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1 ARTICLE 5

1.1 Text of Article 5

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

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

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

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

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

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

(footnote original)[3] For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

> 8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.[1]

1.2 General

1.2.1 Standard of review

1. With regard to the role of panels in reviewing whether an SPS measure is based on a risk assessment, the Panel in *EC – Hormones* stated:

> "[I]t is for the European Communities to submit evidence before the Panel that its measures are based on a risk assessment; it is not for the Panel itself to conduct its own risk assessment on the basis of scientific evidence gathered by the Panel or submitted by the parties during the Panel proceedings."[2]

2. The Panel in *Australia – Salmon* made a similar statement, holding that it did not attempt to conduct its own risk assessment, but merely examined and evaluated evidence:

> "[W]e stress that in examining this case we did not attempt (nor are we, in our view, allowed) to conduct our own risk assessment or to impose any scientific opinion on Australia. We only examined and evaluated the evidence – including the information we received from the experts advising the Panel – and arguments put before us in light of the relevant WTO provisions and, following the rules on burden of proof set out above, based our findings on this evidence and these arguments."[3]

3. The Appellate Body in *US/Canada – Continued Suspension* determined that a panel reviewing the consistency of an SPS measure with Article 5.1 must determine whether that SPS measure is based on a risk assessment. It is the WTO Member's task to perform the risk assessment. The Panel's task is to review the risk assessment. Where a panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own scientific judgment for that of the risk assessor and, consequently would exceed its functions under Article 11 of the DSU. Therefore, the review power of the Panel is not to determine whether the risk assessment undertaken by a WTO Member is correct but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.[4] The Appellate Body then set out four key indicators that must be taken into account by a panel when reviewing a Member's risk assessment:

(a) Whether the views upon which an SPS measure is based are from qualified and respected sources;

(b) Whether the reasoning articulated on the basis of scientific evidence is objective and coherent;

(c) Whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon; and

(d) Whether the results of the risk's assessment sufficiently warrant the SPS measure at issue.[5]

4. In *US/Canada – Continued Suspension*, the Appellate Body found that the Panel failed to apply the proper standard of review. The Appellate Body stated:

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[1] See also paras. 4 and 5 of Annex 1A.
[2] Panel Reports, *EC – Hormones (Canada)*, para. 8.104; and *EC – Hormones (US)*, para. 8.101.
[3] Panel Report, *Australia – Salmon*, para. 8.41.
[4] Appellate Body Reports, *US/Canada – Continued Suspension*, para 590.
[5] Appellate Body Reports, *US/Canada – Continued Suspension*, para 591.

> "We have found that the Panel did not apply the proper standard of review. This is a legal error and does not fall within the authority of the Panel as the trier of facts. Moreover, we have found instances in which the Panel exceeded its authority in the assessment of the testimony of the scientific experts. By merely reproducing testimony of some experts that would appear to be favourable to the European Communities' position, without addressing its significance, the Panel effectively disregarded evidence that was potentially relevant for the European Communities' case. This cannot be reconciled with the Panel's duty to make an 'objective assessment of the facts of the case' pursuant to Article 11 of the DSU.
>
> For these reasons, we find that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 of the DSU, in determining whether the European Communities' risk assessment satisfied the requirements of Article 5.1 and Annex A of the *SPS Agreement*."[6]

5. The Appellate Body in *Australia – Apples* reiterated the four indicators for evaluating a Member's risk assessment duties of a panel discussed in *US/Canada – Continued Suspension*.[7] The Appellate Body noted that the applicable standard of review, set out in Article 11 of the DSU, requires that a panel reviewing a risk assessment under Article 5.1 of the SPS Agreement neither undertake a *de novo* review, nor give total deference to the risk assessment it reviews.[8]

6. The Appellate Body in *Australia – Apples* then grouped the four indicators that it identified in *US/Canada – Continued Suspension* into two broad aspects of a panel's review of a risk assessment under Article 5.1: (i) a determination that the scientific basis of the risk assessment comes from a respected and qualified source and can accordingly be considered "legitimate science" according to the standards of the relevant scientific community; and (ii) a determination that the reasoning of the risk assessor is objective and coherent and that, therefore, its conclusions find sufficient support in the underlying scientific basis.[9] Further, the Appellate Body established a hierarchy in these duties by stating that "a panel should first determine whether the scientific basis relied upon by the risk assessor is 'legitimate' before reviewing whether the reasoning and the conclusions of the risk assessor that rely upon such a scientific basis are objective and coherent".[10]

7. The Appellate Body in *Australia – Apples* stated that a panel has some flexibility in determining how many flaws are enough to justify a determination that a Member has not complied with Article 5.1. In particular, the Appellate Body stated:

> "[A]s we have explained above, we do not consider that a panel is required to establish whether each fault it finds with a risk assessment is, in itself, serious enough to undermine the entire risk assessment. A comprehensive analysis of all the steps and factors reviewed may be sufficient to determine whether various flaws are, when taken together, serious enough to render a risk assessment one that does not constitute a proper risk assessment within the meaning of Article 5.1 of the *SPS Agreement*." [11]

8. The Appellate Body in *Australia – Apples* also noted that whether a panel reviews the risk assessment as a whole or whether it bases its overall conclusions on the analyses of the individual steps and factors reviewed will depend on the type and structure of risk assessment reviewed and how the complainant presents and develops its claims.[12]

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[6] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 615-616.
[7] Appellate Body Report, *Australia – Apples*, paras. 213-214.
[8] Appellate Body Report, *Australia – Apples*, paras. 211-212.
[9] Appellate Body Report, *Australia – Apples*, para. 220.
[10] Appellate Body Report, *Australia – Apples*, para. 220.
[11] Appellate Body Report, *Australia – Apples*, para. 258.
[12] Appellate Body, *Australia – Apples*, para. 258.

1.2.2 Risk assessment versus risk management

9. The Appellate Body in *EC – Hormones* rejected the distinction between "risk assessment" and "risk management" used by the Panel in its interpretation and application of Articles 5.1 and 5.2 of the SPS Agreement:

> "The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a 'scientific' examination of data and factual studies; it is not, in the view of the Panel, a 'policy' exercise involving social value judgments made by political bodies. The Panel describes the latter as 'non-scientific' and as pertaining to 'risk management' rather than to 'risk assessment'. We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of 'risk assessment' only and that the term 'risk management' is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used."[13]

10. In *US/Canada – Continued Suspension*, the Appellate Body held that the Panel misinterpreted the Appellate Body's ruling in *EC – Hormones* and therefore misconstrued the distinction between risk assessment and risk management. The Appellate Body thus rejected the Panel's interpretation of risk assessment on the ground that such interpretation was too rigid and would lead to legal error:

> "We find it difficult to reconcile the Panel's understanding of *EC – Hormones* with what the Appellate Body held in that Report. As we noted above, in that case, the Appellate Body rejected the rigid distinction drawn by the Panel between 'risk assessment' and 'risk management', explaining:
>
> > We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of 'risk assessment' only and that the term 'risk management' is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis.[14]
>
> Subsequently in the same Report, the Appellate Body reiterated its view that 'the concept of 'risk management' is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more *restrictive* interpretation of 'risk assessment' than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*'. Therefore, in our view, the Panel's interpretation of 'risk assessment' resulted in the same 'restrictive notion of risk assessment' that the Appellate Body found to be erroneous in *EC – Hormones*. The Panel sought in this case to rewrite the Appellate Body Report in *EC – Hormones* and to re-establish the rigid distinction between 'risk assessment' and 'risk management' that the Appellate Body had rejected in that case."[15]

1.2.3 Relationship of Article 5 generally with other provisions of the SPS Agreement

1.2.3.1 Articles 2 and 3

11. For a discussion on the relationship between Articles 2, 3 and 5, see the Sections on Articles 2 and 3.

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[13] Appellate Body Report, *EC – Hormones*, para. 181.
[14] (*footnote original*) Appellate Body Report, *EC – Hormones*, para. 181.
[15] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 541-542.

1.3 Article 5.1

1.3.1 General

12. The Appellate Body in *Japan – Apples* held that Article 5.1 sets out a key discipline under Article 5, namely that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment … of the risks to human, animal or plant life or health". This discipline informs the other provisions of Article 5, including Article 5.7.[16]

13. The Panel in *US – Poultry (China)* observed that an analysis under Article 5.1 consists of answering two fundamental questions: "[F]irst, was a risk assessment, appropriate to the circumstances, taking into account risk assessment techniques developed by the relevant international organizations and the elements listed in Article 5.2, conducted? Second, is the SPS measure based on that risk assessment?"[17]

1.3.2 "risk assessment"

1.3.2.1 General

14. The Appellate Body in *EC – Hormones*, when considering altogether the object and purpose of requirements under Articles 2.2, 3.3 and 5.1, held that the provisions of Article 5.1 intervene as a "countervailing factor" to those under Article 3.3. They serve – along with the requirement of "sufficient scientific evidence" under Article 2.2 – the purpose of ensuring the balance between promotion of international trade and protection of human life and health within the SPS Agreement:

> "Consideration of the object and purpose of Article 3 and of the *SPS Agreement* as a whole reinforces our belief that compliance with Article 5.1 was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection. In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both 'necessary to protect' human life or health and 'based on scientific principles', and without requiring them to change their appropriate level of protection. The requirements of a risk assessment under Article 5.1, as well as of 'sufficient scientific evidence' under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings."[18]

15. In *Australia – Salmon*, the Appellate Body held that the presence of unknown and uncertain elements should not affect compliance with the requirements of Articles 5.1, 5.2 and 5.3:

> "[T]he existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3, read together with paragraph 4 of Annex A, for a risk assessment. We recall that Article 5.2 requires that 'in the assessment of risk, Members shall take into account available scientific evidence'. We further recall that Article 2, entitled 'Basic Rights and Obligations', requires in paragraph 2 that 'Members shall ensure that any sanitary … measure … is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."[19]

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[16] Appellate Body Report, *Japan – Apples*, para. 179.
[17] Panel Report, *US – Poultry (China)*, para. 7.173.
[18] Appellate Body Report, *EC – Hormones*, para. 177.
[19] Appellate Body Report, *Australia – Salmon*, para. 130.

1.3.2.2 Definition of a risk assessment

16. In *EC – Hormones*, the Panel defined a risk assessment as "a scientific process aimed at establishing the scientific basis for the sanitary measure a Member intends to take". The Appellate Body expanded the scope of this definition by clarifying that not all factors to be considered as part of a risk assessment are capable of being quantitatively analysed:

> "[T]he listing in Article 5.2 begins with 'available scientific evidence'; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is 'a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take'. To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable. However, to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some of the kinds of factors listed in Article 5.2 such as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[20]

17. Regarding the definition of risk assessment within the meaning of Annex A paragraph 4, see the Section on Annex A(4).

1.3.2.3 Types of risk assessment

18. In *Australia – Salmon*, the Appellate Body acknowledged that paragraph 4 of Annex A defines two types of risk assessment, noting that the type of risk assessment required in that case was the type defined in the first part of paragraph 4 of Annex A.[21] The Appellate Body went further to link the type of risk assessment required in the case to the type of the SPS measure in place, as described in paragraph 1 of Annex A.[22]

19. In *EC- Approval and Marketing of Biotech Products*, the Panel noted that the Appellate Body in *Australia – Salmon* merely observed that the first clause and second clause of paragraph 4 are substantially different but provided little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Panel then stated:

> "We note that, unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires 'only' the evaluation of the 'potential' for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the 'likelihood' of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences. We note that the dictionary defines the term 'potential' as 'the possibility of something happening … in the future'."[23]

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[20] Appellate Body Report, *EC – Hormones*, para. 187.
[21] Appellate Body Report, *Australia – Salmon*, para. 120.
[22] Appellate Body Report, *Australia –Salmon*, fn 67.
[23] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3048.

1.3.2.4 Elements of the risk assessment process

20. In *Australia – Salmon*, the Appellate Body identified three elements of the risk assessment process prescribed in the first clause of paragraph 4 of Annex A:

> "On the basis of this definition, we consider that, in this case, a risk assessment within the meaning of Article 5.1 must:
>
> (1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
>
> (2) *evaluate the likelihood* of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
>
> (3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*."[24]

21. The Appellate Body in *EC – Hormones* confirmed the two elements of the risk assessment process prescribed in the second clause of paragraph 4 of Annex A that were identified by the Panel but cautioned against the use of the word "probability" in the place of "potential":

> "Paragraph 4 of Annex A of the *SPS Agreement* sets out the treaty definition of risk assessment: This definition, to the extent pertinent to the present appeal, speaks of:
>
> > … the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. (underlining added)
>
> Interpreting the above definition, the Panel elaborates risk assessment as a two-step process that 'should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat …, and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects'.
>
> The European Communities appeals from the above interpretation as involving an erroneous notion of risk and risk assessment. Although the utility of a two-step analysis may be debated, it does not appear to us to be substantially wrong. What needs to be pointed out at this stage is that the Panel's use of "probability" as an alternative term for "potential" creates a significant concern. The ordinary meaning of 'potential' relates to 'possibility' and is different from the ordinary meaning of 'probability'. 'Probability' implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk."[25]

1.3.2.5 Format of the risk assessment

22. The Panel in *Australia – Salmon* held that a risk assessment need not be an official government report:

> "We note that these reports do not form part of Australia's formal risk assessment nor represent Australia's official government policy. However, to the extent they constitute relevant available scientific information which was submitted to the Panel, we consider it our task to take this evidence into account. We consider that, for

[24] Appellate Body Report, *Australia – Salmon*, para. 121. In *Japan – Agricultural Products II*, the Appellate Body endorsed the aforesaid three-pronged test. See Appellate Body Report, *Japan – Agricultural Products II*, para. 112. This test was also used in Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, para. 7.41.

[25] Appellate Body Report, *EC – Hormones*, paras. 182-184.

> purposes of our examination, the scientific and technical content of these reports and studies is relevant, not their administrative status (i.e., whether they are official government reports or not).
>
> … Whether or not this evidence is part of official Australian government policy does not, in our mind, change the scientific weight to be given to it".[26]

23. The Panel in *Japan – Apples (Article 21.5 – US)* found that the most important consideration is not the form of the risk assessment, but rather the substance and whether the scientific evidence evaluated supports the conclusions of the risk assessment:

> "The consideration of whether there exists a risk assessment appropriate to the circumstances is not limited to a procedural review as to whether the risk assessment followed a certain form, *in casu*, the IPPC Standards. More importantly, the substance of the [risk assessment], that is the scientific evidence which is being evaluated, must support the conclusions of the [risk assessment]."[27]

1.3.2.6 Whether a Member should carry out its own risk assessment

24. In *EC – Hormones*, the Appellate Body addressed the question of whether a Member should carry out its own risk assessment for a SPS measure:

> "Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment … The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization."[28]

1.3.2.7 Relevance of the timing of publication of the risk assessment

25. With respect to the risk assessment requirement for SPS measures enacted before the entry into force of the SPS Agreement, the Panel in *EC – Hormones* noted:

> "Article 5.1 provides in general terms, without any limitation in time, that 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances of the risks ...' It does not prevent that with respect to a sanitary measure enacted *before* the entry into force of the *SPS Agreement*, the risk assessment is carried out or invoked *after* the entry into force of that Agreement (and thus *after* the enactment of the sanitary measure in question). However, the fact that a sanitary measure may be enacted *before* the entry into force of the *SPS Agreement* does not mean that, once the *SPS Agreement* entered into force, there is no obligation for the Member in question to base that measure on a risk assessment."[29]

26. The Panel in *Australia – Salmon*, while addressing Canada's complaint that Australia's measure was maintained without any form of risk assessment, stated:

> "Article 5.1 does not qualify – either in terms of application in time or product coverage – the substantive obligation imposed on all WTO Members to base their sanitary measures on a risk assessment.
>
> …
>
> We note Australia's statement that its policy of allowing imports of salmon products heat-treated in accordance with the 1988 Conditions will be reviewed and that for these purposes an import risk analysis is scheduled. It is possible that this risk

[26] Panel Report, *Australia – Salmon*, paras. 8.136-8.137.
[27] Panel Report, *Japan – Apples (Article 21.5 – US)*, para. 8.129
[28] Appellate Body Report, *EC – Hormones*, para. 190. See also Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3024.
[29] Panel Reports, *EC – Hormones (Canada)*, para. 8.102; and *EC – Hormones (US)*, para. 8.99.

> analysis provides a rational basis for the measure at issue. However, as of today and on the basis of the risk assessment before us, we do not detect such basis."[30]

27. In *Australia – Salmon (Article 21.5 – Canada)*, Canada claimed that the new Australian measures could not be said to be based on a risk assessment, because the 1999 Import Risk Analysis (IRA) (the Australian risk assessment for the amended measure) was only published in its final form on 12 November 1999, i.e. after the publication of the new measures which had occurred on 19 July 1999. The Panel rejected this argument as follows:

> "We note that the final form of the 1999 IRA, though only edited and published in book form on 12 November 1999, is still dated July 1999 and that … the amendments made in the final 1999 IRA 'do not alter the substance or the conclusions of the report as announced on 19 July'.
>
> On these grounds, we find that the fact that the 1999 IRA was only published in final form subsequent to the date the new sanitary measures were taken, does not, in this case, preclude the measures from being *based on* the 1999 IRA. All substantive elements of the risk assessment we looked at earlier were already included in the draft 1999 IRA of July 1999, i.e. *before* the new measures were taken."[31]

28. The Panel in *EC – Approval and Marketing of Biotech Products* found that SPS measures must be "based on" a risk assessment throughout the duration of their application. The Panel found that both a risk assessment carried out before and one carried out after a measure was adopted could satisfy the requirement that the measure be "based on" a risk assessment:

> "Regarding the requirement that SPS measures be 'based on' a risk assessment, it is clear to us that SPS measures must be 'based on', or 'sufficiently warranted' or 'reasonably supported' by, a risk assessment throughout the period of time for which these measures are maintained. In our view, both a risk assessment carried out before the adoption of a particular safeguard measure and a risk assessment carried out after its adoption could 'sufficiently warrant', or 'reasonably support', the maintenance of that measure."[32]

1.3.2.8 Studies not sufficiently specific to the case at hand

29. The Appellate Body in *EC – Hormones* also rejected certain studies submitted by the European Communities as risk assessment for the purpose of Article 5.1, holding that these studies were general and "not sufficiently specific to the case at hand":

> "[T]he studies submitted by the respondent] constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes -- as is required by paragraph 4 of Annex A of the *SPS Agreement*. Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand."[33]

30. In *Japan – Apples*, the Appellate Body upheld the Panel's finding that Japan's risk analysis did not satisfy the definition of "risk assessment" in Annex 4(A) because it failed to evaluate the likelihood of entry, establishment or spread of fire blight specifically through apple fruit:

> "Under the *SPS Agreement*, the obligation to conduct an assessment of 'risk' is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of a phytosanitary measure. The Appellate Body found the risk assessment at issue in *EC – Hormones* not to be "sufficiently specific" even though the scientific articles cited by the importing Member had evaluated the 'carcinogenic potential of

[30] Panel Report, *Australia – Salmon*, paras. 8.56 and 8.100.
[31] Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.76-7.77.
[32] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3030.
[33] Appellate Body Report, *EC – Hormones*, para. 200.

> entire *categories* of hormones, or of the hormones at issue *in general*.' In order to constitute a 'risk assessment' as defined in the *SPS Agreement*, the Appellate Body concluded, the risk assessment should have reviewed the carcinogenic potential, not of the relevant hormones in general, but of "residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes". Therefore, when discussing the risk to be specified in the risk assessment in *EC – Hormones*, the Appellate Body referred in general to the harm concerned (cancer or genetic damage) *as well as* to the precise agent that may possibly cause the harm (that is, the specific hormones when used in a specific manner and for specific purposes).
>
> In this case, the Panel found that the conclusion of the 1999 PRA with respect to fire blight was 'based on an overall assessment of possible modes of contamination, where apple fruit is only one of the possible hosts/vectors considered.' The Panel further found, on the basis of the scientific evidence, that the risk of entry, establishment or spread of the disease varies significantly depending on the vector, or specific host plant, being evaluated. Given that the measure at issue relates to the risk of transmission of fire blight through apple fruit, in an evaluation of whether the risk assessment is "sufficiently specific to the case at hand", the nature of the risk addressed by the measure at issue is a factor to be taken into account. In the light of these considerations, we are of the view that the Panel properly determined that the 1999 PRA 'evaluat[ion of] the risks associated with all possible hosts taken together' was not sufficiently specific to qualify as a 'risk assessment' under the *SPS Agreement* for the evaluation of the likelihood of entry, establishment or spread of fire blight in Japan through apple fruit."[34]

1.3.2.9 Scope of the risk assessment

1.3.2.9.1 Assessment of each individual substance

31. In *EC – Hormones*, the Appellate Body upheld the Panels' finding that "there was no risk assessment with regard to MGA"[35], one of the six growth hormones at issue, stating that "[i]n other words, there was an almost complete absence of evidence on MGA in the Panel proceedings."[36] On this point, the Panels had explained that "one of the basic principles of a risk assessment appears to be that it needs to be carried out for each individual substance".[37]

1.3.2.9.2 Different product categories

32. The Panel in *Australia – Salmon* held that studies on one particular product category could be relevant for a risk assessment in respect of another product category:

> "We do, however, agree with Australia that some of the evidence, assessments and conclusions contained in the 1996 Final Report might be relevant for the risk assessment to be carried out (or relied upon) for the other categories of salmon products and that, therefore, a completely new risk assessment for these other categories of salmon products might not be necessary."[38]

1.3.2.9.3 One risk assessment for different SPS measures

33. In *EC – Approval and Marketing of Biotech Products*, the Panel agreed with the European Communities argument that one particular risk assessment could serve as a basis for different SPS measures:

> "[T]he European Communities contends that the same risk assessment can 'sufficiently warrant', or 'reasonably support', more than one type of SPS measure, or,

[34] Appellate Body Report, *Japan – Apples*, paras. 202-203.
[35] Appellate Body Report, *EC – Hormones*, para. 201.
[36] Appellate Body Report, *EC – Hormones*, para. 201.
[37] Panel Reports, *EC – Hormones (US)*, para. 8.257; and *EC – Hormones (Canada)*, para. 8.258.
[38] Panel Report, *Australia – Salmon*, para. 8.58.

> as the European Communities puts it, one and the same risk assessment may justify 'divergent responses by equally responsible and representative governments'.
>
> As a general matter, the Panel agrees with the European Communities that a particular risk assessment might conceivably serve as a basis for different types of SPS measures. Indeed, there may be a range of measures that may be rationally related to a given risk assessment, at least in cases where a risk is determined to exist."[39]

1.3.2.10 No threshold level of risk required

34. In *EC – Hormones*, the Appellate Body addressed the European Communities' appeal that the Panel was "in effect requiring a Member carrying out a risk assessment to quantify the potential for adverse effects on human health".[40] The Appellate Body elaborated on the term "scientifically identified risk" that the Panel had employed and the notion of "theoretical uncertainty" in the context of Article 5.1. The Appellate Body indicated that Article 5.1 does not address theoretical uncertainty since science can never provide absolute certainty that a given substance will not ever have adverse health effects:

> "It is not clear in what sense the Panel uses the term 'scientifically identified risk'. The Panel also frequently uses the term 'identifiable risk', and does not define this term either. The Panel might arguably have used the terms 'scientifically identified risk' and 'identifiable risk' simply to refer to an ascertainable risk: if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists? In one part of its Reports, the Panel opposes a requirement of an 'identifiable risk' to the uncertainty that theoretically always remains since science can never provide absolute certainty that a given substance will not ever have adverse health effects. We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed. In another part of its Reports, however, the Panel appeared to be using the term 'scientifically identified risk' to prescribe implicitly that a certain magnitude or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with Article 5.1. To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the SPS Agreement. A Panel is authorized only to determine whether a given SPS measure is 'based on' a risk assessment. As will be elaborated below, this means that a Panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment."[41]

35. The Appellate Body in *US/Canada – Continued Suspension* modified its position on the "minimum magnitude of risk" element discussed in paragraph 34 above. In estimating the magnitude of risk in risk assessment considered that since risk assessment consists in appraising the potential of occurrence of adverse effect, potentiality represents a foundational requirement of the latter concept. That said, the assessment of risk need not be expressed in numerical terms:

> "Although the definition of a risk assessment does not require WTO Members to establish a minimum magnitude of risk, it is nevertheless difficult to understand the concept of risk as being devoid of any indication of potentiality. A risk assessment is intended to identify adverse effects and evaluate the possibility that such adverse effects might arise. This distinguishes an ascertainable risk from theoretical uncertainty. However, the assessment of risk need not be expressed in numerical terms or as a minimum quantification of the level of risk. We are also mindful that the risk assessment at issue in this case concerns the *potential* for adverse effects under

[39] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.3063-7.3064.
[40] Appellate Body Report, *EC – Hormones*, para. 185.
[41] Appellate Body Report, *EC – Hormones*, para. 186.

> the second sentence of paragraph 4 of Annex A and not an evaluation of likelihood under the first sentence of paragraph 4.[42]"[43]

36. In *Japan – Apples*, the Appellate Body agreed with the Panel that "scientific prudence" displayed by the experts should not be equated to "theoretical uncertainty" that is inherent in the scientific method:

> "The comments of the Panel in response to the argument of the United States on 'theoretical risk' should be viewed in their appropriate context. … We understand that the 'scientific prudence' displayed by the experts in this case related to risks that might arise from radical changes in Japan's current system of phytosanitary controls, taking into account Japan's island environment and climate. The scientific prudence displayed by the experts did not relate to the 'theoretical uncertainty' that is inherent in the scientific method and which stems from the intrinsic limits of experiments, methodologies, or instruments deployed by scientists to explain a given phenomenon. Therefore, we agree with the Panel that the scientific prudence displayed by the experts should not be 'completely assimilated' to the 'theoretical uncertainty' that the Appellate Body discussed in *EC – Hormones* as being beyond the purview of risks to be addressed by measures subject to the *SPS Agreement*."[44]

1.3.2.11 The concept of "zero risk"

37. The Panel in *Australia – Salmon* held that "a risk assessment, on which to base an import prohibition in accordance with Article 5.1, cannot be premised on the concept of 'zero risk'. Otherwise, all import prohibitions would be based on a risk assessment since there is a risk (i.e., a possibility of an adverse event occurring), however remote, associated with most (if not all) imports".[45] On appeal, the Appellate Body emphasized the distinction between risk assessment under Article 5.1 and the determination, by a Member, of its own appropriate level of protection:

> "[I]t is important to distinguish – perhaps more carefully than the Panel did – between the evaluation of 'risk' in a risk assessment and the determination of the appropriate level of protection. As stated in our Report in *European Communities – Hormones*, the 'risk' evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is 'not the kind of risk which, under Article 5.1, is to be assessed.' This does not mean, however, that a Member cannot determine its own appropriate level of protection to be 'zero risk'."[46]

1.3.2.12 Completing the Panel's analysis of a risk assessment

38. The Panel in *Australia – Salmon* found that the Australian heat treatment requirement was not "based on" a risk assessment within the meaning of Article 5.1, because the Final Report (the risk assessment) made "no substantive assessment of the risk or the risk reduction related to the heat requirements in effect imposed by the measure at issue" … but stated that there is insufficient data on whether or not heat treatment inactivates the disease agents in dispute".[47] The Appellate Body, reversed this finding[48] and completed the analysis by examining whether the import prohibition on fresh, chilled and frozen salmon was based on a risk assessment. It found that the 1996 Final Report did not fulfil the requirements needed to constitute a "risk assessment" within the meaning of Article 5.1:[49]

> "With regard to the second requirement for a risk assessment of the type applicable in this case ... [w]e believe ... that on the basis of the facts found by the Panel, it could,

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[42] (*footnote original*) The Appellate Body found in *EC – Hormones* that the term "potential" in the second sentence of paragraph 4 of Annex A refers to the "possibility" of occurrence of adverse effects, which implies a lower degree of potentiality than "probability". (Appellate Body Report, *EC – Hormones*, para. 184).
[43] Appellate Body Reports, *US/Canada - Continued Suspension*, para 569.
[44] Appellate Body Report, *Japan – Apples*, para. 241.
[45] Panel Report, *Australia – Salmon*, para. 8.81.
[46] Appellate Body Report, *Australia – Salmon*, para. 125.
[47] Panel Report, *Australia – Salmon*, para. 8.98.
[48] Appellate Body Report, *Australia – Salmon*, para. 104.
[49] Appellate Body Report, *Australia – Salmon*, para. 136.

> and should, have come to the conclusion that the 1996 Final Report does not contain the 'evaluation of the likelihood of entry, establishment or spread' of the diseases of concern 'and of the associated potential biological and economic consequences' as required by paragraph 4 of Annex A of the *SPS Agreement*. As we have already emphasized, *some* evaluation of the likelihood is not enough.
>
> … We turn now to the third requirement of a risk assessment … We agree with the Panel that the measures which might be applied are those which reduce the risks of concern, and are referred to in the 1996 Final Report as risk reduction factors … On the basis of its factual findings, the Panel should have come to the conclusion that the 1996 Final Report does not fulfil the third requirement for the type of risk assessment applicable in this case, i.e., it does not contain the required evaluation of the likelihood of entry, establishment or spread of the diseases of concern according to the SPS measures which might be applied. We recall that, contrary to the Panel, we consider that *some* evaluation of the likelihood is not enough.
>
> We conclude, on the basis of the factual findings made by the Panel and the requirements for a risk assessment as set forth above, that the 1996 Final Report meets neither the second nor the third requirement for the type of risk assessment applicable in this case, and, therefore, that the 1996 Final Report is *not* a proper risk assessment within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A."[50]

1.3.3 "based on" an assessment of the risks

1.3.3.1 General

39. In *EC – Hormones*, the Panel had held that the European Communities' measure was in violation of Article 5.1 since "the European Communities did not provide any evidence that the studies … or the scientific conclusions reached therein 'have actually been taken into account by the competent EC institutions either when it enacted those measures (in 1981 and 1988) or at any later point in time'".[51] The Appellate Body characterized this "minimum procedural element" as "some subjectivity … present in certain individuals" and disagreed with this standard:

> "We are bound to note that, as the Panel itself acknowledges, no textual basis exists in Article 5 of the *SPS Agreement* for such a 'minimum procedural requirement'. The term 'based on', when applied as a 'minimum procedural requirement' by the Panel, may be seen to refer to a human action, such as particular human individuals 'taking into account' a document described as a risk assessment. Thus, 'take into account' is apparently used by the Panel to refer to some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals. We believe that 'based on' is appropriately taken to refer to a certain *objective relationship* between two elements, that is to say, to an *objective situation* that persists and is observable between an SPS measure and a risk assessment. Such a reference is certainly embraced in the ordinary meaning of the words 'based on' and, when considered in context and in the light of the object and purpose of Article 5.1 of the *SPS Agreement*, may be seen to be more appropriate than 'taking into account'. We do not share the Panel's interpretative construction and believe it is unnecessary and an error of law as well.
>
> Article 5.1 … only requires that the SPS measures be 'based on an assessment, as appropriate for the circumstances …'. The 'minimum procedural requirement' constructed by the Panel, could well lead to the elimination or disregard of available scientific evidence that rationally supports the SPS measure being examined. This risk of exclusion of available scientific evidence may be particularly significant for the bulk of SPS measures which were put in place before the effective date of the *WTO Agreement* and that have been simply maintained thereafter."[52]

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[50] Appellate Body Report, *Australia – Salmon*, paras. 127-135.
[51] Appellate Body Report, *EC – Hormones*, para. 188.
[52] Appellate Body Report, *EC – Hormones*, paras. 189-190.

40. The Panel in *EC – Approval and Marketing of Biotech Products* contemplated the meaning of words "based on" and "conform to" used in the context of Articles 3.1 and 5.1 of the SPS Agreement. The Panel made it clear that this expression holds a different meaning in Article 5.1 given the differences between situations under Article 3.1 and Article 5.1 and also due to the compelling requirement, under Article 5.1, to base SPS measures on a risk assessment:

> "We note the European Communities' argument that 'based on' does not mean 'conform to'. To the extent the European Communities means to argue that Members are free to adopt any kind of SPS measure provided there exists a risk assessment for the product subject to the SPS measure, we disagree. It is correct that the Appellate Body in *EC – Hormones* has said that the expression 'based on' as it appears in Article 3.1 of the *SPS Agreement* does not mean 'conform to'. However, the Appellate Body also said in *EC – Hormones* that in the specific context of Article 5.1, the expression 'based on' should be interpreted to mean 'sufficiently warranted by', 'reasonably supported by' or 'rationally related to'. … At any rate, if we were to allow Austria effectively to ignore favourable risk assessments, we would turn these assessments into documents without any substantive importance and the conduct of these assessments into a mere formality. Yet, the requirement in Article 5.1 to 'base' an SPS measure on a risk assessment is plainly a substantive requirement, and not simply a formal requirement to accompany an SPS measure by a risk assessment."[53]

1.3.3.2 SPS measure based on a divergent opinion contained in the risk assessment

41. In *EC – Approval and Marketing of Biotech Products*, the Panel addressed the question of whether an SPS measure could be considered "based on" a risk assessment if it reflects a divergent opinion expressed in the risk assessment. The Panel, following the Appellate Body's ruling in *EC – Hormones*, concluded that in certain circumstances an SPS measure that reflects a divergent opinion from the risk assessment could still be considered to be "based on" that risk assessment:

> "Where a given risk assessment sets out a divergent opinion and this opinion comes from qualified and respected sources, it can be reasonably said that an SPS measure which reflects the divergent opinion is 'based on' the risk assessment in question inasmuch as the divergent opinion is expressed in that risk assessment. In contrast, where a given risk assessment sets out a single opinion, it cannot be reasonably said that an SPS measure is 'based on' *that* risk assessment if the relevant SPS measure reflects a divergent opinion which is not expressed in the risk assessment in question."[54]

1.3.3.3 Rational relationship between the SPS measure and the risk assessment

42. The Appellate Body in *EC – Hormones* held that the requirement of Article 5.1 – that an SPS measure be "based on" a risk assessment – was a substantive requirement that "there be a rational relationship between the measure and the risk assessment":

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

[53] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3067.
[54] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3060. See also Appellate Body Report, *EC – Hormones*, paras. 193-194.

> We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. … In most cases, responsible and representative governments tend to base their legislative and administrative measures on 'mainstream' scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety."[55]

1.3.3.4 Scientific uncertainty

43. The Appellate Body in *Australia – Apples* expressed the view that, if a risk assessor reaches certain conclusions based on its expert judgment, having determined that there is a certain degree of scientific uncertainty, this does not preclude a panel from assessing whether those conclusions are objective and coherent and have a sufficient basis in the available scientific evidence.[56]

1.3.3.5 Determination of relationship on "a case-by-case" basis

44. The Appellate Body in *EC – Hormones* considered that determination of the presence or absence of the relationship between the SPS measure and the risk assessment can only be done on a case-by-case basis, upon consideration of all elements relevant to the issue of potential adverse health effects.[57]

45. The Appellate Body in *Australia – Apples* observed that a panel must be able to review whether the conclusions of a risk assessor are based on the scientific evidence and are, accordingly, objective and coherent. According to the Appellate Body, whether or not the requisite rational or objective relationship exists can only be ascertained through the examination of how the scientific evidence is used and relied upon to reach a particular conclusion. In this respect, the Appellate Body noted that the reasoning employed by the risk assessor plays an important role in revealing whether or not such a relationship exists.[58]

1.3.4 "as appropriate to the circumstances"

1.3.4.1 Flexibility

1.3.4.1.1 General

46. When addressing the applicability of the SPS Agreement to measures adopted before the entry into force of the WTO Agreement, the Appellate Body in *EC – Hormones* noted that the phrase "as appropriate to the circumstances" provides for a certain degree of flexibility:

> "We are aware that the applicability, as from 1 January 1995, of the requirement that an SPS measure be based on a risk assessment to the many SPS measures already in existence on that date, may impose burdens on Members. It is pertinent here to note that Article 5.1 stipulates that SPS measures must be based on a risk assessment, *as appropriate to the circumstances*, and this makes clear that the Members have a certain degree of flexibility in meeting the requirements of Article 5.1."[59]

[55] Appellate Body Report, *EC – Hormones*, paras. 193-194.
[56] Appellate Body Report, *Australia – Apples*, paras. 236 and 242.
[57] Appellate Body Report, *EC – Hormones*, para. 194.
[58] Appellate Body Report, *Australia – Apples*, paras. 225 and 227.
[59] Appellate Body Report, *EC – Hormones*, para. 129.

47. The Panel in *Australia – Salmon* held that the phrase "as appropriate to the circumstances" created the possibility "to assess the risk, on a case-by-case basis, in terms of product, origin and destination, including, in particular, country-specific situations":

> "Following Article 5.1, a risk assessment needs to be 'appropriate to the circumstances'. Answering a Panel question in this respect, Canada is of the view that the circumstances thus referred to are the source of the risk (e.g., an animal pathogen or a chemical contaminant) and the subject of the risk (i.e., whether it is to human, animal or plant life or health). For Australia, the phrase 'as appropriate to the circumstances' confers a right and obligation on WTO Members to assess the risk, on a case by case basis, in terms of product, origin and destination, including, in particular, country specific situations. We agree that both interpretations may be covered by the term 'as appropriate to the circumstances'. In our view, also the OIE risk assessment techniques as well as the scientific opinions we gathered, may shed light on what is a risk assessment 'appropriate to the circumstances'."[60]

48. In *US/Canada – Continued Suspension*, the Appellate Body disagreed with the European Communities' interpretation of the Panel's views on the requirement for a risk assessment to be appropriate to the circumstances, under Article 5.1 of the SPS Agreement. The Appellate Body stated:

> "[W]e are not persuaded by the European Communities suggestion that the Panel required testing in humans in order to specifically evaluate the risks associated with the consumption of meat from cattle treated with oestradiol-17β. We do not see this as a necessary implication of the Panel's analysis. There is no indication in the Panel Report to suggest that the evaluation could not proceed on the basis of experimentation in laboratory animals and extrapolating the results to humans, or by other means. Certainly, where a substance may be potentially toxic, requiring a WTO Member to evaluate specifically the risks through actual human consumption of the substance would be unethical and would not be 'appropriate to the circumstances' within the meaning of Article 5.1."[61]

49. The Appellate Body in *US/Canada – Continued Suspension* discussed Members' discretion to adopt or not an SPS measures upon completion of the risk assessment process:

> "Whilst WTO Members have the right to take SPS measures, they are not required to do so. The risk assessment may conclude that there is no ascertainable risk, in which case no SPS measure can be taken. Alternatively, a WTO Member may conclude that an SPS measure is not necessary in the light of the risks determined in the risk assessment and the acceptable level of protection determined by that WTO Member.
>
> ...
>
> [T]here may be situations where the relevant scientific evidence is sufficient to perform a risk assessment, a WTO Member performs such a risk assessment but does not adopt an SPS measure either because the risk assessment did not confirm the risk, or the risk identified did not exceed that Member's chosen level of protection. Also, there may be situations where there is no pertinent scientific information available indicating a risk that such an SPS measure would be unwarranted even on a provisional basis."[62]

1.3.4.1.2 Temporal application of flexibility

50. In *EC – Approval and Marketing of Biotech Products*, the Panel considered that the flexibility provided by the phrase "as appropriate to the circumstances" does not apply where relevant circumstances change over time. In the Panel's view, whenever the relevant circumstances vary, the risk assessment could no longer be appropriate to the circumstances:

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[60] Panel Report, *Australia – Salmon*, para. 8.71.
[61] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 563.
[62] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 563 and 681.

> "We note that the Appellate Body observed that the phrase 'as appropriate to the circumstances' provides Members with 'a certain degree of flexibility in meeting the requirements of Article 5.1'. However, this statement did not relate to a situation such as the one we are considering here where relevant circumstances change over time. We see nothing in the ordinary meaning of the phrase 'as appropriate to the circumstances', or in the aforementioned observation by the Appellate Body, to contradict our view that a change in relevant circumstances could in some cases render a completed risk assessment no longer 'appropriate to the circumstances'.
>
> This approach is also supported by the context of Article 5.1. Article 5.6 provides that 'when establishing or *maintaining* [SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection' (emphasis added). We have previously observed that one of the purposes of a risk assessment is to allow the importing Member to determine the measure to be applied, if any, for achieving its appropriate level of protection. Thus, if a Member could maintain under Article 5.1 a significantly trade-restrictive SPS measure on the basis of a risk assessment which is no longer appropriate to the circumstances (*e.g.*, due to new scientific evidence which affects the continued relevance and validity of the risk assessment in question), and a risk assessment appropriate to the circumstances would establish that essentially no risk in fact exists, then that Member would be 'maintaining' an SPS measure which *ex hypothesi* is more trade-restrictive than required to achieve its appropriate level of protection, contrary to the requirements of Article 5.6. Irrespective of whether the trade-restrictive measure could be challenged under Article 5.6, we consider that it would be improper to interpret Article 5.1 so as to allow the Member to maintain its trade-restrictive measure, as such an interpretation would frustrate an important purpose of a risk assessment, which is 'to serve as a basis for regulatory actions'. The determination of a measure which is not more trade-restrictive than required to achieve a Member's appropriate level of protection is a relevant 'regulatory action'."[63]

1.3.4.2 Does not supersede the duty to base a measure on a risk assessment

51. The Panel in *Australia – Salmon* held that the phrase "as appropriate to the circumstances" did not alleviate the duty to base a measure on a risk assessment:

> "As to the product coverage of Article 5.1, the reference contained in Article 5.1 to base sanitary measures on an assessment 'as appropriate to the circumstances' cannot, in our view, annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute (irrespective of the products that measure may cover) on a risk assessment. We consider that the reference 'as appropriate to the circumstances' relates, rather, to the way in which such risk assessment has to be carried out. Only Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment."[64]

52. The Panel in *EC – Approval and Marketing of Biotech Products* emphasized that flexibility must be granted to parties with respect to their obligation to base their measures on a risk assessment if the locution "as appropriate to the circumstances" is considered but qualified the level of this flexibility:

> "According to the European Communities, the phrase 'as appropriate to the circumstances' makes it clear that Members have a certain degree of flexibility in meeting the requirements of Article 5.1. The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient.
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> We need not determine whether relevant scientific evidence was or is insufficient for Austria, and if so, whether this would be a relevant circumstance. Even if this were

[63] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.3032-7.3033.
[64] Panel Report, *Australia – Salmon*, para. 8.57. See also Appellate Body Reports: *Australia – Salmon*, para. 130; *US/Canada – Continued Suspension*, para. 562 and *Australia – Apples*, paras. 237 and 244.

> the case, the flexibility which the phrase 'as appropriate to the circumstances' may in some situations provide does not relieve Austria from the requirement in Article 5.1 to base its safeguard measure on a risk assessment which meets the definition of Annex A(4).[65] All of the Annex A (4) definition of the term 'risk assessment' which are applicable to Austria's safeguard measure, must, in our view, be met. It is useful to recall in this respect that the Appellate Body in *Australia – Salmon* observed that an evaluation of the likelihood of entry, establishment or spread of a pest could be done both quantitatively and qualitatively. Moreover, in circumstances where there is little available scientific evidence, the phrase 'as appropriate to the circumstances' may provide a measure of flexibility in terms of how (but not whether) the applicable elements of the Annex A(4) definition, including the likelihood evaluation, are satisfied. In the case at hand, we have answered in the negative the question of whether the documents which Austria relied on satisfy the applicable elements of the Annex A(4) definition of the term 'risk assessment'. Therefore, we see no need to examine further the European Communities' argument in relation to the phrase 'as appropriate to the circumstances'."[66]

1.3.4.3 Direct causality between the substance and the possibility of adverse health effects

53. In *Japan – Apples*, the Appellate Body explained that an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause:

> "Indeed, we are of the view that, as a general matter, 'risk' cannot usually be understood only in terms of the disease or adverse effects that may result. Rather, an evaluation of risk must connect the possibility of adverse effects with an antecedent or cause. For example, the abstract reference to the 'risk of cancer' has no significance, in and of itself, under the *SPS Agreement*; but when one refers to the 'risk of cancer from smoking cigarettes', the particular risk is given content."[67]

54. In *US/Canada – Continued Suspension*, the Appellate Body emphasized the obligation for the risk assessor to consider the connection between the substance and the possibility of adverse health effect even in case where the existence of multiple factors may cause particular methodological difficulties:

> "Where multiple factors may contribute to a particular risk, a risk assessor is not required to differentiate the individual contribution made by each factor. Article 5.1 requires that SPS measures be based on a risk assessment 'as appropriate to the circumstances', which suggests that the scientific inquiry involved in a risk assessment must take due account of particular methodological difficulties posed by the nature and characteristics of the particular substance and risk being evaluated. However, that does not excuse the risk assessor from evaluating whether there is a connection between the particular substance being evaluated and the possibility that adverse health effects may arise."[68]

1.3.5 "taking into account risk assessment techniques"

1.3.5.1 Risk assessment techniques of international organizations

55. The Appellate Body in *Australia – Apples* noted that, while Article 5.1 directs a Member conducting a risk assessment to take into account internationally developed risk assessment techniques, "this does not mean that a risk assessment must be based on or conform to such techniques". The Appellate Body also considered that compliance with such techniques alone does not suffice to demonstrate compliance with a Member's obligations under the SPS Agreement.

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[65] (*footnote original*) We note in this context the statement by the Panel in *Australia – Salmon* to the effect that the phrase "as appropriate to the circumstances" "cannot [...] annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute [...] on a risk assessment". Panel Report, *Australia – Salmon*, para. 8.57.

[66] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3053.

[67] Appellate Body Report, *Japan – Apples*, fn 372 to para. 202.

[68] Appellate Body reports, *US/Canada – Continued Suspension*, para. 562.

However, the Appellate Body acknowledged that reference by the risk assessor to such techniques "is useful both to the risk assessor, should a dispute arise in relation to the risk assessment, and to the Panel that is called upon to review the consistency of that risk assessment with the provisions of the *SPS Agreement*".[69]

1.3.5.2 Whether risk was assessed versus how risk was assessed

56. In *EC – Approval and Marketing of Biotech Products*, the European Communities argued that Article 5.1 did not require that a measure be based on a risk assessment, but rather that it takes account of risk assessment techniques. The Panel rejected the European Communities' argument and found that the phrase referred not to whether the risks are required to be assessed, but rather how risks are to be assessed:

> "As the European Communities points out, Article 5.1 provides that Members must base their SPS measures on an appropriate assessment of risks, 'taking into account risk assessment techniques developed by relevant international organizations'. In our view, the phrase taking into account risk assessment techniques developed by relevant international organizations' does not address the issue of whether risks are to be assessed, but rather how risks are to be assessed. This is clear from the reference to 'techniques' of risk assessment. Contrary to the European Communities, we therefore do not consider that the phrase in question supports the view that no assessment of risks is required. To the contrary, the phrase in question would, in our view, be unnecessary if there were no requirement to assess risks."[70]

1.3.5.3 Mention of scientific studies in the domestic directive

57. The Appellate Body in *EC – Hormones* disagreed with the Panel's finding that certain scientific studies were not taken into consideration, inter alia, because these studies were not mentioned in the preambles to the relevant European Communities' directives:

> "In the course of demanding evidence that EC authorities actually 'took into account' certain scientific studies, the Panel refers to the preambles of the EC Directives here involved. The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the Panel proceedings. Preambles of legislative or quasi-legislative acts and administrative regulations commonly fulfil requirements of the internal legal orders of WTO Members. Such preambles are certainly not required by the *SPS Agreement*; they are not normally used to demonstrate that a Member has complied with its obligations under international agreements. The absence of any mention of scientific studies in the preliminary sections of the EC Directives does not, therefore, prove anything so far as the present case is concerned."[71]

1.3.6 The appropriate level of protection

58. The Appellate Body in *US/Canada – Continued Suspension* asserted that the risk assessment is intricately bound to the appropriate level of protection. The Appellate Body held that the chosen level of protection affects the scope of the risk assessment especially in cases where that level stands beyond the level set up by internationally recognized standard:

> "The risk assessment cannot be entirely isolated from the appropriate level of protection. There may be circumstances in which the appropriate level of protection chosen by a Member affects the scope or method of the risk assessment. This may be the case where a WTO Member decides not to adopt an SPS measure based on an international standard because it seeks to achieve a higher level of protection. In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as part of its risk assessment

[69] Appellate Body Report, *Australia – Apples*, para. 246.
[70] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3022.
[71] Appellate Body Report, *EC – Hormones*, para. 191.

> that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard."[72]

59. The Appellate Body in *US/Canada – Continued Suspension* also took the view that there is no obligation for a WTO Member choosing to adopt a level of protection higher than international standards' level to use same methods and parameters as the international body that adopted the standards at issue:

> "[W]e recognize that, in order to perform a risk assessment, a WTO Member may need scientific information that was not examined in the process leading to the adoption of the international standard. We see no basis in Articles 3.3 and 5.1 of the *SPS Agreement* to conclude that WTO Members choosing a higher level of protection than would be achieved by a measure based on an international standard must frame the scope and methods of its risk assessment, including the scientific information to be examined, in the same manner as the international body that performed the risk assessment underlying the international standard."[73]

60. Further, the Appellate Body in *US/Canada – Continued Suspension* considered that, even if the chosen level of protection may influence the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk, it is important that the level of protection a Member chooses does not pre-determine the results of the risk assessment:

> "[T]he chosen level of protection must not affect the rigour or objective nature of the risk assessment, which must remain, in its essence, a process in which possible adverse effects are evaluated using scientific methods. Likewise, whatever the level of protection a Member chooses does not pre-determine the results of the risk assessment. Otherwise, the purpose of performing the risk assessment would be defeated.
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> …
>
> … We disagree with the Panel's finding that 'the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.' We emphasize, however, that whatever level of protection a WTO Member chooses does not pre-determine the outcome of its determination of the sufficiency of the relevant scientific evidence. The determination as to whether available scientific evidence is sufficient to perform a risk assessment must remain, in essence, a rigorous and objective process."[74]

1.3.7 Relevance of precautionary principle to Article 5.1

61. In *EC – Approval and Marketing of Biotech Products*, when addressing the European Communities' argument that each of its safeguard measures was based on the precautionary principle, the Panel conceded that such an approach could affect the Panel's assessment of the scientific basis of the measures under Article 5.1. The Panel considered that those safeguard measures still needed to be based on a valid risk assessment to be consistent with the SPS Agreement:

> "We would agree that the fact that a Member has decided to follow a precautionary approach could have a bearing on a Panel's assessment of whether an SPS measure is 'based on' a risk assessment as required by Article 5.1. We consider that if there are factors which affect scientists' level of confidence in a risk assessment they have carried out, a Member may in principle take this into account in determining the measure to be applied for achieving its appropriate level of protection from risks. Thus, there may conceivably be cases where a Member which follows a precautionary approach, and which confronts a risk assessment that identifies uncertainties or constraints, would be justified in applying (i) an SPS measure even though another Member might not decide to apply any SPS measure on the basis of the same risk

[72] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 685.
[73] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 685.
[74] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 534 and 686.

> assessment, or (ii) an SPS measure which is stricter than the SPS measure applied by another Member to address the same risk. However, even if a Member follows a precautionary approach, its SPS measures need to be 'based on' (*i.e.*, 'sufficiently warranted' or 'reasonably supported' by) a risk assessment. Or, to put it another way, such an approach needs to be applied in a manner consistent with the requirements of Article 5.1."[75]

1.3.8 Relationship with other paragraphs of Article 5

1.3.8.1 Article 5.2

62. In *Australia – Apples*, the Panel noted that Article 5.2 is inextricably linked to Article 5.1, as the former provision enumerates a list of factors that must be taken into account by Members when conducting their risk assessments:

> "[A]rticle 5.2 is inextricably linked to Article 5.1, as the former provision enumerates a list of factors that must be taken into account by Members when conducting their risk assessments. As noted by the Panel in *Japan – Apples*, Articles 5.1 and 5.2 'directly inform each other, in that paragraph 2 sheds light on the elements that are of relevance in the assessment of risks foreseen in paragraph'. Accordingly, the order of analysis issue in the present case is really between Articles 2.2 and 5.1 of the SPS Agreement, as Article 5.2 would be considered when looking at Article 5.1."[76]

63. For discussion on the risk factors to be taken into account, see Article 5.2 below.

1.3.8.2 Article 5.5

64. On the relationship between Articles 5.1 and 5.5, the Panel in *Australia – Salmon* stated:

> "[T]the obligations contained in Article 5.1 (risk assessment) and Article 5.5 are complementary, not mutually exclusive. We consider, therefore, that a WTO Member cannot justify the inconsistency with one Article on the ground that such inconsistency avoids an additional inconsistency with another Article."[77]

1.3.8.3 Article 5.7

65. The Appellate Body in *Australia – Apples* noted the following difference between the application of Articles 5.1 and 5.7:

> "We observe that, if a Member chooses to base SPS measures on a risk assessment [as governed by Article 5.1], it must have made the preliminary determination that the relevant scientific evidence is sufficient to perform a risk assessment. If however, the Member considers that scientific evidence is insufficient to perform a risk assessment, it may instead choose to take provisional SPS measures based on Article 5.7 of the SPS Agreement."[78]

66. For further information rregarding the relationship between Articles 5.1 and 5.7 see paragraphs 220-224 below.

1.3.9 Relationship with other provisions of the SPS Agreement

1.3.9.1 Article 2.2

67. Regarding the relationship between Article 5.1 and Article 2.2, see the Section on Article 2.2.

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[75] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3065.
[76] Panel Report, *Australia – Apples*, para. 7.211. The reference to the Panel report in *Japan – Apples* is also cited at Panel Report, *US – Poultry (China)*, para. 7.172.
[77] Panel Report, *Australia – Salmon*, para. 8.126.
[78] Appellate Body Report, *Australia – Apples*, para. 238.

1.3.9.1.1 Order of analysis

68. In *Australia – Apples*, the Panel, having regard to the circumstances of the case, decided to deal with the complainant's simultaneous claims under Article 2.2 and Article 5.1 of the SPS Agreement, beginning its analysis with the "more specific" claims under Articles 5.1 and 5.2.[79] In that case, the Panel found that Australia's requirements regarding fire blight, European Canker and ALCM on New Zealand apples, as well as additional "general" measures were inconsistent with Articles 5.1 and 5.2 of the SPS Agreement. The Panel then held that by implication, the requirements were also inconsistent with Article 2.2 of the Agreement.[80]

1.4 Article 5.2

1.4.1.1 Scope of application

69. In *Australia – Salmon*, the Panel noted that Articles 5.2 and 5.3, only qualify the way in which a risk assessment has to be carried out, not the substantive obligation to base a sanitary measure on a risk assessment.[81]

70. In *Australia – Apples*, the Appellate Body observed that Article 5.2 requires a risk assessor to take into account the available scientific evidence, together with other factors. According to the Appellate Body, whether a risk assessor has taken into account the available scientific evidence in accordance with Article 5.2 of the SPS Agreement and whether its risk assessment is a proper risk assessment within the meaning of Article 5.1 and Annex A(4) "must be determined by assessing the relationship between the conclusions of the risk assessor and the relevant available scientific evidence".[82]

1.4.1.2 Risk factors to be taken into account

1.4.1.2.1 Not a closed list

71. In *EC – Hormones*, the Appellate Body held that "there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list".[83]

1.4.1.2.2 Risk ascertainable by scientific and non-scientific processes

72. With respect to the risk factors to be examined in the context of a risk assessment, the Appellate Body in *EC – Hormones* agreed with the Panel's emphasis of the scientific nature of risk assessment, but added a qualification on the nature of the "risk":

> "The listing in Article 5.2 begins with 'available scientific evidence'; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is 'a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take'. To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable. However, to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some of the kinds of factors listed in Article 5.2 such as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the

[79] Panel Report, *Australia – Apples*, para. 7.215
[80] Panel Report, *Australia – Apples*, paras. 7.472, 7.779, 7.887 and 7.905.
[81] Panel Report, *Australia – Salmon*, para. 8.57.
[82] Appellate Body Report, *Australia – Apples*, para. 208.
[83] Appellate Body Report, *EC – Hormones*, para. 187. See also Appellate Body Reports, *US/Canada – Continued Suspension,* para. 527; and *Australia – Apples*, para. 207.

> listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[84]

73. The Panel in *Australia – Apples* acknowledged that Members are free to choose either a qualitative or quantitative methodology to conduct their risk assessment. However, they qualified this choice noting that a quantitative methodology should only be used "when reliable specific numeric data are available" to support the choice ranges required. In the absence of sufficient data, a quantitative method may be misleading:

> "'The statements above should not be interpreted as an *a priori* criticism of Australia's decision to resort to a semi-quantitative methodology for assessing the likelihood of entry, establishment and spread of the pests at issue. Under the SPS Agreement, Members are free to choose either a qualitative or a quantitative methodology, in accordance with the appropriate applicable standards. However, as noted by the experts consulted by the Panel, a quantitative methodology should only be used 'when reliable specific numeric data are available' to support the choice of probability ranges and probability shapes. In the absence of sufficient data, and particularly if numbers are chosen in an arbitrary manner, a quantitative method would only give a misleading impression of objectivity and precision."[85]

1.4.1.2.3 Risks arising from difficulties of compliance with certain requirements

74. The Appellate Body in *EC – Hormones* recalled its finding that "risk assessment" does not only refer to the risk ascertainable in a scientific laboratory operating under strictly controlled conditions. On this basis, it considered that, for instance, risks arising from difficulties of control of compliance with certain requirements could be taken into account in the context of a risk assessment:

> "It should be recalled that Article 5.2 states that in the assessment of risks, Members shall take into account, in addition to 'available scientific evidence', 'relevant processes and production methods; [and] relevant inspection, sampling and testing methods'. We note also that Article 8 requires Members to 'observe the provisions of Annex C in the operation of control, inspection and approval procedures …'. The footnote in Annex C states that 'control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification'. We consider that this language is amply sufficient to authorize the taking into account of risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice."[86]

1.4.1.2.4 Risks arising from abuse of controlled substances

75. In *EC - Hormones*, the Appellate Body, in the context of interpreting the SPS Agreement's provisions relating to risk assessment, stressed a rather open-ended approach, where the risk assessment technique, under Article 5 of the SPS Agreement, includes the consideration of factors such as risks arising from abuse and misuse in the administration of hormones:

> "The Appellate Body has not provided a clear demarcation of the factors that may be considered in a 'risk assessment' under the *SPS Agreement*, but it has held that the list of factors provided in Article 5.2 is not a closed list and, in particular, that abuse or

[84] Appellate Body Report, *EC – Hormones*, para. 187.
[85] Panel Report, *Australia – Apples*, para. 7.441.
[86] Appellate Body Report, *EC – Hormones*, para. 205.

misuse and difficulties of control in the administration of hormones may be considered in the context of a risk assessment."[87]

76. The Appellate Body in *EC – Hormones* added a caveat to its finding referred to in paragraphs 72 and 74 above. It held that risks arising from the potential abuse of controlled substances in practice need not necessarily be taken into account in each and every case; it explained that its findings in paragraph 75 above were to be interpreted as meaning that such types of risk should not be excluded a priori:

> "[T]he *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2."[88]

77. In line with its ruling in *EC – Hormones*, the Appellate Body in *US/Canada – Continued Suspension*, considered that the list of factors to be considered in the risk assessment is not a closed list and therefore, the Panel had wrongly dismissed the risk arising from abuse or misuse in the administration of the hormones. For the Appellate Body, the SPS Agreement values examination and evaluation of all risks to human health "whatever their precise and immediate origin may be":

> "The relevance of the risks relating to abuse or misuse in the administration of hormones was … addressed in *EC – Hormones*. In that case, the Appellate Body noted that '[s]ome of the kinds of factors listed in Article 5.2 such as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology' and that 'there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list.' It then specifically examined whether risks relating to misuse or abuse in the administration of the hormones could be considered as part of the 'risk assessment':
>
> > Where the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is *not* followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be 'safe'. The *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2. We disagree with the Panel's suggestion that

[87] Appellate Body Report, *EC – Hormones*, para. 187 and 206.
[88] Appellate Body Report, *EC – Hormones*, para. 206.

> exclusion of risks resulting from the combination of potential abuse and difficulties of control is justified by distinguishing between 'risk assessment' and 'risk management'. As earlier noted, the concept of 'risk management' is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more restrictive interpretation of 'risk assessment' than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*."[89]

78. The Appellate Body in *US/Canada – Continued Suspension* considered that risks arising from misuse or abuse in the administration of hormones could be considered as part of the risk assessment process and in fact should be considered by a panel when reviewing the risk assessment made by a Member. The Appellate Body criticised the Panel's failure to consider the evidence on misuse or abuse referred to in the European Communities' submissions and in testimony of the scientific experts that recognized, in this instance, the relevance of this evidence and the potential adverse effects of the misuse or abuse in the administration of the hormones:

> "[T]he risks arising from the abuse or misuse in the administration of hormones can properly be considered as part of a risk assessment. Where a WTO Member has taken such risks into account, they must be considered by a Panel reviewing that Member's risk assessment. Any suggestion that such risks cannot form part of a risk assessment would constitute legal error … The Panel had a duty to engage with this evidence and with the discussion of this evidence in the SCVPH Opinions. By summarily dismissing the evidence on the misuse or abuse in the administration of the hormones and the consequent conclusions in the SCVPH Opinions in the manner that it did, the Panel incorrectly applied Article 5.1 and the definition of 'risk assessment' in Annex A of the *SPS Agreement*, as interpreted by the Appellate Body."[90]

1.4.1.3 Relationship with other provisions of the SPS Agreement

1.4.1.3.1 Article 5.1

79. For a discussion on the relationship between Articles 5.1 and 5.2, see paragraphs 12-13 and 62 above.

1.4.1.3.2 Articles 2.2 and 5.1

80. In *Australia – Salmon*, the Appellate Body agreed[91] with the finding of the Panel that a violation of Article 5.1 or 5.2 would imply a violation of the more general provision of Article 2.2:

> "Articles 5.1 and 5.2 – in the words of the Appellate Body in *EC – Hormones* when dealing with the relationship between Articles 2.3 and 5.5 – 'may be seen to be marking out and elaborating a particular route leading to the same destination set out in' Article 2.2. Indeed, in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence. We conclude, therefore, that if we find a violation of the more specific Article 5.1 or 5.2 such finding can be presumed to imply a violation of the more general provisions of Article 2.2. We do recognize, at the same time, that given the more general character of Article 2.2 not all violations of Article 2.2 are covered by Articles 5.1 and 5.2."[92]

[89] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 544 (quoting Appellate Body Report, *EC – Hormones*, para. 206).
[90] Appellate Body Report, *US/Canada – Continued Suspension*, paras. 545 and 553.
[91] Appellate Body Report, *Australia – Salmon*, para. 138.
[92] Panel Report, *Australia – Salmon*, para. 8.52.

1.5 Article 5.3

1.5.1 General

81. In *Australia – Salmon*, the Panel noted that Articles 5.2 and 5.3 only qualify the way in which a risk assessment has to be carried out, not the substantive obligation to base a sanitary measure on a risk assessment.[93]

82. Regarding the scope of Member's obligation under Article 5.3, the Panel in *Russia – Pigs (EU)* found this provision to refer to two distinct situations:

> "The first situation is when a Member is 'assessing the risk to animal or plant life or health". The second is when a Member is 'determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection'. Pursuant to Article 5.3, in both these situations Members 'shall take into account' as relevant economic factors, those listed at the end of this provision. We observe that there is no indication in the text that the factors listed are only by way of example, rather this is presented as a complete list. In order to interpret the scope of a Member's obligation under Article 5.3, we first need to address the meaning of the expression 'shall take into account'.
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> …
>
> The first situation is informed by the obligations that a Member imposing an SPS measure has pursuant to Articles 2.2, 5.1, and 5.2 of the SPS Agreement. These include the obligation to base SPS measures on scientific principles (Article 2.2), through an assessment of risk appropriate to the circumstances (Articles 5.1 and 5.2). In this respect, the obligation to take into account relevant economic factors when assessing the risk to animal life and health is contingent upon the obligation to base an SPS measure on a risk assessment pursuant to Articles 5.1 and 5.2 of the SPS Agreement. If a Member does not base its measures on a risk assessment it has performed or that is otherwise available to it, unless such Member is justified in not doing so (due to conformity to an international standard or adoption of a provisional measure pursuant to Article 5.7), it would not be in conformity with Article 5.3.
>
> The second situation is informed by the text of Articles 2.2, 5.4 and 5.6 of the SPS Agreement. Among other aspects, Article 2.2 provides that Members shall ensure that their SPS measures are applied only to the extent necessary to protect human, animal or plant life or health. Pursuant to Article 5.4, when determining their ALOP, Members should take into account the objective of minimizing negative trade effects. In addition, according to Article 5.6, Members shall ensure that their SPS measures are not more trade-restrictive than required to achieve their ALOP. It is in the context of complying with these other obligations that a Member shall take into account the relevant economic factors listed in Article 5.3 when determining the measure it will apply to achieve its ALOP."[94]

1.5.2 "taking into account as relevant economic factors"

83. In *Russia – Pigs (EU)*, the Panel referred to the interpretations of the term "take into account" in other provisions of the SPS Agreement and other covered agreements to conclude that in the context of Article 5.3:

> "[A] Member has the obligation to give consideration to the relevant economic factors listed therein when either assessing the risk to animal or plant life or health or determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection, and not to other economic factors. This obligation does

[93] Panel Report, *Australia – Salmon*, para. 8.57.
[94] Panel Report, *Russia – Pigs (EU)*, paras. 7.759 and 7.770-7.771.

> not imply, however, that consideration of the relevant economic factors will require a particular course of action from the Member imposing an SPS measure."[95]

1.5.3 Burden of proof

84. The Panel in *Russia – Pigs (EU)* held that "it is the complaining party who bears the burden to demonstrate that the responding party did not take into account the relevant economic factors listed therein."[96]

1.5.4 Relationship with other provisions of the SPS Agreement

1.5.4.1 Article 5.1

85. In *Russia – Pigs (EU)*, the Panel held that, "if a Member had an obligation to perform a risk assessment pursuant to [Articles 5.1 and 5.2], it also has the obligation to take into account the relevant economic factors listed in Article 5.3 when assessing those risks, and only those economic factors identified as being relevant."[97]

1.5.4.2 Article 5.7

86. The Panel in *Russia – Pigs (EU)* noted that:

> "[I]f a measure is adopted pursuant to Article 5.7 of the SPS Agreement, a Member does not have the obligation to base its provisional measure on an assessment of risk pursuant to Article 5.1. As a consequence, a Member in such situation will not have to take into account the relevant economic factors listed in Article 5.3 for the purposes of assessing the risk to animal or plant life and health. However, even when a Member has adopted a provisional SPS measure pursuant to Article 5.7, it will still have the obligation to take into account, in determining the measure it will apply to achieve its ALOP, the relevant economic factors listed in Article 5.3."[98]

1.5.4.3 Annex A(1)(d)

87. Article 5.3 states that relevant "economic factors" to be taken into account in a risk assessment include "the potential damage in terms of loss of production or sales in the event of the entry or establishment or spread of a pest or a disease. In *EC – Approval and Marketing of Biotech Products*, the Panel noted that the category of "other damage" is very broad and encompasses different types of harm resulting in a reduction of economic value. In this sense, Article 5.3 contemplates a situation similar to the one contemplated in Annex A(1)(d):

> "The residual category of 'other damage' is potentially very broad. In our view, 'other damage' could include damage to property, including infrastructure (such as water intake systems, electrical power lines, etc.). In addition, we think 'other damage' could include economic damage (such as damage in terms of sales lost by farmers). The dictionary defines the term 'damage' as 'physical harm impairing the value, usefulness, or normal function of something' and 'unwelcome and detrimental effects', or 'a loss or harm resulting from injury to person, property, or reputation'. These definitions cover harm resulting in a reduction of economic value, adverse economic effects, or economic loss. Also, interpreting 'other damage' to include economic damage is consistent with the context of Annex A(1)(d). Article 5.3 of the *SPS Agreement* states that relevant 'economic factors' to be taken into account in a risk assessment include 'the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or a disease'. Thus, Article 5.3 shows that the *SPS Agreement* elsewhere uses the term 'damage' in an economic

[95] Panel Report, *Russia – Pigs (EU)*, para. 7.767.
[96] Panel Report, *Russia – Pigs (EU)*, para. 7.768.
[97] Panel Report, *Russia – Pigs (EU)*, para. 7.774.
[98] Panel Report, *Russia – Pigs (EU)*, para. 7.772.

> sense, and it does so in connection with damage from 'pests'. Thus, Article 5.3 contemplates a similar situation to that contemplated in Annex A(1)(d)."[99]

1.6 Article 5.4

1.6.1 Objective of minimizing negative trade effects

88. The Panel in *EC – Hormones* held that Article 5.4 does not impose any obligation upon the Members (and is more of a hortatory provision), it still has to be taken into account when interpreting the other provisions of the SPS Agreement:

> "Guided by the wording of Article 5.4, in particular the words 'should' (not 'shall') and 'objective', we consider that this provision of the *SPS Agreement* does not impose an obligation. However, this objective of minimizing negative trade effects has nonetheless to be taken into account in the interpretation of other provisions of the *SPS Agreement*."[100]

89. Having analysed the text of Article 5.4, as well as the context of other provisions on the appropriate level of protection (ALOP) and the rest of the SPS Agreement, the Panel in *US – Animals* agreed with the Panel in *EC – Hormones* that Article 5.4 does not impose an affirmative obligation on WTO Members.[101]

1.6.2 Relationship with other paragraphs of Article 5

1.6.2.1 Article 5.1

90. For a discussion on the relationship between Articles 5.1 and 5.2, see paragraphs 12-13 above.

1.6.2.2 Articles 5.4 to 5.6 and Articles 2.2 and 2.3

91. The Panel in *EC – Hormones* concluded that Articles 5.4 to 5.6 may be viewed as specific applications of the basic obligations provided for in Articles 2.2 and 2.3:

> "Articles 5.4 to 5.6 are particularly relevant to the risk management decision. Article 5.4 establishes the objective of minimizing negative trade effects in the *determination* by a Member of its appropriate level of protection. Article 5.5 aims at achieving consistency in the *application* of the concept of appropriate level of protection. Article 5.6, in turn, provides that the sanitary *measure* which is finally adopted shall not be more trade-restrictive than required to achieve the appropriate level of protection of the Member concerned. Articles 5.4 to 5.6 may be viewed as specific applications of the basic obligations provided for in Article 2.2 which, *inter alia*, states that 'Members shall ensure that any sanitary or phytosanitary measure is *applied only to the extent necessary to protect* human, animal or plant life or health' (emphasis added) and Article 2.3 which provides that 'Members shall ensure that their sanitary and phytosanitary measures do *not arbitrarily or unjustifiably discriminate between Members* where identical or similar conditions prevail …' and that 'Sanitary and phytosanitary measures *shall not be applied in a manner which would constitute a disguised restriction* on international trade'."[102]

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[99] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.370.
[100] Panel Report, *EC – Hormones (Canada)*, para. 8.169; Panel Report, *EC – Hormones (US)*, para. 8.166.
[101] Panel Report, *US – Animals*, paras. 7.399-7.404.
[102] Panel Reports, *EC – Hormones (US)*, para. 8.99; and *EC – Hormones (Canada)*, para. 8.96.

1.7 Article 5.5

1.7.1 The elements of Article 5.5

92. In *EC – Hormones*, the Appellate Body found that three elements must be demonstrated to establish an inconsistency with Article 5.5:

(a) The Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations.

(b) Those levels of protection exhibit arbitrary or unjustifiable differences ("distinctions" in the language of Article 5.5) in their treatment of different situations.

(c) The arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade.[103]

93. The Appellate Body in *EC – Hormones* also noted that the three elements are cumulative in nature. In other words, all of the elements must be demonstrated to be present if a claim of violation of Article 5.5 is to be sustained. It emphasized in particular, that the third element, should be demonstrated positively and independently of the second element:

> "We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element – the arbitrary or unjustifiable character of differences in *levels of protection* considered by a Member as appropriate in differing situations – may in practical effect operate as a 'warning' signal that the implementing *measure* in its application *might* be a discriminatory measure or *might* be a restriction on international trade disguised as an SPS measure for the protection of human life or health. Nevertheless, the measure itself needs to be examined and appraised and, in the context of the differing levels of protection, shown to result in discrimination or a disguised restriction on international trade."[104]

94. In *Australia – Apples*, due to the special circumstances of the case, the Panel departed from a strict application of the "three elements" test laid down by the Appellate Body in *EC – Hormones*:

> "The Panel is cognizant that in *EC – Hormones* the Appellate Body referenced 'three distinct elements' that need to be addressed under Article 5.5. However, this dispute has specific circumstances in that New Zealand contests alleged differences in the level of protection achieved in practice by the measures applied in comparable situations, despite Australia's generically stated ALOP. Given these special circumstances, the Panel finds it appropriate to refrain from a detailed analysis of risks under the first element of the Article 5.5 test, and to assess under the second element of this test whether there is a difference in the levels of protection achieved by the measures applied in the different situations at issue."[105]

95. The Panel in *Australia – Apples* found that New Zealand had not demonstrated the second and the first elements of the three-pronged Article 5.5 test. Given that the elements of the test are

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[103] Appellate Body Report, *EC – Hormones*, para 214.

[104] Appellate Body Report, *EC – Hormones*, para. 215. See also Panel Reports, *EC – Approval and Marketing of Biotech Products*, para. 7.1415; and *Australia - Salmon (Article 21.5 - Canada)*, paras. 7.86-7.108. In *Australia – Salmon (Article 21.5 - Canada)*, the Panel found that Australia had not violated 5.5 because neither the second, nor the third element of Article 5.5 were met.

[105] Panel Report, *Australia – Apples*, para. 7.985.

cumulative, the Panel did not proceed to the third element and dismissed New Zealand's claim under Article 5.5.[106]

1.7.2 The definition of an "implementing measure" for the purposes of Article 5.5

96. In light of the Appellate Body's discussion of the elements of Article 5.5 in *EC – Hormones* (described in paragraphs 91-92 above), the Panel in *EC – Approval and Marketing Products* determined that although Article 5.5 does not explicitly refer to "SPS measures", implicitly it envisages that the "measure complained of" is an "implementing measure". In other words, the measure complained of must be an SPS measure applied for achieving a particular level of sanitary or phytosanitary protection.[107]

97. Having based their considerations on the argument that Article 5.5 implies a reference to "SPS measures", the Panel in *EC – Approval and Marketing of Biotech Products* decided that the general definition of that term as set out in Annex A(1) of the SPS Agreement must be applicable in the context of Article 5.5 as well. In light of this, the Panel found that the European Communities' decision to apply a general moratorium on approvals did not meet the definition of the term "SPS measure" as it appears in Annex A(1):

> "In the light of this, we consider that although Article 5.5 does not explicitly refer to 'SPS measures', implicitly it envisages that the 'measure complained of' is an 'implementing measure' (footnote omitted). In other words, the measure complained of must be an SPS measure applied for achieving a particular level of sanitary or phytosanitary protection ...
>
> If, as Appellate Body jurisprudence leads us to believe, Article 5.5 implies a reference to 'SPS measures', the general definition of that term set out in Annex A(1) of the *SPS Agreement* must be applicable in the context of Article 5.5 as well. We have found ... that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term 'SPS measure' as it appears in Annex A(1). However, we also stated that in interpreting the term 'SPS measure', in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears ...
>
> [T]he SPS measures at issue in Article 5.5 are those applied for achieving a particular level of protection. We found above that the pre-marketing approval requirement which results in a provisional marketing ban may be properly considered a measure which is applied for achieving the European Communities' appropriate level of protection. Similarly, we found that final substantive approval decisions on individual applications are measures applied for achieving the European Communities' appropriate level of protection. But, most importantly, we found that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve a particular level of protection, and did not imply a particular level of protection either. That decision cannot, therefore, be considered an 'implementing measure'.
>
> This being so, it is clear that the provisions of Article 5.5 as interpreted by the Appellate Body and the SPS Committee do not undermine, but reinforce the provisional conclusion we have reached on the basis of the Annex A(1) definition.[108]

1.7.3 Standard of review

98. While examining whether Australia imposed different levels of protection in respect of "different situations" in the sense of Article 5.5, the Panel in *Australia – Salmon* ruled on the consideration by one scientific expert (consulted by the Panel *in casu*) that to compare two products, there may be a need to have two more or less complete sets of data, including two risk assessments. The Panel emphasized that its mandate does not allow it to conduct such comparison

[106] Panel Report, *Australia – Apples*, paras. 7.1089-7.1090.
[107] Panel Report, *EC – Approval and Marketing of Biotech Products*, para 7.1416.
[108] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1416-7.1419.

or to conduct its own risk assessment, but rather, it is bound to solely weigh the evidence before it:

> "We cannot conduct our own risk assessment. Nor do we attempt to do so in this report. The fact that one of the experts advising the Panel stated that 'if you are trying to say which [of two products] is the most risky, then you need to know something about and possibly do a full assessment for [the other] product' and that 'it would be sensible to assess that which you have prioritized initially to have the highest risk first, but until you have done the risk assessment, you actually cannot be sure you have got that right', does not change our position. Nor do we disagree with these statements. Indeed, for a scientist to say with scientific certainty that one product represents a higher risk than the other, there may be a need to have two, more or less, complete sets of data, including two risk assessments. And even on that basis a scientist would probably not be able to state with absolute certainty that one product is riskier than the other. Our mandate is different. We are not asked to make a scientific risk comparison nor to state with scientific certainty that one product is riskier than the other. We can only weigh the evidence put before us and, on the basis of the rules of burden of proof we adopted, including the use of factual presumptions, decide whether sufficient evidence is before us – evidence which has not been rebutted – in order to state that it can be presumed that one product is riskier than the other."[109]

1.7.4 "appropriate level of protection"

1.7.4.1 Whether the first element of Article 5.5 establishes a legal obligation to achieve consistency

99. In *Australia – Salmon*, the Appellate Body determined that the SPS Agreement contains an implicit obligation that WTO Members determine their appropriate level of protection, which is reflected in paragraph 3 of Annex B, Article 4.1, Article 5.4 and Article 5.6 of the SPS Agreement.[110]

100. In *EC – Hormones*, with respect to the first part of Article 5.5, the Appellate Body held that the statement of the goal of consistency did not establish a legal obligation of consistency of appropriate levels of protection:

> "The objective of Article 5.5 is formulated as the 'achieving [of] consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection'. Clearly, the desired consistency is defined as a goal to be achieved in the future. To assist in the realization of that objective, the Committee on Sanitary and Phytosanitary Measures is to develop guidelines for the practical implementation of Article 5.5, bearing in mind, among other things, that ordinarily, people do not voluntarily expose themselves to health risks. Thus, we agree with the Panel's view that the statement of that goal [consistency] does not establish a legal obligation of consistency of appropriate levels of protection. We think, too, that the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an ad hoc basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided."[111]

1.7.4.2 Relationship between the level of protection and the risk assessment

101. The Panel in *Australia – Salmon* observed that for any given situation, a level of protection of applies and a Member need not complete a risk assessment in order to have a specific level of protection. A panel examining a claim under Article 5.5 is not tasked with determining whether the levels of protection applied by a Member are based on a risk assessment. The Panel stated:

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[109] Panel Report, *Australia – Salmon*, para. 8.126.
[110] Appellate Body Report, *Australia – Salmon*, paras. 205-207.
[111] Appellate Body Report, *EC – Hormones*, para. 213.

> "[T]o have a specific level of protection, there is no need to first complete a risk assessment. … First, … for any given situation a level of protection applies. Article 5.5 directs us to compare for different situations the related levels of protection as they are currently considered to be appropriate by Australia and this whether or not the sanitary measures enacted to achieve that level are based on a risk assessment. Of course, such comparison would be easier and more accurate if for both situations an appropriate risk assessment were available. However, according to Article 5.5 and our mandate set out in Article 11 of the DSU (to make an 'objective assessment of the matter before [us], including an objective assessment of the facts of the case'), we are called upon in this case to make this comparison and to do so on the basis of the evidence before us. We cannot conduct our own risk assessment. Nor do we attempt to do so in this report."[112]

1.7.4.3 Determination of the appropriate level of protection

102. The Panel in *Australia – Apples* noted that Members should not be allowed to hide behind a generically stated appropriate level of protection. Otherwise, Members' obligations under Article 5.5 would be diminished. This would be particularly serious in the case of a Member whose generically stated appropriate level of protection covers a wide range of products and diseases, and thus a wide range of potentially comparable situations:

> "The Panel agrees with New Zealand that Members should not be allowed to hide behind a generically stated ALOP. Otherwise, Members' obligations under Article 5.5 would be diminished. This would be particularly serious in the case of Australia – or, for that matter, any other Members – whose generically stated ALOP covers a wide range of products and diseases, and thus a wide range of potentially comparable situations.
>
> The Panel notes that in *Australia – Salmon* the Appellate Body warned in general terms against reading out entire provisions from the SPS Agreement. 'It would obviously be wrong to interpret the *SPS Agreement* in a way that would render nugatory entire articles or paragraphs of articles of this Agreement and allow Members to escape from their obligations under this Agreement.'"[113]

103. The Panel in *US – Poultry (China)* found that even when there exists an expressly stated ALOP, a panel should still proceed to determine whether that ALOP is the one actually being applied. The Panel stated:

> "The Panel recognizes that the United States is free to decide its own ALOP and thus accepts that the United States' ALOP for poultry, in general, is embodied in Section 466 of the PPIA. This however does not mean that we will not examine whether the ALOP actually being applied by the United States to poultry products from China differs from that in the PPIA. We note that the Appellate Body in *Australia – Salmon* explained that a panel may deduce an unexpressed ALOP from the measure being applied. In our view, even in a case where a Member has expressed a particular ALOP, a panel should nevertheless examine the measure in question to determine whether that ALOP is the one actually being applied via that measure. To ignore the measure and rely solely on a Member's declared ALOP could permit a Member to evade the disciplines of Article 5.5 by simply declaring one generic ALOP for all SPS-related matters."[114]

104. In *Australia – Salmon (Article 21.5 – Canada)*, in the context of its analysis under Article 5.6 of the SPS Agreement, the Panel noted that while a vaguely determined appropriate level of protection is not ideal, it should not prevent scrutiny under the SPS Agreement, including under Article 5.5:

> "Although, according to the Appellate Body, Australia determined its ALOP with sufficient precision to apply Article 5.6, we find it rather difficult to evaluate whether

[112] Panel Report, *Australia – Salmon*, paras. 8.125-8.126.
[113] Panel Report, *Australia – Apples*, paras. 7.970-7.971.
[114] Panel Report, *US – Poultry (China)*, para. 7.244.

> any of the options before us would also meet Australia's somewhat vaguely determined level of 'a high or very conservative level of protection aimed at reducing risk to very low levels, while not based on a zero-risk approach'. We are of the view, however, that this should not prevent us from carrying out the task. As noted by the Appellate Body, '[o]therwise, a Member's failure to comply with the implicit obligation to determine its appropriate level of protection – with sufficient precision – would allow it to escape its obligations under this Agreement and, in particular, its obligations under Articles 5.5 and 5.6'. We note, parenthetically, that a more explicit and in particular a quantitative expression of a Member's ALOP would greatly facilitate the consideration of compliance with not only Article 5.6 but with other provisions of the SPS Agreement as well."[115]

105. The Panel in *US – Poultry (China)* noted that the first element of Article 5.5 appears to have "two, closely related aspects: (1) the existence of different situations, and (2) the existence of different ALOPS in such situations".[116]

1.7.4.4 Comparability of different situations

106. The Appellate Body in *EC – Hormones* found that for an inquiry of arbitrariness under Article 5.5 to proceed, the different levels of sanitary protection deemed appropriate by a Member must be comparable. The Appellate Body stated:

> "Clearly, comparison of several levels of sanitary protection deemed appropriate by a Member is necessary if a Panel's inquiry under Article 5.5 is to proceed at all. The situations exhibiting differing levels of protection cannot, of course, be compared unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable. If the situations proposed to be examined are totally different from one another, they would not be rationally comparable and the differences in levels of protection cannot be examined for arbitrariness."[117]

107. The Appellate Body also held that situations cannot be deemed to be comparable when there is a fundamental distinction between the situations at issue. The Panel in *EC – Hormones* had found arbitrary or unjustifiable distinction in the level of protection in the European Communities' regulation in that while the European Communities prohibited added hormones (natural or synthetic) with respect to beef, it did not attempt to limit naturally occurring hormones.[118] The Appellate Body disagreed:

> "We do not share the Panel's conclusions that the above differences in levels of protection in respect of added hormones in treated meat and in respect of naturally-occurring hormones in food, are merely arbitrary and unjustifiable. We consider there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods. In respect of the latter, the European Communities simply takes no regulatory action; to require it to prohibit totally the production and consumption of such foods or to limit the residues of naturally-occurring hormones in food, entails such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people as to reduce the comparison itself to an absurdity."[119]

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[115] Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, para. 7.129. These statements by the Panel were referred to and relied on by the Panel in *Australia – Apples*. See Panel Report, *Australia – Apples*, paras. 7.972-7.973.

[116] Panel Report, *US – Poultry (China)*, para. 7.225.

[117] Appellate Body Report, *EC – Hormones*, para. 217.

[118] Panel Reports, *EC – Hormones (Canada)*, para. 8.193; and *EC – Hormones (US)*, para. 8.190.

[119] Appellate Body Report, *EC – Hormones*, para. 221. When comparing the levels of protection for hormones used for growth promotion purposes and hormones used for therapeutic and zootechnical purposes – a comparison not further pursued by the Panels – the Appellate Body, referring to the differences in frequency and scale of the two treatments and the strict mode of administration of the latter treatment, found that the distinction in levels of protection "is not, in itself, 'arbitrary or unjustifiable'." Appellate Body Report, *EC – Hormones*, paras. 222-225.

108. The Panel in *EC – Hormones* found that the "different situations" that can be compared under Article 5.5 were situations "where the same substance or the same adverse health effect is involved".[120]

109. In *Australia – Salmon*, the Appellate Body held that comparable situations under Article 5.5 were those where either the same or a similar disease, or where the same biological and economic consequences were involved:

> "Situations which involve a risk of entry, establishment or spread of the same or a similar disease have some common elements sufficient to render them comparable under Article 5.5. Likewise, situations with a risk of the same or similar associated potential biological and economic consequences also have some common elements sufficient to render them comparable under Article 5.5. We, therefore, consider that for 'different' situations to be comparable under Article 5.5, there is no need for both the disease *and* the biological and economic consequences to be the same or similar."[121]

110. The Panel in *Australia – Apples* applied the test of comparability identified by the Appellate Body in *Australia – Salmon* (discussed in paragraph 109 above). The Panel noted that the two conditions of comparability – (i) a risk of entry, establishment or spread of the same or a similar disease and (ii) a risk of the same or similar associated potential biological and economic consequences – were cumulative:

> "The first condition of comparability identified by the Appellate Body refers to 'a risk of entry, establishment or spread of the same or a similar disease'. In the light of the above, the Panel needs to assess whether the diseases involved in the allegedly comparable situations are effectively the same or similar. The second condition of comparability identified by the Appellate Body refers to 'a risk of the same or similar associated potential biological and economic consequences'. This requires an assessment of whether the potential biological and economic consequences associated with the diseases are the same or similar. These two conditions of comparability being non-cumulative, the Panel will turn to the second, alternative condition only if it finds that the first one is not fulfilled."[122]

111. In response to Australia's argument that a "situation" cannot be compared under Article 5.5 if no risk assessment has been made in respect of it, the Panel in *Australia – Salmon* found that since Australia had a sanitary regime to address situations in respect of which no risk assessment existed, a level of protection existed:

> "[W]e consider that even though Australia has not yet conducted import risk analyses for the other products compared under Article 5.5, Australia does, nevertheless, have a level of protection it considers to be appropriate for these other products. Australia currently has a sanitary regime, imposing specific sanitary measures or refraining from such regulation, for these other products. This sanitary regime (whether or not specific measures are enacted) reflects a level of protection. To have a specific level of protection, there is no need to first complete a risk assessment … Article 5.5 directs us to compare for different situations the related levels of protection as they are currently considered to be appropriate by Australia and this whether or not the sanitary measures enacted to achieve that level are based on a risk assessment. Of course, such comparison would be easier and more accurate if for both situations an appropriate risk assessment were available. However, according to Article 5.5 and our mandate set out in Article 11 of the DSU (to make an 'objective assessment of the matter before [us], including an objective assessment of the facts of the case'), we are called upon in this case to make this comparison and to do so on the basis of the evidence before us."[123]

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[120] Panel Reports, *EC – Hormones (Canada)*, para. 8.179; and *EC – Hormones (US)*, para. 8.176.
[121] Appellate Body Report, *Australia – Salmon*, para. 146.
[122] Panel Report, *Australia – Apples*, para. 7.944.
[123] Panel Report, *Australia – Salmon*, paras. 8.125-8.126.

1.7.5 "Arbitrary or unjustifiable" distinctions in levels of protection

112. The Appellate Body in *EC – Hormones* observed that distinction in the levels of protection applied by a Member could only be determined through comparison. The Appellate Body stated that the "comparison of several levels of sanitary protection deemed appropriate by a Member is necessary if a panel's inquiry under Article 5.5 is to proceed at all".[124]

113. The Panel in *US – Poultry (China)*, in its discussion of the ordinary meaning of the phrase "arbitrary or unjustifiable" began by examining the dictionary definitions of the terms "arbitrary" and "unjustifiable". The Panel stated:

> "In examining the terms 'arbitrary or unjustifiable', we recall the customary rules of interpretation set out in the VCLT. Article 31 of the VCLT prescribes that a treaty has to be interpreted 'in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.' The starting point for determining the ordinary meaning of the terms is, of course, the dictionary. A dictionary definition of the term 'arbitrary' is 'based on mere opinion or preference as opp. to the real nature of things, capricious, unpredictable, inconsistent.' In turn, the term 'unjustifiable' is defined as 'not justifiable, indefensible' with 'justifiable' meaning '[c]apable of being legally or morally justified or shown to be just, righteous, or innocent; defensible' and '[c]apable of being maintained, defended, or made good'."[125]

114. The Panel also made reference to the prior findings of the Appellate Body regarding the meaning of "arbitrary or unjustifiable" in Article XX of GATT 1994. The Panel noted:

> "The Appellate Body has also clarified that its findings with respect to the ordinary meaning of 'arbitrary or unjustifiable' from the chapeau of Article XX of the GATT 1994 are relevant and provide guidance in interpreting the terms 'arbitrary or unjustifiable discrimination' in Article 2.3 of the *SPS Agreement*. Although the Appellate Body's conclusions were with respect to the use of the terms in Article 2.3, we believe that they are equally relevant for an interpretation of the obligation in Article 5.5 which is, after all, a more specific enunciation of the basic obligation in Article 2.3.
>
> Turning therefore, to the prior reasoning on the chapeau of Article XX of the GATT 1994, we note that the Appellate Body Reports in *US – Gasoline*, *US – Shrimp*, *US – Shrimp (Article 21.5 - Malaysia)* show that the analysis of whether the application of a measure results in arbitrary or unjustifiable discrimination should focus on the cause of the discrimination, or the rationale put forward to explain its existence. In *Brazil – Retreaded Tyres*, the Appellate Body's analysis of the measures at issue under the chapeau of Article XX focused on whether discrimination that might result from the application of the measures at issue had a *legitimate cause or rationale* in the light of the objectives listed in the paragraphs of Article XX. Further, the Appellate Body explained that the assessment of whether discrimination is 'arbitrary or unjustifiable' should be made in light of the objectives of the measure and whether the discrimination bears a rational connection to the stated objective of the measure. It is important thus to remember that not all discrimination in the application of measures is necessarily 'arbitrary or unjustifiable' and it is only the arbitrary or unjustifiable inconsistencies that are to be avoided."[126]

115. Based on the analysis conducted under the chapeau of Article XX, the Panel concluded that, in the context of Article XX, "we must focus on the justification for the distinction and whether that justification bears a rational relationship to the objective of the measures".[127] With particular reference to what may be deemed as a justification for the distinction in Article 5.5, the Panel stated:

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[124] Appellate Body Report, *EC – Hormones*, para. 217.
[125] Panel Report, *US – Poultry (China)*, para. 7.259.
[126] Panel Report, *US – Poultry (China)*, paras. 7.260-7.261.
[127] Panel Report, *US – Poultry (China)*, para. 7.262.

> "[I]ndeed, in the context of Article 5.5 to show that the distinction in ALOPS is not arbitrary or unjustifiable, a Member must demonstrate that there are differing levels of risk between the comparable situations. We are of the view that such a demonstration requires scientific evidence."[128]

116. The Appellate Body has found that distinctions in the level of protection can be said to be arbitrary or unjustifiable where the risk is at least equally high between the different situations at issue. The Panel in *Australia - Salmon*, in a ruling upheld by the Appellate Body, found that, on the basis of the evidence before it, the distinctions in levels of sanitary protection reflected in Australia's treatment of, on the one hand, ocean-caught Pacific salmon and, on the other, herring used as bait and live ornamental finfish, are "arbitrary or unjustifiable" in the sense of the second element of Article 5.5.[129] The Appellate Body noted:

> "Australia determined explicitly that its appropriate level of protection with respect to ocean-caught Pacific salmon is 'a high or 'very conservative' level of sanitary protection aimed at reducing risk to 'very low levels', 'while not based on a zero-risk approach'.' The level of protection reflected in Australia's treatment of herring used as bait and live ornamental finfish is definitely lower. We note the Panel's factual finding that herring used as bait and live ornamental finfish can be presumed to represent at least as high a risk - if not a higher risk - than the risk associated with ocean-caught Pacific salmon. Therefore, we uphold the Panel's finding … to the extent that the Panel found that the second element of Article 5.5 is fulfilled."[130]

1.7.6 Distinctions which "result in discrimination or a disguised restriction on international trade"

1.7.6.1 Factors that result in a disguised restriction on international trade and related "warning signals"

117. With respect to the third element of Article 5.5, i.e. that the arbitrary or unjustifiable distinctions in levels of protection result in "discrimination or a disguised restriction on international trade", the Panel in *Australia – Salmon* identified three "warning signals" that, taken together with other factors, can be considered relevant in a decision on the third element of Article 5.5.[131] The first "warning signal" the Panel considered was the arbitrary or unjustifiable character of the differences in levels of protection. The second "warning signal" considered by the Panel was the rather substantial difference in levels of protection between an import prohibition on ocean-caught pacific salmon, as opposed to tolerance for imports of herring used as bait and of live ornamental finfish.[132] In this regard, the Panel noted the Appellate Body's statement in *EC - Hormones* that:

> "[T]he degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure."[133]

118. The third "warning signal" the Panel considered was the inconsistency of the SPS measure at issue with articles 5.1 and 2.2 of the *SPS Agreement*.

> "We note that a finding that an SPS measure is not based on an assessment of the risks to human, animal or plant life or health - either because there was no risk assessment at all or because there is an insufficient risk assessment - is a strong indication that this measure is not really concerned with the protection of human, animal or plant life or health but is instead a trade restrictive measure taken in the guise of an SPS measure, i.e., a 'disguised restriction on international trade'. We,

[128] Panel Report, *US – Poultry (China)*, para. 7.263.
[129] Appellate Body Report, *Australia – Salmon*, para. 155.
[130] Appellate Body Report, *Australia – Salmon*, para. 158.
[131] Appellate Body Report, *Australia – Salmon*, paras. 159, 161, 163 and 165.
[132] Panel Report, *Australia – Salmon*, para. 8.150.
[133] Appellate Body Report, *EC – Hormones*, para. 240.

> therefore, consider that the finding of inconsistency with Article 5.1 is an appropriate warning signal for a 'disguised restriction on international trade'."[134]

119. In *Australia – Salmon*, the Appellate Body addressed the Panel's ruling on three additional factors taken into account in its decision on the third element of Article 5.5 i.e., that the arbitrary or unjustifiable distinctions in levels of protection result in "discrimination or a disguised restriction on international trade". The first "additional factor" considered by the Panel was the fact that the two substantially different SPS measures that Australia applies (import prohibition versus import tolerance) lead to discrimination between salmon, on the one hand, and herring used as bait and live ornamental finfish on the other. The second "additional factor" considered by the Panel was the substantial, but unexplained change in conclusion between the 1995 Draft Report (which recommended allowing the importation of ocean-caught Pacific salmon under certain conditions) and the 1996 Final Report (which recommended continuing the import prohibition). The third "additional factor" considered by the Panel was the absence of controls on the internal movement of salmon products within Australia compared to the prohibition of the importation of ocean-caught Pacific salmon.[135] The Appellate Body upheld the Panel's findings on the second and third "additional factors" but reversed the Panel's findings on the first additional factor. However, the Appellate Body took the view that its reversal of the Panel's conclusion on the first "additional factor" had no bearing on its consideration that the Panel validly concluded that the previously identified "warning signals" and "other factors", considered cumulatively, lead to the conclusion that the distinctions in the levels of protection imposed by Australia result in a disguised restriction on international trade.[136]

120. The Appellate Body in *EC – Hormones* agreed that a conclusion regarding "discrimination or a disguised restriction on international trade" can only be arrived at by examining several other factors including the "warning signals" indicated in *Australia – Salmon*. However, the Appellate Body cautioned that the application of the three warning signals utilized in *Australia – Salmon* alone is not necessarily sufficient to prove whether arbitrary or unjustifiable distinctions in a Member's levels of protection have resulted in discrimination or a disguised restriction on international trade. The Appellate Body stated:

> "In our view, the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. Thus, we do not think that the difference between a 'no residues' level and 'unlimited residues' level is, together with a finding of an arbitrary or unjustifiable difference, sufficient to demonstrate that the third, and most important, requirement of Article 5.5 has been met. It is well to bear in mind that, after all, the difference in levels of protection that is characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the SPS Agreement. Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case."[137]

121. The Panel in *US – Poultry (China)* interpreted the Appellate Body's ruling in *EC – Hormones* to mean that the Appellate Body did not agree with the analysis of the three warning signals in *Australia – Salmon*. The Panel observed:

> "The Appellate Body seems to have recognized that the analysis in *Australia – Salmon* did not fully address the third element of Article 5.5 when it noted in *EC – Hormones* that 'the difference in levels of protection that is characterizable as arbitrary or

[134] Appellate Body Report, *Australia – Salmon*, para. 165. See also Panel Report, *US – Poultry (China)*, para. 7.277.
[135] Appellate Body Report, *Australia – Salmon*, paras. 167-174.
[136] Appellate Body Report, *Australia – Salmon*, paras. 167-170, 174 and 177.
[137] Appellate Body Report, *EC – Hormones*, para. 240.

> unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade.'
>
> …
>
> Therefore, it seems, according to the Appellate Body, that even if the presence of all three warning signals was demonstrated, that would not necessarily support a conclusion that the measure results in discrimination or a disguised restriction on trade."[138]

1.7.6.2 Applicability of panel and Appellate Body rulings on GATT Articles III and XX

122. The Panel in *EC – Hormones* found the Appellate Body's jurisprudence under Articles III and XX of the GATT 1994 pertinent in its analysis of the terms "discrimination" and "disguised restriction on international trade". The Appellate Body disagreed with this finding:

> "We agree with the Panel's view that 'all three elements [of Article 5.5] need to be distinguished and addressed separately'.[139] We also recall our interpretation that Article 5.5 and, in particular, the terms 'discrimination or a disguised restriction on international trade', have to be read in the context of the basic obligations contained in Article 2.3, which requires that 'sanitary … *measures* shall not be *applied in a manner which would constitute a disguised restriction on international trade*'. (emphasis added)
>
> However, we disagree with the Panel on two points. First, in view of the structural differences between the standards of the *chapeau* of Article XX of the GATT 1994 and the elements of Article 5.5 of the *SPS Agreement*, the reasoning in our Report in *United States – Gasoline*, quoted by Panel, cannot be casually imported into a case involving Article 5.5 of the *SPS Agreement*. Secondly, in our view, it is similarly unjustified to assume applicability of the reasoning of the Appellate Body in *Japan – Alcoholic Beverages* about the inference that may be drawn from the sheer size of a tax differential for the application of Article III:2, second sentence, of the GATT 1994, to the quite different question of whether arbitrary or unjustifiable differences in levels of protection against risks for human life or health, 'result in discrimination or a disguised restriction on international trade'."[140]

123. The Appellate Body in *EC – Hormones* explained its reluctance to apply its jurisprudence under Article III:2 of the GATT 1994 to Article 5.5 of the SPS Agreement. The Appellate Body noted that while there was a "clear and linear relationship" between a tax differential and protection given to domestic products, no such clear relationship existed between differentials of levels of protection of human health and protection given to domestic products:

> "The differential involved in *Japan – Alcoholic Beverages* was a tax differential, which is very different from a differential in levels of protection. Unlike a differential in levels of protection, a tax differential is always expressed in quantitative terms and a significant tax differential in favour of domestic products will inevitably affect the competitiveness of imported products and thus afford protection to domestic products. There is a clear and linear relationship between a tax differential and the protection afforded to domestic products. There is, however, no such relationship between a differential in levels of human health protection and discrimination or disguised restriction on trade."[141]

124. In a later dispute, the Panel in *US – Poultry (China)* relied on the interpretation of discrimination in *US – Shrimp* to arrive at a conclusion on whether the US measure in question resulted in discrimination. The Panel stated:

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[138] Panel Report, *US – Poultry (China)*, paras. 7.280 and 7.282.
[139] The Appellate Body cited Panel Reports, *EC – Hormones (US)*, para. 8.184; and *EC – Hormones (Canada)*, para. 8.187.
[140] Appellate Body Report, *EC – Hormones*, paras. 238-239.
[141] Appellate Body Report, *EC – Hormones*, fn 251.

> "We also recall the finding of the Appellate Body in *US – Shrimp* that 'discrimination results not only when countries in which the same conditions prevail are differently treated, but also when the application of the measure at issue does not allow for an inquiry into the appropriateness of the regulatory program for the conditions prevailing in those exporting countries.' It would seem that a ban preventing the FSIS from considering China's application for equivalency would be just such a measure as that described by the Appellate Body."[142]

1.7.6.3 Applicability of panel ruling on Articles 3 and 4 of the TRIPS Agreement

125. In determining whether discrimination exists, in the context of Article 5.5, the Panel in *US – Poultry (China)* made reference to the language of the Panel in *Canada – Pharmaceutical Patents*, which dealt with the TRIPS Agreement.[143] The Panel noted:

> "We note that the Panel in *Canada – Pharmaceutical Patents* considered that 'discrimination' refers to 'results of the unjustified imposition of differentially disadvantageous treatment.' Therefore, a determination that 'discrimination' exists would still rest on whether the different treatment applied was 'justified'. Having determined that the differences in ALOPs are unjustified, we can reasonably conclude that the differences in ALOPs results in discrimination against China."[144]

1.7.7 Relationship with other paragraphs of Article 5

126. On the relationship between Articles 5.1 and 5.5, see paragraph 64 above.

127. See also paragraph 12 above, for a discussion on the relationship between Article 5.1 and the other provisions of Article 5.

1.7.8 Relationship with other provisions of the SPS Agreement

1.7.8.1 Article 2.2

128. On the relationship between Articles 2.2 and 5.5, see paragraphs 117 above.

1.7.8.2 Article 5.6

129. The Panel in *US – Poultry (China)* held that a finding, under Article 5.5, that a Member is applying different ALOPs does not take away the right of the importing Member to determine its ALOP particularly for the purpose of the analysis under Article 5.6. The Panel stated:

> "We note that Article 5.5 deals with determining whether a Member is applying distinctions that are arbitrary or unjustifiable in the application of ALOPs to the same risk. We note that the analysis under Article 5.5 is with respect to determining whether the Member is applying different ALOPs to the same risk. Article 5.6 deals with whether a particular measure is more trade restrictive than required to achieve the Member's ALOP. In our view, in a dispute where claims are made under both Articles 5.5 and 5.6 a finding of inconsistency with Article 5.5 cannot be taken to mean that the ALOP used in the analysis under 5.6 would always necessarily be the less restrictive ALOP of those being applied. Therefore, a finding that a Member is applying different ALOPs cannot be taken to mean that the Panel is determining which ALOP the Member should apply. A finding of inconsistency with Article 5.5 cannot deprive the importing Member of its prerogative to choose its own ALOP."[145]

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[142] Panel Report, *US – Poultry (China)*, para. 7.292.
[143] Panel Report, *US – Poultry (China)*, para. 7.289.
[144] Panel Report, *US – Poultry (China)*, para. 7.291.
[145] Panel Report, *US – Poultry (China)*, para. 7.333.

1.7.9 Relationship with other Agreements

130. On the relationship between Article 5.5 and Article XX of GATT 1994, see paragraphs 114-115 above.

131. With respect to the relationship between Article 5.5 and Articles 3 and 4 of the TRIPS Agreement, see paragraph 125 above.

1.8 Article 5.6

1.8.1 Applicability

132. The Panel in *EC – Approval and Marketing of Biotech Products* held that only SPS measures are governed by the provisions of Article 5.6. The Panel found that Article 5.6 was not applicable to the EC measures at issue as the Panel had found them not to be SPS measures within the definition of Annex A (1) of the SPS Agreement:

> "We note that, by its clear terms, Article 5.6 applies to '[SPS] measures'. Accordingly, for a particular measure to be subject to Article 5.6 it must be an SPS measure. Pursuant to Article 1 of the *SPS Agreement*, the Annex A(1) definition of the term 'SPS measure' is directly applicable to Article 5.6. We have found above that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term 'SPS measure' as it appears in Annex A(1). However, we also stated that in interpreting the term 'SPS measure', in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we proceed to analyse whether the provisions of Article 5.6 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.
>
> When analysing the Complaining Parties' claim under Article 5.1, we have highlighted the fact that Article 5.6 explicitly refers to '[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection'. It is therefore clear that the SPS measures at issue in Article 5.6 are those applied for achieving the appropriate level of protection.
>
> We found above that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve the European Communities' appropriate level of protection. It follows that that decision cannot be considered an 'SPS measure' within the meaning of Article 5.6. Reinforcing this view is the fact that the procedural decision to delay final approval decisions did not itself restrict trade. Trade was restricted as a result of a distinct measure, namely, the pre-marketing approval requirement which imposes a provisional marketing ban on biotech products. Consequently, the provisions of Article 5.6 support rather than undermine the provisional conclusion we have reached on the basis of the Annex A(1) definition.
>
> Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an 'SPS measure' within the meaning of Article 5.6 and Annex A(1). As only 'SPS measures' are subject to the provisions of Article 5.6, we consider that the provisions of Article 5.6 are not applicable to the European Communities' decision to apply a general moratorium on approvals.
>
> In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.6."[146]

133. In *Korea – Radionuclides*, the Panel found the obligation in Article 5.6 of the SPS Agreement to apply "not only when the measures are adopted, but throughout the time they remain in force."[147]

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[146] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1402–7.1406.

1.8.2 Three cumulative elements

1.8.2.1 General

134. In *Australia – Salmon*, with respect to the structure of Article 5.6, the Appellate Body identified three separate elements and found that these elements applied cumulatively:

> "We agree with the Panel that Article 5.6 and, in particular, the footnote to this provision, clearly provides a three-pronged test to establish a violation of Article 5.6. As already noted, the three elements of this test under Article 5.6 are that there is an SPS measure which:
>
> (1) is reasonably available taking into account technical and economic feasibility;
>
> (2) achieves the Member's appropriate level of sanitary or phytosanitary protection; and
>
> (3) is significantly less restrictive to trade than the SPS measure contested.
>
> These three elements are cumulative in the sense that, to establish inconsistency with Article 5.6, all of them have to be met. If any of these elements is not fulfilled, the measure in dispute would be consistent with Article 5.6. Thus, if there is no alternative measure available, taking into account technical and economic feasibility, *or* if the alternative measure does not achieve the Member's appropriate level of sanitary or phytosanitary protection, *or* if it is not significantly less trade-restrictive, the measure in dispute would be consistent with Article 5.6."[148]

135. In *Japan – Agricultural Products II*, the Appellate Body confirmed its finding set out at paragraph 134 above.[149]

1.8.2.2 Burden of proof

136. In *Japan – Agricultural Products II*, the Appellate Body considered that the burden rests on the complaining party to establish a prima facie case that there is an alternative measure that meets all three elements under Article 5.6 in order to establish a prima facie case of inconsistency with Article 5.6.[150]

1.8.2.2.1 A complainant must satisfy its burden of proof with scientific evidence

137. The Appellate Body in *Australia – Apples* found that, to analyse the alternative proposed measures, the Panel should also take into account scientific evidence. The Appellate Body stated:

> "This, too, is consistent with the view that a complainant pursuing a claim under Article 5.6 is not required to undertake or furnish a risk assessment relating to the alternative measure proposed. At the same time, we cannot conceive of how a complainant could satisfy its burden of demonstrating that its proposed alternative measure would meet the appropriate level of protection under Article 5.6 without relying on evidence that is scientific in nature. The objective of ensuring protection against risks to human, animal or plant life or health is key to SPS measures, to a Member's appropriate level of protection, and to the SPS Agreement as a whole. Furthermore, the basic obligations set out in Article 2 – which inform the more specific obligations in Article 5 – include the stipulation in Article 2.2 that SPS measures must

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[147] Panel Report, *Korea – Radionuclides*, para. 7.135.

[148] Appellate Body Report, *Australia – Salmon*, para. 194; and Panel Report, *Japan – Apples (21.5)*, para. 8.162.

[149] Appellate Body Report, *Japan – Agricultural Products II*, para. 95. See also Panel Reports, *US – Poultry (China)*, para. 7.331; and *Australia – Apples*, para. 7.1098.

[150] Appellate Body Report, *Japan – Agricultural Products II*, para. 126. See also Panel Reports, *US – Poultry (China)*, para. 7.332; and *Australia – Apples*, paras. 7.1104-7.1105.

> be based on scientific principles and not maintained without sufficient scientific evidence. This implies that evidence demonstrating that a proposed alternative measure takes adequate account of these key characteristics of SPS measures will necessarily form part of a complainant's attempt to prove that a contested SPS measure fails to meet the requirements of Article 5.6. In our view, this is also reinforced by the important role that science plays throughout the SPS Agreement in maintaining 'the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings.'"[151]

1.8.2.2.2 Role of experts

138. In *Australia – Apples* the Appellate Body stated that it had "certain reservations" about the fact that the Panel had specifically asked the experts whether the alternative measures suggested by New Zealand would achieve Australia's ALOP. The Appellate Body added that:

> "Experts may assist a panel is assessing the level of risk associated with SPS measures and potential alternative measures, but whether or not an alternative's measure's level of risk achieves a Member's appropriate level of protection is a question of legal characterization, the answer to which will determine the consistency or inconsistency of a Member's measure with its obligation under Article 5.6. Answering this question is not a task that can be delegated to scientific experts."[152]

1.8.2.3 Order of analysis

139. The Panel in *Australia – Apples* noted that previous panels and the Appellate Body had not established a specific order for analysing the three conditions of Article 5.6 test. Thus, the Panel concluded that it was at liberty to select the order of analysis that best suited its case:

> "Previous panels and the Appellate Body did not establish a specific order for analysing the three conditions of the Article 5.6 test. They followed different approaches. In *Australia – Salmon*, the Panel and the Appellate Body followed the order of the three conditions as they appear in footnote 3 to Article 5.6 of the SPS Agreement: they analysed the first, the second and then the third condition. Conversely, the Panel in *Japan – Agricultural Products II* analysed the first and third conditions of the Article 5.6 test before turning to the second condition. The compliance Panel in *Australia – Salmon (Article 21.5 – Canada)* followed a third approach. It first examined the second condition, which it described as the 'most controversial element' of the three-pronged Article 5.6 test. After having found that the second condition was fulfilled, the compliance Panel turned to the other two conditions.
>
> In light of Australia's request, the Panel will follow the same sequence in the present dispute in regard to the pest-specific measures contested by New Zealand (Measures 1-8 for fire blight, Measures 9-11 and 13 for European canker, and Measure 14 for ALCM). The Panel will first analyse whether the second condition of the Article 5.6 test is fulfilled, namely whether the alternative measures properly identified by New Zealand for these pest-specific measures achieve Australia's ALOP. Only if the Panel finds that the second condition is fulfilled, will it turn to the first and third of the three cumulative conditions under Article 5.6."[153]

1.8.3 Alternative measure

1.8.3.1 "another measure"

140. In *Korea – Radionuclides*, the respondent argued that because one of the components of the alternative measure suggested by the complainant was incorporated in the challenged measures, it

[151] Appellate Body Report, *Australia – Apples*, para. 364.
[152] Appellate Body Report, *Australia – Apples*, para. 384.
[153] Panel Report, *Australia – Apples,* paras. 7.1106-7.1107. See also Panel Report, *Korea – Radionuclides*, para. 7.118.

was not "another" measure within the meaning of footnote 3 to Article 5.6. The Panel disagreed with this interpretation, reasoning that "a measure cannot be rejected *a priori* because it contains some elements of the original measure, but only after full evaluation of all the factors in footnote 3 and Article 5.6."[154]

1.8.3.2 "reasonably available"

141. The Panel in *Australia – Salmon (Article 21.5 – Canada)*, while examining one of the four alternatives proposed by Canada, stated with respect to whether a measure was "reasonably available" within the meaning of footnote 3 in Article 5.6:

> "[S]ince one can assume that current Australian requirements are 'reasonably available taking into account technical and economic feasibility', also a regime without the consumer-ready requirements [the current Australian requirements] … would be so. Given that inspection and control to release from quarantine only product that meets the consumer-ready requirements would no longer be necessary, a regime without the consumer ready requirements would be even more reasonably available in the sense of Article 5.6."[155]

1.8.3.3 "taking into account technical and economic feasibility"

142. In *Japan – Apples (Article 21.5 – United States)*, the Panel was of the view that, when considering whether an alternative measure is reasonably available taking into account technical and economic feasibility, a panel should determine whether the alternative measure would constitute an option reasonably available taking into account technical and economic feasibility in the real world. In the Panel's opinion, the risk of incorrect enforcement is part of the technical feasibility of a measure.[156]

1.8.3.4 "to achieve the appropriate level of sanitary or phytosanitary protection"

143. In *Japan – Agricultural Products*, the Appellate Body shed light on the elements of the requirement under Article 5.6 not to adopt measures which are more restrictive than required to achieve the Member's appropriate level of protection:

> "Article 5.6 of the *SPS Agreement* prohibits SPS measures that are more trade-restrictive than required to achieve a Member's appropriate level of protection. According to the footnote to Article 5.6, a measure is considered more trade-restrictive than required if there is another SPS measure which:
>
> (1) is reasonably available taking into account technical and economic feasibility;
>
> (2) achieves the Member's appropriate level of protection; and
>
> (3) is significantly less restrictive to trade than the SPS measure contested.
>
> As we have stated in our Report in *Australia – Salmon*, these three elements are cumulative in nature."[157]

144. In *India – Agricultural Products*, the Appellate Body further held that:

> "[T]he identification of the respondent's appropriate level of protection is not *per se* the ultimate aim of the analysis. Rather, the ultimate aim in conducting this analysis is to determine whether a significantly less trade-restrictive alternative measure that would meet the respondent's appropriate level of protection is available."[158]

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[154] Panel Report, *Korea – Radionuclides*, para. 7.127.
[155] Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, para. 7.146.
[156] Panel Report, *Japan – Apples*, para. 8.171.
[157] Appellate Body Report, *Japan – Agricultural Products*, para. 93.
[158] Appellate Body Report, *India – Agricultural Products*, para. 5.223.

1.8.3.4.1 Distinction between "appropriate level of protection" and "SPS measure"

145. In *Australia – Salmon*, the Appellate Body stressed that the "appropriate level of protection" established by a Member and the "SPS measure" have to be clearly distinguished.[159] The first is an *objective*, the second is an *instrument* chosen to attain or implement that objective. What is required under Article 5.6 is an examination of whether possible alternative measures meet the appropriate level of protection as determined by the Member concerned:

> "[T]he words of Article 5.6, in particular the terms '*when establishing or maintaining* sanitary … protection', demonstrate that the determination of the level of protection is an element in the decision-making process which logically *precedes* and is *separate* from the establishment or maintenance of the SPS measure. It is the appropriate level of protection which determines the SPS measure to be introduced or maintained, not the SPS measure introduced or maintained which determines the appropriate level of protection. To imply the appropriate level of protection from the existing SPS measure would be to assume that the measure always achieves the appropriate level of protection determined by the Member. That clearly cannot be the case.
>
> We, therefore, conclude that the Panel's statement that 'to determine whether any of the alternative measures meet Australia's appropriate level of protection, we should […] examine whether these alternatives meet the level of protection currently achieved by the measure at issue' is wrong. What is required under Article 5.6 is an examination of whether possible alternative SPS measures meet the appropriate level of protection *as determined by the Member concerned*." [160]

146. In *Russia – Pigs (EU)*, the Panel reiterated that it would examine the importing Member's ALOP on the basis of the totality of evidence on the record. In that connection, while recognizing an SPS measure does not determine the ALOP, but rather that the measure is based on an ALOP, the Panel found it helpful to examine the SPS measures in question as "an important element in supporting the determination" of the Member's ALOP, in particular by providing an indication of the risk that the Member is willing to accept in respect of the entry and further spread of a disease in its territory.[161]

1.8.3.4.2 Relationship between "appropriate level of protection" and "risk"

147. The Appellate Body in *Australia – Apples* considered that the concept of "appropriate level of protection" also referred to as the "acceptable level of risk" is informed by the meaning of "risk" in the phrase "risk assessment" in Annex A(4) namely, an assessment of "the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences". The Appellate Body concluded that: "[W]e accept that the 'risk' associated with a pest or disease may encompass 'consequences'".[162]

1.8.3.4.3 Determining "appropriate level of …protection" as a "prerogative" of the Member concerned

148. The Appellate Body in *Australia – Salmon* emphasized that determining the appropriate level of protection is the prerogative of the Member concerned:

> "We do not believe that Article 11 of the DSU, or any other provision of the DSU or of the *SPS Agreement*, entitles the Panel or the Appellate Body, for the purpose of applying Article 5.6 in the present case, to substitute its own reasoning about the implied level of protection for that expressed consistently by Australia. The determination of the appropriate level of protection, a notion defined in paragraph 5 of

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[159] (*footnote original*) That the level of protection and the SPS measure applied have to be clearly distinguished results already from our Report in *European Communities – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 214.

[160] Appellate Body Report, *Australia – Salmon*, paras. 203-204.

[161] Panel Report, *Russia – Pigs (EU)*, para. 7.747.

[162] Appellate Body Report, *Australia – Apples*, para. 405.

> Annex A … is a *prerogative* of the Member concerned and not of a Panel or of the Appellate Body."[163]

149. In *Japan – Agricultural Products II*, the Panel emphasized that it was for Japan to determine its appropriate level of protection:

> "Both parties agree that it is up to Japan to determine its appropriate level of phytosanitary protection with respect to codling moth. We agree since the *SPS Agreement* (in paragraph 5 of Annex A) defines the 'appropriate level of … phytosanitary protection' as '[t]he level of protection *deemed appropriate by the Member* establishing a … phytosanitary measure to protect … plant life or health within its territory', *in casu*, the level deemed appropriate by Japan."[164]

150. The Appellate Body in *US/Canada – Continued Suspension* reviewed the jurisprudence relating to Members' prerogative to choose their appropriate level of protection. The Appellate Body then went on to recall the requirements within the SPS Agreement that facilitate consistency of Members level of protection with the Agreement's rationale:

> "It is the 'prerogative' of a WTO Member to determine the level of protection that it deems appropriate. The SPS measure is the 'instrument' chosen by the WTO Member to implement its sanitary or phytosanitary objective. Based on the wording of Article 5.6 of the *SPS Agreement*, the Appellate Body has explained that the 'determination of the level of protection is an element in the decision-making process which logically precedes and is separate from the establishment or maintenance of the SPS measure. In other words, the appropriate level of protection determines the SPS measure to be introduced or maintained, rather than the appropriate level of protection being determined by the SPS measure. The Appellate Body has also found that 'the *SPS Agreement* contains an implicit obligation to determine the appropriate level of protection.' Although it need not be determined in quantitative terms, the level of protection cannot be determined 'with such vagueness or equivocation that the application of the relevant provisions of the *SPS Agreement* … becomes impossible'."[165]

1.8.3.4.4 Implicit obligation to determine the appropriate level of protection

151. In *Australia – Salmon*, the issue arose whether a WTO Member is obliged to determine its appropriate level of protection. While the Panel had held that no such obligation existed[166], the Appellate Body determined that such an obligation exists under the SPS Agreement, albeit only implicitly. However, it also held that where a Member fails to determine its appropriate level of protection, this level of protection can be established by a panel on the basis of existing relevant SPS measures:

> "We recognize that the *SPS Agreement* does not contain an *explicit* provision which obliges WTO Members to determine the appropriate level of protection. Such an obligation is, however, implicit in several provisions of the *SPS Agreement*, in particular, in paragraph 3 of Annex B, Article 4.1, Article 5.4 and Article 5.6 of the *SPS Agreement* …
>
> We thus believe that the *SPS Agreement* contains an implicit obligation to determine the appropriate level of protection. We do not believe that there is an obligation to determine the appropriate level of protection in quantitative terms. This does not mean, however, that an importing Member is free to determine its level of protection with such vagueness or equivocation that the application of the relevant provisions of the *SPS Agreement,* such as Article 5.6, becomes impossible. It would obviously be wrong to interpret the *SPS Agreement* in a way that would render nugatory entire

[163] Appellate Body Report, *Australia – Salmon*, para. 199. See also Appellate Body Report, *Australia – Apples*, para. 342.
[164] Panel Report, *Japan – Agricultural Products II*, para. 8.81.
[165] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 523.
[166] Panel Report, *Australia – Salmon*, para. 8.107.

> Articles or paragraphs of Articles of this Agreement and allow Members to escape from their obligations under this Agreement.
>
> … we believe that in cases where a Member does not determine its appropriate level of protection, or does so with insufficient precision, the appropriate level of protection may be established by Panels on the basis of the level of protection reflected in the SPS measure actually applied. Otherwise, a Member's failure to comply with the implicit obligation to determine its appropriate level of protection – with sufficient precision – would allow it to escape from its obligations under this Agreement and, in particular, its obligations under Articles 5.5 and 5.6."[167]

152. In *Australia – Salmon*, the Panel found that "the level of protection implied or reflected in a sanitary measure or regime imposed by a WTO Member can be presumed to be at least as high as the level of protection considered to be appropriate by that Member."[168] The Appellate Body disagreed with this statement, in particular because Australia had explicitly stated that its level of protection was different from the one reflected in its measure. The Appellate Body stressed that an explicit statement by a Member about its level of protection could not be questioned by a panel or the Appellate Body.

153. In *US/Canada – Continued Suspension*, the Appellate Body stated that "[a]lthough it is for a WTO Member to choose its level of protection, the *SPS Agreement* provides for disciplines that a Member must respect when it has done so".[169]

1.8.3.4.5 Test for the Panel to determine whether an alternative measure achieves a WTO Member's ALOP

154. The Appellate Body in *Australia – Apples* considered that a panel first has to identify both ALOPs, the one achieved by the proposed alternative measure and the one that the importing Member has identified. Thereafter, the Panel has to compare them and determine whether the level of protection of the proposed alternative measure meets or exceeds the ALOP of the Member, as follows:

> "Under Article 5.6, in order to assess whether a significantly less trade-restrictive alternative measure that would meet the appropriate level of protection is available, we consider that a panel must identify both the level of protection that the importing Member has set as its appropriate level, and the level of protection that would be achieved by the alternative measure put forth by the complainant. Thereupon the Panel will be able to make the requisite comparison between the level of protection that would be achieved by the alternative measure and the importing Member's appropriate level of protection. If the level of protection achieved by the proposed alternative meets or exceeds the appropriate level of protection, then (assuming that the other two conditions in Article 5.6 are met) the importing Member's SPS measure is more trade restrictive than necessary to achieve its desired level of protection."[170]

155. The Appellate Body then established three requirements to determine that an alternative proposed measure achieves the WTO Member's ALOP:

> "In keeping with this approach, we must ascertain whether the factual findings made by the Panel and undisputed facts in the record demonstrate that New Zealand has established that its proposed alternative measure would meet Australia's appropriate level of protection. In particular, we must ascertain whether the Panel made relevant factual findings or whether there are sufficient undisputed facts on the Panel record that would allow us to: (i) identify the level of protection that Australia has set as its appropriate level; (ii) determine what level of protection would be achieved by New Zealand's alternative measure; and (iii) determine whether the level of protection

[167] Appellate Body Report, *Australia – Salmon*, paras. 205-207. See also Appellate Body Report, *Australia – Apples*, para. 343.
[168] Panel Report, *Australia – Salmon*, para. 8.173.
[169] Appellate Body Reports, *US/Canada – Continued Suspension*, fn 1088.
[170] Appellate Body Report, *Australia – Apples*, para. 344.

> that would be achieved by the alternative measure would satisfy Australia's appropriate level of protection."[171]

156. The Appellate Body in *Australia – Salmon* reversed the Panel's conclusion that that "to determine whether any of the alternative measures meet Australia's appropriate level of protection, we should […] examine whether these alternatives meet the level of protection currently achieved by the measure at issue". In doing so, the Appellate Body noted that "[w]hat is required under Article 5.6 is an examination of whether possible alternative SPS measures meet the appropriate level of protection *as determined by the Member concerned*."[172]

1.8.3.5 Whether the alternative is significantly less restrictive to trade than the SPS measure contested

157. In *Australia – Salmon*, the Panel examined whether Canada's proposed alternative measures met the requirement of being alternative measures that are "significantly less restrictive to trade".[173] The Panel found in Canada's favour, stating:

> "Canada argues that all four alternative options set out in the 1996 Final Report are significantly less trade restrictive. In its request for access to the Australian market, Canada examined in particular headless, eviscerated product and advocated that these products could be safely imported. We recall that the measure imposed by Australia (in effect, certain heat treatment requirements) *prohibits* the importation into Australia of fresh, chilled or frozen salmon, including the salmon products further examined. All four alternative options outlined above would *allow* imports of the salmon products further examined, albeit under specific conditions (e.g., the salmon products would have to be retail-ready fillets, eviscerated, headless or gilled, etc...). We consider that even imposing the most stringent of these specific conditions would still be significantly less restrictive to trade than an outright prohibition. As opposed to any of the other conditions, heat treatment actually changes the nature of the product and limits its use. Heat-treated salmon can obviously no longer be consumed as fresh salmon. Eviscerated, headless or filleted salmon, on the other hand, can either be consumed as fresh salmon or cooked salmon. We consider, therefore, that Canada has raised a presumption that all four alternatives outlined in the 1996 Final Report are 'significantly less restrictive to trade' than the measure in dispute and that Australia has not rebutted this presumption."[174]

1.8.4 Burden of proof

158. In *Japan – Agricultural Products II*, the Appellate Body reversed the Panel's findings on Article 5.6, holding that the Panel could not have made the finding at issue, because the United States as the complaining party had not made a relevant claim and, *a fortiori*, had not established a *prima facie* case. The Appellate Body then stressed that the investigative authority of a panel did not stretch so far as to "make the case for a complaining party":

> "Pursuant to the rules on burden of proof set out above, we consider that it was for the United States [complainant] to establish a *prima facie* case that there is an alternative measure that meets all three elements under Article 5.6 in order to establish a *prima facie* case of inconsistency with Article 5.6. Since the United States did not even claim before the Panel that the 'determination of sorption levels' is an alternative measure which meets the three elements under Article 5.6, we are of the opinion that the United States did not establish a *prima facie* case that the 'determination of sorption levels' is an alternative measure within the meaning of Article 5.6."[175]

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[171] Appellate Body Report, *Australia – Apples*, para. 368.
[172] Appellate Body Report, *Australia – Salmon*, para. 204.
[173] Panel Reports, *Australia – Salmon*, para. 8.182; *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.150-7.153; and *Japan – Agricultural Products II*, paras. 8.79, 8.89, 8.95-8.96 and 8.103-8.104.
[174] Panel Report, *Australia – Salmon*, para. 8.182.
[175] Appellate Body Report, *Japan – Agricultural Products II*, para. 126.

159. In *India – Agricultural Products*, the Panel opined that "in order to discharge its burden of proof under the second element of Article 5.6, the United States' assertion that its alternative measure satisfies India's ALOP must be based on evidence that demonstrates that its alternative takes adequate account of scientific principles and the requirement that SPS measures are not maintained without sufficient scientific information."[176]

160. On appeal, the Appellate Body rejected India's contention that it is for the complainant to identify the respondent Member's ALOP. The Appellate Body pointed out that:

> "[T]here is a distinction between the burden of proof borne by a complainant in establishing a claim under Article 5.6 of the SPS Agreement, on the one hand, and the analysis that must be undertaken by a panel in assessing such a claim, on the other hand. In order to establish a claim under Article 5.6, a complainant must put forth arguments and evidence in respect of all relevant elements under this provision, including the respondent's appropriate level of protection and the level of protection of the proposed alternative measure. At the same time, the panel examining such claim is charged with, inter alia, identifying the level of protection of the Member whose SPS measure is challenged and the level of protection of the proposed alternative measure. In conducting this examination, the panel is not constrained to verifying only whether or not the complainant's allegations in this regard are substantiated. This is particularly so with respect to a responding Member's appropriate level of protection."[177]

161. The Appellate Body emphasized that "in the context of the WTO dispute settlement proceedings, a responding Member is generally better placed … to know what objective it has set in terms of the level of SPS protection it wishes to achieve" and that "typically a panel adjudicating a claim under Article 5.6 of the SPS Agreement would be expected to accord weight to the respondent's articulation of its appropriate level of protection."[178] The Appellate Body cautioned at the same time that a panel should not "defer completely to a respondent's characterization of its own appropriate level of protection", but rather "ascertain the respondent's appropriate level of protection on the basis of the totality of the arguments and evidence on the record."[179]

1.8.5 Relationship with other paragraphs of Article 5

1.8.5.1 Article 5.1

162. The Panel in *Australia – Apples*, in its Article 5.1 analysis, found that Australia's risk assessment was flawed and over-estimated the risks from New Zealand's apples. In its Article 5.6 analysis, the Panel considered that these errors in the risk assessment meant that Australia's assessment of the risks associated with the alternative measures proposed by New Zealand was exaggerated.[180] However, the Appellate Body established that the obligations in Article 5.1 and Article 5.6 are not dependent upon each other, as follows:

> "While several aspects of these relationships – between the basic rights and obligations set out in Article 2, in particular its second paragraph, on the one hand, and the more specific elaborations of these basic obligations in Article 5, on the other hand – have thus been clarified, the relationships between the various paragraphs within Article 5 remain relatively unexplored. As a general matter, we see the various paragraphs of Article 5 as setting out distinct legal obligations with which Members must comply. For example, Article 5.1 seeks to ensure that a Member's SPS measure has an appropriate scientific basis, whereas Article 5.6 seeks to ensure that appropriate limits are placed on the trade-restrictiveness of a Member's SPS measure. A complainant may challenge the consistency of a specific SPS measure with either or both of these obligations. When a complainant seeks to establish violations of both obligations, some of the factual circumstances that it chooses to rely upon to establish a violation of one obligation may also be relevant to, and appropriately form part of,

[176] Panel Report, *India – Agricultural Products*, para. 7.584.
[177] Appellate Body Report, *India – Agricultural Products*, para. 5.220.
[178] Appellate Body Report, *India – Agricultural Products*, para. 5.221.
[179] Appellate Body Report, *India – Agricultural Products*, para. 5.221.
[180] Panel Report, *Australia – Apples*, para. 7.1149.

> the evidence upon which it relies to establish a violation of the other, separate, obligation. However, the obligations in Article 5.1 and Article 5.6 are not dependent upon each other. Thus, the legal analysis of an SPS measure's consistency with Article 5.1 is separate and distinct from the legal analysis of that measure's consistency with Article 5.6. Violation of one obligation does not, without more, imply the violation of the other. As the Appellate Body opined in *Australia – Salmon*, an SPS measure that is consistent with Article 5.1 may nonetheless be inconsistent with either Article 5.5 or Article 5.6, or with both. "[181]

163. See also paragraph 12 above, for a discussion on the relationship between Article 5.1 and the other provisions of Article 5.

1.8.6 Relationship with other provisions of the SPS Agreement

1.8.6.1 Article 2.2

164. In *Australia – Salmon*, the Panel noted that "Article 5.6 must be read in context … an important part of the context of Article 5 is Article 2. We consider that Article 5.6 should, in particular, be read in light of Article 2.2".[182] The Appellate Body reversed the Panel's finding because it found that the Panel had examined the wrong measure.[183] The Panel in *Japan – Agricultural Products II* reached the same conclusion on the relationship between Articles 2.2 and 5.6. The Appellate Body did not address this issue on appeal.[184]

165. In *Japan – Agricultural Products II*, the Panel noted that its "findings under Article 5.6 would stand even if the measure in dispute were not in violation of Article 2.2".[185] It added that "even if we were to have found that Japan's measure is maintained with sufficient scientific evidence in accordance with Article 2.2, we would then be called upon to examine whether the measure is consistent with Article 5.6."[186] The Appellate Body did not specifically address this statement on appeal.

166. In *Australia – Apples*, the Appellate Body recalled its earlier finding that Article 2.2 informs, imparts meaning to, and is made operative in other provisions of the SPS Agreement, including some of the more specific obligations set out in Article 5. The Appellate Body took "particular note of the similarities between the requirement in Article 2.2 that Members apply their SPS measures 'only to the extent necessary to protect', and the requirement in Article 5.6 that SPS measures 'be no more trade restrictive than required to achieve' the relevant objectives".[187]

167. In *India – Agricultural Products*, the Panel grappled with the question whether the notion of "necessity" is different under Articles 2.2 and 5.6. In that regard, the Panel noted the common elements of the "necessity" tests found in Article XX of the GATT 1994, Article XIV of the GATS, Article 2.2 of the TBT Agreement and Article 5.6 of the SPS Agreement.[188] To the Panel, "the Appellate Body's interpretation of each of these provisions is probative of the relationship between Article 2.2 and Article 5.6 of the SPS Agreement."[189] On these grounds, and taking into account that Article 5.6 elaborates on the more specific obligation in Article 2.2, the Panel concluded that "a finding that a measure is inconsistent with Article 5.6 may lead to a presumption that the same measure is inconsistent with the obligation in Article 2.2".[190]

1.8.6.2 Articles 5.4 to 5.6 and Articles 2.2 and 2.3

168. The Panel in *EC – Hormones (Canada)* held that Articles 5.4 to 5.6 are specific applications of the obligations under Articles 2.2 and 2.3. See paragraph 91 above.

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[181] Appellate Body Report, *Australia – Apples*, para. 341. See also ibid. para. 354.
[182] Panel Report, *Australia – Salmon*, para. 8.165.
[183] Appellate Body Report, *Australia – Salmon*, para. 213.
[184] Panel Report, *Japan – Agricultural Products II*, para. 8.71.
[185] Panel Report, *Japan – Agricultural Products II*, para. 7.4.
[186] Panel Report, *Japan – Agricultural Products II*, para. 8.102.
[187] Appellate Body Report, *Australia – Apples*, para. 339.
[188] Appellate Body Report, *India – Agricultural Products*, para. 7.611.
[189] Panel Report, *India – Agricultural Products*, para. 7.613.
[190] Panel Report, *India – Agricultural Products*, para. 7.614.

1.8.7 Relationship with other Agreements

169. The Panels in *US – Clove Cigarettes* and *US – Tuna II (Mexico)* discussed the relationship between Article 5.6 of the SPS Agreement and Article 2.2 of the TBT Agreement.[191] See the Section on Article 2.2 of the TBT Agreement.

1.9 Article 5.7

1.9.1 Whether Article 5.7 operates as a qualified exemption or an autonomous right

170. The Appellate Body in *Japan – Agricultural Products II* referred to Article 5.7 as a "qualified exemption":

> "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless."[192]

171. The Panel in *EC – Approval and Marketing of Biotech Products*, however, disagreed with the Appellate Body's characterization of Article 5.7 as a qualified exemption from Article 2.2. Instead, the Panel applied the Appellate Body's logic in *EC – Tariff Preferences* and *EC – Hormones* and found that Article 5.7 establishes an autonomous right of the importing Member:

> "Thus, we find the general test provided by the Appellate Body in *EC – Tariff Preferences* to be applicable, and application of that test leads us to the conclusion that Article 5.7 should be characterized as a right and not an exception from a general obligation under Article 2.2.[193] In other words, we consider that in the same way that 'Article 3.1 of the SPS Agreement … excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement', Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7."[194]

172. In *EC – Approval and Marketing of Biotech Products*, the Panel however stressed that Article 5.7 does not establish an absolute or unqualified right. The Panel recalled that in *Japan – Agricultural Products II*, the Appellate Body made clear that there are four cumulative requirements in Article 5.7 which must be met in order for a Member to adopt and maintain a provisional SPS measure consistently with Article 5.7 and speculated that these requirements were the reason why the Appellate Body in *Japan – Agricultural Products II* emphasised that "Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[195]

173. In *US/Canada – Continued Suspension*, the Appellate Body clarified the purpose of Article 5.7. The Appellate Body held that this provision intervenes in cases where a Member would revise its SPS measure in light of scientific progresses but where relevant scientific evidence does not allow performance of an adequate risk assessment:

> "We agree that scientific progress may lead a WTO Member and international organizations to reconsider the risk assessment underlying an SPS measure. In some cases, new scientific developments will permit a WTO Member to conduct a new risk assessment with the sufficient degree of objectivity. There may be situations, however, where the new scientific developments themselves do not permit the

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[191] Panel Reports, *US – Clove Cigarettes*, paras. 7.365-7.366, and *US – Tuna II (Mexico)*, paras. 7.461-7.464.

[192] Appellate Body Report, *Japan – Agricultural Products II*, para. 80.

[193] *(footnote original)* Regarding our use of the term "right", we note that the Appellate Body's test in *EC – Tariff Preferences* does not provide a term to characterize the permissive provision in the kind of relationship we found to exist between Article 2.2 and Article 5.7. However, as we have noted, the Appellate Body referred to the relationship between Articles 3.1 and 3.3 as an illustration of the relevant kind of relationship. We have also pointed out that in *EC – Hormones*, the Appellate Body referred to the permissive provision, Article 3.3, as an "autonomous right", noting also that Article 3.3 does not constitute an exception from a general obligation under Article 3.1.

[194] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2969.

[195] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2973.

performance of a new risk assessment that is sufficiently objective. Such a situation would fall within the scope of Article 5.7 of the *SPS Agreement*."[196]

1.9.2 Scope

174. The Panel in *EC – Approval and Marketing of Biotech Products* found that just because an SPS measure was "provisionally adopted" does not mean that it falls within the ambit of Article 5.7. Basing its views on the manner in which the provision was drafted and on the Appellate Body's jurisprudence, the Panel found that the provisional adoption of an SPS measures is not a condition for the applicability of Article 5.7, but rather the provisional adoption of an SPS measure is permitted if the measure satisfies the criteria set forth in Article 5.7:

> "The first sentence of Article 5.7 provides in relevant part that 'in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information'. The first sentence follows a classic 'if – then' logic: if a certain condition is met (*in casu*, insufficiency of relevant scientific evidence), a particular right is conferred (*in casu*, the right provisionally to adopt an SPS measure based on available pertinent information). Thus, it is clear that Article 5.7 is applicable whenever the relevant condition is met, that is to say, in every case where relevant scientific evidence is insufficient.[197] The provisional adoption of an SPS measure is not a condition for the applicability of Article 5.7. Rather, the provisional adoption of an SPS measure is permitted by the first sentence of Article 5.7.
>
> If the provisional adoption of an SPS measure had been intended as a condition for the applicability of Article 5.7, the first sentence of Article 5.7 would, in our view, have opened with a different phrase, such as 'In cases where a Member provisionally adopts an SPS measure …'. Also, we note that in *Japan – Apples* the Appellate Body stated that 'the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence'. The Appellate Body made no mention of any additional 'triggering factors'."[198]

175. In *US/Canada – Continued Suspension*, the Appellate Body held that Article 5.7 is concerned with situations where deficiencies in the body of scientific evidence do not allow a WTO Member to arrive at a sufficiently objective conclusion in relation to risk.[199]

1.9.3 Four cumulative requirements

176. In *Japan – Agricultural Products II*, the Appellate Body identified four requirements imposed upon a Member having recourse to this provision. The Appellate Body added that these four requirements are cumulative in nature:

> "Article 5.7 of the *SPS Agreement* sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:
>
> (1) imposed in respect of a situation where 'relevant scientific information is insufficient'; and
>
> (2) adopted 'on the basis of available pertinent information'.
>
> Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

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[196] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 701.

[197] *(footnote original)* When we refer to the "applicability of Article 5.7", we address the issue of whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case, a Member must, of course, satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7.

[198] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.2939 and 7.240.

[199] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 677.

> (1) 'seek[s] to obtain the additional information necessary for a more objective assessment of risk'; and
>
> (2) 'review[s] the … measure accordingly within a reasonable period of time'.
>
> These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[200]

177. In *EC – Approval and Marketing of Biotech Products*, the Panel held that the first sentence of Article 5.7 relates to the adoption of a provisional SPS measure while the second sentence sets forth the applicable requirements relating to the maintenance of the provisional SPS measure.[201]

1.9.3.1 "where relevant scientific evidence is insufficient"

1.9.3.1.1 Meaning

178. In upholding the Panel's finding that Japan's phytosanitary measure at issue was not imposed in a situation "where relevant scientific evidence is insufficient", the Appellate Body in *Japan – Apples* said that "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement:

> "[J]apan's reliance on the opposition between evidence 'in general' and evidence relating to specific aspects of a particular subject matter is misplaced. The first requirement of Article 5.7 is that there must be insufficient scientific evidence. When a Panel reviews a measure claimed by a Member to be provisional, that Panel must assess whether 'relevant scientific evidence is insufficient'. This evaluation must be carried out, not in the abstract, but in the light of a particular inquiry. The notions of 'relevance' and 'insufficiency' in the introductory phrase of Article 5.7 imply a relationship between the scientific evidence and something else. Reading this introductory phrase in the broader context of Article 5. of the *SPS Agreement*, which is entitled 'Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection', is instructive in ascertaining the nature of the relationship to be established. Article 5.1 sets out a key discipline under Article 5, namely that 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment … of the risks to human, animal or plant life or health'. This discipline informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a 'more objective assessment of risks'. These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it 'general' or 'specific', in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan."[202]

179. The Appellate Body in *Japan – Apples* also rejected Japan's interpretation of Article 5.7 through the concept of "scientific uncertainty", and said that the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific

[200] Appellate Body Report, *Japan – Agricultural Products II*, para. 89. In this case, the Panel examined whether the measure at issue met with these four requirements. See Panel Report, *Japan – Agricultural Products II*, paras. 8.56-8.57 and 8.60.
[201] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.3251 and 7.3252.
[202] Appellate Body Report, *Japan – Apples*, para. 179.

evidence and these two concepts – "insufficiency of scientific evidence" and "scientific uncertainty" – are not interchangeable:

> "Japan challenges the Panel's statement that Article 5.7 is intended to address only 'situations where little, or no, reliable evidence was available on the subject matter at issue' because this does not provide for situations of 'unresolved uncertainty'. Japan draws a distinction between 'new uncertainty' and 'unresolved uncertainty', arguing that both fall within Article 5.7. According to Japan, 'new uncertainty' arises when a new risk is identified; Japan argues that the Panel's characterization that 'little, or no, reliable evidence was available on the subject matter at issue' is relevant to a situation of 'new uncertainty'. We understand that Japan defines 'unresolved uncertainty' as uncertainty that the scientific evidence is not able to resolve, despite accumulated scientific evidence. According to Japan, the risk of transmission of fire blight through apple fruit relates essentially to a situation of 'unresolved uncertainty'. Thus, Japan maintains that, despite considerable scientific evidence regarding fire blight, there is still uncertainty about certain aspects of transmission of fire blight. Japan contends that the reasoning of the Panel is tantamount to restricting the applicability of Article 5.7 to situations of 'new uncertainty' and to excluding situations of 'unresolved uncertainty'; and that, by doing so, the Panel erred in law.
>
> We disagree with Japan. The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of 'scientific uncertainty'."[203]

180. The Panel in *EC – Approval and Marketing of Biotech Products* rejected the European Communities' argument that the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member:

> "While the Appellate Body has said that the notion of 'insufficiency' implies a 'relationship' between the scientific evidence and something else, it nowhere said that the notion of 'insufficiency' implies a relationship between the scientific evidence and the matters of concern to the legislator. The Appellate Body identified, and acknowledged the existence of, only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1.
>
> …
>
> … relevant scientific evidence is insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). At any rate, this is the interpretation of the concept of 'insufficiency' in Article 5.7 which we believe to be correct."[204]

181. In *US/Canada – Continued Suspension*, the Appellate Body added a factor to be considered in determining the insufficiency of scientific evidence within the meaning of Article 5.7. In its view, the mere fact that further scientific investigation is possible does not, by itself, mean that the relevant scientific evidence is insufficient:

> "The Appellate Body has explained that 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*.' The body of scientific evidence underlying a risk assessment can always be supplemented with additional information. Indeed, the nature of scientific inquiry is such that it is always possible to conduct more research or obtain additional information. The possibility of conducting further research or of analyzing

[203] Appellate Body Report, *Japan – Apples*, paras. 183-184.
[204] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.3234 and 7.3237.

> additional information, by itself, should not mean that the relevant scientific evidence is or becomes insufficient."[205]

182. The Appellate Body in *US/Canada – Continued Suspension*, considered that the existence of scientific controversy should not lead to the conclusion that the relevant scientific evidence is "insufficient". For the Appellate Body, divergent or minority views that are from respected and qualified sources are sufficient for the adoption of provisional SPS measures under Article 5.7:

> "Article 5.7 begins with the requirement that the 'relevant scientific evidence' be insufficient'. As explained earlier, the relevant scientific evidence is 'insufficient' where 'the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*.' Under Article 5.1, WTO Members are allowed to base SPS measures on divergent or minority views provided they are from a respected and qualified source. Thus the existence of scientific controversy in itself is not enough to conclude that the relevant scientific evidence is 'insufficient'. It may be possible to perform a risk assessment that meets the requirements of Article 5.1 even when there are divergent views in the scientific community in relation to a particular risk. By contrast, Article 5.7 is concerned with situations where deficiencies in the body of scientific evidence do not allow a WTO Member to arrive at a sufficiently objective conclusion in relation to risk. When determining whether such deficiencies exist, a Member must not exclude from consideration relevant scientific evidence from any qualified and respected source. Where there is, among other opinions, a qualified and respected scientific view that puts into question the relationship between the relevant scientific evidence and the conclusions in relation to risk, thereby not permitting the performance of a sufficiently objective assessment of risk on the basis of the existing scientific evidence, then a Member may adopt provisional measures under Article 5.7 on the basis of that qualified and respected view."[206]

183. In *Korea – Radionuclides*, the Panel rejected the respondent's argument about the insufficiency of scientific information relating to potential future contamination, as opposed to the existing contamination. The Panel noted that such a risk is not limited to the particular emergency that was subject to the dispute, but could happen in any nuclear power plant at any time. In the Panel's view, this "is precisely the kind of inherent and permanent uncertainty that Article 5.7 was not meant to address."[207] The Panel added that "if another incident were to occur, Korea would be within its rights, to re-evaluate the sanitary risk posed by food products affected by that incident and impose appropriate SPS measures."[208]

1.9.3.1.2 Existence of an international standard does not prove sufficiency of evidence for purposes of Article 5.7 of the SPS Agreement

184. In *US/Canada – Continued Suspension*, the Appellate Body considered that whenever a Member chooses a higher level of protection than the level set up in international standards, it may consider that the available scientific evidence is insufficient and adopt provisional SPS measures under Article 5.7. For the Appellate Body, the existence of an international standards does not prove sufficiency of the scientific evidence supporting provisional SPS measures, especially when a Member has chosen a higher level of protection:

> "Article 3.2 is inapplicable where a Member chooses a level of protection that is higher than would be achieved by a measure based on an international standard. The presumption in Article 3.2 cannot be interpreted to imply that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher level of protection.
>
> This is borne out by Article 5.7, which provides that WTO Members may adopt provisional SPS measures 'on the basis of available pertinent information, including

[205] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 702.
[206] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 677.
[207] Panel Report, *Korea – Radionuclides*, para. 7.95.
[208] Panel Report, *Korea – Radionuclides*, para. 7.95.

> that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members'. There is no indication in Article 5.7 that a WTO Member may not take a provisional SPS measure wherever a relevant international organization or another Member has performed a risk assessment. Information from relevant international organizations may not necessarily be considered 'sufficient' to perform a risk assessment, as it may be part of the 'available pertinent information' which provides the basis for a provisional SPS measure under Article 5.7. Moreover, scientific evidence that may have been relied upon by an international body when performing the risk assessment that led to the adoption of an international standard at a certain point in time may no longer be valid, or may become insufficient in the light of subsequent scientific developments."[209]

185. The Appellate Body in *US/Canada – Continued Suspension* then took the view that, while it is reasonable for a WTO Member challenging the inconsistency with Article 5.7 of provisional measure to put forward an international standard as evidence that the scientific evidence is not insufficient to perform a risk, this evidence is not dispositive and may be rebutted by the Member taking the provisional SPS measure:

> "In our view, it is reasonable for a WTO Member challenging the consistency with Article 5.7 of a provisional SPS measure adopted by another Member to submit JECFA's risk assessments and supporting studies leading to the adoption of international standards as evidence that the scientific evidence is not insufficient to perform a risk assessment. However, such evidence is not dispositive and may be rebutted by the Member taking the provisional SPS measure.
>
> … As we pointed out above, the existence of an international standard does not create a legal presumption of sufficiency for purposes of Article 5.7." [210]

186. In *US/Canada – Continued Suspension*, the Appellate Body made it clear that while the existence of an international standard means that the relevant scientific evidence is not insufficient within Article 5.7, when a Member adopts a level of protection higher than the level within an international standard, a panel should not apply a stricter legal test to assess insufficiency of the evidence under Article 5.7[211]:

> "[T]he existence of an international standard for which a risk assessment was conducted could be offered as evidence in support of an assertion that the relevant scientific evidence is not insufficient within the meaning of Article 5.7 of the *SPS Agreement*. It is an evidentiary issue in the sense that the scientific information underlying the international standard has probative value as to the sufficiency of the scientific evidence needed for conducting a risk assessment at a discrete point in time. However, in circumstances where a Member adopts a higher level of protection than that reflected in the international standard, the legal test that applies to the 'insufficiency' of the evidence under Article 5.7 is not made stricter."[212]

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[209] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 694 and 695.

[210] Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 696 and 697.

[211] In para. 698 of the Appellate Body Reports, *US/Canada – Continued Suspension*, the Appellate Body criticised the Panel's adoption of a critical mass test in its interpretation of Article 5.7. The Panel had found:

> "We therefore conclude that if relevant evidence already exists, not any degree of insufficiency will satisfy the criterion under Article 5.7 that 'relevant scientific evidence is insufficient'. Having regard to our reasoning above, particularly with respect to scientific uncertainty and the existence of international standards, we consider that, depending on the existing relevant evidence, there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. In the present case where risk assessments have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risks assessments."

Panel Reports, *US – Continued Suspension*, para. 7.648; and *Canada – Continued Suspension*, para. 7.626.

[212] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 708.

187. In *Russia – Pigs (EU)*, the Panel distinguished the situation before the Appellate Body in *US/Canada – Continued Suspension* on the grounds that in *Russia – Pigs (EU)* the responding Member claimed that challenged measures were based on an international standard "to the extent possible".[213] This, according to the Panel, implied the respondent's recognition "of the scientific basis of the international standard relevant for [that] dispute", which the Panel took into account in determining whether the relevant scientific evidence is insufficient within the meaning of Article 5.7.[214]

1.9.3.1.3 The standard of insufficiency

188. See also Article 2.2 above, regarding the threshold of insufficiency within Article 2.2 of the SPS Agreement.

189. In *US/Canada – Continued Suspension*, the Appellate Body rejected the insufficiency threshold set by the Panel in its assessment of the extent of scientific knowledge which might command revision of the provisional SPS measures. The Appellate Body then submitted its own interpretation of the insufficiency requirement within Article 5.7:

> "[T]he Panel applied an excessively high threshold in relation to the new scientific evidence which is required to render previously sufficient scientific evidence 'insufficient' within the meaning of Article 5.7. … [T]he Panel erred to the extent that it considered that a paradigmatic shift in the scientific knowledge was required in order to render the scientific evidence relied by JECFA now 'insufficient' within the meaning of Article 5.7. The 'insufficiency' requirement in Article 5.7 does not imply that new scientific evidence must entirely displace the scientific evidence upon which an international standard relies. It suffices that new scientific developments call into question whether the body of scientific evidence still permits of a sufficiently objective assessment of risk."[215]

190. In *Korea – Radionuclides*, the Panel noted "that scientific evidence need not be 100% complete or perfect to be sufficient to form the basis for an objective assessment of the risk."[216]

1.9.3.1.4 The relevant period for assessment of "insufficiency of relevant scientific evidence"

191. In *EC – Approval and Marketing of Biotech Products*, the Panel concluded, based on a textual reading of the first sentence of Article 5.7, that whether there was insufficient relevant scientific evidence must be assessed by reference to the time the measure was adopted:

> "Since the phrase '[i]n cases where relevant scientific evidence is insufficient' is part of the first sentence of Article 5.7, and since the above considerations lead us to conclude that the requirements contained in the first sentence relate only to the adoption of a provisional SPS measure, we are of the view that a determination of whether a particular case is a case 'where relevant scientific evidence is insufficient' must be made by reference to the time the relevant provisional SPS measure was adopted."[217]

192. In *US/Canada – Continued Suspension*, the Appellate Body estimated the amount of time within which the scientific evidence needed to undertake a risk assessment could be considered insufficient under Article 5.7:

> "The 'insufficiency' of the scientific evidence is not a perennial state, but rather a transitory one, which lasts only until such time as the imposing Member procures the

[213] Panel Report, *Russia – Pigs (EU)*, para. 7.668.
[214] Panel Report, *Russia – Pigs (EU)*, para. 7.668.
[215] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 725.
[216] Panel Report, *Korea – Radionuclides*, para. 7.89.
[217] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3253.

> additional scientific evidence which allows the performance of a more objective assessment of risk."[218]

193. The Panel in *Korea – Radionuclides* noted that "[s]imply because a measure is adopted in response to an emergency situation does not necessarily mean that there is insufficient scientific evidence to conduct a risk assessment."[219] The Panel then went on to assess whether there was sufficient scientific information at the time of adoption of each of the challenged measures.[220] In that regard, the Panel considered the time that lapsed between the accident giving rise to the measures, their adoption and the information that became available during that time.[221]

1.9.3.1.5 Risk assessment and provisional SPS measures

194. In *US/Canada – Continued Suspension*, the European Communities asserted that "SPS measures are either 'based on' a risk assessment under Article 5.1, or otherwise the relevant scientific evidence will be 'insufficient' within the meaning of Article 5.7, so that provisional SPS measures may be justified". The Appellate Body rejected this view and held that a risk assessment is not always followed by the adoption of an SPS measure. Moreover, insufficiency of the relevant scientific evidence is not always a ground for the adoption of provisional measures:

> "The European Communities argues that SPS measures are either 'based on' a risk assessment under Article 5.1, or otherwise the relevant scientific evidence will be 'insufficient' within the meaning of Article 5.7, so that provisional SPS measures may be justified. We do not agree. There may be situations where the relevant scientific evidence is sufficient to perform a risk assessment, a WTO Member performs such a risk assessment, but does not adopt an SPS measure either because the risk assessment did not confirm the risk, or the risk identified did not exceed that Member's chosen level of protection. Also, there may be situations where there is no pertinent scientific information available indicating a risk such that an SPS measure would be unwarranted even on a provisional basis."[222]

1.9.3.2 adopted "on the basis of available pertinent information"

195. In *US/Canada – Continued Suspension*, the Appellate Body considered that in cases of insufficient scientific evidence, a Member may take provisional SPS measures. However, for the Member to adopt this provisional measure there must be a rational and objective relationship between the information concerning the risk and the measure:

> "WTO Members' right to take provisional measures in circumstances where the relevant scientific information is 'insufficient' is also subject to the requirement that such measures be adopted 'on the basis of available pertinent information'. Such information may include information from 'the relevant international organizations' or deriving from SPS measures applied by other WTO Members. Thus, Article 5.7 contemplates situations where there is some evidentiary basis indicating the possible existence of a risk, but not enough to permit the performance of a risk assessment. Moreover, there must be a rational and objective relationship between the information concerning a certain risk and a Member's provisional SPS measure. In this sense, Article 5.7 provides 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.'"[223]

196. In *Korea – Radionuclides*, the Panel found that merely listing the relevant documents is not enough to demonstrate that provisional measures have been adopted on the basis of available

[218] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 679.
[219] Panel Report, *Korea – Radionuclides*, para. 7.84.
[220] Panel Report, *Korea – Radionuclides*, para. 7.83.
[221] Panel Report, *Korea – Radionuclides*, paras. 7.84-7.86.
[222] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 681.
[223] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 678.

pertinent information. In the Panel's view, "a Member must demonstrate that the available pertinent information served as the basis for its measure."[224]

1.9.3.3 "seek to obtain the additional information necessary for a more objective assessment of risk"

197. In *Japan – Agricultural Products II*, in respect of the third requirement under Article 5.7, the Appellate Body stated that the additional information to be sought must be "germane" to conducting a more objective risk assessment:

> "Neither Article 5.7 nor any other provision of the *SPS Agreement* sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is to 'seek to obtain' additional information. However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct 'a more objective assessment of risk'. Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied. We note that the Panel found that the information collected by Japan does not 'examine the appropriateness' of the SPS measure at issue and does not address the core issue as to whether 'varietal characteristics cause a divergency in quarantine efficacy'. In the light of this finding, we agree with the Panel that Japan did not seek to obtain the additional information necessary for a more objective risk assessment."[225]

198. In *EC – Approval and Marketing of Biotech Products*, the Panel asserted that the requirement to seek to obtain additional information is a foundational element within Article 5.7 and an indispensable condition for compliance with Article 5.1:

> "According to the Appellate Body, 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*'. Thus, if a Member may provisionally adopt an SPS measure on the basis of available pertinent information in situations where the scientific evidence is insufficient for an adequate risk assessment, as required by Article 5.1 and as defined in Annex A(4), it makes sense to require, as the second sentence of Article 5.7 does, that that Member seek to obtain 'the additional information necessary' for such a risk assessment. Once a Member has obtained the additional information necessary for a risk assessment which meets the definition of Annex A(4), it will be in a position to comply with its obligation in Article 5.1 to base its SPS measure on a risk assessment which satisfies the definition of Annex A(4)."[226]

199. With respect to the requirement to conduct a more objective assessment of risk, the Panel in *EC – Approval and Marketing of Biotech Products* provided additional information on the content of the risk assessment to be conducted within the meaning of Article 5.7, focusing on whether this risk assessment needs to comply to the general rules provided under Annex A(4) of the Agreement:

> "The second sentence of Article 5.7 refers to 'a *more objective* assessment of risk' (emphasis added). The element 'more objective' suggests that SPS measures provisionally adopted pursuant to the first sentence of Article 5.7 must also be based on a risk assessment, namely, a risk assessment which takes into account available pertinent information. It follows that if the first sentence of Article 5.7 required a risk assessment, it would necessarily be different in nature from the kind of risk assessment envisaged in Annex A(4). In other words, any risk assessment which might be required by the first sentence of Article 5.7 would not need to meet the definition of a risk assessment contained in Annex A(4). The above-mentioned

[224] Panel Report, *Korea – Radionuclides*, para. 7.100.
[225] Appellate Body Report, *Japan – Agricultural Products II*, para. 92.
[226] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2990.

> interpretation by the Appellate Body of the phrase '[i]n cases where relevant scientific evidence is insufficient' also supports this view. For if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as required by Article 5.1 and as defined in Annex A(4), then the kind of risk assessment which the first sentence might require by definition could not meet the standard set out in Annex A(4)."[227]

200. In *US/Canada – Continued Suspension*, the Appellate Body explained the meaning of the requirement to "seek to obtain additional information":

> "The requirement that the WTO Member 'shall seek to obtain the additional information necessary for a more objective assessment of risk' implies that, as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiencies in the relevant scientific evidence with additional scientific research or by gathering information from relevant international organizations or other sources.[228] Otherwise, the provisional nature of measures taken pursuant to Article 5.7 would lose meaning."[229]

201. In *US/Canada – Continued Suspension*, the Appellate Body discussed the Members obligation to "seek to obtain additional information" linking it with the Member's obligation to review its provisional measure within a reasonable period of time:

> "A Member is required under Article 5.7 to seek to obtain additional information but is not expected to guarantee specific results. Nor is it expected to predict the actual results of its efforts to collect additional information at the time when it adopts the SPS measure. Finally, the Member taking the provisional SPS measure must review it within a reasonable period of time."[230]

202. As regards the volume of new evidence that could lead to a review of provisional SPS measures, the Appellate Body in *US/Canada – Continued Suspension* rejected the Panel's requirement for a critical mass of new evidence[231], arguing that this approach is too inflexible[232]:

> "The Panel's statement that 'there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient' could be understood as requiring that the new scientific evidence lead to a paradigm shift. As we have said, such an approach is too inflexible. Although the new evidence must call into question the relationship between the body of scientific evidence and the conclusions concerning risk, it need not rise to the level of a paradigm shift."[233]

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[227] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2992.

[228] (*footnote original*) Pursuant to Article 10.1 of the *SPS Agreement*, due account shall be taken of the special needs of developing country Members.

[229] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 679.

[230] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 679.

[231] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 706.

[232] The Appellate Body rejected the Panel's "critical mass of new evidence" based on the following understanding of the term as applied by the Panel:

> "[T]he Panel again required that the scientific evidence be 'sufficient to call into question the fundamental precepts of previous knowledge and evidence'. The Panel's explanation that 'the new scientific information and evidence must be such that they are *at the origin* of a change in the understanding of a scientific issue' also connotes a paradigm shift."

See Appellate Body Reports, *US/Canada – Continued Suspension*, para. 707.

[233] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 705.

1.9.3.4 "review the SPS measure accordingly within a reasonable period of time"

1.9.3.4.1 Temporary or provisional nature of the measure

203. The Panel in *EC – Approval and Marketing of Biotech Products* noted that Article 5.7 makes it clear that SPS measures adopted and maintained pursuant to Article 5.7 are meant to be temporary in nature.[234]

204. The Appellate Body in *Japan – Agricultural Products II* found that the "reasonable period of time" had to be established on a case-by-case basis:

> "In our view, what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure. In the present case, the Panel found that collecting the necessary additional information would be relatively easy. Although the obligation 'to review' the varietal testing requirement has only been in existence since 1 January 1995, we agree with the Panel that Japan has not reviewed its varietal testing requirement 'within a reasonable period of time'."[235]

205. In *US/Canada – Continued Suspension*, the Appellate Body highlighted the provisional nature of measures taken under Article 5.7. The Appellate Body stressed that a Member adopting such a measure must make best efforts to remedy the insufficiencies in the relevant scientific evidence. Otherwise, the provisional nature of the measures taken pursuant to Article 5.7 would lose meaning:

> "The second sentence of Article 5.7 requires that the available pertinent information which provides a basis for a Member's provisional SPS measure be supplemented with 'the additional information necessary for a more objective assessment of risk' within a 'reasonable period of time'. As the Appellate Body noted, these two conditions 'relate to the *maintenance* of a provisional [SPS] measure and highlight the *provisional* nature of measures adopted pursuant to Article 5.7.' The requirement that the WTO Member 'shall seek to obtain the additional information necessary for a more objective assessment of risk' implies that, as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiencies in the relevant scientific evidence with additional scientific research or by gathering information from relevant international organizations or other sources.[236] Otherwise, the provisional nature of measures taken pursuant to Article 5.7 would lose meaning. The 'insufficiency' of the scientific evidence is not a perennial state, but rather a transitory one, which lasts only until such time as the imposing Member procures the additional scientific evidence which allows the performance of a more objective assessment of risk. … Finally, the Member taking the provisional SPS measure must review it within a reasonable period of time."[237]

206. The Panel in *Korea – Radionuclides* found that in a case where the review of provisional measures has never been concluded, the measures cannot be considered to have been reviewed within a reasonable period of time.[238]

1.9.3.4.2 Relevance of appropriate level of protection to the review of provisional measures

207. In *EC – Approval and Marketing of Biotech Products*, the Panel considered that a Member's chosen level of protection is irrelevant when applying the requirement to seek to obtain more information and review the provisional SPS measures within a reasonable period of time. In

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[234] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2971.
[235] Appellate Body Report, *Japan – Agricultural Products II*, para. 93.
[236] (*footnote original*) Pursuant to Article 10.1 of the *SPS Agreement*, due account shall be taken of the special needs of developing country Members in respect of their ability to procure the additional information for a more objective assessment of risk.
[237] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 679.
[238] Panel Report, *Korea – Radionuclides*, para. 7.107.

addition, the Panel rejected the European Communities argument that in the context of Article 5.7 the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. The Panel held that Members are bound to seek more information and review their provisional SPS measures in a reasonable period of time when the available scientific information is objectively sufficient to carry out a more objective assessment of risk:

> "[W]e note the European Communities' argument that the phrase 'within a reasonable period of time' in the second sentence of Article 5.7 supports its view that the importing Member's appropriate level of protection is relevant to determining whether available scientific evidence is insufficient within the meaning of Article 5.7 to perform a risk assessment. The second sentence of Article 5.7 requires that Members seek to obtain the information necessary for a more objective assessment of risk and review provisional SPS measures accordingly within a reasonable period of time. In *Japan – Agricultural Products II*, the Appellate Body stated that what constitutes a 'reasonable period of time' depends, *inter alia*, on the difficulty of obtaining the information necessary for a more objective assessment of risk. We think that in cases where additional information obtained by a Member is objectively sufficient to perform 'a more objective assessment of risk', the phrase 'review … within a reasonable period of time' would not provide a justification for delaying the performance of such an assessment on the grounds that an assessment incorporating the additional information would not allow the importing Member to determine 'with a sufficient degree of precision' whether a measure different from its provisional measure would achieve its appropriate level of protection. Here again, we consider that if there are factors which affect scientists' level of confidence in 'a more objective assessment of risk' they have performed, the importing Member may take this into account when reviewing its provisional measure in the light of the 'more objective assessment'. Thus, we are unable to accept the European Communities' argument concerning the phrase 'within a reasonable period of time'."[239]

1.9.3.4.3 Evolution of scientific evidence

208. In *EC- Approval and Marketing of Biotech Products*, the Panel held that evidence that comes into light between the time of adoption of a provisional measure and the time a Panel's terms of reference are fixed, may be relevant to a determination of whether the Member invoking the exception under Article 5.7 has conducted a "review" of its provisional measure "within a reasonable period of time":

> "We have concluded that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted. This conclusion warrants some elaboration, to avoid possible misinterpretation. First of all, we are not suggesting that evidence which establishes that, at some point between the time of adoption of a provisional SPS measure and the time a Panel's terms of reference were fixed, relevant scientific evidence became sufficient, or was still insufficient, to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4), is *a priori* irrelevant to an Article 5.7 inquiry. To the contrary, such evidence may be relevant to an inquiry under the second sentence of Article 5.7. It may shed light on whether the Member invoking the exception under Article 5.7 has complied with the requirement to 'seek to obtain the additional information necessary for a more objective risk assessment'. Alternatively, such evidence may be relevant to a determination of whether the Member invoking the exception under Article 5.7 has conducted a 'review' of its provisional measure 'within a reasonable period of time'."[240]

209. The Appellate Body in *US/Canada – Continued Suspension*, agreed with the Panel's statements that "science continuously evolves", and that it "cannot be excluded that new scientific evidence or information calls into question existing evidence" or that "different risk assessments reach different interpretations of the same scientific evidence".[241] On this basis, the Appellate Body

[239] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3245.
[240] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3255.
[241] Panel Reports, *US – Continued Suspension*, para. 7.645; and *Canada – Continued Suspension*, para. 7.623.

observed that "scientists will often be asked to review studies performed by other scientists and that the scientific community must constantly reassess theories in the light of scientific progress".[242]

210. In *US/Canada – Continued Suspension*, the Appellate Body in rejecting the Panel's requirement for a "critical mass of new evidence", set the level of new evidence that may lead a WTO Member to take provisional measures:

> "It may be useful to think of the degree of change as a spectrum. On one extreme of this spectrum lies the incremental advance of science. Where these scientific advances are at the margins, they would not support the conclusion that previously sufficient evidence has become insufficient. At the other extreme lie the more radical scientific changes that lead to a paradigm shift. Such radical change is not frequent. Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too inflexible an approach. WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. We are referring to circumstances where new scientific evidence casts doubts as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk."[243]

1.9.4 Burden of proof

211. In *EC – Approval and Marketing of Biotech Products*, the Panel acknowledged that characterizing Article 5.7 as a right rather than as an exception (see the discussion in paragraph 171 above) has implications for the allocation of the burden of proof[244]:

> "Characterizing Article 5.7 as a qualified right and not an exception also has implications for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. According to the Appellate Body's statement in *EC – Tariff Preferences*, in cases where the permissive provision constitutes a right rather than an exception, 'the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour'. And in *EC – Sardines*, the Appellate Body observed that '[i]n *EC – Hormones*, we found that a 'general rule-exception' relationship between Articles 3.1 and 3.3 of the *SPS Agreement* does not exist, with the consequence that the complainant had to establish a case of inconsistency with *both* Articles 3.1 and 3.3'. We deduce from these two statements that in cases where a complaining party alleges that an SPS measure is inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged SPS measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, does the relevant obligation in Article 2.2 apply to the challenged SPS measure."[245]

212. The Panel in *EC – Approval and Marketing of Biotech Products* thus concluded that it is incumbent on the complaining party to establish a *prima facie* case of inconsistency with both Articles 2.2 and 5.7.[246]

213. The Panel in *US – Animals* took a somewhat different approach in its assessment of a claim under Article 5.1 of the SPS Agreement. The Panel held that because the respondent "has chosen to assert that its measures fall within the scope of Article 5.7, it carries the burden to prove that each of the four cumulative requirements have been satisfied."[247]

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[242] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 477.
[243] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 703.
[244] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2969.
[245] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2976.
[246] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2979.
[247] Panel Report, *US – Animals*, para. 7.293.

214. In *Korea – Radionuclides*, the Panel rejected the respondent's argument that in a claim of inconsistency with Article 5.1 of the SPS Agreement, a complainant must establish a *prima facie* case of inconsistency with both Articles 5.1 and 5.7. The Panel reasoned that "[s]uch an interpretation would require every complainant raising claims under the *SPS* Agreement to invoke Article 5.7 in its request, even if it were irrelevant, and expend considerable time disproving its applicability simply to forestall such a litigation tactic being employed."[248]

215. In *Japan – Apples*, Japan presented a defence under Article 5.7 which operated in the alternative. This means that the defence was only made in the event that the Panel rejected Japan's view that "sufficient scientific evidence" exists to maintain the measure within the meaning of Article 2.2. In this regard, the Panel assigned the burden of proof to Japan, the respondent:

> "We understand Japan to be claiming that the phytosanitary measure at issue is justified under Article 5.7 'in the alternative', should the Panel find that the measure is maintained without sufficient scientific evidence within the meaning of Article 2.2. We first note that arguing in the alternative is a well-established judicial practice and arguing a point in the alternative of another point often implies that there may be some contradictions between the two lines of argumentation if they were presented concurrently.
>
> In this instance, we have determined above that Japan's measure is maintained without sufficient scientific evidence within the meaning of Article 2.2, which is the circumstance in which Japan invokes Article 5.7 in the alternative and claims that this provisional measure has been in place since the date of entry into force of the *SPS Agreement* in 1995.
>
> We will therefore now consider whether the measure at issue can be justified as a provisional measure within the meaning of Article 5.7 of the *SPS Agreement*. Before doing so, however, we find it relevant to recall that the burden is on Japan, as the party invoking Article 5.7 to make a prima facie case in support of its position."[249]

1.9.5 Precautionary principle

216. The Appellate Body in *EC – Hormones* noted that although the precautionary principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of the Agreement, it still finds reflection in Article 5.7 of the SPS Agreement. The Appellate Body cautioned that the Panel should not assume that the Article exhausts the relevance of the precautionary principle as it also finds reflection in other provisions of the SPS Agreement – such as the sixth paragraph of the preamble and Article 3.3. Despite the relevance of the precautionary principle, the Appellate Body upheld the Panel's finding that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement:

> "[A] panel charged with determining, for instance, whether 'sufficient scientific evidence' exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. … [H]owever, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.
>
> We accordingly agree with the finding of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the *SPS Agreement*."[250]

217. The Panel in *EC – Approval and Marketing of Biotech Products* reiterated the Appellate Body's statement in *EC – Hormones* that Article 5.7 reflects the precautionary principle, and that

[248] Panel Report, *Korea – Radionuclides*, para. 7.74.
[249] Panel Report, *Japan – Apples*, paras. 8.210-8.212.
[250] Appellate Body Report, *EC – Hormones*, paras. 124-125.

the precautionary principle as such has not been written into the SPS Agreement as a ground for justifying an SPS measure that is otherwise inconsistent with that Agreement. In that dispute, the European Communities asserted that each of the safeguard measures at issue in this dispute was based on the precautionary principle. Since the Panel had examined whether the challenged safeguard measures were consistent with the requirements of Article 5.7, in view of the statement by the Appellate Body, the Panel saw no need to separately examine the European Communities' argument that its measures were based on the precautionary principle.[251]

218. In *US/Canada – Continued Suspension*, the Appellate Body, after reviewing the purpose of the four cumulative requirements under Article 5.7, cautioned that these provisions need to be interpreted, in this particular context, with consideration to the precautionary principle:

> "These four conditions set out in Article 5.7, however, must be interpreted keeping in mind that the precautionary principle finds reflection in this provision. …
>
> In emergency situations, for example, a WTO Member will take a provisional SPS measure on the basis of limited information and the steps it takes to comply with its obligations to seek to obtain additional information and review the measure will be assessed in the light of the exigencies of the emergency."[252]

1.9.6 Relationship with other paragraphs of Article 5

1.9.6.1 Article 5.1

219. See paragraph 12 above, for a discussion on the relationship between Article 5.1 and the other provisions of Article 5.

220. The Panel in *EC – Approval and Marketing of Biotech Products*, applying the reasoning that Article 5.7 is a qualified right and not an exception found that Article 5.7, implicitly refers to Article 5.1:

> "Article 5.7 contains implicit references to Article 5.1. First, the second sentence of Article 5.7 refers to 'a more objective risk assessment', a phrase which we have construed to refer to a risk assessment within the meaning given to that term in Annex A(4). We have also noted that only Article 5.1 requires a risk assessment as defined in Annex A(4). Secondly, we have noted earlier that according to the Appellate Body, relevant scientific evidence is 'insufficient' within the meaning of the first sentence of Article 5.7 if it does not allow the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A(4). Thus, through its interpretation of the phrase '[i]n cases where relevant scientific evidence is insufficient', the Appellate Body has made explicit a reference to Article 5.1 which in its view is implicit in Article 5.7. Indeed, the Appellate Body justified its interpretation on the basis that there is 'a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1'. In view of these elements, we conclude that Article 5.7 should be considered to refer to Article 5.1.[253]

221. The Panel in *EC – Approval and Marketing of Biotech Products* concluded that Article 5.7 permitted Members to do, in certain circumstances, that which they would not be permitted to do under Article 5.1:

> "[U]nlike Article 2.2, Article 5.1 does not explicitly say that its provisions apply 'except as provided for in paragraph 7 of Article 5'. However, Article 5.7 opens with the phrase '[i]n cases where relevant scientific evidence is insufficient'. As mentioned by us before, the Appellate Body opined that ''relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an

[251] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3220.
[252] Appellate Body Reports, *US/Canada – Continued Suspension*, para. 680.
[253] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2994.

> adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement'. Accordingly, if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as defined in Annex A(4), and if, as the Appellate Body suggests, Article 5.1 requires such a risk assessment, then the logical conclusion to be drawn is that the obligation in Article 5.1 to base SPS measures on a risk assessment was not intended to be applicable to measures falling within the scope of Article 5.7. Indeed, '[i]n cases where relevant scientific evidence is insufficient', it is impossible, under the Appellate Body's interpretation of that phrase, for Members to meet the obligation to base their SPS measures on a risk assessment as defined in Annex A(4). We find it unreasonable to assume that Members would accept, even in principle, an obligation with which they cannot comply. In our view, the phrase '[i]n cases where relevant scientific evidence is insufficient' should, therefore, be taken to suggest that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7.
>
> In addition, we think the clause 'except as provided for in paragraph 7 of Article 5' in Article 2.2 also suggests that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7. We recall in this regard that in *EC – Hormones* the Appellate Body agreed with a statement by the Panel in that case that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2.[254] If Article 5.1 is properly viewed as a specific application of the obligations provided for in Article 2.2, it follows that Article 5.1 cannot be applicable in situations where Article 2.2 is not applicable. We have explained above that the clause 'except as provided for in paragraph 7 of Article 5' exempts the kinds of situations covered by Article 5.7 from the obligation in Article 2.2 to ensure that SPS measures are not maintained without sufficient scientific evidence. Since Article 5.1 is not applicable in situations where Article 2.2 is not applicable, the clause 'except as provided for in paragraph 7 of Article 5' in Article 2.2 necessarily implies that Article 5.1 cannot be applicable in situations covered by Article 5.7."[255]

222. The Panel in *EC – Approval and Marketing of Biotech Products* thus concluded that Article 5.7 should be characterized as a right in relation to Article 5.1 rather than a qualified exception from a general obligation under Article 5.1:

> "From our analysis above, it is clear that the general test stated by the Appellate Body in *EC – Tariff Preferences* can be applied also to the relationship between Article 5.1 and Article 5.7. Our application of that test has shown that this relationship meets all the elements which according to the Appellate Body support characterizing Article 5.7 as a right vis-à-vis Article 5.1. Furthermore, we think it would be incongruous to reach the conclusion that Article 5.7 is a right vis-à-vis Article 2.2, but an exception vis-à-vis Article 5.1. For these reasons, we conclude that Article 5.7 should be characterized as a right also in relation to Article 5.1, rather than as an exception from a 'general obligation' under Article 5.1. In our view, Article 5.7 operates as a qualified exemption from the obligation under Article 5.1 to base SPS measures on a risk assessment."[256]

223. The Panel in *EC – Approval and Marketing of Biotech Products* found that, as Article 5.7 is a right rather than an exception to Article 5.1, the complaining party bears the burden of proving inconsistency of a challenged SPS measure with Article 5.7 first. The Panel found that only if an inconsistency with Article 5.7 was established could a claimant sustain an allegation of a violation of Article 5.1:

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[254] *(footnote original)* Appellate Body Report, *EC – Hormones*, para. 180. *See also* Appellate Body Report, *Japan – Agricultural Products II*, para. 82. It appears that the Appellate Body views Article 5.1 as a specific application of the second and third obligation in Article 2.2, *i.e.*, the obligation to base SPS measures on scientific principles and the obligation not to maintain SPS measures without sufficient scientific evidence. In *Australia – Salmon*, the Appellate Body agreed with the Panel in that case that in the event an SPS measure is not based on a risk assessment as required in Article 5.1, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence within the meaning of Article 2.2. Appellate Body Report, *Australia – Salmon*, para. 138.

[255] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.2995-7.2996.

[256] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2997.

> "We now turn to the implications of characterizing Article 5.7 as a qualified right rather than as an exception for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. In our view, the implication is that in cases where a complaining party alleges that an SPS measure is inconsistent with Article 5.1, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, is Article 5.1 applicable to the challenged SPS measure. Accordingly, we think that when a complaining party presents a claim of violation under Article 5.1, the burden is on the complaining party to establish a prima facie case of inconsistency with both Articles 5.1 and 5.7."[257]

1.9.7 Relationship with other provisions of the SPS Agreement

1.9.7.1 Article 2.2

224. See paragraph 222 above, for a discussion on the relationship between Articles 2.2, 5.1 and 5.7.

1.9.7.2 Article 3.2

225. The Appellate Body in *US/Canada – Continued Suspension* elaborated on whether the presumption in Article 3.2 implied that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher level of protection, a situation that may be borne out in Article 5.7.

1.9.7.3 Article 6.3

226. The Panel in *Russia – Pigs (EU)* distinguished between the examination of evidence provided by the exporting Member to demonstrate the pest- or disease-free status of an area, or a low pest or disease prevalence under Article 6.3, from that of the insufficiency of scientific evidence under Article 5.7. The Panel held that its findings under Article 6.3 could only inform its analysis of the evidence relevant to the assessment under Article 5.7.[258]

1.9.7.4 Similarity of relationships between Articles 3.1 and 3.3 and Articles 2.2 and 5.7

227. The Panel in *EC – Approval and Marketing of Biotech Products* considered that in the same way Article 3.1 excludes from its scope of application the kinds of situations covered by Article 3.3, Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7.[259]

228. The Panel in *EC – Approval and Marketing of Biotech Products* also stated that Articles 3.1 and 3.3 are part of the context of Articles 2.2 and 5.7 and the two sets of Articles bear textural and structural similarity:

> "[A]s an initial matter, we note that Articles 3.1 and 3.3 are part of the context of Articles 2.2 and 5.7. Moreover, we consider that there is an undeniable structural and textual similarity between Articles 3.1 and 3.3 and Articles 2.2 and 5.7. Both pairs of articles are linked to each other through a textual cross- reference, and Article 3.1 contains an 'except as provided for' clause which is textually almost identical to the corresponding clause in Article 2.2. It is primarily this structural and textual similarity of Articles 3.1 and 3.3, coupled with the fact that these provisions, and their mutual relationship, have already been interpreted by the Appellate Body, which renders them relevant to, and hence has factored in, our examination of the relationship between Article 2.2 and Article 5.7."[260]

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[257] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3000.
[258] Panel Report, *Russia – Pigs (EU)*, para. 7.1153.
[259] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2969.
[260] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2982.

1.10 Article 5.8

1.10.1 General

229. The Panel in *EC – Hormones* allocated the burden of proof to the responding party, where the responding party enacted a measure not based on an international standard. In doing so, the Panel based its finding partially upon Article 5.8. The Appellate Body disagreed and indicated that Article 5.8 is not intended to address the burden of proof problem:

> "Article 5.8 of the *SPS Agreement* does not purport to address burden of proof problems; it does not deal with a dispute settlement situation. To the contrary, a Member seeking to exercise its right to receive information under Article 5.8 would, most likely, be in a pre-dispute situation, and the information or explanation it receives may well make it possible for that Member to proceed to dispute settlement proceedings and to carry the burden of proving on a *prima facie* basis that the measure involved is not consistent with the *SPS Agreement*."[261]

1.10.2 Relationship with other paragraphs of Article 5

1.10.2.1 Article 5.1

230. See paragraph 12 above, for a discussion on the relationship between Article 5.1 and the other provisions of Article 5.

1.10.3 Relationship with other provisions of the SPS Agreement

1.10.3.1 Article 2.2

231. While discussing the burden of proof under Article 2.2, the Appellate Body in *Japan – Agricultural Products II* made reference to Article 5.8.[262]

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[261] Appellate Body Report, *EC – Hormones*, para. 102. This was reiterated in Panel Report, *Japan – Apples*, para. 8.41.
[262] See Appellate Body Report, *Japan – Agricultural Products II*, para. 138.