to represent a hierarchy, but the draftsmen intended to give an *order* […].[63]

227. The reason for applying this order is essentially one of *specificity*, treaty law normally being of a more specific nature than customary law and general principles. [64] However, as *Lauterpacht*, points out

> […] the order of the sources of international law as thus indicated cannot be applied in a mechanical way. Nor does it fully express their relative importance. Undoubtedly, the rights and duties of States must be determined in the first instance by reference to applicable treaties. Yet, while it is true that international customary law applies only in the absence of available provisions of treaties, and that 'general principles of law' are merely a residuary source of law in cases in which there is no applicable treaty or custom, treaties, in turn, must be interpreted in the light of customary international law [footnote omitted] - just, as the latter, as well as treaties, must be interpreted against the background of general principles of law. When the meaning of a treaty is not clear, it must be assumed that the parties intended it to be in conformity with general customary, international law – and it is then that customary international law becomes relevant and decisive, notwithstanding any hierarchical order establishing the priority of a treaty.[65]

228. The panel in the case *Korea – Government Procurement* accurately applied these concepts to the issue of the relationship between the WTO agreements and customary international law, when stating that

> Customary international law applies generally to the economic relations between the WTO Members. Such international law applies to the extent that the WTO treaty agreements do not "contract out" from it. To put it another way, to the extent there is

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[62] 2002 ILC Report, at p. 506. *See* also, for example, *Knut Ipsen*, Völkerrecht, 3. Auflage, at p.222, para. 1 : "Die Lösung [von] Konfliktfälle[n] [zwischen Normen die verschiedenen Rechtsquellen angehören] bereitet Schwierigkeiten, weil dem Völkerrecht eine dem innerstaatlichen Recht vergleichbare Normenhierarchie fremd ist und es an allgemeinen, auf alle Konfliktfälle anwendbaren Kollisionsregeln fehlt." (The resolution of conflicts between norms of different sources is difficult as public international law is lacking a hierarchy of norms comparable to domestic law and as there are no general rules of conflict that would apply to all cases of conflict.)

[63] *Ian Brownlie* – Principles of Public International Law, Fifth Edition 1998, at p. 3.

[64] As *Lauterpacht* explains : "The rights and duties of States are determined, in the first instance, by their agreement as expressed in treaties – just as in the case of individuals their rights are specifically determined by any contract which is binding upon them. When a controversy arises between two or more States with regard to a matter regulated by a treaty, it is natural that the parties should invoke, and the adjudicating agency should apply, in the first instance, the provisions of the treaty in question [...] Within these limits – which may be substantial [footnote omitted] – a treaty overrides international customary law and even general principles of law; […], *see Hersch Lauterpacht*, International Law – Collected Papers edited by E. Lauterpacht, Edition 1970, at p. 87.

[65] *Ibid.* (previous footnote) at p. 88.

> 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.[66]

229. Against this background, the following comments apply to the two issues raised in the Panel's question:

230. As regards the principle *clausula rebus sic stantibus* the European Communities, in its First Written Submission has already referred to the fact that the basis for the DSB authorization changes fundamentally once a Member has properly implemented.[67] This fact, however, does not lead to a *direct* application of the principle of *clausula rebus sic stantibus*. Indeed, there is no need for that, given that the obligation to cease the application of the suspension of concessions can be directly inferred from Article 22.8.

231. As regards the issue of a possible conflict between the principle of good faith and a DSB authorization, a few clarifications seem necessary. First, for the sake of accuracy it should be pointed out that the principle of good faith is a general principle of international law and not, as suggested in the question, a rule under customary international law.[68]

232. Second, we explained in the reply to Question 61 the relationship between the *principle* of good faith and a *presumption* of good faith (or more broadly, of compliance).

233. Third, assuming the question aims at the issue of a possible conflict between the presumption of good faith (or more generally of compliance) and that DSB authorization. In that regard the European Communities takes the view that no such conflict exists. The presumption that a Member is acting consistently with its WTO obligations is the very basis of the dispute settlement system. It is the reason why disputes are about inconsistency and not about consistency, why complaining parties assert violations and not the absence of a violation. That presumption is therefore also inherent to Article 22.8 and it is that provision which governs a Member's right to suspend obligations pursuant to a DSB authorization.[69]

Q64. If the Panel were not able to reach a conclusion on the first claim of the European Communities under DSU Article 23, do you think the Panel should proceed to examine the second claim of violation of Article 22.8 of the DSU?

234. The European Communities is not quite sure how to understand this question.

235. If this question refers to a situation where the Panel would find that there is no violation with regard to the two claims which the European Communities has set out under Article 23 (Article 23.1 in conjunction with Article 23.2(a) and 21.5, on the one hand, and Article 23.1 in conjunction with Article 22.8, on the other), then the European Communities would indeed request the Panel to proceed to examine the claim under Part II of the EC First Written Submission.

236. However, if the question means to refer to the possibility of a "non liquet" decision by the Panel on Article 23, the European Communities would contest that such a possibility exists. Panels

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[66] Panel Report, *Korea – Procurement*, at para. 7.96.

[67] EC First Written Submission in DS320 (US), at para. 108.

[68] *See* only Appellate Body Report *US – Shrimp*, para. 158.

[69] Note that Article 22.8 is "primary" law compared to the DSB authorization, which, emanating from a body set up under the "primary" law (i.e. the agreements), is "secondary" law. It is worthwhile thinking about hierarchy issues in that regard. In the European Communities' view (admittedly drawing a direct analogy to EC law), the "secondary" law is subordinated to "primary" law requirements.

do not have the option of making "non liquet" decisions under the dispute settlement system. As the Appellate Body has emphasised in the context of the discussion on judicial economy and in reference to Article 3.7, second sentence, it is the role of the Panels to *secure a positive solution to a dispute*.[70] The Appellate Body has gone on to state that

> A panel has to address those claims on which a finding is necessary in order to enable the DSB to make sufficiently precise recommendations and rulings so as to allow for prompt compliance by a Member with those recommendations and rulings "in order to ensure effective resolution of disputes to the benefit of all Members." [footnote omitted][71]

237. It is, therefore, excluded, to simply "not reach a conclusion" on a claim that is not only central to, but indeed the very essence of the dispute at hand. If a panel were to do so it would be either diminishing the rights of one party or adding to the rights of the other. Article 3.2 DSU prohibits both such outcomes.

Q65. Canada and the United States have argued that the EC measure taken to comply with the recommendations and rulings of the DSB in the Hormones case are incompatible with Article 5.1 and 5.7 of the *SPS Agreement.* However, the European Communities does not make any reference to these provisions, either in its request for establishment of the panel, or in its first written submission. Do the parties believe that the Panel has, nonetheless, jurisdiction to review the compatibility of the EC implementing measure with Articles 3.3, 5.1 and 5.7 of the *SPS Agreement*? On what legal basis should the Panel consider itself entitled/not entitled to address the arguments of Canada and the United States in relation to the *SPS Agreement*?

238. The Panel's jurisdiction is governed by its terms of reference. As the Appellate Body has made clear

> The jurisdiction of a panel is established by that panel's terms of reference, which are governed by Article 7 of the DSU. A panel may consider only those claims that it has the authority to consider under its terms of reference. A panel cannot assume jurisdiction that it does not have.[72]

239. It seems clear, thus, that in the present case the Panel has no jurisdiction to address Articles 3.3, 5.1 and 5.7 of the *SPS Agreement*, which do not appear anywhere in the request for establishment of the Panel on which the Panel's terms of reference are based.

240. The 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 (other aspects of which have been discussed elsewhere in this submission.[73]) 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.

241. At best, one could venture to draw an analogy to affirmative defences. These are raised by a defending party without usually being referred to by the complaining party in its request for establishment of a Panel or its first written submission. The violation claims raised by the defending

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[70] *See* only Appellate Body Report, *Australia – Salmon*, at para. 223.
[71] *Ibid.*
[72] Appellate Body Report, *India – Patents*, at para. 92.
[73] *See* for example, Question 62.

parties here, thus, would have to be assimilated to affirmative defences. The burden of proof to establish a *prima facie* case on such violations would, as with affirmative defences, then rest on the defending parties.[74]

Q66. In this particular case, would it be for the European Communities to prove the compatibility of its measure with Article 5.7 of the *SPS Agreement* because it applies certain aspects of that measure provisionally or would it be for Canada and the United States to demonstrate a violation of Article 5.7 because they consider that the EC measure is in breach of that provision? Could the parties discuss the application of the burden of proof in relation to Article 5.7 in light of the panels and Appellate Body findings with respect to that provision in *Japan – Agricultural Products II* and *Japan – Apples*?

242. The United States and Canada have the burden of asserting and making a *prima facie* case on, a violation of Article 5.7 of the *SPS Agreement*. There are at least two reasons for it. The first reason is the specific procedural constellation of this case: It is not for the European Communities to show compliance, but for the United States and Canada to show non-compliance, all the more if that non-compliance relates – as is the case with Article 5.7 – to an inconsistency which did not exist in the original case and is therefore not covered by the rulings and recommendations of the DSB.[75]

243. The second reason is, more generally, that according to the burden of proof rules, it is for the party asserting the affirmative of a particular claim or defence to make a *prima facie* case. Article 5.7, in the view of the European Communities does not constitute a defence (of the kind that Article XX of the GATT is) but is rather a special regime in relation to Article 5.1 of the *SPS Agreement*. Thus, it is not an exception any more than Article 3.3 of the *SPS Agreement* is an exception. It applies to provisional measures as opposed to the regular (definitive) measures under Article 5.1. As a regular claim, therefore, it is for the side alleging the violation, to make a *prima facie* case.

244. This reading is not contradicted by the case law so far. Indeed, it cannot be inferred from the case *Japan – Apples* that the burden of proof would be on the party that has adopted the provisional measure. Japan in that case, had voluntarily accepted the burden of proof. The Appellate Body was careful to stress that this assignment of the burden of proof to Japan by the panel was not challenged on appeal.[76]

245. The European Communities notes that on this point it shares the position of the United States. At the meeting of the DSB held on 10 December 2003 when the panel report in the case DS245 *Japan – Apples* was adopted, one of the points of disagreement expressed by the US delegate related to that panel's approach to the burden of proof under Article 5.7. According to the report of the meeting the delegate stated:

> The second point the United States wished to note was the Panel's conclusion that the Member maintaining the measure had the burden of establishing that it met the requirements of Article 5.7. Neither Japan nor the United States had supported this conclusion, taking the position that here, as with other claims, the complaining party had to bear the burden of proving that the measure did not meet the obligations set forth in a WTO provision.[77]

Q67. Do the parties consider that Article 5.7 applies only when no risk assessment can be made at all or also when scientific evidence exists but is insufficiently specific?

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[74] *See* also reply to Question 62.
[75] *See* also reply to Question 65.
[76] Appellate Body Report, *Japan – Apples*, paras 175 and Footnote 316.
[77] WT/DSB/M/160 of 27 January 2004 at para 9.

246. It is generally accepted that Article 5.7 is applicable both when no risk assessment can be made at all, as well as when scientific evidence exists but is insufficiently specific or when the latest scientific evidence from any credible and objective source raises doubts or puts into questions the previously held scientific opinion about the safety or dangerous nature of the substances in question. This is very well explained by the Appellate Body *inter alia* in paragraphs 194 and 205 of its report in the hormones dispute.

Q68. Do all parties agree that the term "on the basis" in Article 5.7 of the *SPS Agreement* has the same meaning as "on the basis" in Article 5.1, i.e. that a "rational relationship" is required?

247. First, it should be noted that there is a difference in wording in the two Articles. Article 5.1 requires that SPS measures are "based on" a risk assessment, whereas Article 5.7 requires that provisional SPS measures be adopted "on the basis of" available pertinent information. Arguably, "on the basis of" would suggest a more remote relationship than "based on." That reading would tie in with the following substantive analysis:

248. It is clear that both "based on" and "on the basis of" suggest a – as the Appellate Body put it in the context of Article 5.1 ("based on") – "objective relationship between two elements."[78] The crux, however is, that that relationship is between *different elements* depending on whether one is in the context of Article 5.1 or in the context of Article 5.7. In the context of Article 5.1, it is the relationship between the SPS measure and a risk assessment, in the context of Article 5.7 it is the relationship between the (provisional) SPS measure and available pertinent information. That difference necessarily changes the nature of the relationship. Indeed, it would be illogical to apply the same standard of objective or rational relationship to a situation where there is full scientific evidence available and a situation where that evidence is insufficient.

Q69. During the *EC – Hormones* proceedings, the European Communities was of the view that "the scientific evidence concerning the need to regulate the use of hormones was in itself sufficient to justify its legislation and the European Communities did not need to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient" (DS26/R/USA, para.4.239). Does this mean that "the evidence concerning the need to regulate the use of hormones generally" is different from the specific evidence concerning the health risk associated with the administration of hormones in animals for growth promotion purpose? Is there sufficient evidence concerning the latter?

249. It is not entirely clear why only this sentence is cited from paragraph 4.239, which is much longer. It would also seem that the reply to this question is intimately linked to the replies to Question No 19 above (why is the ban on five hormones now provisional), Question 30 (insufficiency of the information), Question 34 (safety of the hormones), Question 70 (available pertinent information), Question 73 (evolution of scientific understanding) and all other Questions dealing with the different steps of the risk assessment. The European Communities respectfully refers the Panel back to its replies to these questions.

250. The European Communities found that the evidence which is normally taken into account for the assessment of substances of this kind, whether of general or specific nature, is insufficient, inconclusive and contradictory for five of these hormones. Indeed, the new scientific studies that have been initiated since the DSB recommendation in the hormone case, in order to address the scientific information that was found by the panel and the Appellate Body to be missing, have now identified new important gaps, insufficiencies and contradictions in the scientific information and knowledge

[78] Appellate Body Report, *EC – Hormones,* at para. 189.

now available on these hormones, which have together reinforced the need for even more studies. Evidence from other sources is also putting in doubt the sufficiency of the basis upon which the defending members and other bodies have come to the conclusions that the residues of these hormones in meat from animals treated for growth promotion (see, e.g., the study contained in the exhibit to Question No 34 above).

251. The previous Directive 96/22/EC was drafted in 1995 and adopted in 1996 as a codification of the pre-existing European Community measures in this area. This happened at a time where international guidance on how to perform a risk assessment was not yet available to tackle situations where scientific information was insufficient to conclusively assess a particular risk, in accordance with a member's chosen level of health protection. For example, at that time there did not exist standards nor guidelines from the Codex Alimentarius Commission on how to perform a risk assessment and risk analysis. Moreover, the provisions of Article 5.7 have now been clarified in a number of panel and Appellate Body reports, starting with their reports in the *hormones* case, which was not the legal situation before 1996.

252. Substantive international discussions have lead to the development of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius Commission[79] after 1996. This has only been adopted by the Codex Alimentarius Commission in at the 26th Codex Alimentarius Commission meeting at Rome in July 2003. The relevant concepts developed there have been taken into account by the European Communities and have now influenced the drafting of its framework Food Law, namely Regulation 2002/178/EC.

253. It follows that at that time the European Communities believed the information was sufficient – in light of the general knowledge available at the time - because it had identified potential risks which were found to be unacceptable in respect of its own chosen level of protection, and because it could not complete a risk assessment in the sense explained by the Appellate Body and the Panel for the first time in the hormones case, nor according to the Codex Alimentarius guidelines on risk analysis which were adopted much later. This is for all five hormones, and obviously for the melengestrol acetate (MGA).

254. As regards the possible differences between the evidence concerning the health risk associated with the use of hormones generally or with the administration of hormones in animals for growth promotion purposes, they are further elaborated in the reply to the next Question. The short reply is that evidence from both of situations 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. It is also clearly in the case of these hormones the outcome of the European Communities' risk assessment that the specific evidence concerning the health risk associated with the administration of hormones in animals for growth promotion purpose is insufficient and inconclusive, except for oestradiol 17b.

Q70. Having regard to the statement of the United States in paragraphs. 151-152 of the first US written submission, the Panel notes that Article 5.7 of the *SPS Agreement* talks about "available pertinent information" on the health risk. In the parties' views, does this mean that the "available pertinent information" under the circumstances of the current disputes refer to the information on risks associated with the consumption of meat from animals treated with hormones for growth promotion purposes according to good veterinary practice? Or, does it refer to the risk of the five hormones to human health generally?

[79] see at ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_14e.pdf.

255. Both the information concerning the health risk associated with the use of hormone generally and the information on risks associated with the administration of hormones in animals for growth promotion purposes according to GVP, and the consumption of meat thereof, are two distinct but complementary and necessary components of an overall risk assessment of the consumption of meat from animals treated with hormones for growth promotion purposes.

256. This has to be understood as two concentric circles of evidence, both informing the risk assessment, the big circle, with respect to the general use of hormone, and the interior circle, related to the specific use considered. It is only if the latest stage of risk characterization of the inner circle can be reached, once hazards would have been identified and characterised, and exposures properly measured, that the specific risks of the inner circle, for the specific use at stake, could be singled out from the risks of the big circle.

257. In the context of Article 5.7 of the *SPS Agreement*, and under the circumstances of the current disputes, "available pertinent information" therefore refers to either types of information, if one or the other warrants that a provisional measure be taken.

258. As an illustration, if a serious hazard is identified for the general use of a product, before that hazard can be properly characterized in the context of a specific use, and the relevant hazard exposure assessment properly measured for that specific use, the serious hazard identified should certainly be "available pertinent information" in the context of the specific use in order to enable the adoption of provisional measures to circumscribe that potential risk. Ruling to the contrary would seriously undermine public health, for the least, or even be criminal.

Q71. Article 5.7 of the *SPS Agreement* requires that a Member review the measure within a reasonable period of time. In the parties' view, how long should this reasonable period of time be in this case? At which point of time should the calculation of the reasonable period of time start? Has the European Communities conducted such a review after the adoption of Directive 2003/74/EC in September 2003? What is the plan of the European Communities to conduct such review?

259. The length of a reasonable period of time varies from case to case, and depends notably on how quickly and how much additional pertinent information is obtainable. It is noteworthy for instance, that within the European Communities, differences in the constitutional requirements, as compared to the legal system of other members, may require different timings for amending a measure of this kind. It took indeed virtually three years between the time of the proposal of Directive 2003/74/EC and its final adoption and publication.

260. Certainly, the start of the reasonable period of time to review a measure can not seriously start before the provisional measure being enacted, i.e. implemented, namely 14 October 2004 in the case of Directive 2003/74/EC.

261. The whole chronology of the current case, after the Appellate Body report in the *EC – Hormones* case, has indicated a permanent review of the available information and of the risk assessment. The first opinion of the SCVPH was issued in April 1999 and, as explained in recital 8 of Directive 2003/74/EC, the SCVPH reviewed its assessment in May 2000 in the light of new information, including the JECFA opinion of February 2000, as well as in April 2002 in the light of the most recent scientific data.

262. In the present situation, recitals 10, 12 and article 9 of Directive 2003/74/EC set out already identified deadlines to review some elements of the scientific evidence, which related to the

therapeutic and zootechnical uses, and requires that additional information be sought, and that the measure be kept under regular review with a timely presentation of any necessary proposals.

263. The recent draft report from the UK authorities (Exhibit US – 20) has already been referred by the European commission to the European Food Safety Authority for evaluation (EFSA being the new scientific independent advisory body responsible for performing the assessment of risks for this kind of substances).

264. Furthermore, a review of the 2002 SCVPH opinion has been commissioned by EFSA, which has issued on 12 September 2005 a new call for new scientific data and research, from 2002 onwards, on substances with hormonal activity which may be used for growth promotion purposes in bovine meat.[80]

Q72. Please explain what you understand to be the relationship between Article 3.1 and Article 5.7 of the *SPS Agreement*?

265. The European Communities understands this question to be inquiring whether, in the presence of an international standard, guideline or recommendation that is based on a risk assessment it is possible to adopt a provisional sanitary measure on the grounds that the relevant scientific evidence is insufficient.

266. In the European Communities' view, this is indeed possible. 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. Article 3.3 of the SPS Agreement applies, at least by analogy.

267. 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.

Q73. Do you consider it possible that scientific evidence may be judged to be sufficient to undertake a risk assessment at a particular point in time, and yet considered to be insufficient for the same purpose several years later? Does the fact that a significant number of scientific studies have been undertaken with regard to these potential risks in the intervening years have any relevance for your response? Does the existence of international standards have any relevance? Please explain?

268. The first part of the question is obvious. The 20th century's history of Public health is full of such cases in members, whereby a risk assessment at a given point in time was felt to be based on sufficient evidence, while at a later stage new scientific evidence had contradicted previous evidence, and the same situation required the conduct of further scientific studies and the review of its risk assessment.

269. This tautology is the simple consequence of the dynamic nature of scientific knowledge and from the scientific dialectic in research. New findings in scientific research improve scientific understanding, which in terms identifies new questions to resolve, which leads to further research.

[80] *See* http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_238/c_23820050928en00050006.pdf.

270. It is also noteworthy that this goes either way, that is a product may be initially banned or be strictly controlled on the basis of its initial risk assessment, while further scientific information may later suggest that risks may have been originally overestimated and in turn require further scientific information to assess more accurately these risks. Vice versa, a product may have been authorised on the basis that its risk assessment indicated a satisfactory level of protection, while later scientific studies may identify new potential impacts or hazards that require further studies and research to be accurately characterised.

271. This evolution in the scientific understanding of a particular risk assessment may not only come because new scientific evidence may identify new risks (or new reasons of safety), but also because new risk assessments may be performed according to evolving international standards. For instance, there were no international standards or guidelines on how to perform a proper risk assessment at the time of our initial measure, while now there are, which identifies the recommended steps (e.g. risk characterization, dose/exposure response, etc.). These were developed after the first hormone panel and the Appellate Boy reports.

272. There is a plenty of such examples where this occurred, but just to cite a few various ones in public health, here are some: BSE, asbestos, AIDS, DDT, softenon, even radioactivity or some food colouring or flavouring substances.

273. In the case at stake in these proceedings, most importantly, not all scientific evidence was available at the time, and the new scientific studies have certainly modified the content of the risk assessment. By identifying new hazards, it also requires a new risk assessment to be performed to fill the gaps and the uncertainty identified in the scientific evidence.

Q74. Assuming the Panel deems it necessary to determine whether the European Communities revised measure complies with certain provisions of the *SPS Agreement*, do the parties consider that the consultation of scientific experts would be necessary or only useful? What would be the issues on which experts should be consulted? To the extent feasible, should the Panel consult the experts consulted in the *EC – Hormones* case?

274. The scientific issues that are relevant for the use of hormone having oestrogenic, androgenic, or gestagenic action, used as growth promoters in meat production, are extremely complex and difficult. The European Communities' scientific Committees have been working on them for several years. The European Communities does not believe that it is necessary for this Panel to look into any scientific issues to make its necessary findings and rulings within its terms of reference in this particular case.

275. However, the European Communities does not believe that the Panel would have the expertise to decide on such issues itself, should the Panel decide to go down of deciding the scientific issues at stake. In such a scenario, the European Communities believes that the consultation of scientific and technical advice would be absolutely necessary. In such an unlikely scenario, experts should be consulted. However, the European Communities considers that this Panel cannot consult the experts that were used in the original *EC – Hormones* case because three of the five experts are now clearly known to have worked and have close ties with the pharmaceutical industry, the views of one expert were considered not relevant by the Appellate Body in this case, and the fifth one has subsequently conducted scientific studies for the European Commission. Therefore new experts will have to be chosen.

ANNEX B-2

REPLIES OF CANADA TO QUESTIONS POSED BY THE PANEL AFTER THE FIRST SUBSTANTIVE MEETING

(3 October 2005)

Questions to Canada:

Q35. Canada claims that it is entitled to maintain its suspension of concessions or other obligations as long as the DSB has not decided to withdraw its authorization. However, one may argue that, even with the authorization of the DSB, the Member concerned is not obligated to impose the retaliatory measures. In addition, Article 22.8 provides that the suspension of concessions "shall only be applied until such time as the measure found to be inconsistent ... has been removed". In that context, why does Canada believe that a decision of the DSB is necessary for it to remove its retaliatory measures?

1. Canada does not believe that a decision of the DSB is necessary for it to remove its retaliatory measures. As the Panel notes, a Member is not obligated to impose retaliatory measures even when it has authorization to do so. Nor does it have to wait for a decision of the DSB before it may remove them. The issue, however, is not when a Member may remove its retaliatory measures but when it must do so. According to Article 22.8 of the DSU, it must do so when, *inter alia*, the measure found to be inconsistent has been "removed" (*i.e.*, brought into compliance). In the absence of agreement between the disputing parties that the inconsistent measure has been "removed", the question that arises is who may make that determination.

2. In accordance with Articles 21.6 and 22.8, second sentence, of the DSU, disputes remain under the surveillance of the DSB until they are resolved. As a result of this ongoing surveillance, and in the light of an explicit authorization by the DSB under Article 22.7 to suspend concessions, it is for the DSB to confirm that the inconsistent measure has been removed.

3. In the circumstances of this case, the EC claims that it has removed its measure and Canada disagrees. It therefore is the responsibility of the DSB to determine whether the EC has done so before Article 22.8 of the DSU can have been satisfied. A decision by the DSB to terminate the authorization is simply a consequence of the confirmation by the DSB that the conditions of Article 22.8 have been met.

Q36. With reference to paragraph 47 of Canada's first written submission, could Canada explain how the suggested initiation of "new proceedings in which [the EC would request] the Panel to determine the actual compliance of a measure [the EC] has adopted to implement the recommendations and rulings of the DSB" would operate under the WTO dispute settlement system?

4. Paragraph 47 of Canada's First Written Submission refers to panel proceedings *de novo*. The EC would initiate panel proceedings, as it has done in the present case, alleging that one of the conditions of DSU Article 22.8 has been fulfilled. The EC would assume the burden of demonstrating to the panel that its measure is now compliant with the recommendations and rulings of the DSB in *EC – Hormones*, that the EC has "removed" the measure that was previously found to be non-compliant, and that consequently, pursuant to DSU Article 22.8, Canada is no longer entitled to suspend concessions. If the EC had assumed that burden at the outset of these proceedings, as it

appears to have done in Part II of its First Written Submission, then the current proceedings would replicate the scenario set out above.

5. As a responding party, Canada would be entitled to demonstrate, by way of defence, other inconsistencies of the EC's measure with the covered agreements. Such inconsistencies would be an affirmative defence on Canada's part in respect of the alleged violation of DSU Article 22.8. By demonstrating that the EC's measure is inconsistent with other provisions in the covered agreements, Canada would effectively disprove the EC's claim that the measure previously found non-compliant had been "removed" (within the meaning of DSU Article 22.8). The burden would be on Canada to demonstrate the existence of any other inconsistencies on the part of the EC. A responding party is entitled to put forward an exception or other affirmative defence regardless of the terms of reference of the panel.[1]

6. If such a panel were to find that the EC's measure complies with the recommendations and rulings in *EC – Hormones* and Canada were not able to demonstrate any inconsistency with other obligations, the panel would then make a recommendation to Canada that it lift the suspension of concessions. The adoption of such a report would constitute implicit revocation of the DSB's authorization to Canada to suspend concessions.

7. If the panel were to find that the EC measure does not comply with the recommendations and rulings, or is inconsistent with other obligations of the EC in a covered agreement, it would not make a recommendation to Canada.

Q37. Other than through recourse to an Article 21.5 panel, is there any other manner whereby the EC can seek to obtain a *multilateral* determination on whether or not its compliance measure has removed the WTO inconsistency?

8. Adoption by the DSB of a panel report resulting from the process described in Canada's answer to question 36 above, with a finding that the EC had complied, would constitute multilateral confirmation of the EC's compliance.

9. The parties could also, by agreement, have recourse to arbitration pursuant to DSU Article 25, the result of which would be notified to the DSB.

Questions to Canada and the United States:

Q43. Do Canada and the United States agree with the European Communities' statement in paragraph 32 of its first written submission that the specific forms described in paragraph 2 [of Article 23 of the DSU] do not exhaust the list of prohibited unilateral actions and its reference to the Panel Report in *US – Section 301 Trade Act*? Why?

10. Yes, Canada agrees. Article 23.2 of the DSU is not exhaustive but sets out certain "specific and clearly-defined forms of prohibited unilateral action" covered by the general rule in Article 23.1.[2] However, any action impugned under Article 23.2 must first fit under the circumstances described in Article 23.1. In other words, in order for there to be a violation of either the general obligation to

[1] See *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, Report of the Appellate Body, WT/DS33/AB/R and Corr.1, adopted May 23, 1997, at p. 14; *United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities*, Report of the Appellate Body, WT/DS108/AB/RW, adopted January 29, 2002, at para. 133 [*US – FSC (Article 21.5 – EC)*]; and *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, Report of the Appellate Body, WT/DS90/AB/R, adopted September 22, 1999, at para. 136.

[2] See Canada's First Written Submission, at para. 71.

"have recourse to, and abide by, the rules and procedures" of the DSU set out in Article 23.1, or one of the specific prohibitions enumerated in Article 23.2, it has to be established that a Member is "seek[ing] the redress of a violation of obligations" under the covered agreements.

11. The concessions to the EC that Canada is currently suspending are not to redress an alleged WTO inconsistency of the EC's new measure. The concessions are being suspended on the basis of a DSB authorization which has not been terminated nor have the conditions required for its removal been established by the EC. Canada's action in respect of the original measure – which is at issue here – is thus fully consistent with Article 23.1's admonition that Members shall abide by the rules and procedures of the DSU.

Q44. Do Canada and the United States agree with the European Communities that whenever there is a violation of Article 23.2 of the DSU, there is always a violation of Article 23.1?

12. If a Member is seeking redress of a perceived WTO violation by means of one of the specific forms of prohibited unilateral action set out in paragraphs (a) to (c) of Article 23.2 of the DSU, there would also be a violation of the general rule to have recourse to and abide by the rules and procedures of the DSU set out in Article 23.1 of the DSU. Article 23.2 is an illustration of the general rule in Article 23.1 of the DSU and applies only when a Member is seeking redress of a WTO violation. This is apparent from the *chapeau* of Article 23.2, which includes the phrase "in such cases", thereby referring to when Members "seek the redress" of a WTO violation.

Q45. Do Canada and the United States consider that the European Communities could have, as the party having to comply, effectively made a recourse to Article 21.5, in the light of the recourse to Article 21.5 by the European Communities in the *EC - Bananas III* case? If yes, and in light of Article 6 of the DSU, who would be the complainant, and what would be the complaint?

13. Under DSU Article 21.5, the EC could initiate the proceeding and request a ruling that the EC has complied with the recommendations and rulings of the DSB in *EC – Hormones*. The EC would be the "complaining party" in a broad sense, *i.e.*, the party that would initiate the proceedings. Canada notes that DSU Article 6.1 refers to a "complaining party" but DSU Article 6.2 refers to "the applicant". The "complaint" in a broad sense, *i.e.*, the subject matter of the proceeding, would be that the EC has complied with the recommendations and rulings of the DSB. The EC would have the burden of making a *prima facie* case to that effect and would have to put forward sufficient evidence and arguments to meet that burden.

14. A proceeding under DSU Article 21.5 would not necessarily require the involvement of a respondent party. The absence of a respondent party would not deprive a panel of jurisdiction. Even without the participation of a respondent party, legal consequences will flow from the recommendations and rulings of the DSB when it adopts panel and Appellate Body reports.

15. The report in *EC – Bananas III (Article 21.5 – EC)* demonstrates that the DSB established a DSU Article 21.5 panel for the purpose of having the EC seek confirmation of the WTO consistency of its own measure, and that the procedure under DSU Article 21.5 was used by the EC to that effect.[3]

Q46. Presuming that Canada and the United States are interested in a prompt resolution of this dispute, why have they not initiated the expedite procedure of Article 21.5 to challenge the EC implementing legislation as they do in these proceedings?

[3] *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the European Communities*, Report of the Panel, WT/DS27/RW/EEC, April 12, 1999, unadopted.

16. As Canada has explained in its answer to question 50, Members of the WTO have a variety of means and avenues through which to deal with existing trade disputes. Although Canada has no obligation to initiate WTO dispute settlement proceedings, the initiation of proceedings under DSU Article 21.5 is an option that Canada may exercise depending on the particular circumstances of a case. In this case, Canada chose not to exercise that option.

Q47. With reference to the European Communities' statement in paragraph 62 of its oral presentation, could Canada and the United States confirm whether, and explain why, the implementation of the *EC – Hormones* case has "practically not been on the DSB agenda since July 1999?

17. According to Article 21.6 of the DSU, the implementation of adopted recommendations and rulings remains under the surveillance of the DSB until the dispute is resolved. Article 22.8, second sentence, of the DSU provides that DSB surveillance continues even after concessions have been suspended. Article 21.6 of the DSU also provides that disputes will be placed on the meeting agenda of DSB meetings, but provides the DSB with the discretion not to place it on the agenda. In other words, while the DSB has the discretion not to place a dispute on its formal meeting agenda, it does not have the discretion to remove a dispute from its surveillance until it is resolved.

18. The *EC – Hormones* dispute remained on the DSB agenda until the adoption of the authorization to suspend concessions, prior to which time the EC provided regular reports on its plans to implement the recommendations and rulings of the DSB. Once it became clear, however, that the EC would take some time to implement and that the implementation reports were substantially the same from meeting to meeting, the DSB exercised its discretion under Article 21.6 and removed the item from its meeting agenda until there was something new to report. The fact that the EC's implementation of the recommendations and rulings in *EC – Hormones* was removed from the DSB's meeting agenda does not mean, however, that it was no longer legally under the surveillance of the DSB.

19. The EC, in fact, acknowledged that its implementation remained under the surveillance of the DSB when it notified in a communication to the DSB that it had adopted a measure to implement the recommendations and rulings in *EC – Hormones*.[4] For the EC now to call into question the ongoing surveillance of the DSB by arguing that the dispute has "practically not been on the DSB agenda since July 1999" is simply an effort to elevate form over substance.

Q48. The European Communities states in paragraph 44 of its oral statement that "a 'determination' ... need not be pinned down to a specific statement in a specific form, it is the whole conduct a WTO Member is displaying that needs to be looked at". Why would this not be the case here? If the sum of US and Canadian statements, actions and arguments are not a unilateral determination of violation, isn't it at least evidence of their disagreement with the European Communities within the meaning of Article 21.5?

20. A determination within the meaning of Article 23.2(a) of the DSU can only occur, as specified in the *chapeau* of Article 23.2, "in such cases" where a Member seeks the redress of an alleged WTO violation. Canada acknowledges that there is a disagreement regarding the WTO consistency of the EC's new measure within the meaning of Article 21.5 of the DSU. However, this "disagreement" is not tantamount to a "determination" within the meaning of Article 23 since Canada has not acted to seek redress against the EC for this alleged violation. Unlike what is argued by the

[4] *EC – Hormones*, Communication from the European Communities, WT/DS26/22, WT/DS48/20, October 28, 2003.

EC, it cannot be inferred from Canada's continued suspension of concessions that it is seeking the redress of a violation other than that identified in *EC – Hormones*; nor, therefore, can it be inferred that Canada has made a "determination" with regard to the EC's new measure in contravention of Article 23.2(a) of the DSU.

21. The legal basis for Canada's suspension of concessions is not Canada's views on the inconsistency of the EC's purported implementing measure but rather the absence of affirmative multilateral confirmation of the EC's compliance and the ongoing validity of the DSB authorization. Until such time as the DSB authorization is terminated, Canada's assessment of the WTO consistency of the EC's new measure remains unrelated, and irrelevant, to Canada's continued suspension of concessions.

Q49. Can the United States and Canada explain whether they provided answers to the European Communities' requests for information on scientific studies made by the European Communities? If not, why?

22. The EC sent a letter dated April 8, 1998, to the Government of Canada requesting the full scientific studies including raw data on which Canada based its decision to authorize the use of the six hormones in question for growth promotion in cattle.

23. Health Canada responded in a letter dated August 4, 1998, that the Government of Canada is required by Canadian law to hold the requested data and studies in confidence and cannot by law release this information to a third party. In this same letter, Health Canada provided the full names and addresses of each of the firms with proprietary rights to the information the EC had requested, as these are the only parties permitted under Canadian law to release the requested information, and invited the EC to contact these firms directly to request the data and studies.

24. The EC subsequently repeated its request to Canada in another letter, and Health Canada responded on February 26, 1999, further clarifying that Canada's *Access to Information Act* prevents Canada from disclosing any record that contains confidential scientific or technical information supplied to the government by a third party. Canada also noted in this letter that the EC had not yet contacted the companies concerned, *i.e.*, those with proprietary rights to the information the EC had requested. Canada is not aware that the EC has since contacted these firms. Canada received no further requests from the EC for this or other related information.

Questions to all parties:

Q50. Could each party provide the Panel with a detailed account of the efforts it has made to solve this dispute since the notification by the European Communities of its implementing measure in 2003?

25. Members of the WTO have a variety of means and avenues through which to discuss existing or potential trade disputes. Some of these are more formal than others; informal discussions prior to the commencement of WTO consultations under DSU Article 4 were "diplomatic" in nature and therefore normally considered to be confidential. Canada can confirm that through its Missions in Brussels and Geneva, as well as through capital-based officials, it held a series of informal discussions with various officials of the EC Commission soon after the announcement by the EC of its purported compliance measure. These discussions were aimed at resolving both the substantive and the procedural elements of the current dispute.

26. More formally, since the implementation of the EC's 2003 Directive, Canada has repeatedly indicated – including through comments made at meetings of the DSB – its desire to discuss with the EC the reasons why it considers it has brought itself into compliance.

27. Canada and the EC held a videoconference in April 2004, with the express purpose of clarifying the alleged scientific basis for the EC's claims to have brought itself into compliance. The EC was unable to provide complete responses to many of Canada's questions presented in this exchange. Canada has continued to express its willingness to engage in further technical discussions, but none has taken place.

Q51. Having regard to the first claim of the European Communities, in a post-retaliation phase, if a suspension of concessions is consistent with Article 22.8, can it nevertheless be inconsistent with Article 23 of the DSU? Under what circumstances? Please elaborate.

28. No. A measure suspending concessions that is consistent with Article 22.8 of the DSU cannot at the same time be inconsistent with Article 23. A measure that is authorized by the DSB cannot be conduct that constitutes a unilateral determination for the purposes of DSU Article 23.2(a). A determination for purposes of a breach of Article 23.2(a) involves conduct by a WTO Member that is otherwise prohibited. If the suspension of concessions is still authorized for the purposes of Article 22.8, it cannot at the same time be prohibited for the purposes of Article 23.2(a).

29. The EC has attempted to define Articles 23.2(a) and 22.8 in a manner that makes them operate independently of one another. There are, of course, circumstances in which a breach of Article 23 can be found that does not involve Article 22.8 (such as when there is no DSB authorization). However, when the conduct complained of is the same for the purposes of both provisions – in this case, the suspension of concessions – these provisions cannot be interpreted and applied in isolation of each other.

Q52. In the *US – FSC* case, the European Communities suspended the application of its suspension of concessions and then initiated an Article 21.5 procedure because it considered that the US implementing legislation was inconsistent, *inter alia*, with the SCM Agreement. Please give your views on whether it would also be possible to request the establishment of an Article 21.5 panel while continuing to apply the suspension of concessions pending the outcome of the Article 21.5 procedure?

30. Yes, it would be possible for a WTO Member to request the establishment of an Article 21.5 panel while continuing to apply the suspension of concessions authorized by the DSB, pending the outcome of the procedure under DSU Article 21.5.

31. Notwithstanding the decision of the EC in *United States – FSC*, a WTO Member that has acted on a DSB authorization to suspend concessions is not obliged to reinstate concessions as a precondition to a challenge of compliance of another Member's implementation measure, to discontinue the suspension of concessions. In the absence of a "mutually satisfactory solution", Members are entitled to look to the DSB for multilateral confirmation that their suspension of concessions is no longer authorized. There is no obligation to discontinue an authorized suspension unless there is multilateral confirmation that the measure taken to comply with the recommendations and rulings is consistent with the covered agreements. Seeking such confirmation would be the purpose of a proceeding under DSU Article 21.5.

Q53. Are the parties of the view that, in the absence of a challenge by the implementing party against the continued suspension of concessions, such suspension can continue for an indefinite period of time, even though they are supposed to be only temporary. If not, what provision of

the DSU can serve as a legal basis for *preventing* the suspension of concessions for an indefinite period of time?

32. While Article 22.8 of the DSU specifies that suspension of concessions is to be only "temporary", it does not impose actual time limits on the duration of that suspension of concessions. The effective time limit, however, is always within the control of the implementing Member, in this case the EC. When there is multilateral confirmation that the measure found to be inconsistent has been removed, such that the conditions of Article 22.8 have been satisfied, the time limit expires and the suspension of concessions is no longer justified. The failure of the implementing Member to seek such multilateral confirmation, however, cannot be used to suggest that the Member suspending concessions is attempting to do so "indefinitely".

Q54. Could the parties provide the Panel with their understanding of the meaning of the term "measure" in Article 19.1 of the DSU and of the term "measures taken to comply with the recommendations and rulings [of the DSB]" in Article 21.5 of the DSU? More particularly, do the parties consider that a measure taking, e.g., the form of a ban remains the same measure, irrespective of the change in supporting legislation, as long as it is a ban? If not, what makes a "measure taken to comply" different from the measure which had to be brought into conformity?

33. As DSU Article 19.1 applies generally to the dispute settlement system, the term "measure" in DSU Article 19.1 has a broader meaning than "measures taken to comply with the recommendations and rulings [of the DSB]" in DSU Article 21.5.

34. The EC is not contesting that Directive 96/22/EC, as amended by Directive 2003/74/EC, qualifies as a "measure taken to comply" within the meaning of DSU Article 21.5. Canada and the EC disagree about the compliance of the EC's measure with the recommendations and rulings of the DSB in *EC – Hormones*; not about whether the EC's measure is a "measure taken to comply" within the meaning of DSU Article 21.5.

Q55. When does the legal effect of the DSB authorization lapse and by what procedures? Where parties disagree on the consistency of a notified implementing measure effected after the DSU retaliation authorization, does the DSU authorization lapse at the time when (i) the DSB makes a decision of compliance with respect to the implementing measure, or (ii) the implementing measure is in actual compliance regardless of whether the DSB has made a determination of compliance or not, or (iii) the Member concerned notifies its implementing measure to the DSB and declares its compliance, or (iv) the DSB makes a specific determination to terminate its previous retaliation authorization?

35. Option (i) is the correct interpretation of when the authorization lapses. That is, where parties disagree whether a measure originally found non-compliant has been brought into compliance, the DSB authorization ceases to have effect when compliance has been confirmed multilaterally by the DSB. The DSB need not formally revoke the authorization; rather, the end of the authorization may be implicit in the adoption by the DSB of panel and/or Appellate Body findings that an implementing measure is compliant. Of course, there may be circumstances in which the DSB would also formally terminate the authorization at the same time that it confirms compliance, in which case option (iv) would also apply.

Q56. Article 21.5 of the DSU provides that where there is a "*disagreement* as to the existence or consistency with a covered agreement of measures taken to comply with ... such dispute shall be decided through recourse to these dispute settlement procedures." Since Article 21.5

provides that "such dispute *shall* be decided"[5] through recourse to [the DSU]", would the parties consider that either of them has an obligation to refer the matter to the DSB under Article 21.5? If yes, why?

36. No, there is no obligation on either party to initiate proceedings under DSU Article 21.5. The obligation is for WTO Members, once they decide to resolve their disagreements, to do so within the framework of the DSU and not outside.

Q57. How would you distinguish between expressing "disagreement" over the WTO compatibility of a measure taken to comply with recommendations and rulings adopted by the DSB for the purpose of deciding whether or not to start an Article 21.5 procedure and a unilateral "determination" of WTO compatibility of such a measure?

37. A WTO Member may examine and analyze the measures of another Member and arrive at certain views on the compliance of those measures. Such examination and analysis may result in the Members disagreeing about the WTO consistency of the measures. This would not constitute a "determination" within the meaning of DSU Article 23.2(a). In the light of Article 23.1, a "disagreement" only becomes a "determination" once a Member takes action to "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 agreement". An example of a "determination" within the meaning of Article 23.2(a) would be the hypothetical case of Canada suspending further concessions to the EC, and thereby exceeding the level of suspension of concessions authorized by the DSB, in response to the alleged WTO inconsistency of the EC's implementing measure.

38. A disagreement in and of itself is not sufficient to constitute a violation of Article 23. Rather, there must be action outside the rules and procedures of the DSU that seeks redress of the perceived violation before there can be a violation of Article 23.

Q58. In a situation where an Article 21.5 panel, requested to examine the compatibility of an implementing measure, finds that only partial compliance has been achieved, what is the procedure available to the original complainant:

(a) Can it continue to apply the suspension of concessions initially authorized by the DSB?
(b) Does it need to request a new authorization?
(c) Can the implementing party object to the level of suspension and request an Article 22.6 arbitration to determine a new level of suspension of concessions?

39. When a panel finds that only partial compliance has been achieved, it is effectively finding that the authorized level of suspension of concessions is no longer equivalent to the level of nullification and impairment caused by the "partially compliant" implementing measure, as is required by Article 22.4 of the DSU. There is no express mechanism in the DSU by which the level of suspension of concessions can be readjusted to be equivalent again to the level of nullification and impairment. However, any difficulties caused by the absence of such a mechanism arise in any proceedings that review a measure taken to comply, regardless of who initiates the proceedings.

40. The fact that there are systemic difficulties in readjusting the levels does not mean that this scenario creates insurmountable hurdles in resolving a dispute. If such a situation were to occur, the parties to the dispute would work out in good faith between themselves how the level would be

[5] Emphasis added by the Panel.

readjusted. The initial authorization would remain in effect, but the level of suspension of concessions could be modified by the parties, either through mutual agreement or by recourse to Article 25 arbitration.

41. Therefore, only option (a) is appropriate, where the party suspending concessions would continue to do so, albeit at an appropriately adjusted level. Neither option (b) nor option (c) is appropriate because Article 22.7 specifically prohibits a new arbitration to establish the level of nullification and impairment, which would be required to obtain a new authorization.

Q59. Is Article 23 of the DSU applicable to a suspension of concessions under a previous authorization of the DSB and in the absence of a new DSB decision of termination of the previous authorization?

42. Article 23 of the DSU does not apply to authorized suspension of concessions in the absence of some intervention by the DSB that – either explicitly or implicitly – terminates the DSB authorization. WTO Members that continue to suspend concessions under such authority – even in the face of an implementing measure by the other Member – are not "seeking redress" of a perceived violation. For a Member to be found in breach of Article 23 of the DSU, it must have acted in response to a perceived violation by another Member of that Member's WTO obligations. If the DSB authorization to suspend concessions remains in effect, a WTO Member that simply continues to suspend concessions on the basis of this authorization cannot be found to have engaged in conduct prohibited by Article 23. In such circumstances, the Member's conduct continues to be based on the DSB authorization and is therefore unrelated to the perceived compliance or non-compliance of the implementing measure.

Q60. Having regard to the US reference to the DSU negotiations in footnote 202 of its first written submission, could the parties indicate which proposals have been made in that context that would represent *amendments* to the current text of Articles 21.5, 22.8, 23.1 and 23.2(a) of the DSU?

43. With respect to the relationship of the present case to the DSU review process, the DSU review process is entirely separate from and unrelated to the issues the Panel has been called upon to resolve. The information requested concerns proposals by various WTO Members for future amendments to the text of the DSU. Canada respectfully submits that it is the Panel's responsibility to resolve the issues presented to it in the present case on the basis of the current text of the DSU (and any other relevant covered agreements). The amendments that have been proposed to the text of the DSU are therefore irrelevant to the issues the Panel has been asked to address under its terms of reference. This being said, the documents that contain proposals for amendments to Articles 21.5, 22.8, 23.1 and 23.2(a) of the DSU are contained in working documents JOB(04)/52, JOB(05)/47 and JOB(05)/71. An earlier proposal was contained in WTO document TN/DS/W/32.

Q61. How does the principle of good faith affect the allocation of burden of proof in these two disputes? What kind of presumption should be made by the Panel if/when applying this principle? Does the application of this principle under the circumstances of the present disputes lead to the conclusion that the EC's implementing measure shall not be presumed WTO-inconsistent? Or, should the conclusion be that the US and Canadian measures of suspension of obligations shall not be presumed to be inconsistent with the DSU? Please elaborate on why one specific conclusion is preferable than the other in your view.

44. The principle of good faith is not relevant to the allocation of the burden of proof in this dispute. The application of this principle therefore does not create a presumption in favour of either party.

45. In repeatedly raising the issue of good faith, the EC has confused the issues by suggesting that to deny it a presumption of compliance in these circumstances would be tantamount to a presumption that the EC has acted in bad faith. Canada does not argue that the EC has acted in bad faith, nor even that it should be presumed not to comply.

46. Rather, the allocation of the burden of proof in this dispute is determined by the existence of the multilateral authorization and the existence of Canada's measure taken on the basis of that authorization. That is, the EC cannot benefit from a presumption of compliance – such that it would be presumed to have satisfied one of the conditions of Article 22.8 – for the simple reason that allowing such a presumption would have the consequence of automatically rendering WTO inconsistent a measure of another Member that was and remains authorized by the DSB. Since the EC is in a state of non-compliance in the *EC – Hormones* dispute, it bears the burden of confirming multilaterally that it has now complied in order to have the authorization terminated.

Q62. Do you agree with the view that (i) if an original complaining party initiates an Article 21.5 dispute challenging the consistency of an implementing measure, that party shall bear the burden to prove that the implementing measure is WTO-inconsistent during the compliance procedure, and that (ii) if an original defending party initiates an Article 21.5 dispute claiming the WTO-consistency of its measure, that original defending party shall bear the burden of establishing the consistency of its implementing measure as a complaining party to the Article 21.5 dispute? Please elaborate on your response.

47. Yes, Canada agrees with the statements in the question.

48. If the original responding party initiates the proceeding under DSU Article 21.5, it bears the burden of demonstrating that its measure is compliant with the recommendations and rulings of the DSB. Since the objective of the proceeding under DSU Article 21.5 is to achieve conformity with all provisions of the covered agreements, it would then be open to any other WTO Member that participates in such proceedings to demonstrate that the measure at issue is not consistent with other provisions of the covered agreements.

49. If the proceeding under DSU Article 21.5 is initiated by the original complaining party, it would bear the burden of demonstrating that the implementing measure is inconsistent with any provisions in any of the covered agreements. It is established case law that panels acting under DSU Article 21.5 may deal with all issues of consistency of the measure concerned with the covered agreements. The Appellate Body in *Canada – Aircraft (Article 21.5 – Brazil)* confirmed this.[6]

Q63. Would the parties consider that the principle *rebus sic stantibus*, could apply to a decision of the DSB (see, *inter alia*, para. 26 of Canada's oral presentation regarding the legal status of DSB decisions)? In its oral comments on Canada's oral presentation, the EC stated that there is no hierarchy in customary international law, the principle of good faith in this case, and a treaty language, the DSB authorization in the current dispute. Could the parties provide evidence that the EC statement is or is not supported by international jurisprudence?

50. Regardless of whether the principle of *rebus sic stantibus* (*i.e.*, fundamental change in circumstances) applies to decisions of the DSB as a general matter, the conditions for it to be invoked successfully in these circumstances are not present.

[6] See *Canada – Aircraft (Article 21.5 – Brazil)*, at para. 41. See also *Australia – Measures Affecting the Importation of Salmon – Recourse to Article 21.5 of the DSU by Canada*, Report of the Panel, WT/DS18/RW, adopted March 20, 2000; and *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by Ecuador*, Report of the Panel, WT/DS27/RW/ECU, adopted May 6, 1999.

51. The EC has not itself invoked the principle to argue that the DSB authorization is no longer in effect. Moreover, even if the EC were to invoke the principle, it could not do so successfully. One of the cumulative conditions codified in Article 62 of the *Vienna Convention on the Law of Treaties* is that the circumstances that are said to have fundamentally changed must have been "unforeseen" at the time the agreement was made (in this case, the adoption of the DSB authorization). At the time WTO Members, acting through the DSB, authorized Canada to suspend concessions, it could hardly be considered unforeseen that the EC would adopt a measure to comply with findings that it was in breach of its obligations under the WTO. On the contrary, the purpose of the authorization to suspend concessions was precisely to induce the EC to adopt such a measure. Therefore, far from being unforeseen, it was expected that the EC would adopt an implementing measure.

52. With respect to the relationship between treaty law and customary international law, the EC has initiated an unnecessary discussion of the hierarchy between sources of international law. The point made by Canada on which the EC was commenting did not depend on resolving issues of hierarchy between sources of international law. Canada has argued that its authorization from the DSB to suspend concessions (specifically granted by treaty) prevails over any claim by the EC to a presumption of compliance.[7] Canada does not argue that there is a conflict, the resolution of which requires the Panel to determine a hierarchy. It is simply that a presumption of compliance does not apply to the EC measure in these circumstances as a result of the DSB surveillance regime. See also Canada's answer to question 61 above.

53. In any event, even if the Panel were to find that there is a conflict between these principles in these circumstances, it could resolve this conflict with reference to the specific principle of treaty interpretation of *lex specialis derogat legi generali*, which provides that specific treaty rules (*i.e.,* those governing the DSB authorization) will prevail over general rules of customary international law (*i.e.,* those providing for a general presumption of compliance).[8] The relationship between the DSB authorization and the EC's claim to a presumption of compliance could also be decided with reference to specific provisions of the DSU. Articles 3.2 and 19.2 of the DSU both provide that panels cannot add to or change the rights and obligations of WTO Members in the resolution of disputes. If the Panel were to find in favour of the EC's arguments – by finding that the EC has satisfied the conditions of Article 22.8 on the basis of this presumption – it would alter Canada's rights under the DSU. Such a decision would alter Canada's rights not only by depriving Canada of the legal basis on which its measure is based but, more importantly, would do so without having the issue of whether the conditions of Article 22.8 have been satisfied confirmed by the DSB.

Q64. If the Panel were not able to reach a conclusion on the first claim of the European Communities under DSU Article 23, do you think the Panel should proceed to examine the second claim of violation of Article 22.8 of the DSU?

54. Canada is not in a situation covered by Article 23 of the DSU because it is not seeking the redress of an alleged WTO violation. Therefore, the examination by the Panel of the status of the DSB authorization for the purposes of the EC's claims under Article 22.8 of the DSU remains the fundamental issue to be determined in this dispute.

Q65. Canada and the United States have argued that the EC measure taken to comply with the recommendations and rulings of the DSB in the Hormones case are incompatible with

[7] For Canada's comments on the EC's efforts to confuse the "presumption of compliance" and the "principle of good faith", see Canada's answer to question 61 from the Panel.

[8] See, for example, Malcolm N. Shaw, *International Law,* 5th ed. (Cambridge: Cambridge University Press, 2003), at 116 [Exhibit CDA-24]. See also *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R, adopted February 13, 1998, at para. 124.

Article 5.1 and 5.7 of the SPS Agreement. However, the European Communities does not make any reference to these provisions, either in its request for establishment of the panel, or in its first written submission. Do the parties believe that the Panel has, nonetheless, jurisdiction to review the compatibility of the EC implementing measure with Articles 3.3, 5.1 and 5.7 of the SPS Agreement? On what legal basis should the Panel consider itself entitled/not entitled to address the arguments of Canada and the United States in relation to the SPS Agreement?

55. The Panel has jurisdiction to review the consistency of the EC's new measure with Articles 3.3, 5.1 and 5.7 of the *SPS Agreement*. The EC alleges that Canada has acted inconsistently with Article 22.8 of the DSU by maintaining its suspension of concessions despite the EC's "removal" of its offending measure. There is no presumption of compliance that operates in favour of the EC in this case. In the alternative, if a presumption exists, that presumption is rebuttable. In either case, the Panel's determination that the EC has actually "removed" its offending measure (in other words, that it has actually brought its measure into compliance with the recommendations and rulings of the DSB) is a prerequisite to any finding that Canada has breached Article 22.8 of the DSU by maintaining its suspension of concessions. Thus, because the recommendations and rulings of the DSB require that the EC base its measure on a risk assessment as required by Articles 3.3 and 5.1 of the *SPS Agreement*, the Panel has jurisdiction to examine the consistency of the EC's measure with these and related provisions of the *SPS Agreement*.

56. As to the consistency of the EC's measure with Article 5.7 of the *SPS Agreement*, the EC is claiming that it cannot perform a risk assessment on five of the six hormones in question because there is insufficient scientific evidence to do so. The EC thus bears the burden of justifying its "provisional" measure on the basis of the exemption contained in Article 5.7 of the *SPS Agreement*. Consequently, in the context of determining whether the EC's new measure complies with the recommendations and rulings of the DSB, the Panel has jurisdiction to determine whether the EC is able to justify its provisional measure on the basis of Article 5.7 of the *SPS Agreement*.

57. Finally, in the light of the EC's alternative argument in Part II of its First Written Submission, in which it claims that its new measure is "fully compliant with the recommendations and rulings of the DSB", this Panel has full jurisdiction to examine the actual consistency of the EC's measure with the relevant provisions of the *SPS Agreement*. In this regard, we draw the Panel's attention to paragraphs 137 to 147 of the EC's First Written Submission, which set out its claims of compliance with the recommendations and rulings of the DSB.

Q66. In this particular case, would it be for the European Communities to prove the compatibility of its measure with Article 5.7 of the SPS Agreement because it applies certain aspects of that measure provisionally or would it be for Canada and the United States to demonstrate a violation of Article 5.7 because they consider that the EC measure is in breach of that provision? Could the parties discuss the application of the burden of proof in relation to Article 5.7 in light of the panels and Appellate Body findings with respect to that provision in *Japan – Agricultural Products II* and *Japan – Apples*?

58. As the Appellate Body has explicitly noted in *Japan – Agricultural Products II*, Article 5.7 "operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[9] This means that Article 5.7 enables WTO Members, in certain, limited circumstances, to adopt and maintain SPS measures despite the fact that they are not supported by sufficient scientific evidence. Article 5.7 does not exist as an option that can be freely

[9] See *Japan – Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R, adopted March 19, 1999, at para. 80 [emphasis in original] [*Japan – Agricultural Products II*].

chosen by the Member concerned in place of Article 2.2. It plays a role as a temporary "safety valve" in situations where some evidence of a risk exists but not enough to complete a full risk assessment, thus making it impossible to meet the more rigorous standards set by Articles 2.2 and 5.1.

59. In the present case, it is the EC that is alleging that there is insufficient scientific evidence to conduct an adequate risk assessment in respect of five of the six hormones at issue. Therefore, it is the EC, as the WTO Member invoking Article 5.7 to justify its provisional measure, that bears the burden of making a *prima facie* case in support of its position. For example, in *Japan – Apples* the panel assigned the burden of proof to Japan to demonstrate that the four cumulative requirements of Article 5.7 had been met.[10] In the present case, Canada has submitted evidence and arguments to demonstrate that the EC has not met its burden and that, in any event, it would be unable to meet this burden.

Q67. Do the parties consider that Article 5.7 applies only when no risk assessment can be made at all or also when scientific evidence exists but is insufficiently specific?

60. The Appellate Body in *Japan – Apples* found that "relevant scientific evidence" will be "insufficient" when the scientific evidence available does not allow, in quantitative or qualitative terms, the performance of a risk assessment as required under Article 5.1 of the *SPS Agreement*.[11] Consequently, Article 5.7 applies when "no risk assessment can be made at all" either because there is simply not enough evidence to conduct a risk assessment, or when the evidence available is insufficiently specific to conduct a risk assessment as defined in Annex A of the *SPS Agreement*.

Q68. Do all parties agree that the term "on the basis" in Article 5.7 of the SPS Agreement has the same meaning as "on the basis" in Article 5.1, i.e. that a "rational relationship" is required?

61. The requirement that a Member adopt a measure "on the basis" of available pertinent information under Article 5.7 is similar to the obligation under Article 5.1 that a Member's SPS measure be "based on" a risk assessment. In other words, in both instances there must be a "rational relationship" between the measure at issue and, in the case of a measure adopted under Article 5.7, the "available pertinent information" and, in the case of any other measure not captured by Article 3.2 of the *SPS Agreement*, the risk assessment. This interpretation is consistent with the need for SPS measures to be based on science as set out in Article 2.2 of the *SPS Agreement*.

Q69. During the *EC – Hormones* proceedings, the European Communities was of the view that "the scientific evidence concerning the need to regulate the use of hormones was in itself sufficient to justify its legislation and the European Communities did not need to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient" (DS26/R/USA, para.4.239). Does this mean that "the evidence concerning the need to regulate the use of hormones generally" is different from the specific evidence concerning the health risk associated with the administration of hormones in animals for growth promotion purpose? Is there sufficient evidence concerning the latter?

62. There is a difference in "the evidence concerning the need to regulate the use of hormones generally" in veterinary medicine and the specific evidence concerning the health risk associated with the administration of hormones in animals for growth-promotion purposes. In particular, the exposure data needed to evaluate hormones used for growth-promotion purposes would have to be use specific. Canada considers that a "risk assessment" of a veterinary drug is designed to address a specific use of

[10] See *Japan – Measures Affecting the Importation of Apples*, Report of the Panel, WT/DS245/R, adopted December 10, 2003, at para. 8.212.

[11] See *Japan – Measures Affecting the Importation of Apples*, Report of the Appellate Body, WT/DS245/AB/R, adopted December 10, 2003, at para. 179.

the drug. Therefore, in the case of use of these hormones for growth-promotion purposes, the hormone residue data used to estimate the dietary hormone intake from growth-promotion use would need to be generated specifically, as would the residue data from the use of these hormones for any therapeutic purpose. In this case, there is sufficient scientific evidence to conduct a risk assessment in respect of all six hormonal growth promotants in question. This conclusion is supported by regulatory decisions in many countries and by the fact that JECFA has allocated ADIs (acceptable daily intake) for all six hormones at issue.

Q70. Having regard to the statement of the United States in paragraphs. 151-152 of the first US written submission, the Panel notes that Article 5.7 of the SPS Agreement talks about "available pertinent information" on the health risk. In the parties' views, does this mean that the "available pertinent information" under the circumstances of the current disputes refer to the information on risks associated with the consumption of meat from animals treated with hormones for growth promotion purposes according to good veterinary practice? Or, does it refer to the risk of the five hormones to human health generally?

63. The "available pertinent information" on oestradiol 17β and the other five hormones is adequate to conduct a risk assessment on the use of oestradiol 17β and the other five hormones when used for growth promotion according to good veterinary practices. However, the use of any of these hormones for purposes other than growth promotion (according to good veterinary practices) would require specific risk assessments and the "available pertinent information" would have to be assessed as such.

Q71. Article 5.7 of the SPS Agreement requires that a Member review the measure within a reasonable period of time. In the parties' view, how long should this reasonable period of time be in this case? At which point of time should the calculation of the reasonable period of time start? Has the European Communities conducted such a review after the adoption of Directive 2003/74/EC in September 2003? What is the plan of the European Communities to conduct such review?

64. With regard to the requirement under the second sentence of Article 5.7 of the *SPS Agreement* that a Member review its provisional measure within a reasonable period of time, the Appellate Body in *Japan – Agricultural Products II* found that the reasonable period of time should be assessed on a case-by-case basis and depends on (1) the specific circumstances of each case and (2) the characteristics of the SPS measure at issue.[12] In the case of a total import ban like the one currently facing Canada and the United States, which has the most trade-distorting effect possible, the reasonable period of time should not be construed so as to prolong unnecessarily the trade impact of the provisional measure. The second sentence of Article 5.7 imposes a stringent burden on Members to make active and ongoing efforts to gather and review additional information necessary for a risk assessment. Consequently, from the moment that the measure is adopted, the Member should be acting with diligence to fulfill this substantive requirement of Article 5.7 of the *SPS Agreement*.

Q72. Please explain what you understand to be the relationship between Article 3.1 and Article 5.7 of the SPS Agreement?

65. Consistent with the goal of the *SPS Agreement* to harmonize SPS measures, Article 3.1 sets out the basic obligation of Members to base their measures on international standards except as otherwise provided for in the Agreement. In a case where a Member wishes to introduce a measure with a higher level of SPS protection than that of the relevant international standard, it must do so on the basis of a risk assessment. Article 5.7 allows Members to adopt provisional measures in a situation

[12] See *Japan – Agricultural Products II*, at para. 93.

where there is insufficient scientific evidence to conduct such a risk assessment. However, it does not give Members *carte blanche* in this area. The provisional measure must be based on "available pertinent information", including that from relevant international organizations and measures of other WTO Members. Where a relevant international organization has adopted standards on a particular SPS issue, it makes it extremely difficult for a Member to argue that there is insufficient scientific evidence to conduct a risk assessment, because the existence of an international standard implies that sufficient scientific evidence exists to complete a risk assessment. The burden rests with the EC in this case to demonstrate that, despite the adoption of international standards by Codex regarding the hormones at issue, the scientific evidence is insufficient to allow it to conduct a risk assessment.

Q73. Do you consider it possible that scientific evidence may be judged to be sufficient to undertake a risk assessment at a particular point in time, and yet considered to be insufficient for the same purpose several years later? Does the fact that a significant number of scientific studies have been undertaken with regard to these potential risks in the intervening years have any relevance for your response? Does the existence of international standards have any relevance? Please explain?

66. Yes, it is theoretically possible that scientific evidence judged to be sufficient to undertake a risk assessment at a particular point in time may be considered to be insufficient to conduct a risk assessment for the same purpose several years later. For example, this could be due to a change in the basic understanding of a biological event that is triggered by the chemical under assessment, new scientific data that identify new adverse effects or adverse effects at lower exposure levels. New sources of exposure could also trigger the need to reassess the adequacy of the risk assessment.

67. It would not be the number of scientific studies conducted in the intervening years that would determine whether a new risk assessment was necessary but rather the nature of the studies. For example, if new residue studies (*i.e.*, an analysis of the chemical and significant metabolites in food) were carried out then this would require minimally an exposure reassessment and possibly a risk characterization reassessment. If studies addressed biological endpoints that had not been previously addressed (*e.g.*, the immune system), used new study protocols or more sensitive methodologies, a new hazard identification assessment would be in order.

68. Furthermore, it would be essential to take international standards into consideration. More important than the numerical standard is the basis, support or risk assessment for that international standard. For example, it is recognized that JECFA only allocates an ADI for a food additive or veterinary drug under review when JECFA considers that its scientific data base is complete and that there are no outstanding scientific issues.

Q74. Assuming the Panel deems it necessary to determine whether the European Communities revised measure complies with certain provisions of the SPS Agreement, do the parties consider that the consultation of scientific experts would be necessary or only useful? What would be the issues on which experts should be consulted? To the extent feasible, should the Panel consult the experts consulted in the *EC – Hormones* case?

69. If the Panel deems it necessary to consider whether the EC's revised measure complies with the *SPS Agreement*, the complexity of the issues in this case would require consultation with scientific experts. Were the Panel to so decide, those experts should be consulted as to (1) whether the Opinions and/or studies relied on by the EC constitute the necessary risk assessment identifying the risks to consumers that flow from the ingestion of meat from animals treated with oestradiol 17β; (2) whether there is sufficient scientific evidence regarding the other five hormonal growth promotants at issue to enable the EC to conduct a risk assessment; and (3) whether current scientific knowledge warrants the EC's ongoing ban regarding the six hormonal growth promotants.

70. If the Panel decides to consult experts, those experts who advised the panel in the original *EC – Hormones* case should be among the candidates. However, Canada may wish to propose several other recognized experts as candidates.

ANNEX B–3

REPLIES OF CANADA TO QUESTIONS POSED BY THE EUROPEAN COMMUNITIES AFTER THE FIRST SUBSTANTIVE MEETING

(3 October 2005)

Questions to the United States and Canada:

Q1. According to the United States and Canada the continued suspension of concessions and related obligations is based on the original DSB authorization and not on the (alleged) WTO-inconsistency of the EC's compliance measure. Does this mean that the United States and Canada claim a right to continue the application of sanctions even if the EC measure is WTO-consistent as long as the DSB authorization has not been formally withdrawn?

1. Canada would not claim a right to suspend concessions in circumstances where there has been multilateral confirmation that a measure taken to comply with recommendations and rulings of the DSB actually does comply. Multilateral confirmation of this compliance would come in the form of the adoption by the DSB of findings and recommendations of a WTO dispute settlement panel and/or the Appellate Body. The adoption of such findings by the DSB would at the same time be sufficient to constitute revocation of the DSB authorization, whether implicit or explicit.

Q2. You argue that the DSB authorization to suspend concessions can only be revoked following a multilateral determination of compliance of the EC's implementing measure. You suggest that this could be achieved, inter alia, through an Article 21.5 procedure initiated by the European Communities. In such a case would the European Communities be the "complaining party" within the meaning of Article 6? Who would be the "defending party"? What would be "the specific measures at issue"? What would be the legal basis for the "complaint"? What would the European Communities be complaining against?

2. See Canada's answer to questions 45 and 62 from the Panel**.**

Q3. Would the United States and Canada participate in a self-initiated Article 21.5 proceeding, such a proceeding? If yes, would they do so because of a legal obligation?

3. Yes. Regardless of whether there is a legal obligation to participate, it would be in Canada's interest to participate if the EC initiated a proceeding under DSU Article 21.5 to obtain confirmation of the compliance of its measure with the recommendations and rulings of the DSB in *EC – Hormones.*

Q4. What would be the terms of reference of a self-initiated Article 21.5 proceeding? Would the European Communities be required to anticipate any possible claims by the United States and Canada? Could the United States and Canada raise new claims outside the legal basis for the "EC complaints"? If yes, how could this be squared with the terms of reference?

4. See Canada's answers to questions 45 and 62 from the Panel.

Q5. In the oral hearing, Canada submitted that under an Article 21.5 proceeding it would not only be possible to review the compliance measure but also the legality of the continued application of the sanctions? According to Canada, is the continued application of the

suspension of obligations therefore a measure which can be reviewed under Article 21.5? What are the US' views on this suggestion?

5. No, the measure suspending concessions *per se* would not be reviewed by an Article 21.5 panel. However, if a panel established under Article 21.5 confirmed the compliance of an implementing measure, it could recommend that the DSB authorization be terminated. See Canada's answer to question 7 below.

Q6. In the oral hearing, the United States argued that there is no "disagreement" between the United States and the European Communities as to the WTO-consistency of the new compliance measure. If this is correct, how could the European Communities self-initiate an Article 21.5 proceeding as suggested by the United States?

Q7. Assuming that a proceeding under Article 21.5 comes to the conclusion that the EC's compliance measure is WTO-consistent. How would this lead to a withdrawal of the DSB authorization? What would be the legal basis for the DSB to "withdraw" the authorization, and what decision-making mechanism would apply for that DSB action.

6. A finding in a proceeding under Article 21.5 that a measure taken by the EC to comply is WTO consistent would lead to a withdrawal of the DSB authorization by the adoption by the DSB of the panel's findings confirming compliance. See Canada's answer to question 55 from the Panel.

7. Although Canada does not see it as necessary, if the EC were concerned about the effect of such findings on the ongoing validity of the DSB authorization, it could also cite Article 22.8 of the DSU in its request for the establishment of the panel under Article 21.5. There would then be no doubt as to whether the panel could make recommendations that the DSB authorization is no longer in effect. See also Canada's answer to question 8 below.

Q8. Canada argued in its First Written Submission that as the outcome of a new proceeding "the result would be a recommendation to the DSB to terminate the DSB authorization" (para. 47)? How can this statement be reconciled with Article 19 DSU whereby the Panel or Appellate Body only issues recommendations to the "Member concerned" but not to the DSB? What does the United States think?

8. Article 19 of the DSU simply sets out what panels shall do with respect to recommendations to Members to bring themselves into compliance. Nothing in that provision prevents panels from recommending to the DSB that the authorization be terminated.

Q9. How is the theory of the "withdrawal of the DSB authorization" in line with the text of Article 22.8, first sentence, of the DSU, and what is the need for it in the light of that provision?

9. The formal "withdrawal of the DSB authorization" is not required by the dispute surveillance regime set up by the DSU. Rather, it is the confirmation by the DSB of the EC's compliance that is required for the DSB authorization no longer to be available to Canada. See Canada's answer to question 55 from the Panel.

Q10. Is it Canada' opinion that the DSB authorization which it received in the Brazil – Aircraft case (WT/DS46) is (implicitly?) revoked after the Panel under the second Article 21.5 proceeding found that Brazil' compliance measure was WTO-consistent? What are the United States' views on this issue?

10. The premise of the EC's question is in error.

11. Although the panel ruled, in *Brazil – Aircraft (Article 21.5 – Canada II)*, that Brazil's program PROEX III as such was not inconsistent with the *SCM Agreement*,[1] PROEX III did not withdraw PROEX I and PROEX II, nor any subsidies issued under these programs. PROEX I and PROEX II were programs that had previously been found inconsistent with the *SCM Agreement*. Thus there is no basis for any suggestion on the part of the EC that Canada's authorization to suspend concessions to Brazil was implicitly terminated.

Q11. Canada argues that it has not violated Article 21.5 because the EC's could have initiated a compliance Panel itself (para. 76). Could Canada please explain how such a possibility for the European Communities affects Canada's obligations under Article 23.1 and 21.5 of the DSU?

12. The EC mischaracterizes Canada's arguments in paragraph 76. Canada's argument that it has not violated Article 21.5 does not depend upon the fact that the EC could have initiated proceedings under Article 21.5.

Q12. According to the United States and Canada the continued imposition of sanctions is justified because of the DSB authorization. Assuming the European Communities would try to seek a revocation of the DSB authorization based on a new case under Article 22.8, how could such a proceeding result in a Panel finding that the sanctions are illegal (implying according to the United States and Canada that the DSB authorization would end) if at the same time the Panel accepts the US' and Canada's theory that due to the DSB authorization the sanctions are per se WTO consistent?

13. Proceedings under Article 22.8 of the DSU would, as Canada argues these proceedings should, include as an initial issue the confirmation of the compliance of the underlying measure claimed to have been removed, prior to any finding on the ongoing authorization of the suspension of concessions. If a panel confirms the actual compliance of the measure taken to comply, it would make recommendations that the DSB authorization should be terminated and, further, make recommendations that Canada remove its suspension of concessions. See Canada's answer to question 55 from the Panel.

Q13. The United States and Canada accept that the purpose of suspension of concessions is to rebalance the rights and obligations of WTO Members and/or to induce compliance. Therefore, would the United States and Canada agree that the purpose of the current continuation of the suspension of concessions is also to rebalance rights and obligations and/or to induce compliance?

14. In the absence of a mutually satisfactory agreement or of multilateral confirmation that the EC's measure now complies with the recommendations and rulings in *EC – Hormones,* and thus has been "removed" within the meaning of DSU Article 22.8, the suspension of concessions continues to serve the purpose(s) for which the authorization to suspend concessions was originally granted by the DSB to Canada.

Q14. In its First Written Submission, Canada states that the European Communities is still today under an ongoing obligation to comply despite its implementing measure (para. 40). Does the United States agree? If the European Communities are still under an obligation to comply is it correct to assume that the United States and Canada consider the EC's compliance measure as WTO-inconsistent?

[1] *Brazil – Export Financing Programme for Aircraft: Second Recourse by Canada to Article 21.5 of the DSU*, Report of the Panel, WT/DS46/RW2, adopted August 23, 2001, at para. 6.1.

15. The fact that the EC has adopted a measure that it alleges complies with the recommendations and rulings of the DSB in the *EC – Hormones* dispute is not, in and of itself, determinative of the actual compliance of that measure. If the EC wishes to have Canada's DSB authorization terminated, it must do more than simply adopt a new measure and then assert compliance. In the absence of a mutually satisfactory solution, the EC must obtain multilateral confirmation that its measure complies with the recommendations and rulings of the DSB in *EC – Hormones*.

Q15. How does such a conclusion affect the US' and Canada's allegation that they have not yet made a "determination" as to the WTO-inconsistency of the EC's compliance measure?

16. See Canada's answer to question 57 from the Panel. See also Canada's answers to questions 43, 44 and 48 from the Panel.

Q16. Do Canada and the United States consider that it is at all possible to make a "determination" in the present situation given that they are acting under a DSB authorization? If you do, could you give an example of what would constitute a "determination" in your view?

17. Canada's continued reliance on the DSB authorization for its suspension of concessions to the EC is not a "determination" regarding the EC's new measure within the meaning of Article 23.2(a) of the DSU. See Canada's answer to question 57 from the Panel. See also Canada's answers to questions 43, 44 and 48 from the Panel.

Q17. What is a reasonable timeframe for developing a view on the WTO-consistency of the EC's compliance measure in the present case in the light of the continued application of sanctions against the European Communities?

18. In the absence of a mutually satisfactory solution, it is in the discretion of the EC, if it wishes to have the DSB's authorization to suspend concessions terminated, to obtain multilateral confirmation of the compliance of its new measure with the recommendations and rulings of the DSB.

Q18. In its First Written Submission Canada refers to an "[abuse of] its right to implement" in case of a scam measure (para. 45) Is it Canada's view that the EC's compliance act is a "scam measure"? What is the US' view?

19. Canada has not argued that the EC measure is a "scam measure". In fact, the issue is not whether the EC measure is a "scam measure"; the issue is whether the EC measure complies with the recommendations and rulings in *EC – Hormones*.

Q19. What is the textual basis in the WTO Agreement for a reversal of the burden of proof in a "post-implementation" scenario (Canada's First Written Submission, paras. 56 to 58), and how does this theory of the reversal of the burden of proof fit with the WTO jurisprudence? Does the United States agree with Canada's theory?

20. Paragraphs 56 to 58 of Canada's First Written Submission do not present a theory of the reversal of the burden of proof. In those paragraphs, Canada argues that the EC is not entitled to rely on a presumption of compliance such that it has automatically satisfied one of the conditions of Article 22.8 of the DSU. As a result of the specific authorization of Canada's suspension of concessions, and in the light of the EC's obligation to comply with the recommendations and rulings in *EC – Hormones*, the EC now bears the burden of demonstrating that it has done so. See Canada's answer to question 61 from the Panel.

Q20. During the Oral hearing the United States submitted that the EC's approach in the FSC-case was "appropriate". Why does the United States believe that the same approach is not

"appropriate" in the present case where the United States is continuing sanctions despite an EC's compliance measure?

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