

<b>1 ANNEX A .....</b>	<b>3</b>
1.1 Text of Annex A.....	3
1.2 Annex A(1): sanitary or phytosanitary measure .....	4
1.2.1 The definition of an SPS measure .....	4
1.2.1.1 Relevance of trade effects of a measure.....	5
1.2.1.2 Purpose, form and nature .....	5
1.2.1.3 Principal and ancillary measures .....	8
1.2.1.4 Substantive SPS measures and procedural requirements .....	8
1.2.1.5 SPS measures' identification in terms of their purpose.....	9
1.2.1.5.1 General.....	9
1.2.1.5.2 SPS measure versus environment protection measure .....	9
1.2.1.6 Whether a law, or a requirement contained therein, may be deemed to embody an SPS measure as well as a non-SPS measure .....	10
1.2.2 Annex A(1)(a) .....	12
1.2.2.1 General .....	12
1.2.2.2 "to protect animal or plant life or health" .....	13
1.2.2.3 "risks arising from" .....	13
1.2.2.4 "entry, establishment or spread".....	13
1.2.2.5 "pests" .....	14
1.2.2.6 "diseases, disease carrying organisms or disease-causing organisms" .....	14
1.2.3 Annex A(1)(b).....	15
1.2.3.1 General .....	15
1.2.3.2 "foods, beverages or feedstuffs" .....	15
1.2.3.3 "additives" .....	15
1.2.3.3.1 Concept .....	15
1.2.3.3.2 Relevance of Codex .....	16
1.2.3.4 "contaminants".....	16
1.2.3.5 "toxins" .....	17
1.2.3.5.1 Definition .....	17
1.2.3.5.1.1 Relevance of the criteria related to "unintentional addition to food" .....	17
1.2.3.5.1.2 Relevance of the poisonous effect of the toxins .....	18
1.2.3.5.2 Allergens as toxins .....	18
1.2.3.5.3 Definition of allergens.....	18
1.2.3.5.4 Inclusion of allergens in the categories within Annex A .....	19
1.2.4 Relationship between Annex A(1)(a) and Annex A(1)(b).....	19
1.2.5 Annex A(1)(c) .....	20
1.2.5.1 The issue of presence of allergens in the environment.....	20
1.2.5.2 Possible health effects from increased herbicide use associated with GMOs .....	20
1.2.6 Annex A(1)(d).....	21
1.2.6.1 "other damage" .....	21

1.2.6.2	Relationship with other provisions of the SPS Agreement .....	21
1.2.6.2.1	Article 5.3 .....	21
1.2.7	Annex A(1) second paragraph .....	22
1.2.7.1	General .....	22
1.2.7.2	"all relevant laws, decrees, regulations" .....	22
1.2.7.3	"requirements and procedures" .....	23
1.2.7.4	"labelling requirements" .....	24
1.2.7.4.1	General .....	24
1.2.7.4.2	Purpose of labelling requirements .....	24
1.2.7.5	"directly related to food safety" .....	25
1.3	Annex A(3): "international standards, guidelines and recommendations" .....	25
1.3.1	Relationship with Articles 3.1 and 3.2 .....	25
1.4	Annex A(4): "risk assessment" .....	25
1.4.1	General .....	25
1.4.2	First part of Annex A(4): First definition of risk assessment .....	26
1.4.2.1	Types of risks .....	26
1.4.2.2	Elements of a risk assessment .....	27
1.4.2.3	Identifying risk on a disease-specific basis .....	27
1.4.2.4	"likelihood" .....	27
1.4.2.5	"according to the [SPS] measures which might be applied" .....	28
1.4.2.6	"Evaluation of likelihood of entry, establishment or spread of a pest or disease" .....	29
1.4.2.6.1	Risk assessment to be specific to the product at issue .....	29
1.4.3	Second part of Annex A(4): Second definition of risk assessment .....	30
1.4.3.1	Distinction from the first definition of risk assessment .....	30
1.4.3.2	No requirement to quantify the level of risk .....	30
1.4.3.3	Methodology of risk assessment .....	31
1.4.3.3.1	Two-step analysis .....	31
1.4.3.3.2	Specific attribution of risk .....	31
1.4.4	Relationship with other provisions of the SPS Agreement .....	32
1.5	Annex A(5) : "appropriate level of protection" .....	32
1.5.1	General .....	32
1.5.1.1	Right to determine the appropriate level of protection .....	32
1.5.1.2	Relationship between the "risk assessment" and the "appropriate level of protection" .....	33
1.5.2	Relationship with other provisions of the SPS Agreement .....	33
1.5.2.1	Article 3.3 .....	33
1.5.2.2	Article 5.4 .....	33
1.5.2.3	Article 5.5 .....	33
1.5.2.4	Article 5.6 .....	33
1.5.2.5	Article 5.7 .....	33

## **1 ANNEX A**

### **1.1 Text of Annex A**

#### **ANNEX A**

##### DEFINITIONS<sup>4</sup>

(*footnote original*)<sup>4</sup> For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

1. *Sanitary or phytosanitary measure* – Any measure applied:
  - (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
  - (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
  - (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
  - (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

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

2. *Harmonization* – The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
3. *International standards, guidelines and recommendations*
  - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
  - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
  - (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
  - (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

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

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

6. *Pest- or disease-free area* – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area – whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

## **1.2 Annex A(1): sanitary or phytosanitary measure**

### **1.2.1 The definition of an SPS measure**

1. The Appellate Body in *Australia – Apples* considered that a fundamental element of the definition of an "SPS measure" set out in Annex A(1) is that such a measure must be one applied to protect at least one of the listed interests or to prevent or limit specified damage.<sup>1</sup>

2. In *Costa Rica – Avocados (Mexico)*, the Panel found that reports that contained the findings on risk assessment did not constitute SPS measures.<sup>2</sup> According to the Panel, such reports did not have any effect on the protection of the values listed in Annex A(1):

"In this Panel's view, Reports ARP-002-2017 and ARP-006-2016 are not, in themselves, a measure *applied* to protect in the sense of being implemented in order to have the effect of protecting avocado trees. Costa Rica's risk assessments, which are contained in those reports, do not have any 'application' in or a specific effect on the protection of avocado trees. Even though the reports recommend the three alternative phytosanitary requirements, in order to have concrete effects on the protection of avocado trees, those requirements had to be reflected in Resolutions DSFE-002-2018 and DSFE-003-2018."<sup>3</sup>

3. The Panel in *Costa Rica – Avocados (Mexico)* similarly found that a manual providing guidance on pest risk analyses did not represent an SPS measure because:

"[T]he manual is not in itself a measure *applied* to protect in the sense of producing as an effect the protection of plant life or health, including avocados. The manual contains the methodology for preparing PRAs and may be considered to be 'applied'

---

<sup>1</sup> Appellate Body Report, *Australia – Apples*, para. 172.

<sup>2</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, paras. 7.135-7.136.

<sup>3</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.142. In reaching this conclusion, the Panel found support in the fact that Annex A contains, in its paragraph 4, a separate definition for risk assessment. *Ibid.*, para. 7.153.

when the PRA is being prepared, but it does not have an 'application' pertaining to or a specific effect on the protection of plant life or health."<sup>4</sup>

#### **1.2.1.1 Relevance of trade effects of a measure**

4. In *Japan – Apples*, the Panel noted that the definition in Annex A(1) does not consider the trade effect of a given measure as a factor to determine whether such a measure is or is not a phytosanitary measure.<sup>5</sup>

#### **1.2.1.2 Purpose, form and nature**

5. In *EC – Hormones (Canada)*, the Panel reviewed the test applied by the parties to establish whether the measures at issue were sanitary measures. In accordance with the parties' analysis, the Panel based its review on the definitions provided in Annex A of the SPS Agreement:

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

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

Footnote 4 to Annex A specifies that 'contaminants' include, for the purposes of Annex A, 'pesticide and veterinary drug residues and extraneous matter'. Since the six hormones in dispute are veterinary drugs, the parties agree that the alleged risks at issue arise from contaminants. We agree with the parties that the EC measures in dispute are 'applied to protect human ... life or health' within the territory of the European Communities from risks arising from 'contaminants', namely residues of six specific hormones, in foods (according to paragraph 1(b) of Annex A). That the contested EC measures are, *inter alia*, 'applied to protect human ... life or health' can be inferred from the preambles to, and legislative history of, Directives 81/602/EEC and 88/146/EEC. Since both parties agree that the contested EC measures are 'sanitary measures, we see no need to further examine in this dispute the definition of measures 'applied to protect human ... life or health'."<sup>6</sup>

6. In *EC – Approval and Marketing of Biotech Products*, the Panel examined whether various European Communities' actions constituted an SPS measure that would fall under the SPS Agreement. Specifically, the Panel looked to the definition of a sanitary or phytosanitary measure set out in Annex A(1) and explained that in determining whether a measure is an SPS measure, regard must be had to such elements as the purpose of the measure, its legal form and its nature:

"Annex A(1) indicates that for the purposes of determining whether a particular measure constitutes an 'SPS measure' regard must be had to such elements as the purpose of the measure, its legal form and its nature. The purpose element is addressed in Annex A(1)(a) through (d) ('any measure applied to'). The form element is referred to in the second paragraph of Annex A(1) ('laws, decrees, regulations'). Finally, the nature of measures qualifying as SPS measures is also addressed in the second paragraph of Annex A(1) ('requirements and procedures, including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; [etc.]')."<sup>7</sup>

7. Acknowledging the Panel's decision in *EC – Approval and Marketing of Biotech Products*, the Panel in *Australia – Apples* noted that Annex A(1) contains the legal definition for the term

---

<sup>4</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.212.

<sup>5</sup> Panel Report, *Japan – Apples*, para. 8.24. See also Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.180.

<sup>6</sup> Panel Report, *EC – Hormones (Canada)*, paras. 8.24-8.25.

<sup>7</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.149.

"SPS measure".<sup>8</sup> However, the Panel had a different reading of how two of the elements (form and nature) are reflected in the second paragraph of Annex A(1) from that adopted by the Panel in *EC – Approval and Marketing of Biotech Products*. The Panel did not agree that the list of examples in the second paragraph of Annex A(1) provides a clear-cut division between the elements of form and nature. The Panel considered that the ordinary way to read "laws, decrees, regulations, requirements and procedures" is as an enumeration of five items with the words "all relevant" qualifying each one of them:

"This Panel considers that the second paragraph of Annex A(1) sets out elements of the definition of SPS measures by providing examples. In fact, the second paragraph starts with the words 'Sanitary and phytosanitary measures include'. Thus, the items spelt out in the second paragraph do not form a closed list. This is quite different from the closed list of possible purposes of a covered SPS measure under the first paragraph of Annex A(1), in particular its subparagraphs (a)-(d).

Further, the Panel does not consider that the list of examples in the second paragraph of Annex A(1) provides a clear-cut division between the elements of form and nature, the first three items ('laws, decrees, regulations') corresponding to the form, and the latter two ('requirements and procedures') to the nature of SPS measures. Given the placing of the word 'and' between the fourth and fifth items, the ordinary way to read 'laws, decrees, regulations, requirements and procedures' is as an enumeration of five items, with the words 'all relevant' qualifying each one of them."<sup>9</sup>

8. In arriving at its conclusion on the elements of form and nature, the Panel in *Australia – Apples* recalled the principle of treaty interpretation that "[t]he terms of the treaty are presumed to have the same meaning in each authentic text", and that the treaty interpreter should aim at "the meaning which best reconciles the texts [in the different authentic language versions], having regard to the object and purpose of the treaty."<sup>10</sup> The Panel then examined the English, Spanish and French versions of the SPS Agreement:

"The Spanish version of the second paragraph of Annex A(1) refers to '*todas las leyes, decretos, reglamentos, prescripciones y procedimientos pertinentes*', placing the 'y' before the fifth item of the enumeration, and embracing the five items between the words '*todas*' and '*pertinentes*' ('all relevant' in English). The French version mentions '*toutes lois, tous décrets, toutes réglementations, toutes prescriptions et toutes procédures pertinents*', again with the word '*et*' appearing before the fifth item. Further, the French version makes it evident that both the words in the phrase 'all relevant' at the beginning of the enumeration in the English version should be read as relating to all five items of the list. In fact, the French version repeats the word '*tou[te]s*' before each of the five items. Further, it uses the adjective '*pertinents*' in the masculine, indicating that it cannot relate only to the immediately preceding noun '*procédures*', nor to the two preceding nouns ('*prescriptions*' and '*réglementations*'). ...

In the light of the above, the three authentic language versions of the last paragraph of Annex A(1) are interpreted most harmoniously if the terms 'laws, decrees, regulations, requirements and procedures' are perceived as a list of five items of equal quality and importance, with the words 'all' and 'relevant' referring to each of these items.

...

Since this Panel reads 'all relevant laws, decrees, regulations, requirements and procedures' as a list of five items, it disagrees with the *EC – Approval and Marketing of Biotech Products* Panel that the examples following this list in Annex A(1) would relate only to the last two items of the list ('requirements and procedures'). The Panel is aware that some of the examples repeat the words 'requirements' and 'procedures'. But not all do. Laws, decrees and regulations may typically set out requirements and

---

<sup>8</sup> Panel Report, *Australia – Apples*, para. 7.116.

<sup>9</sup> Panel Report, *Australia – Apples*, paras. 7.144-7.145.

<sup>10</sup> Panel Report, *Australia – Apples*, paras. 7.146.

procedures, so the examples including the words 'requirements' and 'procedures' can be read as also qualifying 'laws, decrees, regulations'."<sup>11</sup>

9. Having reviewed the language of Annex A(1) in all three versions of the SPS Agreement, the Panel in *Australia – Apples* concluded that both the form and nature elements in the definition of SPS measures were broad and closely connected, without a clear distinction between the two:

"In sum, the form and nature elements in the definition of SPS measures in Annex A(1) are both broad, and they are closely connected to each other. Accordingly, the Panel will now analyse whether the 16 measures fit the elements of form and nature spelt out in the second paragraph of Annex A(1). Given the linkage of form and nature under that paragraph, the Panel will assess these two elements together to analyse whether the 16 measures can qualify as SPS measures."<sup>12</sup>

10. The Panel in *US – Poultry (China)* also disagreed with the Panel's findings in *EC – Approval and Marketing of Biotech Products* on the premise that the text of Annex A(1) provides no clear distinction between form and nature. The Panel stated:

"We note that the text of Annex A(1) does not mention the term 'nature' but neither does it mention the terms 'purpose' and 'form'. This does not mean that the analysis of the ordinary meaning of the wording of Annex A(1) in its context and in light of its object and purpose, would not lead us to examining both the purpose and form of Section 727 in order to determine whether it is an SPS measure.

...

The Panel has carefully examined the Panel's findings in *EC – Approval and Marketing of Biotech Products* as regards the legal basis for distinction of 'form' and 'nature' and has difficulty with following the reasoning. The rationale for dividing the phrase 'laws, decrees, regulations, requirements and procedures including ...,' into 'form' and 'nature' is not clear to us as the Panel did not elaborate on this point. The Panel did not explain how 'requirements and procedures' were somehow fundamentally different from 'laws, decrees, regulations' or why it believed that all SPS measures somehow have the nature of a 'requirement' or 'procedure'. If we examine the text of Annex A(1), we note that there is no such separation and a plain reading might lead one to believe that 'requirements and procedures' are also descriptions of the possible types or 'forms' of an SPS measure while the substantive descriptions following 'including *inter alia*' are just illustrative examples of the types of SPS measures Members have imposed."<sup>13</sup>

11. The Panel in *US – Poultry (China)* considered that the first part of Annex A(1) refers to the purpose of the measure while the second part provides a list of the types of SPS measures. The Panel observed:

"We note that the first part of Annex A(1) (a) to (d) refers to an SPS measure as 'any measure applied ... to protect ... to prevent'. Both parties and the Panel agree that this language refers to the 'purpose' of a measure.

The second part of Annex A(1), after having enunciated the possible purposes for which an SPS measure could be applied, goes on to provide a list of the types of SPS measures."<sup>14</sup>

12. The Panel in *Russia – Pigs (EU)* agreed with the Panel in *US – Poultry (China)* that the legal form of a measure may intrinsically determine the nature of that measure "for the purposes of determining whether a measure is of the type listed in the second paragraph of Annex A(1)".<sup>15</sup>

---

<sup>11</sup> Panel Report, *Australia – Apples*, paras. 7.147-7.148, and 7.150.

<sup>12</sup> Panel Report, *Australia – Apples*, para. 7.153. See also Panel Report, *US – Poultry (China)*, para. 7.101.

<sup>13</sup> Panel Report, *US – Poultry (China)*, paras. 7.97 and 7.100.

<sup>14</sup> Panel Report, *US – Poultry (China)*, paras. 7.98-7.99.

13. In *Russia – Pigs (EU)*, the Panel was also confronted with the question whether actions implementing certain requirements adopted by a customs union can be attributed to one of the countries constituting that customs union. The Panel found, *inter alia*, that in addition to the requirements imposed by the customs union regulation, importation of products had to comply with a number of conditions "under the control of Russian authorities."<sup>16</sup> On that basis, and having regard to the relevant evidence, the Panel concluded that the actions taken by Russian authorities constituted a composite measure, which was attributable to Russia.<sup>17</sup>

14. The Panel in *Panama – Import Measures (Costa Rica)* noted that the SPS Agreement does not specify a reference period for the identification of the purpose of a measure:

"The Panel also observes that neither the definition of 'sanitary or phytosanitary measure' in Annex A(1), nor any other provision in the SPS Agreement, indicates a reference period with respect to which a panel should discern the purpose of a measure or how such an analysis should be undertaken."<sup>18</sup>

With respect to a reference period for determining the objective of an SPS measure, it should be noted that Annex B(5)(b) and Annex B(6)(a) to the SPS Agreement, concerning the notification procedures for sanitary and phytosanitary regulations, require that a 'brief indication of the objective and the rationale of the regulation' be given when notifying a regulation. In accordance with these provisions, notifications should take place at an early stage (in the case of draft regulations, as provided for in Annex B(5)(b)) or immediately (in the case of urgent problems of health protection, as provided for in Annex B(6)(a)). However, in the Panel's view, the content of these provisions on when to notify the 'objective and rationale' of a regulation concern compliance with the transparency obligations contained therein, but does not define a reference period for determining the objective of an SPS measure."<sup>19</sup>

### 1.2.1.3 Principal and ancillary measures

15. In *Australia – Apples*, Australia advanced the notion of a distinction between ancillary and principal measures to support its argument that many of the measures at issue could not be reviewed under the SPS Agreement individually, but only in combination with certain other measures, which were supposedly principal measures. The Panel rejected this argument noting that Annex A(1) does not mention any distinction between principal and ancillary measures.<sup>20</sup> The Appellate Body upheld the Panel's finding in this regard.<sup>21</sup>

### 1.2.1.4 Substantive SPS measures and procedural requirements

16. The Panel in *US – Poultry (China)* articulated the distinction between substantive SPS measures and procedural requirements. The Panel stated:

"[P]rior panels have discussed the scope of both Articles 2 and 5 by making a distinction between 'substantive' SPS measures taken to achieve a Member's ALOP and 'procedural requirements'. In particular, the Panel in *Australia – Salmon (Article 21.5 – Canada)* made a distinction between risk reduction measures allegedly needed to achieve a WTO Member's ALOP, which it called 'substantive SPS measures in their own right' and procedures or information requirements to check and ensure

---

<sup>15</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.196.

<sup>16</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.82.

<sup>17</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.83.

<sup>18</sup> (*footnote original*) In particular, the Panel notes that the provisions of the SPS Agreement refer both to the adoption of the measure (e.g. Articles 2.1 and 5.7) and its application (e.g. Articles 1.1, 2.2, and 2.3). However, none of these provisions provide definitive guidance with respect to the appropriate period for the analysis of the measure's objective.

<sup>19</sup> Panel Report, *Panama – Import Measures (Costa Rica)*, paras. 7.64-7.65.

<sup>20</sup> Panel Report, *Australia – Apples*, paras. 7.173-7.174.

<sup>21</sup> Appellate Body Report, *Australia – Apples*, para. 181.

the fulfilment of sanitary measures that are subject to Annex C(1)(c) of the *SPS Agreement*."<sup>22</sup>

#### **1.2.1.5 SPS measures' identification in terms of their purpose**

##### **1.2.1.5.1 General**

17. The Panel in *EC – Approval and Marketing of Biotech Products*, when examining country specific safeguard measures on genetically modified organisms within the European Communities, stated that a panel need not limit its inquiry to determining the purpose for which SPS measures were adopted but also the purposes for which the measures were maintained and applied:

"[W]e consider that it would not be appropriate in this case to limit our inquiry to determining the purposes for which the safeguard measures were adopted. To begin with, we recall that our task in this case is to determine the purposes for which the relevant safeguard measures were maintained in August 2003. Furthermore, Annex A(1) does not refer to measures 'adopted' for one of the enumerated purposes, but, more broadly, to measures 'applied' for one of the enumerated purposes. Moreover, we see nothing in the SPS Agreement which would bar a Panel from considering purposes which were not articulated by the member States when they adopted their safeguard measures. Finally, our approach is consistent with the view expressed by the Appellate Body that in identifying the purposes of a measure, Panels need not seek to determine the subjective intent of the legislators or regulators who adopted the measure. According to the Appellate Body, the purposes of a measure may and should rather be ascertained on the basis of objective considerations, for instance by examining whether there is an objective relationship between the stated purposes and the text and structural features of the relevant measure."<sup>23</sup>

18. In *Australia – Apples*, the Appellate Body considered that the word "applied" in the chapeau of Annex A(1) points to the application of the measure and thus, suggests that the relationship of the measure and one of the objectives listed in Annex A(1) must be "manifest in the measure itself or otherwise evidence from the circumstances related to the application of the measure". This led the Appellate Body to conclude that "the purpose of a measure is to be ascertained on the basis of objective considerations".<sup>24</sup>

##### **1.2.1.5.2 SPS measure versus environment protection measure**

19. On the basis of the definition of an SPS measure within Annex A, the Panel in *EC – Approval and Marketing of Biotech Products*, inferred that since the measures at issue aim at protecting plant life or health as part of the environment protection objective, they might well serve one of the purpose of the SPS Agreement and could therefore be considered, in this particular circumstance, as SPS measure:

"We note that in accordance with Annex A(1)(a) and (b) of the *SPS Agreement*, the *SPS Agreement* covers measures applied to protect animal and plant life or health from certain risks. Thus, to the extent Directives 90/220 and 2001/18 are applied to protect animals and plants as part of their purpose of protecting the environment, they are not *a priori* excluded from the scope of application of the *SPS Agreement*."<sup>25</sup>

20. In *EC – Approval and Marketing of Biotech Products*, the Panel made a distinction between an SPS requirement and an environment protection measure. Drawing from the 1993 GATT Secretariat Background Paper, the panel used examples to warn that the purpose of environmental protection, *per se*, is not sufficient to bring a measure within the scope of application of the SPS Agreement, even if the measure otherwise meets the definition of an SPS measure (e.g., in terms of its form and nature):

---

<sup>22</sup> Panel Report, *US – Poultry (China)*, para. 7.141.

<sup>23</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2558.

<sup>24</sup> Appellate Body Report, *Australia – Apples*, para. 172.

<sup>25</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.207.

"To provide an example, a measure to reduce air pollution may be applied to protect the life or health of plants (to the extent that high levels of air pollution could result in certain plant species lacking sufficient sunlight for them to exist and survive), and hence to protect the environment, but it would nonetheless not be a measure applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement* (in that the measure would not be applied to protect plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms, or to prevent other damage from the entry, establishment or spread of pests)."<sup>26</sup>

21. On addressing the exclusion of environmental measures *per se* of the scope of application of the SPS Agreement, the Panel in *EC – Approval and Marketing of Biotech Products* turned to the 1990 Draft Text on Sanitary and Phytosanitary Measures circulated by the Chairman of the Working Group on Sanitary and Phytosanitary Measures. On consideration of the style used in the draft text, the Panel refrained from considering that the removal of bracketed texts in that instance amounts to dismissal of environmental measures from the scope of the SPS Agreement. The Panel further declined to consider this evidence in the case at issue:

"We note that the draft text contained bracketed text the acceptance of which would have meant that 'measures for the protection of animal welfare and of the environment, as well as of consumer interests and concerns' are 'SPS measures' within the meaning of the Annex A(1) definition. However, the Annex A(1) definition in the Chairman's draft text also contained bracketed text which stated that '[r]equirements concerning quality, composition, grading, [consumer preferences, [...], the environment or ethical and moral considerations] are *not* included in the definition of sanitary or phytosanitary measures'. Neither of the two bracketed texts was included in the final text of the *SPS Agreement*. Since according to one of the two bracketed texts measures taken for the protection of the environment would have been covered by the *SPS Agreement*, while according to the other bracketed text such measures would not have been covered, and since neither text was included in the final text of the *SPS Agreement*, we cannot draw the inference that the European Communities asks us to draw – that the removal of the bracketed text which would have meant that measures taken for the protection of the environment are SPS measures implied a decision that such measures should not be covered by the *SPS Agreement*. In view of the fact that neither of the two bracketed texts was included in the final text of the *SPS Agreement*, we consider that the Working Group Chairman's draft text does not assist us in determining whether all measures applied to protect from risks to the environment other than risks to the life or health of animals or plants fall outside the scope of application of the *SPS Agreement*."<sup>27</sup>

#### **1.2.1.6 Whether a law, or a requirement contained therein, may be deemed to embody an SPS measure as well as a non-SPS measure**

22. In *EC – Approval and Marketing of Biotech Products*, the European Communities requested the Panel to determine "whether a law, or a requirement contained therein, may, if it meets the applicable conditions, be considered to incorporate an SPS measure as well as a distinct measure which falls to be assessed under a WTO agreement other than the SPS Agreement, such as the TBT Agreement". The Panel considered, using a hypothetical example, that the European Communities' view might well be tenable in specific circumstances:

"[W]e consider that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1), it may be properly viewed as a measure which falls to be assessed under the *SPS Agreement*; to the extent it is applied for a purpose which is not covered by Annex A(1), it may be viewed as a separate measure which falls to be assessed under a WTO agreement other than the *SPS Agreement*. It is important to stress, however, that our view is premised on the circumstance that the requirement at issue could be split up into two separate requirements which would be identical to the requirement at issue, and which would

---

<sup>26</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.210.

<sup>27</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.211.

have an autonomous *raison d'être*, *i.e.*, a different purpose which would provide an independent basis for imposing the requirement.

We recognize that, formally, the requirement at issue constitutes one single requirement. However, neither the *WTO Agreement* nor WTO jurisprudence establishes that a requirement meeting the condition referred to in the previous paragraph may not be deemed to embody two, if not more, distinct measures which fall to be assessed under different WTO agreements. We note that Annex A(1) of the *SPS Agreement*, which defines the term 'SPS measure', refers to '[a]ny measure' and to 'requirements'. But these references do not imply that a requirement cannot be considered to embody an SPS measure as well as a non-SPS measure."<sup>28</sup>

23. To further highlight the possibility of a single requirement embodying an SPS as well as a non-SPS measure, the Panel in *EC – Approval and Marketing of Biotech Products* added that, on a procedural level, it is possible to enact a measure which embeds SPS and non-SPS provisions. However, the Panel cautioned that enacting a requirement as a SPS measure and a non-SPS measure might reveal some intricacies that could prejudice the coherence of the adopting Member's legal order:

"In addition to the foregoing considerations, there is another consideration which we think militates against treating the requirement at issue as constituting only an SPS measure. To see this, it should first of all be recalled that, as a general matter, Members impose requirements because they consider it necessary to do so. If they do deem it necessary to impose a particular requirement, it is only logical that they also seek to minimize the risk of a successful legal challenge, whether before a domestic court or at the WTO. In the case of our hypothetical example, the Member concerned would face the risk – for instance, due to uncertainties as to the correct interpretation or application of relevant WTO provisions – that a WTO Panel would find the requirement at issue to be WTO inconsistent as an SPS measure but WTO-consistent as a non-SPS measure, or vice versa, or that a Panel would find the requirement to be WTO-inconsistent either as an SPS or as a non-SPS measure.

If the view were taken that the requirement at issue would constitute an SPS measure only, the Member concerned would have to defend that requirement as an SPS measure. In view of the possibility that the requirement at issue might withstand scrutiny by a WTO Panel as a non-SPS measure, but not as an SPS measure, it is reasonable to assume, however, that, *ex abundanti cautela*, the Member concerned would not want to forgo the opportunity of defending the requirement at issue also as a non-SPS measure. The Member concerned could prevent this by enacting the requirement at issue twice, either in different laws with a statement of the appropriate purpose or in the same law as separate provisions with a statement of their different purpose. However, a Member might face substantial difficulties in convincing its legislators of the need for enacting the same requirement twice, whether it be in different laws or as separate provisions in the same law. Moreover, pursuing this option might run counter to many Members' basic legislative objectives and requirements. It is axiomatic that the primary objective of legislation is to communicate directives to those affected by it in a manner that is clear, easily understandable and reduces uncertainties. By enacting the same requirement twice, in different laws or as separate provisions in the same law, a Member would arguably reduce clarity and create a potential for confusion and uncertainty among those affected by the law. Also, if the same requirement were enacted twice in different laws, the result would be a more fragmented domestic legal order."<sup>29</sup>

24. Having reviewed the benefits of the choice to enact a single requirement as both SPS and non-SPS measure, the Panel in *EC – Approval and Marketing of Biotech Products* conceded that Members remain free to choose the option which better fits into their needs in this particular area, taking into account the need to act in accordance with their legitimate legislative objectives:

---

<sup>28</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.165-7.166.

<sup>29</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.168-7.169.

"[I]f we were to embrace the view that the requirement in the consolidated law must be considered to constitute an SPS measure only, we would effectively impose an unwanted choice on the Member concerned. The Member could either choose to enact the requirement at issue twice and thus possibly act inconsistently with sound legislative objectives. Or it could choose not to enact the requirement twice and thus expose itself to potential legal risks. We think it would be ill-advised to put Members in a situation where they effectively have to make this kind of choice, particularly when it is not imposed by WTO rules. As we have said, we are unaware of a directive in the *WTO Agreement* which says that a requirement can never be deemed to embody two or more distinct measures which fall to be assessed under different WTO agreements.

To be clear, we are not saying that Members cannot, or should not, enact the same requirement twice if they see fit to do so. Plainly, Members may do so. Our concern is with those Members, and the European Communities appears to be among them, that see fit not to do so. We consider that we should not interpret the *WTO Agreement* in a manner which would effectively require Members to choose between enacting a requirement twice, which may be inconsistent with their internal laws or their legitimate preference, and exposing themselves to potential legal risks, which may be imprudent."<sup>30</sup>

## 1.2.2 Annex A(1)(a)

### 1.2.2.1 General

25. The Panel in *EC – Approval and Marketing of Biotech Products* held that in order to determine whether the European Communities' measures fell within the definition of an SPS measure, it needed to consider the meaning and scope of particular terms and phrases in Annex A(1)(a) and whether the potential effects of genetically modified organisms identified as the purpose behind the European Communities' measures meet the definitions of those terms and phrases:

"In order for us to determine whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(a), we need to consider the meaning and scope of some of the terms and phrases used in Annex A(1)(a) and address whether certain potential effects of GMOs identified in the Directives meet the definition of these terms and phrases. Accordingly, we have structured our analysis below according to certain terms and phrases used in Annex A(1)(a), including 'animal or plant life or health', 'risks arising from', 'entry, establishment or spread', 'pests' and 'diseases, disease-carrying organisms or disease-causing organisms.' We note that one specific concern which has been identified in Directives 90/220 and 2001/18 relates to potential adverse effects of GMOs resulting from the use of antibiotic resistance marker genes. A separate subsection addresses whether this concern can be considered to relate to the risks covered in Annex A(1)(a)."<sup>31</sup>

26. In *Australia – Apples*, the Appellate Body made reference to its prior decision under Article III of the GATT 1994, in determining whether a measure fell within the scope of Annex A(1)(a). The Appellate Body stated:

"We consider that the meaning that has been attributed to the phrase 'applied ... so as to afford protection' in the context of Article III:1 of the GATT 1994 may provide some assistance to the interpretative task before us. The language of Annex A(1)(a) to the *SPS Agreement* is similar to Article III:1 of the GATT 1994, to the extent that both provisions use the word 'applied', and in both provisions this word is followed by the infinitive of purpose, namely, 'to protect' or 'to afford protection', respectively. With regard to Article III of the GATT 1994, the Appellate Body has opined that, although the purpose of a measure is not easily ascertained, it can often be discerned from the measure's design, architecture, and structure. A similar approach is called for under Annex A(1)(a) to the *SPS Agreement*. Whether a measure is 'applied ... to

---

<sup>30</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.170-7.171.

<sup>31</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.213.

protect' in the sense of Annex A(1)(a) must be ascertained not only from the objectives of the measure as expressed by the responding party, but also from the text and structure of the relevant measure, its surrounding regulatory context, and the way in which it is designed and applied. For any given measure to fall within the scope of Annex A(1)(a), scrutiny of such circumstances must reveal a clear and objective relationship between that measure and the specific purposes enumerated in Annex A(1)(a)."<sup>32</sup>

#### **1.2.2.2 "to protect animal or plant life or health"**

27. The Panel in *EC – Approval and Marketing of Biotech Products* found that the phrase "to protect animal or plant life or health" in Annex A(1)(a) related to the definitions in footnote 4 and concluded that the phrase included all types of flora and fauna including micro- and macro-flora and fauna and target and non-target organisms:

"[I]t should be recalled that the footnote to the definitions provided in Annex A of the *SPS Agreement* states that: 'For the purpose of these definitions, 'animal' includes fish and wild *fauna*; 'plant' includes forests and wild *flora*; 'pests' include weeds; and 'contaminants' include pesticide and veterinary drug residues and extraneous matter.' The term 'fauna' is commonly defined as 'the animals or animal life of a given area, habitat, or epoch', whereas the term 'flora' is commonly defined as 'plants or plant life of a given area, habitat, or epoch'. The clarification provided in the footnote to Annex A that the terms 'animal' and 'plant' include 'wild fauna' and 'wild flora' indicates to us that the scope of the phrase 'animal or plant life or health' is meant to be comprehensive in coverage. Moreover, we note that, textually, the unqualified terms 'animal' and 'fauna', on the one hand, and 'plant' and 'flora', on the other, can encompass macro- and micro-fauna, on the one hand, and macro- and micro-flora, on the other. We also consider that the terms 'animal' and 'plant' can encompass both target and non-target fauna and flora. By 'non-target' fauna and flora, we mean plants and animals (including insects) which are not themselves the organisms farmers seek to control or eliminate through the cultivation of GM crops, but which are affected by the cultivation of the GM crop, including through consumption of components of the GM plants (e.g., pollen). In the light of this, we consider that non-target microorganisms, such as soil or aquatic micro-organisms, are 'animals' or 'plants' within the meaning of Annex A(1)."<sup>33</sup>

#### **1.2.2.3 "risks arising from"**

28. The Panel in *EC – Approval and Marketing of Biotech Products*, relying on dictionary meanings, found that the phrase "risks arising from" as used in Annex A(1)(a) meant "occur as a result of":

"The Panel notes that the dictionary defines the phrasal verb 'to arise from' as meaning 'occur as a result of'. Thus, the phrase 'risks arising from' indicates that the relevant risks to animal or plant life or health must occur as a result of some event, substance, condition, etc. In the specific context of Annex A(1)(a), the phrase 'risks arising from' implies that the risks to animal or plant life or health must occur as a result of a pest, disease, disease-carrying organism or disease-causing organism."<sup>34</sup>

#### **1.2.2.4 "entry, establishment or spread"**

29. In *EC – Approval and Marketing of Biotech Products*, the Panel, in addressing the SPS criteria of the measures at issue, ruled on whether the purpose of the measures was concerned with the "entry, establishment or spread" of pests, diseases, etc.:

"It is clear to us that the purpose of avoiding disease in general includes the purpose of avoiding, more specifically, the 'entry, establishment or spread' of 'diseases'. ... We

---

<sup>32</sup> Appellate Body Report, *Australia – Apples*, para. 173. See also Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.87.

<sup>33</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.218-7.219.

<sup>34</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.224.

think that the purpose of avoiding 'pest effects' of GMOs includes the purpose of avoiding the 'entry, establishment or spread' of GMOs as 'pests'. ... In the light of this, we are satisfied that Directives 90/220 and 2001/18 can be considered to constitute measures applied to protect against risks arising from the 'entry, establishment or spread' of, *inter alia*, disease and 'pest effects' which may be caused by GMOs."<sup>35</sup>

#### **1.2.2.5 "pests"**

30. The Panel in *EC – Approval and Marketing of Biotech Products* found that, in the context of the SPS Agreement, the term "pests" should be understood as referring to an animal or plant which is destructive, or causes harm to the health of other animals, plants, or humans, or other harm, or a troublesome or annoying animal or plant:

"The Panel notes at the outset that three of the sub-paragraphs of Annex A(1) to the SPS Agreement, namely, Annex A(1)(a), A(1)(c) and A(1)(d), identify 'pests' as a possible source of risks. The word 'pest' ordinarily means 'a troublesome, annoying or destructive person, animal, or thing'. In applying this definition to Annex A(1), we find two contextual elements in particular to be noteworthy. The first is the previously mentioned footnote to the definitions provided in Annex A of the SPS Agreement. It specifies that, for the purposes of the SPS Agreement, the term "pest" includes weeds. Weeds are plants. Therefore, we consider that the term 'pest' in Annex A(1) must be understood to cover plants in addition to animals. The other element which we find instructive are the references in Annex A(1)(a) and A(1)(c) to 'animal or plant life or health' and 'human life or health' as well as the reference in Annex A(1)(d) to 'other damage'. It is apparent from these references that the SPS Agreement is intended to be applicable, not just to measures taken to protect against risks which pose a threat to the life, and thus the very existence, of animals, plants or humans, but also to measures taken to protect against risks to the 'health' of animals, plants or humans, and to measures taken to prevent other 'damage' within the territory of a Member. In the light of this, we consider that the term 'pest' should be interpreted to cover 'destructive' animals or plants – that is animals or plants which destroy the life and threaten the very existence of other animals, plants or humans. Equally, however, we think that, for the purposes of the SPS Agreement, the term 'pest' should be interpreted to cover animals and plants which cause other, less serious, deleterious effects, namely, animals and plants which cause harm to the health of animals, plants or humans or which cause other harm."<sup>36</sup>

31. Rejecting the European Communities' view that pests are meant to be living organisms, the Panel in *EC – Approval and Marketing of Biotech Products* argued that pests do not need to be alive to be considered as liable to exert harmful damages to life or health:

"The European Communities has argued that a pest must be a living organism. We have previously noted that the term 'pest' in Annex A(1) encompasses plants which are destructive, or which cause harm to the health of other animals, plants or humans. While it may be true that many organisms will lose their ability to act as pests if they are no longer alive, we are not persuaded that this is necessarily always the case. In particular, we are not convinced that all plants which are pests as living organisms cease to be destructive or harmful to health immediately after being harvested."<sup>37</sup>

#### **1.2.2.6 "diseases, disease carrying organisms or disease-causing organisms"**

32. In *EC – Approval and Marketing of Biotech Products*, the Panel provided the definition of the terms "diseases, disease carrying organisms or disease-causing organisms", in light of the ordinary meanings given to these words by the World Health Organization:

"The Panel observes that the common definition of the term 'disease' as it appears in Annex A(1)(a) is 'a disorder of structure or function in an animal or plant of such a

---

<sup>35</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.231.

<sup>36</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.238-7.239.

<sup>37</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.351.

degree as to produce or threaten to produce detectable illness or disorder'. The World Health Organization (hereafter the 'WHO') defines disease as 'a pathological condition of the body that presents a group of clinical signs, symptoms, and laboratory findings peculiar to it and setting the condition apart as an abnormal entity differing from other normal or pathological conditions (CMD 1997)'. Regarding the term 'disease-carrying organisms' and 'disease-causing organisms' in Annex A(1)(a), we note that the WHO defines a disease-carrying organism as a 'vector' and a disease-causing organism as a 'pathogen'.<sup>38</sup>

### **1.2.3 Annex A(1)(b)**

#### **1.2.3.1 General**

33. As with the methodology it followed for the previous subparagraph of Annex A, the Panel in *EC – Approval and Marketing of Biotech Products*, assessed the compliance of the measures at issue with the provisions of Annex A(1)(b) by referring to the ordinary meaning given to the concepts in question within the provisions of Annex A:

"We now turn to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(b) of the *SPS Agreement*. As we have done above with regard to Annex A(1)(a), we will structure our analysis below according to certain terms and phrases used in Annex A(1)(b), including 'foods, beverages or feedstuffs', 'additives', 'contaminants' and 'toxins'. The Parties have also addressed concerns relating to potential effects of allergens on human and animal health in the context of Annex A(1)(b), hence we will also consider these concerns below."<sup>39</sup>

#### **1.2.3.2 "foods, beverages or feedstuffs"**

34. The Panel in *EC – Approval and Marketing of Biotech Products* used the dictionary definition of the individual terms in the phrase "foods, beverages or feedstuffs" and found that genetically modified crops eaten by animals can be considered feedstuffs and food:

"The Panel notes that the common definition of a 'food' is a substance taken into the body to maintain life and growth. Thus, we consider that a substance which a human being or an animal consumes for nutritional reasons may be classified as a 'food'. A 'feedstuff' on the other hand is defined as fodder, and 'fodder' is defined as 'food for cattle, horses, etc., and more specifically as dried food, as hay, straw, etc., for stall-feeding'.

Applying these definitions in the context of this dispute, we consider that a GM crop grown for the explicit purpose of providing food to animals, and in particular to farmed animals, would qualify as a 'feedstuff'. A GM crop that has been grown for a different purpose, but is eaten by animals, including wild fauna, can be considered to be a 'food' for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. Contrary to the European Communities, we think GM seeds used for sowing purposes could also be considered animal 'food', for instance if these seeds are spilled next to a field or on a farm and are subsequently eaten by birds, etc."<sup>40</sup>

#### **1.2.3.3 "additives"**

##### **1.2.3.3.1 Concept**

35. The Panel in *EC – Approval and Marketing of Biotech Products* relied on the dictionary and the Codex definition of "additive" to find that a gene could be considered a food additive:

---

<sup>38</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.277.

<sup>39</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.287.

<sup>40</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.291-7.292.

"The Panel notes that the New Shorter Oxford English Dictionary defines 'additives' as 'a substance added to another so as to give it specific qualities'. Given that Annex A(1)(b) is concerned with additives in foods, we also find informative that Codex defines a 'food additive' as: 'Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities.' The Panel is not convinced by the European Communities' categorical assertion that genes cannot be considered substances. A 'substance' is defined as the 'real physical matter of which a person or thing consists'. It is our understanding that genes may be considered as 'real physical matter'. We do not dispute that genes contain and encode instructions for the creation of various substances. However, this does not exclude that genes may themselves constitute substances."<sup>41</sup>

#### **1.2.3.3.2 Relevance of Codex**

36. Although the Panel in *EC – Approval and Marketing of Biotech Products* utilized the Codex definition of additives in its interpretation of Annex A(1)(b), it found that the Codex definition was not dispositive.<sup>42</sup> The Panel found that the specific reliance on international standards found in Article 3 and Annex A(3) of the SPS Agreement did not apply to Annex A(1):

"In any event, the Codex definition is not dispositive of the meaning of the term 'additives' as it appears in Annex A(1)(b). We are aware that pursuant to Article 3(1) of the SPS Agreement Members are to base their SPS measures on 'international standards, guidelines and recommendations', where they exist, and that in accordance with Annex A(3)(a) of the SPS Agreement, Codex standards relating to food additives are relevant 'international standards' within the meaning of Annex A(3)(a). However, unlike Article 3(1) and Annex A(3), Annex A(1) makes no reference to 'international standards, guidelines and recommendations'. Had the drafters of the SPS Agreement intended for terms like 'additives' to have the meaning given to them by definitions contained in relevant international standards, etc., we think Annex A(1) would have made this clear. Looking at the text of Annex A(1)(b), we note that it broadly, and simply, refers to 'additives' 'in foods'.<sup>43</sup>

#### **1.2.3.4 "contaminants"**

37. The Panel in *EC – Approval and Marketing of Biotech Products* also examined the term "contaminants" and found that it must mean something distinct from an "additive". After examining dictionary and Codex definitions as well as the footnote to Annex A, the Panel found that, for a substance to be a contaminant, the presence of the infecting or polluting substance would have to be unintentional:

"The Panel notes that the common meaning of a contaminant is 'a substance which pollutes, corrupts or infects'. We also note that the footnote to Annex A to the SPS Agreement states in relevant part that '[f]or purposes of these definitions ... 'contaminants' include pesticide and veterinary drug residues and extraneous matter'. These definitions have in common the fact that they refer to substances which are not intentionally added to food. This view is consistent with the abovementioned Codex definition of 'contaminant', which refers to any substance not intentionally added to food, and which is present in such food as a result of the production, processing, packaging, etc, or as a result of environmental contamination.

---

<sup>41</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.297-7.298.

<sup>42</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.299.

<sup>43</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.300.

Based on the above elements, and noting that the term 'contaminants' must be interpreted so as to have a meaning that differs from the meaning of the term 'additive' which also refers to substances, we consider that a critical element for determining whether a substance can be considered to be a 'contaminant' is that the presence of the substance which is said to 'infect or pollute' be unintentional. For this reason, we consider that genes intentionally added to GM plants that are eaten or used as inputs into processed foods would not be 'contaminants' in and of themselves. Furthermore, we think that substances such as proteins which are produced by GM plants, and which are intended, should not be considered to be 'contaminants'. However, we agree with Canada that proteins produced through the unintended expression of modified genes in agricultural crops may be considered 'contaminants' within the meaning of Annex A(1)(b), if these proteins 'infect or pollute' the food product."<sup>44</sup>

### **1.2.3.5 "toxins"**

#### **1.2.3.5.1 Definition**

##### **1.2.3.5.1.1 Relevance of the criteria related to "unintentional addition to food"**

38. In *EC – Approval and Marketing of Biotech Products*, the Panel examined the ordinary meaning of the term toxin having regard to the definitions provided under the Codex Alimentarius and other relevant texts. From these definitions, the Panel ruled that "unintentional addition to food" is not an element of the definition of "toxin":

"The Panel notes that common definitions of a 'toxin' are 'a poison produced by a microorganism or other organism and acting as an antigen in the body' or 'any poisonous antigenic substance produced by or derived from micro-organisms, which causes disease when present at low concentration in the body'. Codex Standard 193 defines two types of toxins in the context of describing the general standard for contaminants and toxins in foods. One is a mycotoxin defined as 'a toxicant that is produced as a toxic metabolite of certain microfungi that are not intentionally added to food.' The other is a microbial toxin defined as 'toxicants that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish'. FAO defines a toxin as 'a compound produced by one organism, which is deleterious to the growth and/or survival of another organism of the same or different species'. We note that these definitions do not suggest that toxins in foods are inherently substances which have been unintentionally added to foods. To be sure, every effort is ordinarily made to avoid the presence of toxins in foods. Nonetheless, a toxin specific to a particular pest is sometimes deliberately added to a food for the purpose of controlling or eradicating that target pest."<sup>45</sup>

39. The Panel in *EC – Approval and Marketing of Biotech Products* examined the term "toxin" as used in paragraph (1)(b) and found that, unlike contaminants, the addition of the toxin to the food or feedstuff does not need to be unintentional:

"The European Communities argues that the toxins produced by insecticidal GM plants to kill the target insect are not 'covered' by Annex A(1)(b) since the production by the GM plant of the toxins is intentional and since it is not possible to kill the target insect and at the same time seek to protect the life and health of those very insects. In our view, the mere fact that the toxin is intentionally produced in the GM plant would not necessarily remove any concerns relating to the toxic effect on the target insect from the scope of Annex A(1)(b). For it could be argued, not implausibly, that the insecticide-producing GM plant constitutes a 'toxin' in the food of the target insect which poses a risk to the life and health of the target insect. However, the target insect in the European Communities' example is assumed to be a recognized pest. Accordingly, the release of insecticide-producing GM plants into the environment would normally be controlled, not to protect the life or health of the target insect from

---

<sup>44</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.312-7.313.

<sup>45</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.321.

risks arising from the release of the GM plant, but to protect the life or health of non-target organisms, etc., from any risks arising from the release of the GM plant."<sup>46</sup>

#### **1.2.3.5.1.2 Relevance of the poisonous effect of the toxins**

40. The Panel in *EC – Approval and Marketing of Biotech Products* rejected the argument of the European Communities that the term "toxin" should be construed narrowly so that a measure aimed to protect animal, plant or human life from an allergen would not fall under the definition of an SPS measure in paragraph (1)(b). The Panel stated:

"We see nothing in Annex A(1) or in the ordinary meaning of the term 'toxin' which indicates that for a substance to qualify as a 'toxin' in a food or in a feedstuff, the substance needs to be poisonous for each and every human being or animal which is exposed to it through the consumption of the food or feedstuff. Indeed, we find it difficult to believe that the term 'toxins' was intended to have such a narrow meaning. If that were the case, a measure applied by a Member to protect human health from risks arising from substances present in food which are poisonous for only a small fraction of its population would not be subject to the disciplines of the SPS Agreement. Conversely, a measure applied to protect from risks arising from substances present in food which are poisonous for the entire population would be subject to the *SPS Agreement*. In our view, it would be incongruous if Members were subject to stricter disciplines when it comes to controlling risks affecting the entire population than they would be when they seek to control risks affecting only a small segment of their population. Also, the measures taken in either case might have equivalent effects on trade."<sup>47</sup>

#### **1.2.3.5.2 Allergens as toxins**

##### **1.2.3.5.3 Definition of allergens**

41. In addressing parties' concerns on potential allergic responses to GMOs in the context of Annex A(1)(b), the Panel in *EC – Approval and Marketing of Biotech Products* first noted that Annex A(1)(b) does not mention allergenicity as a food safety concern. The Panel then examined whether allergens in foods or feedstuffs could nevertheless be considered to fall within the category of toxins and therefore be included in the definition of Annex A(1)(b):

"The term 'allergen' is commonly defined as 'a substance that causes an allergic reaction'. The term 'allergic' is defined as 'of, caused by, or relating to an allergy', and the term 'allergy' is defined in turn as 'a damaging immune response by the body to a substance to which it has become hypersensitive'. It may be inferred from these definitions that an 'allergen' is a substance which causes a damaging immune response by the body in humans or animals which have become hypersensitive to that substance. This is consistent with the definition of 'allergen' provided in the FAO Glossary of Biotechnology for Food and Agriculture, which describes an allergen as 'an antigen that provokes an immune response'.

With specific reference to the products at issue in this dispute, we add that, in our understanding, allergens would be proteins generated through the expression of genes. Thus, the concern about potential allergenicity of GMOs relates to the effect of modified genes on protein composition in GM plants and the subsequent exposure of humans or animals to these proteins through the consumption of food or feedstuffs produced using the GM plants."<sup>48</sup>

---

<sup>46</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.322.

<sup>47</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.339.

<sup>48</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.334-7.335.

#### 1.2.3.5.4 Inclusion of allergens in the categories within Annex A

42. Having reviewed the definitions of allergens, the Panel in *EC – Approval and Marketing of Biotech Products* ruled that allergens could be considered as toxins in light of their definition and the damaging effect that they may have on life and health:

"[T]he Complaining Parties argue that 'allergens' would generally meet the definition of the term 'toxins' as it is used in Annex A(1)(b). We have stated earlier that the term 'toxin' in Annex A(1)(b) can be understood to refer to a poisonous substance produced by a micro-organism or other organism and acting as an antigen in the body. A 'poison' is commonly defined as 'a substance that causes death or harm when introduced into or absorbed by a living organism', or as 'a substance that through its chemical action is able to kill, injure, or impair an organism'.

We have said that allergens may be understood as substances which act as antigens and cause a damaging immune response by the body in humans or animals. From the information submitted to us, we understand that such immune responses can be very damaging to health, and in some cases may even be fatal, *e.g.*, in the event of an anaphylactic shock. In the light of this, it seems to us to be correct to characterize food allergens as substances which can 'cause death or harm' to health, or as substances which through their chemical action are able to 'kill, injure or impair an organism'. Thus understood, the kind of food allergens which might be produced by GMOs can be appropriately viewed as poisonous substances produced by an organism and acting as an antigen in the body. Consequently, we think that for the specific purposes of Annex A(1) the term 'toxins' encompasses, *inter alia*, food allergens which might be produced by GMOs. We observe in this connection that we have seen no evidence establishing that the drafters of the *SPS Agreement* intended to exclude food allergens from the scope of the *SPS Agreement* in general, and the term 'toxins' in particular."<sup>49</sup>

#### 1.2.4 Relationship between Annex A(1)(a) and Annex A(1)(b)

43. In *Australia – Salmon*, the Panel examined whether an Australian prohibition on imports of dead salmon was a "sanitary measure" within the meaning of paragraph 1(b) of Annex A of the SPS Agreement. The Panel found that while the definition in Annex A(1)(a) is broad and covers measures intended to protect animal or plant life or health from risks arising as a result of pests and diseases, Annex A(1)(b) focuses on measures intended to protect human or animal life or health from disease-causing organisms contained in food, beverages or feedstuffs. The Panel held:

"In the circumstances at hand, we consider that the definition of a 'sanitary measure' in paragraph 1(a) encompasses the coverage sought by Australia under the definition in paragraph 1(b). The definition in paragraph 1(a) deals with risks arising from 'the entry, establishment or spread of pests, diseases ... or disease-causing organisms' in general. In the context of disease-causing organisms, the definition in paragraph 1(b) is limited in the sense that it only addresses risks arising from 'disease-causing organisms in foods, beverages or feedstuffs' (hereafter also referred to as food-borne risks). We are of the view that, even though both definitions of a 'sanitary measure' invoked by Australia might be applicable to the measure in dispute, the objectives for which that measure is being applied are more appropriately covered by the definition in paragraph 1(a). These objectives have been clearly expressed by Australia on several occasions."<sup>50</sup>

44. With respect to the two definitions of risk assessment under paragraph 4, see paragraph 59 below.

---

<sup>49</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.336-7.337.

<sup>50</sup> Panel Report, *Australia – Salmon*, para. 8.34.

### 1.2.5 Annex A(1)(c)

#### 1.2.5.1 The issue of presence of allergens in the environment

45. In the context of analyzing the broader issue of potential allergenic effects of GMOs which are not used as or in foods within the meaning of Annex A(1) (c) of the SPS Agreement, the Panel in *EC – Approval and Marketing of Biotech Products* considered the issue of exposure of persons working, or otherwise coming into contact, with GMOs by means other than through food. For the Panel, what was at issue was the potential of GMOs to produce allergenic effects when not used as or in foods. The Panel took the view that if GMO's allergenicity was established in the latter context, they could be considered as pests:

"We consider that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be viewed as 'pests' within the meaning of Annex A(1). We recall our view that the term 'pests' in Annex A(1) encompasses plants which are destructive, or which cause harm to the health of other animals, plants or humans. We also recall our view that allergens may be understood as substances which cause a damaging immune response by the body in humans, and that such immune responses can be very damaging to health, and in some cases may even be fatal, *e.g.*, in the event of an anaphylactic shock. In the light of this, we consider that to the extent a GM plant produces allergenic effects other than as a food, it would be a plant which causes harm to the health of humans and, as such, would qualify as a 'pest'. We recognize that a GM crop producing this type of allergenic effects would often be cultivated intentionally. From the perspective of the farmer cultivating the GM crop, the GM crop would not, therefore, constitute a 'pest'. However, from the perspective of the farm worker who is in contact with the crop in the field, or a person walking past the field, the GM crop may constitute a 'pest' if the person is hypersensitive to the allergen."<sup>51</sup>

#### 1.2.5.2 Possible health effects from increased herbicide use associated with GMOs

46. In *EC – Approval and Marketing of Biotech Products*, the Panel discussed the issue of introduction of herbicide-resistant GM plants to the extent that this introduction might lead to the use of herbicides in the field when no herbicides were previously used and increased use of herbicides or use of different herbicides. As this introduction might in turn cause harm to human health, the Panel endorsed the European Communities' hypothesis that the relevant harm deriving from the use of pesticides would not be the result of herbicide residues in the GM plant, but of exposure to the herbicide other than through the consumption of the GM plant. The Panel stated:

"[I]t may be that the European Communities' concern about possible negative health effects relates to improper use, or unanticipated effects, of approved herbicides. We therefore proceed with our analysis, assuming that there may be situations where the use of approved herbicides could cause harm to the health of persons applying the herbicide in the field or otherwise coming into contact with it.

...

[I]n relation to the scenario involving adverse effects on human health, it is clear to us that the weeds against which a particular herbicide is used qualify as 'pests' within the meaning of Annex A(1), and that the herbicide use constitutes a pest control measure. We likewise consider that risks to human health resulting from the use of a herbicide, or of a different herbicide, may be viewed as arising indirectly from the entry, establishment or spread of weeds *qua* relevant pests.

...

The GM plants, the herbicide and the weeds being interlinked in this way, we consider that there is a rational relationship between controlling the release into the environment of herbicide tolerant GM plants and the purpose of protecting human

---

<sup>51</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.350.

health from risks arising indirectly from the entry, spread or establishment of weeds. We recall in this context that there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a herbicide tolerant GM plant to be released into the environment – need itself be the pest which gives rise, directly or indirectly, to the risks from which the measure seeks to protect."<sup>52</sup>

## **1.2.6 Annex A(1)(d)**

### **1.2.6.1 "other damage"**

47. The Panel in *EC – Approval and Marketing of Biotech Products* analysed the term "other damage" as it is used in Annex A(1)(d) and concluded that it must comprise damage other than damage to the life or health of plants, animals, or humans, because these are covered by paragraphs (1)(a), (1)(b), and (1)(c). The Panel noted that "other damage" could include a broad range of possibilities, including damage to property, economic damage and damage to the environment other than damage to the life or health of living organisms:

"The Panel considers that it may be inferred from the reference in Annex A(1)(d) to 'other damage' (emphasis added) that like Annex A(1)(d), sub-paragraphs (a) through (c) of Annex A(1) refer to measures which are applied to protect from a certain kind of potential 'damage'. The 'damage' at issue in sub-paragraphs (a) through (c) of Annex A(1) is damage to plant, animal or human life or health. It follows, therefore, that the category of 'other damage' covered by Annex A(1)(d) must comprise damage other than damage to the life or health of plants, animals or humans. This is indeed the view expressed by all of the Parties.

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 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)."<sup>53</sup>

### **1.2.6.2 Relationship with other provisions of the SPS Agreement**

#### **1.2.6.2.1 Article 5.3**

48. The Panel in *EC – Approval and Marketing of Biotech Products* held that Article 5.3 contemplates a similar situation to that contemplated in Annex A(1)(d) in the interpretation of the word "damage". The Panel noted that the definition of "damage" covers harm resulting in a reduction of economic value, adverse economic effects, or economic loss.<sup>54</sup>

---

<sup>52</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.355, 7.357, and 7.359.

<sup>53</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.369-7.370.

<sup>54</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.370.

### 1.2.7 Annex A(1) second paragraph

#### 1.2.7.1 General

49. For a discussion of whether paragraph provides for two elements – form and nature – that define SPS measures, refer to paragraphs 5 and 7 above.

50. The Appellate Body in *Australia – Apples* discussed the meaning of the first line of Annex A(1) second paragraph: "Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures ...". The Appellate Body emphasized the significance of the words "include", "all", and "relevant" and stated that:

"We note that this last sentence of Annex A(1) follows, and relates to, all of the first sentence, including all of the purposes enumerated in subparagraphs (a) through (d). The first part of this sentence contains a list of legal instruments linked by the conjunction 'and' ('laws, decrees, regulations, requirements and procedures'). This list is modified by the words 'include' and 'all relevant'. The word 'relevant' is, in our view, a key element within this sentence. We see 'relevant' as a reference back to the preceding sentence in Annex A(1), that is, to the list of specific purposes that are the defining characteristic of every SPS measure. The words 'include' and 'all', which also introduce the list of instruments, suggest that the list is both illustrative and expansive. Taken together, the words 'include' and 'all relevant' therefore suggest that measures of a type not expressly listed may nevertheless constitute SPS measures when they are 'relevant', that is, when they are 'applied' for a purpose that corresponds to one of those listed in subparagraphs (a) through (d). Conversely, the fact that an instrument is of a type listed in the last sentence of Annex A(1) is not, in itself, sufficient to bring such an instrument within the ambit of the *SPS Agreement*."<sup>55</sup>

#### 1.2.7.2 "all relevant laws, decrees, regulations"

51. In *EC – Approval and Marketing of Biotech Products*, the Panel noted that the second paragraph of Annex A(1) provides that SPS measures include "all relevant laws, decrees [and] regulations," which suggests that the SPS Agreement does not prescribe a particular legal form and that SPS measures may in principle take many different legal forms:

"Whether a particular DSU measure constitutes, at the same time, an SPS measure is to be determined, according to the above definition, by reference to such criteria as the objective of the measure, its form and its nature. Regarding the objective of SPS measures, subparagraphs (a) through (d) indicate that SPS measures must 'be applied' to protect against certain enumerated risks. Regarding the form of SPS measures, the second paragraph of the definition provides that SPS measures include 'all relevant laws, decrees [and] regulations'. This enumeration suggests that the SPS Agreement does not prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Finally, in relation to the nature of SPS measures, the second paragraph stipulates that SPS measures include 'requirements and procedures'. The second paragraph then goes on to mention, by way of example, a number of relevant substantive requirements (prescribed end product criteria, prescribed quarantine treatments, certain packaging and labelling requirements, etc.) and procedures (testing procedures, inspection procedures, certification procedures, approval procedures, etc.). We note that the term 'requirements' is broad in scope. For instance, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered 'requirements', in that one is effectively a requirement to permit the marketing of a product and the other a requirement to ban the marketing of a product."<sup>56</sup>

---

<sup>55</sup> Appellate Body Report, *Australia – Apples*, para. 175. See also Panel Report, *Panama – Import Measures (Costa Rica)*, para. 7.66.

<sup>56</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1334.

### 1.2.7.3 "requirements and procedures"

52. The Panel in *EC – Approval and Marketing of Biotech Products* found that the reference to "requirements and procedures" in the definition of an SPS measure, as contained in Annex A(1), does not include the application of such requirements and procedures. With respect to the European Communities' general moratorium on approving the applications to place on the market genetically modified organisms, the Panel determined that the decision to apply a general moratorium was a decision concerning the application, or operation of procedures and as such was not an SPS measure within the meaning of Annex A(1)<sup>57</sup>:

"Still in relation to the reference in the second paragraph of Annex A(1) to 'requirements and procedures', we note that no reference is made to the 'application' of 'requirements and procedures'. This omission suggests that whereas requirements and procedures as such may constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure. The provisions of the SPS Agreement support the view that the omission of a reference to 'application' is deliberate, for there are several provisions which establish obligations specifically with regard to the 'application' of SPS measures. For instance, Article 2.3, second sentence, states that SPS measures 'shall not be applied in a manner which constitute a disguised restriction on international trade'. Similarly, Article 10.1 states in relevant part that '[i]n the preparation and application of [SPS] measures, Members shall take account of the special needs of developing country Members'. Finally, we note that Article 8 draws a distinction between, on the one hand, the 'operation' of procedures and, on the other hand, the 'procedures', which, themselves, are defined in Annex A(1) as SPS measures.

...

We have characterized the decision to apply a general moratorium on approvals as a procedural decision to delay final substantive approval decisions. In our assessment, this procedural decision did not impose a substantive 'requirement' in relation to biotech products with pending or future applications. It neither approved nor rejected applications. Similarly, we are of the view that the decision to delay final substantive approval decisions cannot appropriately be viewed as providing for a 'procedure', considering that it did not itself establish a new procedure or amend the existing EC approval procedures. We have said that the decision to delay final approval decisions was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures. However, the mere fact that the decision in question related to the application, or operation, of procedures does not turn that decision into a procedure for the purposes of Annex A(1).

Based on these considerations, we conclude that the European Communities' decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of procedures. As such, it did not provide for 'requirements [or] procedures' within the meaning of Annex A(1)."<sup>58</sup>

53. Although the Panel in *EC – Approval and Marketing of Biotech Products* found that the phrase "requirements and procedures" did not include the application of those requirements and procedures, it did find that the term "requirements" is unqualified and can apply to general regulatory requirements or requirements imposed on a specific product:

"It should be added in this context that the term 'requirements' as it appears in the second paragraph of Annex A(1) is unqualified and thus is applicable both to requirements which are generally applicable and to requirements which have been imposed on specific products. In our view, the application of a generally applicable SPS 'requirement' (e.g., a pre-marketing approval requirement for biotech products)

---

<sup>57</sup> Because the Panel in *EC – Approval and Marketing of Biotech Products* found that the general moratorium on approvals was not an SPS measure, the Panel rejected all of the claims of violations under Articles 5.1, 5.5, 5.6, 2.2, 2.3, and Article 7/Annex B(1) of the SPS Agreement. Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1395, 7.1407, 7.1421, 7.1441, 7.1448, and 7.1465.

<sup>58</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1335 and 7.1382-7.1383.

to a specific product may result in a different, product-specific SPS 'requirement' (e.g., a ban on the marketing of a specific biotech product). In other words, there may be cases where the application of an SPS 'requirement' and, hence, of an SPS measure, may give rise to a new SPS requirement and, hence, a new SPS measure. Applying these considerations to Article 5.1, it could be argued that a generally applicable SPS requirement as set out, e.g., in a law and a product-specific decision based on that requirement might both constitute SPS measures which must be based on a risk assessment."<sup>59</sup>

#### 1.2.7.4 "labelling requirements"

##### 1.2.7.4.1 General

54. In *EC – Approval and Marketing of Biotech Products*, the Panel ruled that Annex A of the SPS Agreement encompasses not only labelling requirements related to food safety<sup>60</sup> but also other labelling requirements. The Panel concluded that the labelling requirement in the measure at issue in that dispute fell within the scope of the SPS Agreement:

"We note that Annex A(1) to the *SPS Agreement* specifies that SPS measures include, '*inter alia*', 'packaging and labelling requirements directly related to food safety'. As is indicated by the term '*inter alia*' in Annex A(1), the requirements specifically mentioned are not necessarily intended to exclude similar requirements. Hence, while recognizing that labelling requirements imposed on food safety grounds may be more common, we consider that labelling requirements imposed for the purpose of protecting plant, animal or human health from the risks covered in Annex A(1)(a) and (c), or for the purpose of preventing or limiting other damage from the risk covered in Annex A(1)(d), would likewise be subject to the disciplines of the *SPS Agreement*.

... To the extent [the labelling requirement in Directive 2001/18] is applied to protect the environment, it would fall within the scope of Annex A(1)(a), (b) or (d), depending on what the adverse effects would be. To the extent it is applied to protect human health, it would fall within the scope of Annex A(1)(b) or (c). Thus, we consider that the labelling requirement in question does not remove Directive 2001/18 from the scope of the *SPS Agreement*."<sup>61</sup>

##### 1.2.7.4.2 Purpose of labelling requirements

55. With respect to the relevance of labelling requirements in the context of Annex A, the Panel in *EC – Approval and Marketing of Biotech Products* examined whether the labelling requirement in one of the measures at issue is linked to the purpose of protecting human health and the environment and hence is a measure applied for one of the purposes identified in Annex A(1)<sup>62</sup>:

"Explicit identification of the presence of a GMO alerts and sensitizes operators and users of a product containing or consisting of a GMO to the possibility that any observed adverse effects of the product on human health or the environment might be attributable to the presence of a GMO as opposed to other factors. Increased awareness of operators and users of the presence of GMOs may be presumed to lead to a situation where more observations which could be indicative of risks associated

---

<sup>59</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1336.

<sup>60</sup> According to the Panel, "labelling requirements related to food safety are labelling requirements which are applied to protect human health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods." Panel Report, *EC – Approval and Marketing of Biotech products*, para. 7.410.

<sup>61</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.390-7.391.

<sup>62</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.390. The Panel stated: "We note that Annex A(1) to the *SPS Agreement* specifies that SPS measures include, '*inter alia*', 'packaging and labelling requirements directly related to food safety'. As is indicated by the term "*inter alia*" in Annex A(1), the requirements specifically mentioned are not necessarily intended to exclude similar requirements. Hence, while recognizing that labelling requirements imposed on food safety grounds may be more common, we consider that labelling requirements imposed for the purpose of protecting plant, animal or human health from the risks covered in Annex A(1)(a) and (c), or for the purpose of preventing or limiting other damage from the risk covered in Annex A(1)(d), would likewise be subject to the disciplines of the *SPS Agreement*."

with a GMO are reported to consent holders and competent authorities, or where relevant observations are reported more promptly. Explicit identification of the presence in a product of a GMO may thus be presumed to result in consent holders and competent authorities being better informed, or informed more promptly, than they otherwise would be of unanticipated risks of a GMO to human health and the environment, allowing them to determine whether additional measures are necessary to protect human health and the environment.

Additionally, we observe that explicit identification of the presence in a product of a GMO serves the purpose of health and/or environmental protection in situations of unexpected, accidental release of a GMO – e.g., in connection with its storage or transport – into an environment in which the GMO is not be used or in which the potential for adverse effects has not specifically been considered in the risk assessment. In such situations, it can, in our view, be presumed that explicit identification of the presence in a product of a GMO will result in consent holders and competent authorities being more promptly and more effectively informed of any relevant incidents than would be the case if the product being stored or transported did not explicitly identify the presence of a GMO. To use again the example of storage or transport, we note that persons storing or transporting GMOs (e.g., the driver of a transportation vehicle) need not necessarily be persons under the supervision of the producer or user of GMOs or persons otherwise familiar with the specific characteristics of the product they are handling. For such persons in particular, explicit identification of the presence of a GMO renders more likely, and facilitates, an adequate and prompt response in situations of unexpected, accidental release of a GMO into the environment."<sup>63</sup>

#### **1.2.7.5 "directly related to food safety"**

56. In *EC – Approval and Marketing of Biotech Products*, the Panel noted that "[t]he term 'food safety' as it is used in the Agreement encompasses the safety of such substances as food additives, contaminants (including pesticide residues), etc."<sup>64</sup>

### **1.3 Annex A(3): "international standards, guidelines and recommendations"**

#### **1.3.1 Relationship with Articles 3.1 and 3.2**

57. The Appellate Body in *US/Canada – Continued Suspension* noted that the relevant "international standards, guidelines or recommendations" that are referred to in Articles 3.1 and 3.2 are those set by the international organizations listed in Annex A, paragraph 3 of the SPS Agreement, which includes Codex as the relevant standard-setting organization for matters of food safety.<sup>65</sup>

58. The Appellate Body in *Australia – Apples* noted that Article 5.1 requires Members performing risk assessments to take "into account risk assessment techniques developed by the relevant international organizations". In this regard, the Appellate Body acknowledged that according to Annex A(3)(c), the international standards, guidelines and recommendations relevant for plant health are those developed under the auspices of the IPPC in cooperation with the regional organizations working within the framework of the IPPC.<sup>66</sup>

### **1.4 Annex A(4): "risk assessment"**

#### **1.4.1 General**

59. The Panel in *Australia – Salmon (Article 21.5 – Canada)* held that a requirement that Members assess risk "according to the [sanitary] measures which might be applied" could not be read into the definition of "risk assessment"; rather, the requirement of a linkage between the risk

---

<sup>63</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.387-7.388.

<sup>64</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.410.

<sup>65</sup> Appellate Body Reports, *US/Canada – Continued Suspension*, para. 693.

<sup>66</sup> Appellate Body Report, *Australia – Apples*, para. 245.

assessment on the one hand, and the final measure and the necessity to use such measure on the other, were to be derived from other provisions of the SPS Agreement:

"Canada's claim ... raises the question of whether the definition of risk assessment as such, requiring Members to assess risk 'according to the [sanitary] measures which might be applied', can be construed so as to include the obligation to make the link between the assessment, the measures finally selected and the necessity to use these measures in order to achieve the [appropriate level of sanitary or phytosanitary protection]. We find it difficult to read such a requirement into paragraph 4 of Annex A.

In our view, the rights and obligations in respect of these linkages are set out not in the definition of risk assessment itself – which logically precedes the selection of measures – but, inter alia, in the obligation to base sanitary measures on a risk assessment in Article 5.1 and to ensure that sanitary measures are not more trade-restrictive than required to achieve the [appropriate level of sanitary or phytosanitary protection] in the sense of Article 5.6. To examine these questions of relationship between the risk assessment, the measures selected and the [appropriate level of sanitary or phytosanitary protection] under the definition of risk assessment – as Canada ... seem[s] to do -- would, in our view, run the risk of adding to or diminishing the more specific rights and obligations of Members set out in other SPS obligations, contrary to Article 19.2 of the DSU.

... In any event, we prefer to address this question of relationship between the measures selected and the risk assessment under the obligation to base measures on a risk assessment pursuant to Article 5.1 rather than under the very definition of risk assessment referred to in the same provision."<sup>67</sup>

#### **1.4.2 First part of Annex A(4): First definition of risk assessment**

##### **1.4.2.1 Types of risks**

60. The Appellate Body in *Australia – Salmon* found that the first type of risk assessment in Annex A(4) is substantially different from the second type of risk assessment contained in the same paragraph. While the second requires only the evaluation of the potential for adverse effects on human or animal health, the first type of risk assessment demands an evaluation of the likelihood of entry, establishment or spread of a disease, and of the associated potential biological and economic consequences.<sup>68</sup>

61. The Panel in *Australia – Salmon*, in statements affirmed by the Appellate Body<sup>69</sup>, discussed the types of risks set that must be examined in first definition of "risk assessment" in Annex A(4):

"Examining the definition of risk assessment applicable to the measure at issue, i.e., the 'evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences', we consider, first of all, that the risk thus to be assessed includes (1) the risk of 'entry, establishment or spread' of a disease and (2) the risk of the 'associated potential biological and economic consequences'. When we refer hereafter to the risk related to a disease, this risk thus includes the risk of entry, establishment or spread of that disease as well as the biological and economic consequences associated therewith.

...

In this dispute, the measure at issue is intended to protect animal health as a sanitary measure defined in paragraph 1(a) of Annex A and is to be based on a risk

---

<sup>67</sup> Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.68-7.70.

<sup>68</sup> Appellate Body Report, *Australia – Salmon*, para. 123, fn 69.

<sup>69</sup> Appellate Body Report, *Australia – Salmon*, para. 120.

assessment in the sense of the first definition in paragraph 4 of Annex A. According to this first definition in paragraph 4, such risk assessment has to take into account risks arising not only from the 'entry, establishment or spread of a pest or disease', but also from the 'associated biological and economic consequences'.<sup>70</sup>

#### 1.4.2.2 Elements of a risk assessment

62. On the three aspects of the first type of risk assessment, see the Section on Article 5.1.

#### 1.4.2.3 Identifying risk on a disease-specific basis

63. The Panel in *Australia – Salmon* stated that where several diseases were involved in the risk assessment, such risk assessment at least had to identify the risk on a disease-specific basis. The Panel also referred to the Appellate Body's findings in *EC – Hormones* to this effect:

"[G]iven the definition of risk assessment applicable in this case (the 'evaluation of the likelihood of entry, establishment or spread of a ... disease', in the singular form), a risk assessment for the measure at issue in this dispute at least has to identify risk on a disease specific basis, i.e., it has to identify the risk for any given disease of concern separately, not simply address the overall risk related to the combination of all diseases of concern. ... The experts advising the Panel on this issue confirmed this. In the *EC – Hormones* case as well, both the Panels and the Appellate Body required some degree of specificity for a risk assessment – or a study or report allegedly part thereof – to be in accordance with the requirements imposed in Article 5.1."<sup>71</sup>

64. Regarding the specificity of risk assessment, the Panel in *Costa Rica – Avocados (Mexico)* stated that "the need for the evidence to be specific depends on the hypothesis to be demonstrated."<sup>72</sup> The Panel then found the evidence underlying the risk assessment at issue to be sufficiently specific.<sup>73</sup>

#### 1.4.2.4 "likelihood"

65. In *Australia – Salmon*, the Appellate Body recalled its finding in *EC – Hormones* where it had distinguished between the terms "potential" and "probability". Finding that the term "likelihood" was synonymous with the term "probability", the Appellate Body disagreed with the Panel's finding that a risk assessment required only some evaluation of likelihood or probability:

"We note that the first definition in paragraph 4 of Annex A speaks about the evaluation of 'likelihood.' In our report in *European Communities – Hormones*, we referred to the dictionary meaning of 'probability' as 'degrees of likelihood' and 'a thing that is judged likely to be true', for the purpose of distinguishing the terms 'potential' and 'probability'. For the present purpose, we refer in the same manner to the ordinary meaning of 'likelihood', and we consider that it has the same meaning as 'probability'. On this basis, as well as on the basis of the definition of 'risk' and 'risk assessment' developed by the Office international des épizooties ('OIE') and the OIE Guidelines for Risk Assessment, we maintain that for a risk assessment to fall within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A, it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the 'likelihood', i.e., the 'probability', of entry, establishment or spread of diseases and associated biological and economic consequences as well as the 'likelihood', i.e., 'probability', of entry, establishment or spread of diseases according to the SPS measures which might be applied.

We note that, although the Panel stated that the definition of a risk assessment for this type of measure requires an 'evaluation of the likelihood', for the purpose of

---

<sup>70</sup> Panel Report, *Australia – Salmon*, paras. 8.72 and 8.116.

<sup>71</sup> Panel Report, *Australia – Salmon*, para. 8.74.

<sup>72</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.1430.

<sup>73</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, para. 7.1433.

satisfying the second and third requirements, it subsequently was hesitant in applying these requirements, by stating or suggesting in paragraphs 8.80, 8.83, 8.89 and 8.91, that some evaluation of the likelihood or probability would suffice. We consider this hesitation unfortunate. We do not agree with the Panel that a risk assessment of this type needs only some evaluation of the likelihood or probability. The definition of this type of risk assessment in paragraph 4 of Annex A refers to 'the evaluation of the likelihood' and not to some evaluation of the likelihood. We agree, however, with the Panel's statements in paragraph 8.80 that the SPS Agreement does not require that the evaluation of the likelihood needs to be done quantitatively. The likelihood may be expressed either quantitatively or qualitatively. Furthermore, we recall, as does the Panel, that we stated in *European Communities – Hormones* that there is no requirement for a risk assessment to establish a certain magnitude or threshold level of degree of risk."<sup>74</sup>

66. The Panel in *Japan – Apples* recalled the Appellate Body's finding in *EC – Hormones* that the evaluation of likelihood involves more than a mere identification of "possibilities" and requires an assessment of probability of entry, which implies a higher degree or a "threshold of potentiality or possibility". The Panel added that such probability need not be expressed in quantitative terms, but may be expressed in qualitative terms.<sup>75</sup>

67. In *EC – Approval and Marketing of Biotech Products*, the Panel considered that the failure to evaluate likelihood in a study meant that the study did not meet the definition of a risk assessment:

"Given the lack of evaluation of likelihood in the Hoppichler study, we consider that the study does not meet the definition of a risk assessment as provided in Annex A(4), and therefore does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1."<sup>76</sup>

68. The Panel in *Costa Rica – Avocados (Mexico)* pointed out, in connection with the definition of risk assessment in Annex A(4), that "[w]hile it is an evaluation of the *potential consequences*, there still needs to be an *evaluation*, which is missing from Reports ARP-002-2017 and ARP-006-2016."<sup>77</sup>

#### **1.4.2.5 "according to the [SPS] measures which might be applied"**

69. Regarding the requirement to evaluate the likelihood of entry, establishment or spread of the diseases according to the SPS measures which might be applied, the Appellate Body in *Japan – Apples* agreed with the Panel that the phrase "according to the [SPS] measures which might be applied" implies that a risk assessment should not be limited to an examination of the measure already in place:

"[A]ccording to the Panel, the terms in the definition of 'risk assessment' set out in paragraph 4 of Annex A to the SPS Agreement – more specifically, the phrase 'according to the sanitary or phytosanitary measures which might be applied' – suggest that 'consideration should be given not just to those specific measures which are currently in application, but at least to a potential range of relevant measures.' ...

The definition of 'risk assessment' in the SPS Agreement requires that the evaluation of the entry, establishment or spread of a disease be conducted 'according to the sanitary or phytosanitary measure which might be applied.' We agree with the Panel that this phrase 'refers to the measures which might be applied, not merely to the measures which are being applied.' The phrase 'which might be applied' is used in the conditional tense. In this sense, 'might' means: 'were or would be or have been able to, were or would be or have been allowed to, were or would perhaps'. We understand this phrase to imply that a risk assessment should not be limited to an

---

<sup>74</sup> Appellate Body Report, *Australia – Salmon*, paras. 123-124.

<sup>75</sup> Panel Report, *Japan – Apples*, para. 8.273 (referring to Appellate Body Report, *EC – Hormones*, para. 184).

<sup>76</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3046.

<sup>77</sup> Panel Report, *Costa Rica – Avocados (Mexico)*, para. 1408.

examination of the measure already in place or favoured by the importing Member. In other words, the evaluation contemplated in paragraph 4 of Annex A to the SPS Agreement should not be distorted by preconditioned views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*."<sup>78</sup>

70. In *US/Canada – Continued Suspension*, the Appellate Body stated that upon completion of a risk assessment, Members are not required to adopt an SPS measure. The decision to adopt an SPS measure or not is dependent on the outcome of the risk assessment. The Appellate Body considered that Members may not deem it appropriate to adopt SPS measure if the result of the risk assessment does not compel to adopt such measure:

"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."<sup>79</sup>

#### **1.4.2.6 "Evaluation of likelihood of entry, establishment or spread of a pest or disease"**

##### **1.4.2.6.1 Risk assessment to be specific to the product at issue**

71. In *Japan – Apples*, the Appellate Body upheld the Panel's finding that Japan's risk assessment did not evaluate the likelihood of entry, establishment or spread of fire blight because its risk assessment was not specific enough about the product at issue – apple fruit:

"[U]nder 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<sup>80</sup> The Appellate Body found the risk assessment at issue in *EC – Hormones* not to be 'sufficiently specific' even though the scientific articles cited by the importing Member had evaluated the 'carcinogenic potential of entire categories of hormones, or of the hormones at issue in general.' In order to constitute a 'risk assessment' as defined in the SPS Agreement, the Appellate Body concluded, the risk assessment should have reviewed the carcinogenic potential, not of the relevant hormones in general, but of 'residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes'. Therefore, when discussing the risk to be specified in the risk assessment in *EC – Hormones*, the Appellate Body referred in general to the harm concerned (cancer or genetic damage) as well as to the precise agent that may possibly cause the harm (that is, the specific hormones when used in a specific manner and for specific purposes).

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.' ... 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 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

---

<sup>78</sup> Appellate Body Report, *Japan – Apples*, paras. 207-208. See also Panel Report, *Costa Rica – Avocados (Mexico)*, paras. 7.1482-7.1484.

<sup>79</sup> Appellate Body Report, *US/Canada – Continued Suspension*, para. 531.

<sup>80</sup> (*footnote original*) 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.

assessment' under the SPS Agreement for the evaluation of the likelihood of entry, establishment or spread of fire blight in Japan through apple fruit."<sup>81</sup>

### 1.4.3 Second part of Annex A(4): Second definition of risk assessment

#### 1.4.3.1 Distinction from the first definition of risk assessment

72. With respect to the second definition of "risk assessment" contained in Annex A(4), the Appellate Body in *Australia – Salmon* noted that while the first definition speaks of "likelihood", the second definition speaks of "potential" for adverse effects:

"We note that the first type of risk assessment in paragraph 4 of Annex A is substantially different from the second type of risk assessment contained in the same paragraph. While the second requires only the evaluation of the potential for adverse effects on human or animal health, the first type of risk assessment demands an evaluation of the likelihood of entry, establishment or spread of a disease, and of the associated potential biological and economic consequences. In view of the very different language used in paragraph 4 of Annex A for the two types of risk assessment, we do not believe that it is correct to diminish the substantial differences between these two types of risk assessments, as the European Communities seems to suggest when it argues that 'the object, purpose and context of the SPS Agreement indicate that no greater level of probability can have been intended for the first type of risk assessment than for the second type, [as b]oth types can apply both to human life or health and to animal or plant life or health'. (Third participant's submission of the European Communities, para. 7)."<sup>82</sup>

#### 1.4.3.2 No requirement to quantify the level of risk

73. With respect to the relevance of the second definition of "risk assessment" within Annex A, the Appellate Body in *US/Canada – Continued Suspension*, reasoned that the Panel's reference to "potential occurrence" of adverse effects when asking questions to the experts, does not amount to the requirement of a quantitative method of risk assessment. On this basis, the Appellate Body also contemplated the relevance of potentiality for the purpose of a "risk assessment" under the second sentence of paragraph 4:

"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 the second sentence of paragraph 4 of Annex A and not an evaluation of likelihood under the first sentence of paragraph 4."<sup>83</sup>

...

[W]e consider that the Panel's reference to 'potential occurrence' of adverse health effects could be read consistently with the definition of a risk assessment in paragraph 4 of Annex A of the *SPS Agreement*, as interpreted by the Appellate Body. Accordingly, we dismiss the European Communities' claim that the Panel incorrectly interpreted Article 5.1 and paragraph 4 of Annex A of the *SPS Agreement* as requiring quantification of risk."<sup>84</sup>

---

<sup>81</sup> Appellate Body Report, *Japan – Apples*, paras. 202-203.

<sup>82</sup> Appellate Body Report, *Australia – Salmon*, footnote 69.

<sup>83</sup> (*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).

<sup>84</sup> Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 569 and 575.

74. On the basis of its ruling that a risk assessment need not be expressed in numerical terms, the Appellate Body in *US/Canada – Continued Suspension* held that the Panel's reference to magnitude when appraising the European Communities' risk assessment did not amount to a requirement that the European Communities quantify the level of risk:

"[A] 'risk assessment' involves an indication of potentiality, even though this need not be expressed in numerical terms or as a minimum quantification of the level of risk. In this sense, the Panel's reference to 'magnitude' is in our view not sufficient to establish that the Panel incorrectly interpreted Article 5.1 and paragraph 4 of Annex A as requiring a quantitative risk assessment.

... For these reasons, we consider that the Panel's reference to 'potential occurrence' of adverse health effects could be read consistently with the definition of a risk assessment in paragraph 4 of Annex A of the *SPS Agreement*, as interpreted by the Appellate Body."<sup>85</sup>

### 1.4.3.3 Methodology of risk assessment

#### 1.4.3.3.1 Two-step analysis

75. In *EC – Hormones*, with respect to the methodology for a risk assessment under the second definition of paragraph 4 of Annex A of the SPS Agreement, the Panels stated that "in this dispute, a risk assessment carried out in accordance with the SPS Agreement should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat or meat products, and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of these effects".<sup>86</sup> The Appellate Body did not disagree with the Panels' two-step analytical approach but cautioned against equating the terms "potential" and "probability":

"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."<sup>87</sup>

#### 1.4.3.3.2 Specific attribution of risk

76. The Appellate Body in *Japan – Apples* agreed with Japan that, whether to analyse the risk on the basis of the particular pest or disease or on the basis of a particular commodity, is a "matter of methodology" that lies within the discretion of the importing Member. However, the Appellate Body found that the Panel did not suggest, as Japan had argued, that there was an obligation to follow any particular methodology in conducting a risk assessment. The Appellate Body emphasized that Members are free to consider, in their risk analysis, multiple agents in relation to one disease, provided that the risk assessment attributes a likelihood of entry, establishment or spread of the disease to each agent specifically:

"Japan contends that the 'methodology' of the risk assessment is not directly addressed by the SPS Agreement. In particular, Japan suggests that, whether to analyze the risk on the basis of the particular pest or disease, or on the basis of a particular commodity, is a 'matter of methodology' not directly addressed by the SPS Agreement. We agree. Contrary to Japan's submission, however, the Panel's reading of *EC – Hormones* does not suggest that there is an obligation to follow any particular methodology for conducting a risk assessment. In other words, even though, in a given context, a risk assessment must consider a specific agent or pathway through which contamination might occur, Members are not precluded from organizing their risk assessments along the lines of the disease or pest at issue, or of

---

<sup>85</sup> Appellate Body Reports, *US/Canada – Continued Suspension*, paras. 574-575.

<sup>86</sup> Panel Reports, *EC – Hormones (Canada)*, para. 8.101; and *EC – Hormones (US)*, para. 8.98.

<sup>87</sup> Appellate Body Report, *EC – Hormones*, para. 184.

the commodity to be imported. Thus, Members are free to consider in their risk analysis multiple agents in relation to one disease, provided that the risk assessment attribute a likelihood of entry, establishment or spread of the disease to each agent specifically. Members are also free to follow the other 'methodology' identified by Japan and focus on a particular commodity, subject to the same proviso[sic]."<sup>88</sup>

77. See also Section on Article 5 regarding risk assessment.

#### **1.4.4 Relationship with other provisions of the SPS Agreement**

78. The Panel in *US – Poultry (China)* considered that, in determining whether a measure is based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement, one needs to first determine whether a risk assessment was conducted at all. The Panel stated that "[i]n order to do so, it is helpful to start by looking into what a risk assessment is, in light of the definition in Annex A(4)".<sup>89</sup>

79. The Panel in *US – Poultry (China)* discussed the relationship between the SPS measures as identified in Annex A(1)(a)-(d) and the two types of risk assessment identified in Annex A(4). The Panel stated:

"[I]t would seem that SPS measures under Annex A(1)(a) and (c) would require risk assessments conducted pursuant to the definition under the first sentence of Annex A(4) while those which satisfy the definition of an SPS measure under Annex A(1)(b) would require that the risk assessment be conducted pursuant to the second sentence of Annex A(4)."<sup>90</sup>

### **1.5 Annex A(5) : "appropriate level of protection"**

#### **1.5.1 General**

##### **1.5.1.1 Right to determine the appropriate level of protection**

80. The Appellate Body in *Australia – Salmon* held that the determination of the appropriate level of protection, a notion defined in Annex A(5), is a prerogative of the Member concerned and not of a panel or the Appellate Body.<sup>91</sup>

81. In *India – Agricultural Products*, the Panel understood the term "level" in the context of Article 5.6 to mean "a position (on a real or imaginary) scale in respect of amount, intensity, extent, etc.; a relative ... amount or value."<sup>92</sup> In this light, the Panel found that:

"Notwithstanding the fact that a Member's ALOP or acceptable level of risk need not be expressed in quantitative terms, we consider that an ALOP or acceptable level of risk will express a certain threshold that denotes the position of the relevant Member in relation to the intensity, extent, or relative amount of protection or risk that the Member deems to be tolerable or suitable."<sup>93</sup>

82. In light of the above, the Panel found that India's stated ALOP, namely "prevention of ingress of LPNAI **and** HPNAI" was "insufficient to satisfy the definition of ALOP or acceptable level of risk in Annex A(5) of the SPS Agreement."<sup>94</sup>

---

<sup>88</sup> Appellate Body Report, *Japan – Apples (Article 21.5 – US)*, para. 204.

<sup>89</sup> Panel Report, *US – Poultry (China)*, para. 7.174.

<sup>90</sup> Panel Report, *US – Poultry (China)*, para. 7.177.

<sup>91</sup> Appellate Body Report, *Australia – Salmon*, para. 199.

<sup>92</sup> Panel Report, *India – Agricultural Products*, para. 7.562.

<sup>93</sup> Panel Report, *India – Agricultural Products*, para. 7.562.

<sup>94</sup> Panel Report, *India – Agricultural Products*, para. 7.571.

### **1.5.1.2 Relationship between the "risk assessment" and the "appropriate level of protection"**

83. In *US/Canada – Continued Suspension*, the Appellate Body reasoned that the choice of an appropriate level of protection has significant bearing on the scope of the risk assessment to be performed by a Member. Reflecting on this statement, the Appellate Body considered that the same remains true in case a Member chooses a protection measure that is more restrictive than an existing international standard. However, the Appellate Body cautioned that the chosen level of protection should not influence the outcome of the risk assessment. The risk assessment must remain an objective and rigorous process:

"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 that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard. However, the 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.<sup>95</sup> 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."<sup>96</sup>

84. See also Section on Article 5 regarding the appropriate level of protection.

## **1.5.2 Relationship with other provisions of the SPS Agreement**

### **1.5.2.1 Article 3.3**

85. See Section on Article 3.3.

### **1.5.2.2 Article 5.4**

86. See the Section on Article 5.4.

### **1.5.2.3 Article 5.5**

87. For a detailed discussion of the application of the term "appropriate level of protection" in Article 5.5, see the Section on Article 5.5.

### **1.5.2.4 Article 5.6**

88. A Member's appropriate level of protection is to be taken into account when a Panel or the Appellate Body is making a determination on a violation of Article 5.6. See also the Section on Article 5.6.

### **1.5.2.5 Article 5.7**

89. 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. See also the Section on Article 5.7.

---

<sup>95</sup> (*footnote original*) We recall, however, that the scientific process must not be understood narrowly as being confined to matters that are "susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences." Instead, the risk to be evaluated also includes the "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". (Appellate Body Report, *EC – Hormones*, para. 187)

<sup>96</sup> Appellate Body Reports, *US/Canada – Continued Suspension*, para. 534.

---

Current as of: December 2024