(iii) various EC member State safeguard measures prohibiting the import and/or marketing of specific biotech products (hereafter the "member State safeguard measures").

7.99 In respect of the first category – the alleged general EC moratorium – we note that it is the only category which consists of one single alleged measure. The Complaining Parties use slightly different language to describe the specific measure at issue, but, as we explain in the relevant section below, we consider that the Complaining Parties are in fact challenging one and the same measure.

7.100 With regard to the second category – the product-specific EC measures – we note that, according to the Complaining Parties, the measures falling within this category are distinct from, albeit related to, the alleged general EC moratorium. As we explain in the relevant section below, the Complaining Parties have defined the measures at issue differently. However, what characterizes each of these measures is that it relates to one specific biotech product, or to be more accurate, an approval procedure concerning a specific biotech product. A total of thirty different products are at issue in this category of measures. In a number of cases, two Complaining Parties are challenging a (differently defined) measure which concerns the same biotech product. But in no case are all three Complaining Parties challenging a measure which concerns the same product.

7.101 Concerning the third category – the member State safeguard measures – we note that this category consists of nine distinct measures taken by six different EC member States, namely, Austria, France, Germany, Greece, Italy and Luxembourg. The Complaining Parties are each challenging a different number of safeguard measures. However, each member State safeguard measure is being challenged by more than one Complaining Party, and two of them are being challenged by all three Complaining Parties. It is important to note that even though the member State safeguard measures were introduced by the relevant member States and are applicable only in the territory of the member States concerned, the European Communities as a whole is the responding party in respect of the member State safeguard measures. This is a direct consequence of the fact that the Complaining Parties have directed their complaints against the European Communities, and not individual EC member States.[275] The European Communities never contested that, for the purposes of this dispute, the challenged member State measures are attributable to it under international law and hence can be considered EC measures. Indeed, it was the European Communities – and it alone – that defended the contested member State safeguard measures before the Panel.[276]

7.102 We address the three categories of measures at issue in this dispute in separate sections below. Thus, in Section D, we examine the alleged general EC moratorium. In Section E, we examine the various product-specific EC measures. Finally, in Section F, we examine the various member State safeguard measures.

C. RELEVANT EC APPROVAL PROCEDURES

7.103 This section describes and analyses the relevant EC procedures for the approval of EC-wide marketing of biotech products. It is useful to do so at the outset, as these procedures are relevant to all

[275] A similar situation has previously arisen in the panel proceedings concerning *EC – Asbestos*, where the European Communities was the responding party, although the measure at issue was being maintained by one member State, namely, France. Panel Report, *EC – Asbestos*, paras. 2.3 and 3.4.

[276] It should be pointed out, however, that representatives of the relevant member States were part of the EC delegations present at the substantive meetings of the Panel with the Parties. Furthermore, as part of its defence of the member State safeguard measures, the European Communities submitted numerous documents which it had obtained from the member States concerned.

three categories of measures which are being challenged by the Complaining Parties. Initially, we provide a factual description of the specific approval procedures at issue in this dispute. We first place them in their historical context, by showing how the EC regime for the approval of biotech products has evolved over time. Then we explain, by reference to the relevant EC legislation, the various stages of the approval procedures at issue. Thereafter, we proceed to a legal analysis of these procedures. It is important to note in this respect that the Complaining Parties are not challenging these procedures as such. What the Complaining Parties are challenging is the European Communities' application of these procedures. In order to assess the legal merits of this challenge, we need to examine, as a threshold matter, whether the WTO agreement on which the Complaining Parties are primarily basing their challenge – the *SPS Agreement* – is applicable to each of these procedures. The European Communities argues that at least in part these procedures fall outside the scope of the *SPS Agreement*.

1. Evolution of the EC regime for the approval of biotech products

7.104 The European Communities' legal regime for the approval of the marketing of biotech products has changed over time, including while these Panel proceedings were ongoing. Since this evolution of the EC approval regime is of some importance in the present dispute, we set out below, in the form of a table, relevant dates and legislative milestones.

Evolution of the EC approval regime for biotech products	
23 April 1990	Adoption of Council Directive 90/220 "on the deliberate release into the environment of genetically modified organisms".
23 October 1991	Entry into force of Council Directive 90/220.
27 January 1997	Adoption of Regulation 258/97 "concerning novel foods and novel food ingredients".
15 May 1997	Entry into force of Regulation 258/97.
23 February 1998	Commission proposal for a European Parliament and Council Directive amending Directive 90/220.
24 and 25 June 1999	2194th Environment Council meeting: Common Position, agreed by the Council on the Commission proposal for a directive amending Directive 90/220, by which the Council reached a political consensus on a number of issues which were still outstanding in the draft legislative text.[277]
12 March 2001	Adoption of Directive 2001/18 of the European Parliament and of the Council "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC".
17 April 2001	Entry into force of Directive 2001/18.
25 July 2001	Commission proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from

[277] In response to a question from the Panel, the European Communities has explained that in the EC legislative process, a common position of the Council is a political decision by the Council which intervenes after the European Parliament has expressed its opinion on a Commission legislative proposal. It reflects the Council's position on those elements of the European Parliament's opinion with which the Council disagrees and which it cannot approve. *See* the EC reply to Panel question No. 93, Annex D.

Evolution of the EC approval regime for biotech products	
	genetically modified organisms and amending Directive 2001/18.
17 October 2002	Repeal of Council Directive 90/220.
22 September 2003	Adoption of Regulation 1829/2003 of the European Parliament and of the Council "on genetically modified food and feed". Adoption of Regulation 1830/2003 of the European Parliament and of the Council "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC".
7 November 2003	Entry into force of Regulation 1829/2003, applying as of 18 April 2004. Entry into force of Regulation 1830/2003.

7.105 In connection with the above table, it is useful to recall that it was on 13 May 2003 that the United States and Canada formally initiated the present dispute settlement proceedings by requesting consultations with the European Communities.[278] Argentina requested consultations with the European Communities on 14 May 2003.[279] The United States, Canada and Argentina each requested the establishment of a panel on 7 August 2003.[280] A single panel was established by the DSB on 29 August 2003.[281] The composition of this Panel was determined and announced on 4 March 2004.[282]

2. Description of the relevant EC approval procedures

7.106 For the purposes of this dispute, the legal instruments of primary relevance are those which were in force on or before the date of establishment of this Panel, *i.e.*, on 29 August 2003. They are:

(a) Directive 90/220/EEC (hereafter "Directive 90/220")[283] "on the deliberate release into the environment of genetically modified organisms" (repealed on 17 October 2002),

(b) Directive 2001/18 (hereafter "Directive 2001/18")[284] "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC",

(c) Regulation 258/97 (hereafter "Regulation 258/97")[285] "concerning novel foods and novel food ingredients".[286]

[278] WT/DS291/1 and WT/DS292/1, respectively.
[279] WT/DS293/1.
[280] WT/DS291/23, WT/DS292/17 and WT/DS293/17, respectively.
[281] WT/DSB/M/155.
[282] WT/DS291/24, WT/DS292/18 and WT/DS293/18.
[283] Published in OJ of the EC N° L 117 of 08.05.1990, p. 15.
[284] Published in OJ of the EC N° L 106 of 17.04.2001, p. 1.
[285] Published in OJ of the EC N° L 43 of 14.02.1997, p. 1.
[286] Under EC law, directives are legislative acts that need to be implemented by EC member States through national legislation. By contrast, regulations are directly applicable in all EC member States and do not require any national implementing legislation.

7.107 Below we provide a brief factual description of Directives 90/220 and 2001/18 as well as Regulation 258/97. We begin with Directives 90/220 and 2001/18.

(a) Deliberate release into the environment of genetically modified organisms: Directives 90/220 and 2001/18

7.108 A fundamental purpose of Directives 90/220 and 2001/18 is to avoid adverse effects on human health and the environment which might arise from the deliberate release into the environment of products consisting of, or containing, genetically modified organisms (hereafter "GMOs"). In the present dispute, Directives 90/220 and 2001/18 are relevant to the extent they regulate the deliberate release of GMOs for placing on the market as or in products.[287]

7.109 Directives 90/220 and 2001/18 lay down administrative procedures for granting consents for the placing on the market of GMOs as or in products. In line with the fact that Directive 2001/18 is a revised version of Directive 90/220, the administrative procedure laid down by Directive 2001/18 has been made more efficient. However, there are more similarities between the two administrative procedures than differences, and so in our description below we deal with them together, while noting important differences. Since the administrative procedures set out in Directives 90/220 and 2001/18 are multi-stage procedures, we have structured our description according to the main procedural stages.

7.110 We note that at the request of the Panel, the European Communities has provided flow charts which illustrate the administrative procedures as described below. These flow charts are reproduced in Annexes A-1 and A-2.

(i) Submission of application by applicant

7.111 Before a GMO as or in a product may be placed on the EC market, the manufacturer or importer of the product (hereafter the "applicant") must submit a notification (hereafter "application") and accompanying dossier to the competent authority of the member State where such a GMO is to be placed on the market for the first time (hereafter the "lead CA").[288] The application and the dossier must include specified information, such as information about the applicant, the nature of the GMO, the commercial names to be used, the intended uses of the product, proposals for labelling or for restrictions on use, and an assessment of any risks for human health and the environment related to the GMO.[289]

(ii) Assessment by lead CA

7.112 On receipt and after acknowledgement of the application, the lead CA must examine the application for compliance with the Directive. To that end, within 90 days after receipt of the application, the lead CA must prepare an assessment report.[290] For the purposes of calculating the 90-day period, any periods of time during which the lead CA is awaiting further information which it may have requested from the applicant shall not be taken into account. If the lead CA's assessment

[287] The deliberate release for research and development purposes, while covered by the Directives, is not at issue in this dispute.
[288] Articles 5 and 11 of Directive 90/220 and Articles 6 and 13 of Directive 2001/18.
[289] Article 11(1) of Directive 90/220 and Article 13(2) and Annexes II, III and IV of Directive 2001/18.
[290] Article 12(1) and (2) of Directive 90/220 and Article 14(1) and (2) of Directive 2001/18.

report concludes that a GMO should not be placed on the market, it rejects the application by a decision that states the reasons, and the procedure is ended.[291]

(iii) Circulation of lead CA assessment report to other member States for comments

7.113 In cases where the lead CA's assessment report concludes that a GMO may be placed on the market, the procedure moves on to the Community level. The lead CA submits the application together with the assessment report to the European Commission (hereafter the "Commission"), which must forward it to the competent authorities (hereafter the "CAs") of all other EC member States.[292] Within a period of 60 days from the date of circulation of the assessment report, a CA of another member State and, in the case of Directive 2001/18, the Commission, may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO in question.

7.114 In the absence of any reasoned objection from the CA of a member State, or in the case of Directive 2001/18, the Commission, within 60 days following the date of circulation of the assessment report, the lead CA must give its consent in writing for placing on the market.[293] Under Directive 2001/18, in cases where the CA of another member State or the Commission raises a reasoned objection, the member States and the Commission may take an additional 45-day period to discuss any outstanding issues with the aim of arriving at an agreement. If outstanding issues are resolved within the prescribed period, the lead CA must give its consent for placing on the market.[294]

(iv) Community-level procedure in case of objections

7.115 In cases where the CA of another member State or, in the case of Directive 2001/18, the Commission, maintains a reasoned objection, the decision on whether to approve the application must be taken at Community level.[295] To that end, the Commission must prepare a draft measure. The Commission begins this process by consulting the relevant EC scientific committee with respect to the objection(s).[296] Once the Commission has prepared a draft measure taking into account the opinion of the relevant EC scientific committee, it must submit it to the appropriate "Regulatory Committee" for a vote.

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[291] Article 12(2)(b) of Directive 90/220 and Articles 14(3)(b) and 15(2) of Directive 2001/18.

[292] Article 13(1) of Directive 90/220 (providing that the Commission must forward the assessment report "immediately") and Article 14(2) of Directive 2001/18, (providing that the Commission must forward the assessment report within 30 days of its receipt).

[293] Article 13(2) of Directive 90/220 and Article 15(3) of Directive 2001/18.

[294] Articles 15(1) and (3) of Directive 2001/18. We note that in accordance with Article 15(1) any periods of time during which further information from the applicant is awaited are not to be taken into account for the purpose of calculating the 45-day period.

[295] Article 13(3) of Directive 90/220 and Articles 18(1) and 30(2) of Directive 2001/18. Article 18(1) of Directive 2001/18 specifies that a decision must be adopted and published within 120 days. For the purposes of calculating the 120-day period, any period of time during which the Commission is awaiting further information which it may have requested from the applicant or is seeking the opinion of an EC scientific committee will not be taken into account.

[296] Under Directives 2001/18 and 90/220, the relevant scientific committee was the Scientific Committee for Plants ("SCP"). The SCP has been replaced by the scientific panel on genetically modified organisms established by the European Food Safety Authority (the "EFSA") which was created pursuant to *Regulation 178/2002*. We note that Article 28 of Directive 2001/18 requires that the Commission consult the scientific committee in case an objection is maintained. According to Article 18(1) of Directive 2001/18, the period of time the Commission is waiting for the scientific committee opinion is not to exceed 90 days. Under Directive 90/220, the Commission was not required to do so, but generally chose to do so.

7.116 The Regulatory Committee is composed of representatives of the member States and chaired by a representative of the Commission.[297] The Regulatory Committee must deliver its opinion on the draft measure within a time limit which the chairman may lay down according to the urgency of the matter.[298] The Regulatory Committee delivers opinions by qualified majority vote. The Commission must adopt the draft measures envisaged if they are in accordance with the opinion of the Regulatory Committee. If the measures envisaged are not in accordance with the opinion of the Regulatory Committee, or if no opinion is delivered, the Commission must, without delay, submit to the Council of Ministers (hereafter the "Council") a proposal relating to the measures to be taken.[299]

7.117 The Council can either adopt or reject the Commission's draft measure by a qualified majority.[300] In either case, it must act within a time-period which shall in no case exceed three months from the date of referral to the Council.[301] If the Council has not acted within that time-period, the Commission must adopt the draft measure it has submitted to the Council.[302]

(v) Member State consent to placing on the market

7.118 Where a favourable decision has been taken at the Community level, whether by the Commission on the basis of a favourable opinion by the Regulatory Committee, by the Council after the submission of a proposal by the Commission, or by the Commission in the event the Council does not act within three months from the date of referral, the lead CA must give consent in writing to the placing on the market of the GMO as or in a product concerned. Such consent is transmitted to the applicant, and the other member States and the Commission must be informed thereof.[303] Once the applicant has received the written consent of the lead CA, it may proceed with the placing on the market. The approved product may be used without further application throughout the Community, subject to any conditions specified in the written consent.[304]

(vi) Transition from Directive 90/220 to Directive 2001/18: Pending applications

7.119 As indicated previously, Directive 90/220 was repealed on 17 October 2002, and EC member States had to implement Directive 2001/18 by the same date. Directive 2001/18 addresses the issue of applications submitted under Directive 90/220 but still pending on 17 October 2002. Thus, Directive 2001/18 makes clear that applications received pursuant to Directive 90/220 and in respect of which the procedures of Directive 90/220 were not completed by 17 October 2002 became subject to the provisions of Directive 2001/18. Furthermore, applicants had until 17 January 2003 to

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[297] Regulatory Committees have their origin in Article 202 of the EC Treaty and act on the basis of Article 5 of Council Decision 1999/468/EC. They assist the Commission in the exercise of the powers delegated to it by the Council for the implementation of its acts.

[298] Article 21 of *Directive 90/220* and Article 30(2) of Directive 2001/18 (referring to Articles 5 and 7 of *Council Decision 1999/468*).

[299] *Ibid*.

[300] Pursuant to Article 148(2) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties*, in force at the time of establishment of this Panel, a qualified majority requires at least 62 votes in favour out of a total of 86 votes. For further details, *see* footnote 580. The Council can also modify the draft measure, albeit by unanimous vote only. Article 250(1) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties*.

[301] According to Article 18(1) of Directive 2001/18, the period of time the Council takes to act is not be taken into account in calculating the 120-day period laid down in Article 18(1).

[302] Article 21 of Directive 90/220 and Article 30(2) of Directive 2001/18 (referring to Articles 5 and 7 of *Council Decision 1999/468*).

[303] Article 13(4) of Directive 90/220 and Article 18(2) of Directive 2001/18.

[304] Article 13(5) of Directive 90/220 and Article 19(1) and (2) 2001 of Directive 2001/18.

complement their applications in accordance with Directive 2001/18.[305] According to the European Communities, this means that pending applications only needed to be updated (complemented), not re-submitted in their entirety. The European Communities has further stated that the new information submitted in relation to the pending applications required a new assessment under the provisions of Directive 2001/18. Thus, irrespective of the procedural stage reached by an application under Directive 90/220, the updated application had to go through all procedural stages provided for in Directive 2001/18, beginning with the initial assessment by the lead CA. However, according to the European Communities, any results and conclusions reached under the procedures of Directive 90/220 on the basis of the then-existing data and information were in principle still relevant under the procedures of Directive 2001/18 and hence did not need to be re-examined.

(vii) Safeguard measures by individual member States

7.120 Where a GMO used as or in a product has been approved for Community-wide marketing under Directives 90/220 or 2001/18, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. Exceptionally, however, member States may provisionally adopt safeguard measures which prohibit or restrict trade in, or use of, biotech products which have been granted Community-wide marketing approval.

7.121 Pursuant to Article 16 of Directive 90/220, a member State may provisionally restrict or prohibit the use and or sale of a product in its territory where it has "justifiable reasons to consider that a product which has been properly notified and has received written consent [...] constitutes a risk to human health or the environment". Article 23 of Directive 2001/18 provides that a safeguard measure may be adopted where, "as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge", a member State has "detailed grounds for considering that a GMO as or in a product [...] constitutes a risk to human health or the environment [...]".

7.122 The safeguard measures taken pursuant to Directives 90/220 and 2001/18 can be maintained only on a provisional basis, pending a full assessment at EC level.[306] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[307] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the safeguard measure.[308]

7.123 According to the procedure laid down in the relevant provisions of Directives 90/220 and 2001/18, the Commission, when making a decision on a safeguard measure which has been notified, is assisted for this purpose by the Regulatory Committee.[309] The Commission must submit a draft of the measure to be taken to the Regulatory Committee, which shall deliver its opinion on the draft.[310] If the draft measure is in accordance with the opinion of the Regulatory Committee or the Standing

[305] Article 35 of Directive 2001/18.

[306] Article 16(1) of Directive 90/220 and Article 23(1), 3rd paragraph of Directive 2001/18.

[307] Article 16(1) of Directive 90/220 and Article 23(1), 3rd paragraph of Directive 2001/18.

[308] Article 21 of Directive 90/220. Under Directive 90/220, such a decision by the Commission must be taken within a period of three months from the time of notification of the measure.

[309] Articles 21 of Directive 90/220 and 30(2) of Directive 2001/18.

[310] Article 21 of Directive 90/220 and Article 30(2) of Directive 2001/18. Article 30(2) of Directive 2001/18 refers to Articles 5, 7 and 8 of Decision 1999/468. According to the European Communities these provisions are similar to Article 21 of Directive 90/220.

Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit a proposal to the Council on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[311]

(viii) Availability under EC and member State law of procedures for administrative and judicial review

7.124 To the extent that an applicant requesting the approval of a biotech product under Directives 90/220 and 2001/18 is dissatisfied with any act or failure to act by a national authority of a member State or of a Community institution, it has the possibility to seek administrative or judicial review of such acts or omissions at the member State and/or Community level. The law of each member State provides for administrative and/or judicial review of acts or omissions relating to the application at the national level. At Community level, Articles 230 and 232 of the EC Treaty provide that the European Court of Justice has jurisdiction to review the legality of acts, or of the failure to act, by the European Commission.

7.125 The European Communities has stated before the Panel that, in respect of the biotech products which are the subject of these proceedings, it is aware of only one instance where legal proceedings were brought at member State level. Those proceedings concerned a safeguard measure introduced by Italy pursuant to Regulation 258/97. According to the European Communities, no applications have been made to the European Court of Justice challenging any actions, or an alleged failure to act, by the Community institutions in respect of any of the relevant biotech products.

(b) Novel foods and novel food ingredients: Regulation 258/97

7.126 We now turn to address Regulation 258/97. Regulation 258/97 concerns the placing on the market of products to be used as a novel food or a novel food ingredient. These products include foods and food ingredients containing or consisting of GMOs within the meaning of Directives 90/220 and 2001/18. They also include foods and food ingredients produced from, but not containing, GMOs.

7.127 A fundamental purpose of Regulation 258/97 is to ensure that the covered novel foods and food ingredients: (1) not present a danger for the consumer; (2) not mislead the consumer; and (3) not differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous to the consumer.

7.128 Applications for the placing on the market of foods and food ingredients containing or consisting of GMOs are assessed under Regulation 258/97 only. However, where an application concerns a product containing, or consisting of, a GMO and that product is intended for use as food as well as for feed and for cultivation, the application is assessed under Regulation 258/97 in relation to its use as food and under Directive 90/220 or Directive 2001/18 in relation to its use as feed and in relation to cultivation.[312]

7.129 Regulation 258/97 lays down administrative procedures for granting authorizations for the placing on the market of the products at issue in this dispute, *i.e.*, foods and food ingredients containing or consisting of GMOs. These administrative procedures are similar to those described

[311] Article 21 of Directive 90/220 and Article 30 of Directive 2001/18.
[312] Article 9(2) of Regulation 258/97.

above for Directives 2001/18 and 90/220. Our description of the procedures laid down in Regulation 258/97 has been structured according to the main procedural stages.

7.130 As with Directives 90/220 and 2001/18, the European Communities has provided flow charts which illustrate the administrative procedures as described below. These flow charts are reproduced in Annex A-3.

(i) Submission of application by applicant

7.131 Before foods containing or consisting of GMOs may be placed on the EC market, the applicant must submit a request (hereafter "application") and accompanying dossier to the CA of the member State where such a product is to be placed on the market for the first time, *i.e.*, the lead CA.[313] The application must contain the necessary information, including the studies and materials which are available to demonstrate that the food complies with the following requirements: (1) that the food not present a danger for the consumer; (2) that it not mislead the consumer; and (3) that it not differ from foods or food ingredients which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous to the consumer.[314] In addition, the application must contain an appropriate proposal for labelling, in accordance with the requirements of Regulation 258/97, of the relevant food.[315] Where the food contains or consists of a GMO, the application must be accompanied by the information required under Directive 90/220 and Directive 2001/18, including the environmental risk assessment.[316]

(ii) Assessment by lead CA

7.132 Upon receipt of the application, the lead CA is to prepare an initial assessment report within a period of three months from receipt of the application. The assessment report must determine whether the application complies with the relevant requirements and is in accordance with the Commission's published recommendations.[317] The assessment report must also decide whether or not an additional assessment is required.[318]

(iii) Circulation of lead CA assessment report to other member States for comments

7.133 Upon completion of its assessment report, the lead CA must, without delay, forward it to the Commission, which in turn must forward it to the other member States. Within a period of 60 days from the date of circulation of the report by the Commission, a member State or the Commission may make comments or present a reasoned objection to the marketing of the food concerned. Comments or objections shall be forwarded to the Commission, which shall circulate them to member States within the 60-day period.[319]

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[313] Article 4(1) of Regulation 258/97.
[314] Articles 6(1) and 3(1) of Regulation 258/97.
[315] Article 8 of Regulation 258/97.
[316] Article 9 of Regulation 258/97.
[317] Article 6(2) and 6(3) of Regulation 258/97. Also Commission Recommendation of 29 July 1997 "concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under *Regulation No 258/97*".
[318] *Ibid*.
[319] Article 6(4) of Regulation 258/97.

7.134 If the lead CA's assessment report reaches the conclusion that no additional assessment is required, and no reasoned objection has been presented by another member State or the Commission, the lead CA must inform the applicant, without delay, that the food may be placed on the market.[320]

(iv) Community procedure in case an additional assessment is required or an objection is raised

7.135 If the lead CA's assessment report reaches the conclusion that an additional assessment is required, or a reasoned objection has been raised by another member State or the Commission, an authorization decision is to be taken at Community level.[321] To that end, the Commission must prepare a draft measure. The Commission ordinarily begins this process by consulting the relevant EC scientific committee – the Scientific Committee for Food (the "SCF").[322] Once the Commission has prepared a draft measure taking into account the opinion of the SCF, it must submit it to the appropriate Regulatory Committee, the so-called Standing Committee for Foodstuffs for a vote.[323] The Standing Committee for Foodstuffs must deliver its opinion on the Commission's draft measure within a time limit which the Chairman may lay down according to the urgency of the matter. The Standing Committee for Foodstuffs delivers opinions by qualified majority vote. The Commission must adopt the draft measure envisaged if it is in accordance with the opinion of the Standing Committee for Foodstuffs. If the draft measure envisaged is not in accordance with the opinion of the Standing Committee for Foodstuffs, or if no opinion is delivered, the Commission must, without delay, submit to the Council a proposal relating to the measures to be taken.[324]

7.136 The Council can either adopt or reject the Commission's draft measure by a qualified majority.[325] In either case, it must act within a time-period which shall in no case exceed three months from the date of referral to the Council. If the Council has not acted within that time-period, the Commission must adopt the draft measure it has submitted to the Council.[326]

7.137 The Commission must without delay inform the applicant of the decision taken at Community level, which will be published in the Official Journal of the European Communities.[327]

(v) Simplified Procedure

7.138 It should be noted that for novel foods which are "substantially equivalent" to existing foods, Regulation 258/97 provides for a simplified procedure.[328] This includes food products which are produced from, but do not contain, GMOs. "Substantial equivalence" can be demonstrated in two ways: (1) by relying on scientific evidence available and generally recognized or (2) by relying on an opinion delivered by one of the competent food assessment bodies of the member States.[329] In the case of substantially equivalent novel foods, the applicant must "notify" the Commission of the

[320] Article 4(2) of Regulation 258/97.
[321] Article 7 of Regulation 258/97.
[322] Article 11 of Regulation 258/97. Since the entry into force of Regulation 178/2002, the tasks of the SCF have been entrusted to the EFSA.
[323] Article 13(1) of Regulation 258/97.
[324] Articles 13(3) and 13(4) of Regulation 258/97.
[325] The Council may also modify the draft measure, although by unanimous vote only. Article 250(1) of the EC Treaty.
[326] Article 13(4) of Regulation 258/97.
[327] Article 7(3) of Regulation 258/97.
[328] Article 5 of Regulation 258/97.
[329] Article 3(4) of Regulation 258/97.

placing on the market when it does so. Then, the Commission forwards to the member States, within 60 days, a copy of the application.[330]

(vi) Safeguard measures by individual member States

7.139 As with Directives 90/220 or 2001/18, where a biotech product has been approved for Community-wide marketing under Regulation 258/97, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. However, Article 12 of Regulation 258/97 provides that a safeguard measure may be adopted where, "as a result of new information or a reassessment of existing information", a member State has "detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment [...]".

7.140 The safeguard measures taken pursuant to Regulation 258/97 can be maintained only on a provisional basis, pending a full assessment at EC level.[331] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[332] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the measure.[333]

7.141 According to Article 13 of Regulation 258/97, when making a decision on a safeguard measure which has been notified, the Commission is assisted by the Standing Committee on Foodstuffs. The Commission must submit a draft of the measure to be taken to the Standing Committee on Foodstuffs, which shall deliver its opinion on the draft. If the draft measure is in accordance with the opinion of the Standing Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit a proposal to the Council on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[334]

(vii) Availability under EC and member State law of procedures for administrative and judicial review

7.142 With regard to the availability of procedures for administrative or judicial review under EC law and member State law, we note that the possibility to challenge actions or omissions by member State or Community authorities exists in the same way under Regulation 258/97 as it exists under Directives 90/220 and 2001/18.

7.143 As we have stated earlier, the European Communities has stated before the Panel that, in respect of the biotech products which are the subject of these proceedings, it is aware of only one instance where legal proceedings were brought at member State level. Those proceedings concerned a safeguard measure introduced by Italy pursuant to Regulation 258/97.[335] According to the European

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[330] Article 5 of Regulation 258/97.

[331] Article 12(1) of Regulation 258/97.

[332] *Ibid*.

[333] In contrast with Directive 90/220, we note that Regulation 258/97 does not establish a timeframe for a decision by the Commission.

[334] Article 13(4)(b) of Regulation 258/97.

[335] On 13 November 2000 Monsanto Agricoltura Italia SpA and others brought proceedings before the Italian courts challenging the validity of the Italian Decree of 4 August 2000 temporarily suspending trade in

Communities, no applications have been made to the European Court of Justice challenging any actions, or an alleged failure to act, by the Community institutions in respect of any of the relevant biotech products.

(c) GM food and feed and traceability and labelling of GMOs and traceability of food and feed products produced from GMOs: Regulation 1829/2003 and Regulation 1830/2003

7.144 Regulation 1829/2003 "on genetically modified food and feed"[336] (hereafter "Regulation 1829/2003") and Regulation 1830/2003 "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC"[337] (hereafter "Regulation 1830/2003") are not directly relevant to this dispute. While there are frequent references to these Regulations in the Panel record, the Parties have provided little information on their content and purpose. Accordingly, we provide merely a very basic description of these most recent legislative instruments concerning the approval of biotech products.

7.145 Regarding Regulation 1829/2003, we note that it replaced Regulation 258/97, although Regulation 258/97 remains applicable to novel foods other than GM foods. Regulation 1829/2003 lays down streamlined Community procedures for the approval of GM food and feed as well as new provisions for the labelling of GM food and feed. Notably, it establishes the "one door-one key" principle whereby the approval of a biotech product which is for use as food and feed and for cultivation can be requested in one single application filed exclusively under Regulation 1829/2003. It appears, however, that the applicant also has the choice of submitting an application both under Directive 2001/18, insofar as the application is for the deliberate release of the relevant product into the environment, and under Regulation 1829/2003, insofar as the application is for the use of the product as or in a food product.

7.146 Regarding Regulation 1830/2003, we note that it applies to all products containing or consisting of GMOs irrespective of their use (*i.e.*, food and feed as well as cultivation). Regulation 1830/2003 provides a Community framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products. Directive 2001/18 already requires member States to take measures to ensure traceability of authorized GMOs at all stages of their placing on the market. However, it does not contain a definition of traceability for GMOs, and it does not include the objectives of traceability or a complete approach for its implementation. Regulation 1830/2003 therefore amends Directive 2001/18 in relevant part. Regulation 1830/2003 sets up a harmonized Community system for the labelling of all products consisting of or containing GMOs and imposes additional labelling requirements for these products.

3. Applicability of the *SPS Agreement*

7.147 The Complaining Parties all allege that the above-mentioned EC approval procedures concerning the deliberate release of biotech products into the environment (Directive 90/220 and subsequently Directive 2001/18) and concerning novel foods and novel food ingredients

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and use of certain novel foods within Italy (issued pursuant to Article 12 of Regulation 258/97), and seeking compensation for loss claimed to result from the Decree. These proceedings are still pending.

[336] Published in OJ N° L 268, 18/10/2003, p. 1.

[337] Published in OJ N° L 268, 18/10/2003, p. 24.

(Regulation 258/97) are SPS measures within the scope of the *SPS Agreement*. The European Communities maintains that the EC approval procedures fall in part within the scope of the *SPS Agreement*, and in part outside of scope of the *SPS Agreement*. In this section, the Panel will determine whether the relevant EC approval procedures are SPS measures which fall to be assessed under the *SPS Agreement*.

7.148 We note that Annex A(1) of the *SPS Agreement* provides the following legal definition of the term "SPS measure":

> **DEFINITIONS**[338]
>
> *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.

7.149 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.]").

[338] (*original footnote*) 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.

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

7.150 Before examining in detail whether the relevant EC approval procedures are SPS measures which are to be assessed under the provisions of the *SPS Agreement*, it is necessary to address an issue put before us by the European Communities. The issue is 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*.

7.151 The **European Communities** argues that the *SPS Agreement* has a limited scope of application and that the scope is defined by reference to the objective, or purpose, of the measure at issue, that is the reasons justifying the measure. The European Communities considers that if a WTO Member acts for two different reasons, one of which falls within the scope of the *SPS Agreement*, and the other of which does not, there are in effect two different measures for WTO purposes. According to the European Communities, this is so even if the two different objectives are sought to be achieved by a measure reflected in a single document. The measure (or part thereof) taken for any of the reasons enumerated in the *SPS Agreement* falls within the scope of that *Agreement*. The measure (or part thereof) taken for other reasons falls outside the scope of the *SPS Agreement*.

7.152 The European Communities argues that there is nothing in the *SPS Agreement* or in any other WTO agreement that obliges a WTO Member to refrain from adopting in its domestic jurisdiction a single act, incorporating two or more measures regulated by more than one WTO agreement or provision. The European Communities submits that this situation is very common in the context of the WTO, and the issue with which the Panel is confronted is thus a horizontal one.

7.153 The European Communities considers that where a Member's regulation pursues an SPS objective and also a non-SPS objective, and that regulation is found by a panel to fall within the scope of the *SPS Agreement* and to be inconsistent with it (because the way in which the SPS objective is dealt with conflicts with the rules in the *Agreement*), the most that the panel could properly find is that the regulation includes an SPS measure and that the SPS measure in the regulation is inconsistent with the *SPS Agreement*. The panel's recommendation could only be that the Member take the measures necessary to bring the SPS measure in the regulation into conformity with the *SPS Agreement*. The European Communities submits that the panel could not make any recommendation in relation to the regulation as a whole, unless it also considered and made findings in relation to the measures in the regulation that fall outside the scope of the *SPS Agreement*. Consequently, when it would come to implementation, the Member concerned would be under an obligation to bring the SPS measure into conformity with the *SPS Agreement*, by removing the SPS objective and the elements of the measure that derive therefrom, but the Member in question would not be under an obligation to remove the regulation.

7.154 In relation to the present dispute, the European Communities submits that the environmental and related objectives of its legislation for the approval of biotech products and of measures taken thereunder which are not governed by the *SPS Agreement* may have to be assessed by reference to the *TBT Agreement*. The European Communities considers that the addition of an SPS objective to a measure does not exclude the application of the *TBT Agreement* to non-SPS aspects of that measure. In such a case, the *SPS Agreement* would apply to the extent that SPS objectives are pursued and the *TBT Agreement* would apply to the extent that non-SPS objectives are pursued.

7.155 The European Communities points out that it is aware of Article 1.5 of the *TBT Agreement*, which provides that:

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

7.156 According to the European Communities, Article 1.5 of the *TBT Agreement* means that a single measure that, at the same time, falls within the scope of the *SPS Agreement* and within the scope of the *TBT Agreement* falls to be considered only under the *SPS Agreement*. Article 1.5 does not mean that an act that contains both an SPS measure and a TBT measure (*i.e.*, a measure falling under the *TBT Agreement* but not under the *SPS Agreement*) falls to be considered only under the *SPS Agreement* and not at all under the *TBT Agreement*. If that were true, it would allow Members to camouflage TBT measures behind the *SPS Agreement*, which is in certain respects less strict than the *TBT Agreement*, by simply adding an SPS aspect to the act. Conversely, it would also lead to the bizarre result that a perfectly lawful TBT measure might suddenly become unlawful, just because it is in the same act as an SPS measure, and happens not to comply with a provision of the *SPS Agreement*. Furthermore, 99 percent of an act might be a TBT measure and 1 percent of the act an SPS measure, and yet the whole act would fall to be considered only under the *SPS Agreement*, and the *TBT Agreement* would not apply at all. In the European Communities' view, that cannot be right.

7.157 The **United States** notes that the European Communities has not disputed that both its novel foods regulation and deliberate release directives are covered within the scope of the *SPS Agreement*. Furthermore, with regard to the member State measures, the European Communities acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*. The United States considers that the European Communities' agreement that its measures were adopted for "some reasons" that fall within the scope of the *SPS Agreement* is more than sufficient to bring those measures with the scope of that Agreement.

7.158 Article 1.5 of the *TBT Agreement* is quite clear in stating that the provisions of the *TBT Agreement* "do not apply" to SPS measures as defined in Annex A of the *SPS Agreement*. Annex A makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the *SPS Agreement*. The Annex does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. Nor does the *SPS Agreement* say that an SPS measure – meaning a measure addressing a risk enumerated in Annex A – somehow loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. Thus, for example, even if the European Communities' deliberate release directives could be construed to cover some risks outside the scope of the *SPS Agreement*, these directives would still be SPS measures, and subject to the disciplines under the *SPS Agreement*.

7.159 **Canada** notes that Article 1.5 of the *TBT Agreement* states that it does not apply to SPS measures as defined in Annex A of the *SPS Agreement*. According to Canada, this does not assist in resolving the more discrete question of whether a single or "indivisible" measure taken for both SPS and non-SPS reasons can be considered as both an SPS measure and a non-SPS measure, or whether, as the European Communities contends, it must be considered to be a series of measures. On balance, Canada is of the view that a hermetic approach to the *SPS Agreement* and the *TBT Agreement*, respectively, is probably neither valid from an interpretive standpoint, nor useful from a practical perspective. A Member's measure is an SPS measure to the extent that it addresses SPS risks; to the extent that it addresses other risks or policy objectives, it is another type of measure, including, possibly, a TBT measure. Whether a measure that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a series of measures is purely semantic.

7.160 Canada notes that, in any event, the European Communities has conceded that its measures are at least in part SPS measures. All Parties agree that a measure taken for reasons having to do with

the definition of an SPS measure in Annex A(1) must be examined in the light of the requirements of the *SPS Agreement*. As a consequence, if that measure does not meet those requirements, it gives rise to a violation of one or more of the provisions of the *SPS Agreement.* The fact that the measure might also have a TBT dimension and may even be TBT-consistent would be entirely beside the point because consistency with one Agreement cannot operate to excuse or remedy a violation under another Agreement.

7.161 **Argentina** argues that the European Communities admits that the measures at issue in this dispute which affect the approval and marketing of biotech products are partially covered by the *SPS Agreement*. According to Argentina, the *SPS Agreement* is the agreement to be applied, since it refers to the protection against certain risks and not against certain products. Argentina further submits that in accordance with Article 1.5 of the *TBT Agreement* the *SPS Agreement* and the *TBT Agreement* are mutually exclusive. Finally, Argentina contends that, by definition, a measure cannot be a series of measures.

7.162 The **Panel** considers that the issue raised by the European Communities is best analysed using a hypothetical example. Thus, assume that a Member imposes two identical requirements with regard to a particular product, and that each of the two requirements is laid down in a separate law. The law containing the first requirement states that that requirement is applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement*. The law containing the second requirement states that the second requirement is applied exclusively for a different purpose, one which is not covered by Annex A(1). Clearly, the first requirement would qualify as an SPS measure, as it meets the form (law), nature (requirement) and purpose (one of the enumerated purposes) elements of the definition of the term "SPS measure" as provided in Annex A(1). Equally clearly, the second requirement would not qualify as an SPS measure. While it would meet the form (law) and nature (requirement) elements of the definition of an SPS measure, it would not satisfy the purpose element, as it is not applied for one of the purposes enumerated in Annex A(1). Needless to say, however, the second requirement would also constitute a measure for WTO purposes. For simplicity, we refer to it here as the "non-SPS measure".

7.163 Now assume that the Member concerned decides to consolidate the two separate laws which contain the identical requirements into one single law. Since the two requirements in question are identical, the relevant requirement is included only once in the consolidated law. As the two independent purposes of the requirement in question remain as valid as before, the consolidated law specifies that the requirement is applied for both purposes. The issue now arises whether the requirement in the consolidated law (hereafter "the requirement at issue") constitutes an SPS measure or a non-SPS measure, or both.

7.164 According to the United States' and Argentina's view, the requirement must be considered an SPS measure, and an SPS measure alone, because it meets all elements of the definition of an SPS measure. It undoubtedly meets the form and nature elements; and since the requirement is at least in part applied for one of the purposes enumerated in Annex A(1), the United States' and Argentina's position is that it also meets the purpose element of the definition of an SPS measure. The European Communities rejects this view, arguing that the requirement at issue should be considered (i) an SPS measure to the extent it is applied for one of the purposes enumerated in Annex A(1) and (ii) a non-SPS measure to the extent it is applied for a purpose which is not covered by Annex A(1).[339]

[339] Canada has stated that a hermetic approach to the *SPS Agreement* and the *TBT Agreement*, respectively, is probably neither valid from an interpretative standpoint, nor useful from a practical perspective. According to Canada, a requirement is an SPS measure to the extent it addresses SPS risks; to the extent that it

7.165 In our assessment, the better and more appropriate view is that of the European Communities. Hence, we 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 have an autonomous raison d'être, *i.e.*, a different purpose which would provide an independent basis for imposing the requirement.

7.166 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.

7.167 We note the United States' and Argentina's argument that Article 1.5 of the *TBT Agreement* supports a different conclusion. To recall, Article 1.5 states that the provisions of the *TBT Agreement* "do not apply" to SPS measures as defined in Annex A(1) of the *SPS Agreement*. The operation of Article 1.5 is best illustrated by reference to the specific case of our hypothetical requirement contained in the consolidated law. To that end, we assume that the consolidated law qualifies as a technical regulation within the meaning of Annex 1(1) of the *TBT Agreement*.[340] We have stated above that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement*, it can be viewed as an SPS measure. As such, it falls to be assessed under the *SPS Agreement*, provided the measure may affect international trade.[341] Article 1.5 makes clear that to the extent the requirement at issue qualifies as an SPS measure, the provisions of the *TBT Agreement* would "not apply", even though the requirement at issue is contained in a law which meets the definition of a technical regulation. We have also said that to the extent the requirement at issue is applied for a purpose not covered by Annex A(1) of the *SPS Agreement*, it can be viewed as embodying a non-SPS measure. By its terms, Article 1.5 is not applicable to non-SPS measures. However, given that the requirement is assumed to be part of a technical regulation, it falls to be assessed under the *TBT Agreement*, to the extent it embodies a non-SPS measure.[342] As the foregoing considerations demonstrate, our view that a requirement may in

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addresses other risks or policy objectives, it is another type of measure, including, possibly, one to be assessed under the *TBT Agreement*. Canada considers that the issue of whether a requirement that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a series of measures is purely semantic.

[340] Annex 1(1) defines a technical regulation as a "[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is necessary". Annex 1(1) further specifies that a technical regulation "may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method".

[341] Articles 1.1 and 1.2 of the *SPS Agreement* make clear that the *SPS Agreement* applies to all measures which (i) meet the definition of an SPS measure provided in Annex A(1) and (ii) may affect international trade.

[342] We note that according to Article 1.4 of the *SPS Agreement*, "[n]othing in this Agreement shall affect the rights of Members under the [*TBT Agreement*] with respect to measures not within the scope of this Agreement".

certain cases incorporate more than one measure is consistent with, and gives meaning and effect to, the provisions of Article 1.5. Therefore, we do not agree that Article 1.5 compels a different view.

7.168 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.[343] 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.

7.169 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.

7.170 Thus, if 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.

7.171 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

[343] Article 2.1 of the *SPS Agreement* provides that "Members have the right to take "[SPS] measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of [the *SPS Agreement*]".

their internal laws or their legitimate preference, and exposing themselves to potential legal risks, which may be imprudent.

7.172 Turning now to the specific case before us, we note the European Communities' assertion that the EC approval legislation which sets out the relevant approval procedures is applied in part for purposes which are identified in Annex A(1) of the *SPS Agreement* and in part for other purposes. The European Communities submits that to the extent the relevant EC approval legislation is applied for purposes which are identified in Annex A(1), it is governed by the *SPS Agreement*; to the extent the legislation is applied for other purposes, it falls within the scope of another WTO agreement, possibly the *TBT Agreement*. Since, as we will see, the approval procedures are conducted for a number of purposes (namely, to avoid various adverse effects), our analysis above suggests that it may conceivably be warranted to view each of the relevant EC approval procedures as incorporating an SPS measure as well as a non-SPS measure.

7.173 Given this, it is pertinent to recall that, according to the European Communities, the question of whether the measures at issue in this dispute are SPS measures or non-SPS measures, or both, may have implications for the implementation of a possible adverse DSB ruling in this dispute, and that, in the European Communities' view, it is therefore important for the Panel appropriately to circumscribe the focus and scope of its findings. We also note that two Complaining Parties, Argentina and Canada, have presented claims under the *TBT Agreement*. Argentina has indicated that its claims under the *TBT Agreement* are made in the alternative, in case we reject its claims under the *SPS Agreement*. Canada, however, has stated that if the Panel were to determine that parts of the measures at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative *vis-à-vis* its claims under the *SPS Agreement*. In the light of these elements, and in the interests of effective dispute resolution, we find it appropriate to analyse for each of the relevant EC approval procedures whether it is an SPS measure, and if so, whether it is an SPS measure only, or whether it may be considered to embody an SPS measure as well as a non-SPS measure. This analysis will also facilitate a similar inquiry to be carried out by us in Section F below, where we examine the Complaining Parties' complaints in respect of the member State safeguard measures.

7.174 Accordingly, we now proceed to examine whether the EC approval procedures are SPS measures within the meaning of Annex A(1) of the *SPS Agreement*. To that end, we will consider one by one the definitional elements of the term "SPS measure" and then will draw appropriate conclusions on whether the EC approval procedures are SPS measures, and if so, on whether they are SPS measures only.

(b) Whether the EC approval procedures are SPS measures in terms of their purpose

7.175 We first analyse whether the EC approval procedures are SPS measures in terms of the purpose element of the Annex A(1) definition of the term "SPS measure". As we set out to determine whether the European Communities is correct in arguing that each of the EC approval procedures can be viewed as embodying both an SPS measure and a non-SPS measure, we consider all relevant purposes for which the EC approval procedures are applied. As always, we begin our analysis with a summary of the Parties' arguments.

7.176 The **United States** argues that the approval regime is unquestionably an SPS measure. It notes that Directive 90/220 states that one of its objectives is "to protect human health and the environment" from, among other things, the "placing on the market [of] genetically modified

organisms as or in products within the Community".[344] The same objective is stated in Directive 2001/18.[345] Regulation 258/97 states that "foods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous".[346]

7.177 According to the United States, the EC approval regime requires consideration of specific risks that fall within the definition of an SPS measure as set out in Annex A(1) to the *SPS Agreement*. Thus, concerns that a biotech product might lead to an allergic or toxic reaction on the part of certain animals or concerns that some biotech plant varieties could harm beneficial organisms as well as target organisms, fall within the definition of Annex A(1)(a). Concerns that a biotech product might lead to an allergic or toxic reaction on the part of consumers or regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, fall within the definition of Annex A(1)(b). Similarly, concerns that widespread consumption of varieties containing antibiotic resistance marker genes might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of Annex A(1)(b). Such concerns have been characterized as food safety issues. Thus, according to the United States, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs."

7.178 The United States further argues that concerns regarding the cross-contamination (or transfer) of biotech products to non-target organisms, *e.g.*, concerns that herbicide tolerance could be transferred from a biotech variety to a wild variety, fall within the scope of Annex A(1)(d). The United States points out in this regard that Annex A defines "pests" to include weeds, and weeds are defined as "plant[s] that grow[]… where [they are] not wanted."[347]

7.179 **Canada** argues that the central purpose of Directive 2001/18 is to protect against the kinds of risks identified in paragraph 1 of Annex A of the *SPS Agreement*. Directive 2001/18 requires that an environmental risk assessment be conducted and lists the following "potential adverse effects" of biotech products that should be addressed:[348]

- diseases to humans including allergenic or toxic effects;
- diseases to animals and plants including toxic, and where appropriate allergenic effects;
- effects on the dynamics of populations of species in the receiving environment and on genetic diversity of each of these populations;
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors.

Canada argues that Annex A(1) defines the purpose of an SPS measure as being to address, *inter alia*, these potential adverse effects.

7.180 Canada further notes that the Directive identifies as a potential concern the "*spread* of GMO(s) in the environment."[349] In this context, according to Canada the Directive requires, where

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[344] Article 1 of Directive 90/220.
[345] Article 1 of Directive 2001/18.
[346] Article 3(1) of Regulation 258/97.
[347] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 2002), Vol. 2, p. 2171.
[348] Annex II C.2.1. of Directive 2001/18.
[349] *Ibid*, emphasis added by Canada.

appropriate, the submission of information in the application for approval relating to the "likelihood of the GMO [becoming] persistent and invasive in natural habitats…"; "any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised…"; and the "potential … environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens".

7.181 Canada also maintains that the requirement in Directive 2001/18 for information regarding "possible…effects on animal health and consequences for the feed/food chain resulting from the consumption of the GMO and any product derived from it, if it is intended to be used as animal feed" is further evidence that Directive 2001/18 is an SPS measure with the objective of addressing concerns identified in Annex A(1) of the *SPS Agreement*.[350]

7.182 Concerning Directive 90/220, Canada notes that similar to its successor Directive, the central objective of Directive 90/220 was "to protect human health and the environment…when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment."[351] Moreover, information similar to that identified under Directive 2001/18 was also to be included in notifications under Directive 90/220.[352] Therefore, according to Canada, Directive 90/220 was also an SPS measure as defined in Annex A(1) of the *SPS Agreement*.

7.183 Regarding Regulation 258/97, Canada argues that the central purpose of Regulation 258/97 is to protect against risks identified in paragraph 1(b) of Annex A of the *SPS Agreement*. Furthermore, Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97.[353] Canada notes that, pursuant to Commission Recommendation 97/618, safety assessments conducted under Regulation 258/97 should include an assessment of contaminants, toxins and disease-causing organisms resulting from the novel elements of the novel food or food ingredient in question. These are among the risks explicitly identified in Annex A(1)(b). The Commission Recommendation states that the safety assessment should address only "[c]hemical or microbiological *contaminants* of novel foods…specifically related to the novelty…" and "the presence of microbial *toxins* and microbial or *viral infective agents*…[when] this is a consequence of the novelty."[354] Canada also points out that Part XIII of the Commission Recommendation sets out the type of toxicological information that should be included in an assessment for novel foods under Regulation 258/97, including *toxicity*, mutagenicity and allergenicity studies.[355]

7.184 **Argentina** maintains that the European Communities' approval procedures are SPS measures, because their stated purpose is to determine, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. The risks to which the EC legislation refers, and the risks which have been evaluated by the respective EC scientific committees, fall within the scope of Annex A(1) of the *SPS Agreement* because they refer to or deal with, *inter alia*, risks such as toxic or

[350] Annex II D.1. of Directive 2001/18.
[351] Article 1 of Directive 90/220.
[352] Annex II, Part IV of Directive 90/220.
[353] Commission Recommendation of 29 July 1997 concerning the scientific aspects of the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97, Commission Recommendation 97/618, (Exhibit CDA-24).
[354] *Ibid*, Art. 5 (emphasis added by Canada).
[355] *Ibid*, p. 14, Part XIII.

allergic effects in humans and animals, the growth of antibiotic-resistant bacteria and cross-contamination.

7.185 The **European Communities** argues that the *SPS Agreement* applies to measures taken to prevent an exhaustive list of narrowly defined risks and that the provisions of the *SPS Agreement* are specifically designed to regulate such measures. However, the issues arising out of the existence of GMOs and the issues addressed by Directives 90/220 and 2001/18 as well as by Regulation 258/97, go beyond the risks envisaged and regulated by the *SPS Agreement*. Thus, according to the European Communities, the *SPS Agreement* does not provide a sufficient legal framework for the examination of the EC measures at issue.

7.186 The European Communities maintains that the *SPS Agreement* is relevant only to some of the issues examined by EC authorities in the course of GMO approval procedures, but does not cover all of the issues of concern. Thus, while Annex A(1)(b) of the *SPS Agreement* concerns certain things "in foods, beverages or feedstuffs", according to the European Communities, a GMO seed destined to be planted in the ground, not eaten by humans or fed to animals cannot be considered to be a "food, beverage or feedstuff". Similarly, a *GM crop* or plant is not in itself necessarily a food, although it may be processed into something that becomes a food. Furthermore, a crop or plant is not necessarily a "feedstuff" for animals – that depends on whether or not it is destined for such use, and whether or not the crop will first be processed.

7.187 The European Communities further argues that while the term "disease" appears in both Annex A of the *SPS Agreement* and the EC legislation, a GMO is not infected or an infection and is not, in itself, a "disease" within the meaning of Annex A(1).[356] Nor is a GMO a "disease-carrying organism" or generally considered a "disease-causing organism" within the meaning of Annex A. Furthermore, with regard to the term "pest" as used in the definition in Annex A(1), the European Communities maintains that, in light of the definition of a pest in the 1997 *International Plant Protection Convention* (hereafter the "IPPC")[357], in order for a GMO to be a pest within the meaning of the *SPS Agreement*, the relevant GMO would have to be "pathogenic" or "injurious" – that is, it would have to do more than merely interact in some way with humans, animals or plants.

7.188 The **Panel** will determine below whether the specific risks or concerns identified in Directives 90/220 and 2001/18 and in Regulation 258/97 are risks that fall within the scope of the definition of an SPS measure in Annex A(1). For this purpose, the Panel will consider separately the approval legislation concerning the deliberate release of biotech products, established by Directive 90/220 and subsequently by Directive 2001/18, and that concerning novel foods established by Regulation 258/97.

(i) Directives 90/220 and 2001/18

7.189 Directive 90/220 indicates that a central purpose of the Directive is "to protect human health and the environment [...] when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment".[358]

[356] The European Communities makes reference to the OIE definition of a disease by the World Organization for Animal Health (OIE) as "the clinical and/or pathological manifestation of infection", International Animal Health Code, 2002.

[357] The European Communities refers to the *International Plant Protection Convention* (IPPC) 1997, which defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products", *International Plant Protection Convention*, FAO, Rome 1997.

[358] Article 1.1, second tiret, of Directive 90/220.

Directive 90/220 also states that "Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs."[359] Although Directive 90/220 does not explicitly identify what potential risks for human health and the environment must be assessed prior to a release of GMOs into the environment, it does identify the information required in an application for marketing approval. Thus, information to be provided by applicants relating to the characteristics of the final GMO includes, *inter alia*, toxic or allergenic effects, information on pathogenicity, communicability, host range, and antibiotic resistance patterns.[360] Information to be provided by applicants relating to the potential environmental impact of the GMOs includes information on:[361]

- potential for excessive population increase in the environment;
- competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
- anticipated mechanism and result of interaction between the released GMOs and the target organism;
- identification and description of non-target organisms which may be affected unwittingly;
- likelihood of post-release shifts in biological interactions or in host range;
- known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
- known or predicted involvement in biogeochemical processes;
- other potentially significant interactions with the environment.

7.190 Turning to Directive 2001/18, we note that as with Directive 90/220, a central purpose of the Directive is to protect human health and the environment when placing on the market genetically modified organisms as or in products.[362] Article 4 further clarifies that the purpose of Directive 2001/18 is to "avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs."[363] Like Directive 90/220, Directive 2001/18 does not explicitly identify what potential risks for human health and the environment must be assessed prior to a release of GMOs into the environment, but identifies the information to be provided by applicants in their applications for marketing approval. The information which we have said was to be provided by applicants under Directive 90/220 is also to be provided under Directive 2001/18.[364] Unlike Directive 90/220, however, Directive 2001/18 also addresses the methodology to be followed to perform an environmental risk assessment. In this context, Annex II.C.2.1 of the Directive mentions that potential adverse effects of GMOs vary from case to case and may include:

- disease to humans including allergenic or toxic effects;
- disease to animals and plants including toxic, and where appropriate, allergenic effects;

[359] Article 4(1) of Directive 90/220.

[360] Annex II.II.C.2(i). The chapeau to the Annex states, *inter alia*, that "[n]ot all the points included will apply to every case. It is to be expected, therefore, that individual notifications will address only the particular subset of considerations that are appropriate to individual situations."

[361] Annex II.IV.C of Directive 90/220.

[362] Article 1, second tiret, of Directive 2001/18.

[363] Article 4(1) of Directive 2001/18.

[364] Annexes IIIA and IIIB.

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these – changes in populations and in genetic diversity brought about by effects on life/health which may have more deleterious effects on one species than another, hence changing population dynamics;
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;
- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

7.191 The Directive states that adverse effects may occur directly or indirectly through mechanisms which may include the spread of the GMO(s) in the environment; the transfer of the inserted genetic material to other organisms or the same organism; phenotypic and genetic instability; interactions with other organisms; and changes in management, including, where applicable, in agricultural practices.[365]

7.192 Furthermore, and again in addition to the provisions of Directive 90/220, Annex II.D.1 of Directive 2001/18 identifies concerns that are to be considered in the case of GMOs other than higher plants, while Annex II.D.2 identifies concerns to be considered in the case of genetically modified higher plants (hereafter "GMHP"). With respect to GMHP, the products at issue in this dispute[366], the following issues are to be considered:

- likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
- any selective advantage or disadvantage conferred to the GMHP;
- potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
- potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
- possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;
- possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s);
- possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed;

[365] Annex II.C.2 of Directive 2001/18.

[366] Annex III of Directive 2001/18 indicates that "higher plants" means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae). The products at issue in this dispute are all Angiospermae.

- possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
- possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

7.193 The Panel notes that in replacing Directive 90/220, Directive 2001/18 was presented as an improvement over the previous Directive, providing, *inter alia*, clarification of the scope of Directive 90/220.[367] Indeed, as we have indicated, Directive 2001/18 specifies or amplifies in its annexes some of the potential risks from GMOs from which protection of human health and the environment is to be provided. In view of the fact that Directive 2001/18 clarifies rather than expands the scope of Directive 90/220, we believe that we can presume that any potential adverse effect within the scope of Directive 2001/18 was also covered by Directive 90/220.

7.194 We note that, according to the European Communities, the EC approval legislation has the objective of addressing concerns relating to:

- herbicide tolerance in GM plants (agricultural persistence of the GM plant and cross-breeds; natural persistence resulting in damage to the ecological balance or biodiversity; effects on human or farm animal health from the modified gene in foodstuffs, from allergens or from increased herbicide use; impact on wild flora and fauna from herbicide use; effects of cross-breeding on wild flora);
- insecticidal properties of GM plants (agricultural insect resistance; spread of insect resistance trait into wild flora; effects on human or farm animal health, including allergies; effects on human or farm animal health from increased insecticide use; effects on wild fauna of the toxin in the GM plant; effect on wild fauna from increased insecticide use); and
- antibiotic resistance.

We consider that these are not concerns *in addition* to those identified in the Directives themselves (see paragraphs 7.189-7.192 above), but rather a different way of describing the concerns contained therein.

7.195 As a result, and given the greater degree of specificity of the relevant provisions of Directive 2001/18 compared to those of Directive 90/220, for the purposes of our analysis, we will focus on the potential adverse effects identified in Directive 2001/18. We are aware that Annex II.C.2 to Directive 2001/18 by stating that "adverse effects *may include*" (emphasis added) is not intended to be a closed list of the possible adverse effects of GMOs on human health and the environment. Therefore, we will also consider the additional possible adverse effects which have been identified by the European Communities in the case at hand. The fact that we address the potential adverse effects of GMOs mentioned in Directive 2001/18, or mentioned separately by the European Communities, should not be construed to mean that we necessarily agree that all GMOs, or even specific GMOs, actually or potentially give rise to such effects.

7.196 Having determined that the purpose of Directives 90/220 and 2001/18 is to protect human health and the environment from adverse effects on human health and the environment which might

[367] 1st and 2nd preambular paragraphs of Directive 2001/18.

result from the deliberate release of GMOs into the environment, we now proceed to examine whether that purpose is covered by the various sub-paragraphs of Annex A(1) to the *SPS Agreement*.

Protection of the environment

7.197 The Panel will first consider the general purpose of protection of the environment as stated in Directives 90/220 and 2001/18.

7.198 The **European Communities** observes that Directives 90/220 and 2001/18 repeatedly state that one of the purposes of these pieces of legislation is to protect the environment. The European Communities contrasts this with Annex A of the *SPS Agreement* which it claims does not address environmental protection, unlike Article 2.2 of the *TBT Agreement*, for example, which expressly refers to "the environment". According to the European Communities, it is clear that when the drafter of an international agreement uses a term in one instrument but not in another, the drafter intended to exclude that term from the latter instrument. The European Communities concludes from this that the *SPS Agreement* was not intended to address the prevention of risks to the environment.

7.199 The European Communities contends that this is also clear from the negotiating history of the *SPS Agreement*. In this context, the European Communities refers to a 1993 Uruguay Round GATT Secretariat background paper on the proposed *SPS Agreement*, wherein it is stated that "[m]easures for environmental protection, *per se*, […] are not covered by the proposed [*SPS*] *Agreement*".[368] The European Communities also refers to the "Cover note to the SPS Decision circulated on 20 December 1990 (also known as the 'Dunkel text')"[369]. However, the European Communities is mistaken in referring to the Dunkel text. The European Communities meant to refer to the cover note to the *Draft Text on Sanitary and Phytosanitary Measures* circulated on 20 November 1990 (not 20 December 1990, as the European Communities contends) by the Chairman of the Working Group on Sanitary and Phytosanitary Measures. The European Communities points out that the cover note at issue addressed certain bracketed elements in the draft text which included a reference to "the environment". The European Communities notes that, according to the cover note, the relevant brackets are "linked to the question of whether or not this agreement should apply to measures taken for the protection of animal welfare and the environment […]".[370] The European Communities further notes that this bracketed text was not retained in the final text of the *SPS Agreement*. The European Communities deduces from this that environmental damage *per se* does not fall within the scope of the *SPS Agreement*.

7.200 The European Communities contends that the ordinary meaning of the word "environment" is broad and includes the protection of biodiversity; it does not focus on a short-term risk to the life or health of a particular animal or plant. Furthermore, according to the European Communities, negative effects on biodiversity may occur without negatively affecting the wild flora and fauna or an area. In the European Communities' view, such effects could result from positive effects on wild fauna and/or flora that disrupt the ecological equilibrium; negative effects on soil or water micro-organisms;

[368] Quoted in EC second written submission, footnote 35.
[369] EC reply to Panel question No. 120(c).
[370] Uruguay Round document MTN.GNG/NG5/WGSP/7, p. 1 (reference identified by Panel).

modification of interactions between two organisms, including through trophic interactions[371]; and negative effects on the biogeochemical processes of an ecosystem.[372]

7.201 The **United States** argues, in contrast, that a biotech plant can only damage biodiversity or the ecological balance through its ability to adversely affect, directly or indirectly, the wild flora or fauna of the area. Any damage would occur due to alterations in the invasiveness or persistence of certain plant species, causing changes in the abundance of different plant species and secondary negative impacts on animal life.

7.202 The United States considers that the European Communities' citation to the negotiating history is incomplete and misleading, and in no way supports the European Communities' contention. The United States notes that the "bracketed text" referred to by the European Communities is actually two different bracketed phrases.. Both of these phrases are contained in the concluding paragraph of the Annex A(1) definition of "SPS measure" (that is, in the paragraph following lettered paragraphs a to d) – a paragraph which (in its final form) describes types of measures – such as labelling and quarantines – as opposed to describing particular types of risks. One of the bracketed phrases would have expressly included animal welfare, environment, and consumer interests and concerns. The second bracketed phrase would have expressly excluded those issues.

7.203 The United States points out that the final text of the *SPS Agreement* drops both the proposal for an explicit inclusion and the proposal for an explicit exclusion of environmental and animal welfare concerns. Thus, contrary to the European Communities' assertions, this change is not the least bit instructive on whether the drafters of the agreement intended to include or exclude environmental issues. On the other hand, this change could support an interpretation that the drafters decided to leave the last paragraph of Annex A(1) to describe types of measures (such as labelling and quarantine) and to place the types of covered risks within the lettered paragraphs a to d.

7.204 The United States argues, moreover, that the European Communities does not make note of a more relevant and significant change between the late 1990 draft text and the final *SPS Agreement*. The late 1990 draft text did not include footnote 4, which defines "animal" to include "wild fauna" and "plant" to include "wild flora". The fact that these clarifications were added to the text means that the issue of environmental damage was in fact considered by the drafters, and that the drafters purposely and specifically decided to include damage to wild flora and fauna within the scope of the *SPS Agreement*. Thus, contrary to the European Communities' assertions, the negotiating history of the *SPS Agreement* provides no support for the European Communities' contention that the *SPS Agreement* was not intended to cover damage to the environment.

7.205 **Canada** argues that the *SPS Agreement* explicitly covers wild flora and fauna. Canada maintains that the term "fauna" encompasses both macrofauna and microfauna, whereas the term "flora" includes also microflora. The types of risk related to the environment that are addressed in Directives 90/220 and 2001/18 are those that ultimately pertain to animal or plant life or health. Nothing in the *SPS Agreement* limits SPS measures to short-term risks. "Biological diversity" is

[371] *The New Shorter Oxford English Dictionary* defines "trophic" as "of or pertaining to nutrition" L. Brown (ed.) (Clarendon Press, 2002), Vol. 2, p. 3403.

[372] In response to a question by the Panel, Dr. Snow, one of the experts consulted by the Panel, indicated that: "The biogeochemical cycle refers to the cycling of nutrients and carbon in any type of ecosystem including a farmer's field. People are asking questions about whether the biotech crop might affect nutrients that come out of the dead materials from the crop and are recycled into the soil so it could affect soil fertility and things like that and just the rate at which nutrients are cycled locally. So biogeochemical, if that is clear enough, nutrients and carbon cycling in the form of organic matter and then back to their original components in an ecosystem. ", Annex J, para. 305.

defined in the *Convention on Biological Diversity* as "the variability among living organisms from all sources…".[373] In the context of this case, any harm to biodiversity or the ecological balance of an area arising from biotech products is through harm to plants and animals, as defined by the *SPS Agreement*. Canada considers that the materials from the negotiating history to which the European Communities refers do not indicate whether WTO Members intended for all types of environmental measures to be excluded; indeed, the more plausible reading of those materials is that the WTO Members intended for more general types of environmental measures, such as those relating to air and water quality, waste management, and the like, to be excluded from the coverage of the *SPS Agreement*, but that environmental effects related to SPS-type risks would remain within the scope of that agreement.

7.206 **Argentina** argues that since humans, animals and plants comprise the universe of living things, and since biodiversity is concerned with the diversity of living things, biodiversity is necessarily related to human, animal or plant life or health. In Argentina's view, the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is through negatively affecting wild flora and/or fauna. A measure taken to protect biodiversity would therefore be covered by the definition of an SPS measure contained in Annex A(1).

7.207 The **Panel** recalls that Directives 90/220 and 2001/18 serve to protect human health and the "environment". It is clear from the Directives that as part of the purpose of protecting the "environment" they address the protection of the health of animals or plants. Indeed, Article 2(8) of Directive 90/220 states that the term "environmental risk assessment" as used in the Directive "means the evaluation of the risk to human health and the environment (*which includes plants and animals*) …" (emphasis added). Among the information required with the submission of an application under Directive 90/220, in the context of "Information on the environment", is information on flora and fauna, including crops, livestock and migratory species.[374]. Directive 2001/18 refers to assessing the accumulated effects of consents for placing on the market on "human health and the environment, including *inter alia* flora and fauna, ... animal health...".[375] 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*.

7.208 The European Communities argues, however, that negative effects on the environment may occur without there being negative effects on wild flora and fauna. The European Communities refers to adverse effects on biodiversity as a relevant example. The European Communities implies that to the extent Directive 90/220 and 2001/18 are applied to protect the environment from such adverse effects, the Directives fall outside the scope of the *SPS Agreement*. We will address this argument below in the context of our analysis of Directives 90/220 and 2001/18 under Annex A(1)(d) of the *SPS Agreement*. Annex A(1)(d) refers to measures applied to prevent or limit "other damage within the territory" from risks associated with "pests". As we will explain, we consider that Annex A(1)(d) covers measures applied to prevent or limit certain forms of damage to the environment. At this point, we need only observe that neither the *TBT Agreement* nor the GATT Secretariat background paper referred to by the European Communities, nor the Working Group

[373] The *Convention on Biological Diversity* defines "biological diversity" in Article 2 as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." *Convention on Biological Diversity* (CBD) done in Rio de Janeiro, 5 June 2002.

[374] Annex II.III.B.9 of Directive 90/220.

[375] Chapeau to Annex II of Directive 2001/18.

Chairman's *Draft Text on Sanitary and Phytosanitary Measures* supports the view that 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*.

7.209 Regarding the European Communities' reliance on the *TBT Agreement*, we do not consider that the fact that the *TBT Agreement* refers to "the environment", and that Annex A(1) does not, precludes us from interpreting the term "other damage" in Annex A(1)(d) to encompass also certain damage to the environment other than damage to the life or health of animals or plants. The fact that the term "other damage" is broad and unqualified suggests to us that it is intended to ensure coverage of a residual category of damage, which, as we will see, is not limited to environmental damage. Therefore, we do not find it surprising that the drafters omitted a reference to "the environment" in Annex A(1)(d).

7.210 As far as the the 1993 GATT Secretariat background paper is concerned, we consider that it merely intended to clarify 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). 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).

7.211 Finally, we turn to the 1990 *Draft Text on Sanitary and Phytosanitary Measures* circulated by the Chairman of the Working Group on Sanitary and Phytosanitary Measures. 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.[376] 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".[377] 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*.

[376] Uruguay Round document MTN.GNG/NG5/WGSP/7, p. 8.
[377] *Ibid*. (emphasis added).

Annex A(1)(a) to the *SPS Agreement:* Protection of animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms

7.212 As indicated, we will now analyse whether Directives 90/220 and 2001/18 can be considered as measures applied for one of the purposes identified in sub-paragraphs (a) through (d) of Annex A(1) of the *SPS Agreement*. We begin this analysis with Annex A(1)(a). Annex A(1)(a) makes clear that the *SPS Agreement* is applicable to measures applied "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".

7.213 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).

"animal or plant life or health"

7.214 The **United States** argues that the EC approval regime requires consideration of, *inter alia*, concerns that a biotech product might harm beneficial organisms as well as target organisms. According to the United States, these are concerns relating to potential risks to animal or plant life or health.

7.215 **Canada** observes that Annex A of the *SPS Agreement* defines plants and animals to include wild flora and wild fauna, which are integral parts of what is commonly understood as "the environment". Furthermore, Canada maintains that the term "fauna" as used in the *SPS Agreement* encompasses both macrofauna and microfauna, whereas the term "flora" includes also microflora. Contrary to the arguments of the European Communities, according to Canada nothing in the *SPS Agreement* limits measures to those that address short-term risks to plant or animal life or health.

7.216 **Argentina** argues that the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is through negatively affecting wild flora and/or fauna. Annex A of the *SPS Agreement* explicitly states that the term "animals" includes wild fauna and the term "plants" includes wild flora.

7.217 The **European Communities** argues that GMOs could affect micro-organisms that are specialized in biophysical or biochemical processes in the soil, or aquatic micro-organisms, and thus affect ecosystems without affecting plant or animal health.

7.218 The **Panel** understands the European Communities to argue that a measure taken to address any adverse effects biotech products might have on soil or aquatic micro-organisms would not be a

measure applied to protect "animal or plant life or health". In considering this argument, it should be recalled that the footnote to the definitions provided in Annex A of the *SPS Agreement* states that:[378]

> "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."

7.219 The term "fauna" is commonly defined as "the animals or animal life of a given area, habitat, or epoch"[379], whereas the term "flora" is commonly defined as "plants or plant life of a given area, habitat, or epoch".[380] 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 micro-organisms, such as soil or aquatic micro-organisms, are "animals" or plants" within the meaning of Annex A(1).[381]

7.220 We note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material".[382] We understand that this concern relates to the potential introduction of transgenes into the soil via the roots of GM plants (*e.g.*, in the case of Bt-producing plants) or through the decomposition of GM plants. This may potentially pose a threat to non-target soil micro-organisms. Presumably the same products of decomposition could be introduced to bodies of water through run-off, and hence pose potential threats to non-target water micro-organisms. We consider that to the extent Directives 90/220 and 2001/18 could be used to protect the life or health of non-target micro-organisms from risks covered by Annex A(1)(a), the Directives would fall within the scope of this Annex.

"risks arising from"

7.221 The **United States** considers that the phrase "arising from" does not require a demonstration that the risk be direct or immediate. Although there may be intermediate effects that occur before the effect of concern appears, the risks nonetheless "arise from" the organism in that it is the presence of the organism that triggers the necessary sequence of events. The United States maintains, for example, that adverse effects on plant and animal health due to the use of more powerful pesticides to control insects or weeds which have developed herbicide resistance as a result of the planting of herbicide-resistant biotech crops would be "risks arising from" the establishment or spread of a pest.

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[378] Emphasis added.

[379] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 931.

[380] *Ibid*., p. 979.

[381] We note that the common definition of an "organism" is: "an organized living body; esp. (the material structure) of an individual animal, plant, bacterium, etc.". *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 2019.

[382] Tiret 6 of Annex II C.2 of Directive 2001/18.

7.222 **Canada** also argues that the phrase "arising from" does not require that the risk be immediate or direct. If, for example, a biotech product qualifies as a "pest" that needs to be controlled with herbicides, any resulting risks to wild flora and/or fauna "arise from" the pest. This includes a situation where a pest management strategy is no longer effective because the target pest has developed resistance, resulting in health risks to wild fauna from increased or altered use of pesticides.

7.223 The **European Communities** argues that the use of the phrase "arising from" indicates a requirement of causality; that is, the measure must be applied with the objective of preventing certain risks "arising from" a certain situation.

7.224 The **Panel** notes that the dictionary defines the phrasal verb "to arise from" as meaning "occur as a result of".[383] 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.

7.225 Article 4 of Directives 90/220 and 2001/18 makes clear that these Directives are measures applied to protect human health and the environment from adverse effects "which might arise from" the deliberate release of GMOs into the environment. Thus, like Annex A(1)(a), the Directives use the phrasal verb "to arise from". We recognize that Annex A(1) uses the phrase "arising from", not "which might arise from". However, the phrase "arising from" is broad and unqualified. We therefore think that Annex A(1) brings within the scope of the *SPS Agreement*, not just measures which are applied to protect against risks which invariably and inevitably arise from, *e.g.*, the spread of a pest, but also measures applied to protect against risks which might arise from, *e.g.*, the spread of a pest.

7.226 We note that Annex II of Directive 2001/18 indicates that direct, indirect, immediate and delayed adverse effects are to be considered in the assessment of GMOs. Here again, we note that the phrase "arising from" in Annex A(1) is broad and unqualified. There is nothing in Annex A(1)(a) which indicates that potential risks to animal or plant life or health must necessarily be the direct or immediate result of, *e.g.*, the spread of a pest. Notably, Annex A(1) does not say that only risks "arising directly and immediately from", *e.g.*, the spread of a pest, are covered. We therefore do not consider that measures taken to protect animal or plant life or health from risks that arise indirectly or in the longer term from pests, diseases, disease-carrying organisms or disease-causing organisms fall outside the scope of Annex A(1)(a). Accordingly, the reference in Annex II of Directive 2001/18 to indirect and delayed adverse effects does not, by itself, remove that Directive from the scope of Annex A(1)(a).

"entry, establishment or spread"

7.227 The **European Communities** argues that concerns regarding the potential development of resistance in target pests are not a question of "establishment or spread" of a pest. The pest, that is, the insect of concern, already exists and will not spread to other areas. Rather the problem relates to the treatment of the pest, and the need to use additional insecticides in order to get rid of the pest.

7.228 The **United States** disagrees, arguing that the concern about the potential development of resistant target insects *is* that those individuals carrying the resistance trait could become established

[383] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 71.

and spread throughout the population. As more insect populations become resistant, more toxic chemical pesticides may need to be applied, causing greater environmental damage.

7.229 **Canada** observes that if a pest management strategy is no longer effective because the target pest has developed resistance, an alternative pest management strategy would still have the objective of addressing risks "arising from" the establishment or spread of the resistant pest.

7.230 **Argentina** notes that if a pest management strategy is no longer effective because the target pest has developed resistance, the "risks arising from the entry, establishment or spread" of that pest have not disappeared. The concern remains that the target pest may become established or spread.

7.231 Before addressing the European Communities' specific argument on resistance in target pests, it is useful to consider more generally whether Directives 90/220 and 2001/18 are concerned with the "entry, establishment or spread" of pests, diseases, etc. The **Panel** recalls in this regard that the purpose of Directive 2001/18 is to avoid adverse effects arising from the "deliberate release into the environment" of GMOs.[384] The term "deliberate release" is defined as "any intentional *introduction* into the environment of a GMO".[385] Annex II.C.2.1 to Directive 2001/18 specifies that potential adverse effects of GMOs may include disease to animals and plants. 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". Furthermore, Annex C.2.1 specifies that effects on the dynamics of populations of species and genetic diversity of populations are relevant adverse effects. These effects relate to potential "pest effects" of GMOs which could occur, *inter alia*, through the spread of pollen from genetically modified plants to other plants ("out-crossing")[386], or through the development of persistence or "invasiveness" of the GMO or GM plant due to a selective advantage.[387] We think that the purpose of avoiding "pest effects" of GMOs includes the purpose of avoiding the "entry, establishment or spread" of GMOs as "pests". We also note that Annex II.C.2.1 of Directive 2001/18 specifically states that adverse effects may occur through the "spread of GMO(s) in the environment". 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.

7.232 We now turn to the European Communities' argument that possible concerns regarding the potential development of resistance in target pests (*e.g.*, insects) are not concerns regarding the "establishment or spread" of a pest. It appears that the effect of the development of resistance in target pests may be a potential adverse effect of GMOs which Directives 90/220 and 2001/18 seek to avoid.[388] We are not persuaded, however, that in terms of Annex A(1) risks associated with the development of resistance would not be risks arising from the "establishment or spread" of the target pest. Even if, as the European Communities argues, the target pest may have existed in a particular area before, if the pest develops resistance, it may be that thanks to the resistance trait the pest can not only exist in the area in question, but also become established and thus become more of a problem.

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[384] Article 4 of the Directives.

[385] Article 2(3) of Directive 2001/18 (emphasis added).

[386] The Panel understands the term "out-crossing" or "cross-breeding" to refer to the unintentional breeding of a cultivated plant, in this case a GM plant, with another cultivated or wild plant, in this case a "conventional" or non-GM, plant.

[387] The Panel understands selective advantage to refer to the enhanced ability of a particular trait to survive in a population, thus leading to a change in the composition of traits within the population. In this case, the spread of herbicide resistance may allow plants with that trait to out-compete other plants for water, nutrients, space, etc.

[388] *See, e.g.*, Annex II.iv.C.4 of Directive 90/220 and Annex IIIA.iv.B.11 and Annex II.D.1.4 of Directive 2001/18.

Similarly, the resistance trait may allow the pest to spread to areas it has not entered before, *e.g.*, because of a pest management strategy which was effective prior to the development of resistance in the relevant pest.

"pests"

7.233 The **United States** notes that the ordinary meaning of the term "pest" is "any thing or person that is noxious, destructive or troublesome".[389] The United States further argues that the IPPC definition of a pest, as contained in the International Standard for Phytosanitary Measures Number 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms* (hereafter ISPM No. 11) supports the view that the scope of IPPC also extends to organisms which may directly affect uncultivated and/or unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms.[390] While the United States does not contend that this is dispositive of the term "pest" under the *SPS Agreement*, the specific inclusion of such damage in ISPM No. 11, by the body explicitly recognized by the *SPS Agreement* as responsible for international standards for plant health, is additional evidence that the ordinary meaning of the term "pest" includes a biotech plant that cross-breeds with existing flora, and consequently, adversely affects biological diversity.

7.234 **Canada** argues that the use of the term "pest" in Annex A(1)(a), (c) and (d) suggests that in the context of the *SPS Agreement*, "pest" should be defined as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants, plant products, animals or humans." In Canada's view, the biotech products at issue in this dispute can be viewed as a potential "pest" to plants, including "wild flora", or a potential "pest" to animals, including "wild fauna".

7.235 **Argentina** recalls that the *International Plant Protection Convention* of 1997 has defined a "pest" to be "[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products." Argentina argues that the phrase "injurious to plants and plant products" should be

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[389] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 2171.

[390] The United States notes that the FAO's *International Plant Protection Convention* of 1997 defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent *injurious* to plants or plant products". The IPPC's 2004 revisions to ISPM No. 11, which modified the existing standard specifically to address risks from a particular category of GM crops ("living modified organisms", or "LMOs"), identifies among the potential phytosanitary risks for LMOs:

> c. Adverse effects on non-target organisms including, for example:
>
> - changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
> - effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
> - capacity to vector other pests
> - negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants." (emphasis added by the United States)

International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1 "Comments on the scope of the IPPC in regard to environmental risks".

interpreted broadly, as is evidenced by the broad interpretation given in the context of ISPM No. 11[391] and that the term "pests" in the *SPS Agreement* should be given a similarly broad interpretation. An organism is a "pest" for the purposes of the *SPS Agreement* and ISPM No. 11 if it is "injurious to plants or plant products" in the sense of causing damage to plant life or health. According to Argentina, any undesirable cross-breed of plants could be considered a "pest"; for instance when a herbicide-tolerance gene is transferred to a crop's weeds. Argentina argues that the *SPS Agreement* covers risks arising from a biotech product that becomes a weed, that is, a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, raising broader ecological concerns.

7.236 The **European Communities** argues that the IPPC definition may provide relevant context for the purposes of interpreting the term "pest" in Annex A(1) of the *SPS Agreement*. In particular, the European Communities insists that (1) a pest must be a living organism, and so isolated strands of modified DNA cannot be, in and of themselves, injurious to human, animal or plant life or health; and (2) the organism must cause injury to a plant. The mere presence of a transgene may be undesirable but it need not present any phytosanitary risk. The European Communities contends that a cross-breed that harms biodiversity, micro-organisms, animals or the environment is not a pest.

7.237 The European Communities maintains that a crop that is resistant to a herbicide is not a pest if it is growing in the right place at the right time. However, in the wrong place (such as a neighbouring field) or at the wrong time (such as the following year in the same field sown with a different crop) the plant may be unwanted. The unwanted plant may compete with other crops, and its herbicide resistant trait could give it a selective advantage. It might choke or stunt other crop plants. It could thus adversely affect or injure other crops. It could therefore become a pest, and a measure taken to control it could be within the scope of the *SPS Agreement*.

7.238 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".[392] 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.

7.239 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

[391] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1, p. 34.

[392] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2 p. 2174.

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.

7.240 Consistent with the foregoing considerations, it may thus be said that in the context of the *SPS Agreement* the term "pest" 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.

7.241 We note that the 1997 IPPC defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent *injurious* to plants or plant products".[393] We agree that plants, or animals, which are "injurious" to other plants or plant products constitute "pests" within the meaning of Annex A(1). Indeed, we have said that, in our view, the term "pest" in Annex A(1) encompasses destructive animals or plants, or animals or plants which cause harm to the health of animals or plants. However, we have determined that the term "pest" in Annex A(1) also encompasses animals or plants which cause other harm, and troublesome or annoying animals or plants. The IPPC definition of the term "pest" does not specifically bear out the second part of our interpretation. We recognize that the definition of the term "pest" in the IPPC may in some respects be informative to, and hence aid, an interpreter of the *SPS Agreement*. But the negotiated IPPC definition is not dispositive of the meaning and scope of the term "pest" as it appears in Annex A(1).[394] Therefore, we do not consider that the IPPC definition of "pest" detracts from our view that plants may be considered as "pests" even if they are not injurious to other plants.

7.242 The Parties have presented various arguments which suggest that GM plants could be considered "pests" within the meaning of Annex A(1) in each of the following three situations: (a) situations where GM plants grow where they are undesired, *e.g.*, as a result of seed spillage or persistence or invasiveness; (b) situations of unintentional gene flow or transfer from a GMO plant ("out-crossing"), leading to cross-breeds between GM plants and other plants, whether conventional crops or wild flora, which have undesired introduced traits (such as herbicide or insect resistance) and may establish or spread; and (c) situations where pesticide-producing (*e.g.*, insecticide-producing) GM plants increase the potential for the development of pesticide-resistance in target organisms, notably insects.[395] We will address these three situations below, as necessary. In addition, in sub-section (d), we will address concerns that GM plants might act as "pests" in other situations, specifically concerns regarding potential adverse effects of GMOs on non-target organisms and on biogeochemical cycles.

GM plants growing where they are undesired

7.243 We first turn to examine whether GM plants which grow where they are undesired can be considered as "pests". The European Communities argues that they can. The United States also argues that a GM plant that might potentially establish or spread into new areas and out-compete and

[393] FAO *International Plant Protection Convention*, 1997, Article II, No. 1 (emphasis added). We note that the 1997 Convention was not in force on the date of establishment of this Panel. However, Article II.2 of the FAO's 1979 *International Plant Protection Convention* defined the term "pest" in very similar terms, stating that the term "pest" includes "any form of plant or animal life, or pathogenic agent, injurious or potentially injurious to plants or plant products".

[394] It is important to note in this context that unlike the *SPS Agreement*, the IPPC is concerned only with plant pests, not animal pests.

[395] The Panel will use the term "pesticide" to encompass both insecticides and herbicides. One of the experts advising the Panel, Dr. Snow, indicated that herbicide resistance can develop from selection of naturally occurring herbicide tolerant plants, but this has only been shown to occur in a few instances. It is much more likely for this trait to be passed due to out-crossing. (Annex H, para. 153.)

displace wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna would be considered to be a "weed". Canada and Argentina as well argue that if a GM plant becomes a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, it becomes a weed or a "pest" in the context of the *SPS Agreement*.

7.244 We recall our view that the term "pest" in Annex A(1) refers to a plant which is destructive, or causes harm to the health of other animals, plants or humans, or other harm, or a plant which is troublesome or annoying. It is clear to us that a plant which grows where it is not wanted may, for that reason, be destructive, cause harm to the health of other organisms or other harm, or be troublesome or annoying. For instance, an unwanted plant in a cultivated field may necessitate control or eradication efforts by a farmer (*e.g.*, in the case of weeds) or diminish the economic value of the crop the farmer is seeking to grow (*e.g.*, because his/her market is non-GMO with low or little tolerance for impurities). We also recall that the footnote to Annex A specifically indicates that "pests" include weeds. A weed is defined as a "wild plant growing where it is not wanted and in competition with wild plants".[396] Thus, the footnote supports the view that plants growing where they are undesired can be considered as "pests".

7.245 An important implication of the view that plants growing where they are undesired may be considered as "pests" is that even a cultivated plant or crop may in some situations be or become a "pest". Whether that is so would depend on the relevant circumstances, and notably where it grows and the perspective of the user of the land where the plant grows. The Panel therefore agrees with the observation of the European Communities that plants which in one situation may be desirable and hence cultivated (i.e., cultivated sunflowers growing in a field of sunflowers), in another context may be considered "pests" (i.e., sunflowers accidentally growing in a soybean field). Similarly, a GM plant cultivated expressly in a particular field would not qualify as a "pest", whereas volunteer[397] GM plants growing in fields of conventional plants might be considered to be undesirable plants and hence "pests", or "weeds", from the perspective of the farmer seeking to grow a crop other than the unwanted GM crop.[398]

7.246 Turning to Directives 90/220 and 2001/18, we note that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. More specifically, Directive 2001/18 specifies that adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these"[399], which in turn include the potential of the GM plant for excessive population increase in the environment and any competitive advantage of the GMOs in relation to the unmodified recipient or parental organisms.[400] Along similar lines, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[l]ikelihood of [GM plants] becoming more

[396] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1623.

[397] Volunteer GM plants are GM plants growing unexpectedly from seeds sown through natural processes, *e.g.*, by wind, animals or birds, or from seeds which were accidentally dropped as they were transported between locations.

[398] This view is also supported by the experts advising the Panel. Dr. Squire, for example, defines volunteer plants as "plants that originate from seed or vegetative material shed or left by a crop, and that inhabit fields, usually emerging as a *weed* within a crop" (emphasis added). Although Dr. Squire uses the term "feral" to describe plants that originate from seed or vegetative material left by crops and that exist outside fields, in waysides and the margins of agriculture, he observes that some authors use the term feral for plants descended from a crop whether they are found inside or outside fields. (Annex H, para. 45.)

[399] Annex II.C.2.1 of Directive 2001/18.

[400] Annex IIIA.IV.B.8 and 9 of Directive 2001/18.

persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats" and "[a]ny selective advantage or disadvantage conferred to the [GM plant]".[401]

7.247 We consider that these potential effects of GM plants relate to situations where GM plants grow where they are undesired. In such situations, due to a potential competitive advantage, persistence and invasiveness, GM plants may crowd out or eliminate other plants. Competitive pressure from GM plants may also affect the genetic diversity of remaining plant populations, putting at risk the survival of certain plant species. As these potential effects of GM plants impact negatively on the ability of other plants to exist and survive in the affected area, we think they can be considered to cause harm to the "life or health" of other plants. In other words, we think that by causing harm in the aforementioned ways, GM plants would act as "pests" within the meaning of Annex A(1)(a).[402] Therefore, to the extent Directives 90/220 and 2001/18 are applied to avoid the adverse effects identified in the previous paragraph, they can, in our view, be considered as measures applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

unintentional gene flow or transfer from a GM plant to other plants

7.248 We next consider the situation where a GM plant cross-breeds with other plants, whether conventional crops or wild flora (out-crossing[403]). The issue is whether in such a situation the GM plant could be considered a "pest" within the meaning of Annex A(1). We first recall the main arguments.

7.249 The **United States** argues that any undesirable cross-breeding of a plant would render the plant a "pest". The United States considers that this view is supported by the Annex to ISPM No. 11 which extends the IPPC definition of a pest to organisms which may directly affect uncultivated and/or unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms.[404]

7.250 **Canada** notes that the focus of inquiry in terms of pest characteristics in the context of Directive 2001/18 is the plant containing the transgene, not the modified DNA itself. Canada considers that an undesirable cross-breed of a plant would be considered a "pest" under the *SPS Agreement* to the extent that the undesirable cross-breed of the plant harms "animal or plant life or health" (Annex A(1)(a)) or "human life or health" (Annex A(1)(c)) or causes "other damage" (Annex A(1)(d)). According to Canada, the risks associated with insecticidal crops, such as those producing Bt, arise from their potential impact on insect populations, whether target insects or

[401] Annex II.D.2.1 and D.2.2 of Directive 2001/18.

[402] If it were considered, contrary to our view, that the adverse effects in question do not cause harm to the "life or health" of other plants, we think they would need to be considered to cause "other damage" within the meaning of Annex A(1)(d).

[403] As previously noted, we use the term "out-crossing" or "cross-breeding" to refer to the unintentional breeding of a cultivated plant, in this case a GM plant, with another cultivated or wild plant, in this case a "conventional" or non-GM, plant. Out-crossing could result in the transfer of characteristics of GM plants, such as herbicide resistance or the production of Bt toxin, into conventional or wild plant populations. The experts advising the Panel indicated that the likelihood of out-crossing depends on the species of plant. Dr. Squire, for example, indicates that in Europe oilseed rape plants are more likely to out-cross with susceptible wild species than cotton or corn plants. He states, however, that the fact that a plant is a GM plant should not markedly affect the likelihood of out-crossing, unless the genetic modification changes the male fertility of the plant. (*See* Annex H, paras. 145-148.)

[404] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1, p. 34.

otherwise. To the extent that insecticidal crops harm insects, they can be considered "pests" to wild fauna. If insecticidal crops increase the potential for the development of resistance to other biological control agents, such as Bt, this may have a corresponding indirect effect on plants. Canada also refers to the statement in ISPM No. 11 that the scope of the IPPC also extends to organisms which are pests because they indirectly affect plants through effects on other organisms.

7.251 **Argentina** considers that any undesirable cross-breed could be considered a "pest"; for instance when a herbicide-tolerance gene is transferred to a crop's weeds.

7.252 The **European Communities** argues that (1) a pest must be a living organism, i.e. isolated strands of modified DNA cannot be, in and of themselves, injurious to human, animal or plant life or health; and (2) the organism must cause injury to a plant. The mere presence of a transgene may be undesirable but not present any phytosanitary risk; plants do not injure flora by cross-breeding with them, and for that reason cannot be considered "pests". Furthermore, the European Communities argues that the transfer of herbicide resistance from genetically modified plants into wild flora could result in the development of a herbicide-resistant wild population which could become invasive and could result in damage to biodiversity, however the European Communities considers that the novel herbicide-resistant wild plant would not be a pest as defined by the IPPC, since it would primarily affect insects and other organisms of the trophic chain.[405]

7.253 The **Panel** notes that according to Annex 3 of FAO's ISPM No. 11, a living modified organism (hereafter an "LMO") may be deemed to be a "pest" if the LMO is associated with "[a]dverse effects of gene flow or gene transfer including, for example [...] transfer of pesticide or pest resistance genes to compatible species".[406] Annex 3 of ISPM No. 11 further states in this regard that:

> "In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk."[407]

7.254 Annex 3 of ISPM No. 11 suggests that contrary to what the European Communities contends in paragraph 7.236 above, an unwanted transgene in a cross-breed between a GM plant and other plants may be considered to present a potential phytosanitary risk. As none of the Parties has argued that a transgene presenting a potential phytosanitary risk should be considered as a "pest" within the meaning of Annex A(1), we see no need to address this issue. We merely note that Annex 3 of ISPM No. 11 does not suggest that the transgene should or could be viewed as a "pest" in its own right. Rather, it states that the LMO which potentially transfers the transgene should be viewed as a "pest".

7.255 Along the lines of the above-quoted statement in Annex 3 of ISPM No. 11, it could be argued that the term "pest" as it appears in Annex A(1) of the *SPS Agreement* should be understood to include GMOs which could act as vectors or pathways for the introduction into the same or another

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[405] *See supra*, footnote 371.

[406] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36. The European Communities has pointed out that the 1997 IPPC on the basis of which ISPM No. 11 was published had not been ratified by the European Communities on the date of establishment of this Panel. We note in this regard that we are neither applying ISPM No. 11 as such nor treating it as dispositive of the meaning of terms used in Annex A(1) of the *SPS Agreement*. However, we think we may refer to it if we find that it is informative and aids us in establishing the meaning and scope of the terms used in Annex A(1).

[407] *Ibid*, Annex 3, p. 37.

plant of a gene presenting a risk for the life or health of other plants or for animals. However, for the purposes of the present dispute, we need not take a position on whether a GM plant which cross-breeds with other plants could be viewed as a "pest" within the meaning of Annex A(1). We are satisfied that even if a GM plant which cross-breeds with other plants were not itself viewed as a "pest", the cross-breeds could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide or insect resistance) and harm animal, plant or human life or health or result in other damage. For instance, the herbicide resistant trait might be conferred to a cross-breed plant, which could give it a selective advantage when the relevant herbicide is used. In other words, the cross-breed could become persistent or invasive and thus pose a risk to the life or health of wild flora or fauna.

7.256 Another concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or for the use of more toxic herbicides, to control the resistant weeds.[408] We recall that the United States points out that section 2.3.1.2 of ISPM No. 11 mentions as an indirect effect of a "pest" "environmental and other undesired effects of control measures".[409] The United States appears to argue on this basis that if a cross-breed plant has acquired herbicide resistance and this necessitates the use of more or different herbicides, any undesired effect of this pesticide use on non-target flora and fauna would qualify as an indirect and undesired effect of the herbicide resistant GMO or cross-breed on non-target flora and fauna. On the other hand, the European Communities argues that potential risks to animal or plant life or health would be the result, not of the spread of resistant cross-breeds, but of steps taken to prevent the spread of resistant crossbreeds, *i.e.*, of the change in the use of pesticides. We accept that any injury to animals or plants would be a direct result of the pesticide use. Nonetheless, any injury to animals or plants would be an indirect result of the entry, establishment or spread of resistant cross-breeds. The harmful pesticide use would not be necessary if the herbicide resistance trait had not been conferred on these cross-breeds by the GM plant. We therefore consider that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We note that this view is also

[408] Dr. Andow, for example, has indicated that "[t]here is abundant evidence that repeated use of a given biotech herbicide tolerant crop would likely result in the evolution of resistance in weeds to the herbicide. [...] Adverse effects on non-target flora and fauna could arise directly from transgene products, directly from the herbicide compounds, or indirectly through the effects of the transgenic crop or the herbicide on the environment. [...] Gene flow from a GMHT crop to a weedy relative can create weeds that are more difficult to control with herbicides." (excerpts from Annex H, paras. 170-172.) Dr. Snow has indicated that "[f]requencies of specific crop genes in free-living plant populations depend on their rates of introduction and also their effects on plant fitness (i.e, relative survival and reproduction). Unlike some types of nontransgenic herbicide tolerance, the transgenes that confer tolerance to glyphosate and glufosinate are not expected to have any negative effects on crop yields or the fitness of crop relatives [...] In the absence of exposure to the herbicide in question, herbicide-tolerant plants will not have any selective advantage over their non-transgenic counterparts. But when the herbicide is used repeatedly, it will select very quickly for plants that are resistant to the herbicide. The scientific literature in weed science is full of examples of rapid evolution and spread of herbicide resistant weeds [...] In principal, the potential for the establishment and spread of herbicide-tolerant plants is similar for nontransgenic vs. transgenic crops that have genes for these traits. [...] The more the herbicide is used, the stronger the selection pressure favoring herbicide-resistant weeds. [...] Another method for suppressing populations of herbicide-resistant weeds is to use several types of herbicides in tank-mixes each year, before or after a crop is grown, to kill off resistant plants. Management options become more challenging and more complicated when the pest population has genes for several types of herbicide resistance. In some cases, it may be necessary to revert to the use of herbicides that have greater toxicity and longer persistence in the environment (*e.g.*, 2,4-D)." (excerpts from Annex H, paras. 150-155)

[409] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Section 2.3.1.2.

consistent with the aforementioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.257 Having regard to Directives 90/220 and 2001/18, we recall, first of all, that they seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential for gene transfer to the same or other sexually compatible plant species […] and any selective advantage or disadvantage conferred to those species"[410], and "possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms [...]."[411] In the light of this, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) or indirectly (*e.g.*, through changes in the use of pesticides) from the entry, establishment or spread of cross-breeds with undesired traits (such as herbicide or insect resistance) resulting from transfer of genetic material from a GM plant.

7.258 We recognize that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs rather than their cross-breeds. Nonetheless, we think the Directives can be viewed as measures protecting from risks arising from cross-breeds of GM plants, given that the relevant cross-breeds would be an effect of the deliberate release of GM plants into the environment. As noted, Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from gene transfer. Hence, there is a rational relationship between controlling the release into the environment of GM plants which might cross-breed with other plants and the purpose of protecting animal or plant life or health from risks arising from the entry, spread or establishment of cross-breads with undesired traits. Also, there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a GM plant to be released into the environment – need itself be the pest which gives rise to the risks from which the measure seeks to protect.

development of pesticide-resistance in target and non-target organisms

7.259 We address next the situation where pesticide-producing (*e.g.*, insecticide-producing) GM plants increase the potential for the development of pesticide-resistance in target and non-target organisms, notably insect populations, and where this leads to negative environmental effects. As in the gene flow situation, the issue is whether in the situation where resistance develops in target and non-target organisms, the GM plant could be considered a "pest" within the meaning of Annex A(1).

7.260 The Panel understands from the evidence provided by the Parties and from the expert advice that resistance in insect populations to pesticides may develop due to frequent exposure to pesticides.[412] This is the case whether the insect is the target of a GM insecticide-producing plant or a

[410] Annex II.D.2.3 of Directive 2001/18.

[411] Annex II.D.2.5 of Directive 2001/18.

[412] One of the experts advising the Panel, Dr. Andow, states that "[t]here is strong evidence that resistance will develop in the field to any insecticide applied uniformly over wide areas for a long enough period of time. This has been a scientific consensus since the 1980s", and further expressed the view that "[...]of all of the potential environmental risks of transgenic Bt crops, it can be said that resistance in the target pests is a real, tangible risk, while risks associated with gene flow and risks to non-target organisms are mostly only potential risks" (Annex H, paras. 92 and 96, respectively). Another expert, Dr. Squire, states that "[t]he emergence of resistance by pest insects to pesticides differs widely from context to context depending on factors such as the exposure to and strength of the toxin, the movement of insect populations from areas where the pesticide is not applied, and the genetics and mating system of the insect. Resistance to Bt crops has occurred and is influenced

non-target insect. We further understand that if high levels of resistance were to develop in insect populations, it is possible that pesticides might be needed where none were applied before, or that increased volumes of the same pesticides or more toxic chemical pesticides might be needed, to control the resistant insects, which might potentially cause greater environmental damage. It is also possible that the resistant insect population would gain a selective advantage with negative consequences for other flora and fauna, or that the development of resistance in the insect population could have deleterious effects on predators of the resistant insects, including on other predator insects, birds or mammals. The Panel further understands that potential impacts of the development of insect resistance include ecosystem effects. Ecosystem effects include negative effects on animal or plant life or health.

7.261 The European Communities argues that the concerns in this situation are not with the GMO as a pest, but with changes in the characteristics or the genetic make-up of the target organisms. According to the European Communities, the potential risks to animal or plant life or health do not arise from the "establishment" or "spread" of the target organisms, since the target organisms already existed before the introduction of the GMO. Furthermore, the European Communities argues that it is the use of the additional pesticides used to control the target organism which may cause adverse environmental effects, not the pest itself. The European Communities does not in this context explicitly address the issue of development of resistance in non-target insect populations.

7.262 The United States argues that the language used in ISPM No. 11 regarding pests, such as "indirectly affect plants […] by other processes such as competition" and "significant reduction, displacement, or elimination of other plant species"[413] clearly includes all reasonably foreseeable injuries that an organism might cause to plant life or health. Annex I of ISPM No. 11 explicitly provides that the scope also extends to those injuries caused by organisms that indirectly affect plant species or health, through effects on other organisms in the ecosystem. The United States appears to argue on this basis that if an insect population develops resistance to a pesticide produced by a GM plant, and this necessitates the use of more or different pesticides, any undesired effect of this pesticide use on non-target flora or fauna would qualify as an indirect and undesired effect of the plant-produced pesticide on non-target flora or fauna. Consequently, in the United States' view, the "pest" would be the pesticide-producing GM plant.

7.263 For the purposes of the present dispute, it is not necessary for us to take a position on whether a GM plant to which target or non-target organisms (*i.e.*, insect populations) develop resistance, with the result that more or different pesticides need to be used to control the resistant organisms and that other non-target organisms are negatively affected by the pesticide use, could be viewed as a "pest" within the meaning of Annex A(1). Even if a GM plant to which insect populations develop resistance were not viewed as a "pest", we think the resistant target or non-target organisms (*i.e.*, the resistant insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. In fact, pesticide-producing or pesticide-resistant GM plants are cultivated precisely because the target organisms are considered "pests".

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by the "dose" of toxin delivered to the pest and the genetic nature of the pest, among other factors. [...] The processes involved in Bt resistance and its management are generally appreciated by scientists, and mitigation strategies that have a strong scientific basis have been considered." (Annex H, para. 105.)

[413] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Article 2.3.1.1 and Annex 1, p.34.

7.264 Turning to Directives 90/220 and 2001/18, we again recall that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GM plant] and target organisms".[414] Similarly, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GM plant] and non-target organisms.[415] In the light of this, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising, directly or indirectly, from the entry, establishment or spread of target or non-target organisms which have developed, or might develop, resistance to a pesticide as a result of interactions with GM plants producing that pesticide.

7.265 We have noted earlier that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs. We have also pointed out, however, that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from the interactions between pesticide-producing GM plants and target organisms. We have explained that the kind of adverse effects on animal or plant life or health which are at issue in the situation we are considering would be indirect effects of the GMO-induced development of resistance in target and non-target organisms. Hence, there is a rational relationship between controlling the release into the environment of pesticide-producing GM plants and the purpose of protecting animal or plant life or health from risks arising indirectly from the entry, spread or establishment of resistant target or non-target organisms.[416] Also, as we have previously stated, there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a pesticide-producing GMO to be released into the environment – need itself be the pest which gives rise to the risks from which the measure seeks to protect.

7.266 The European Communities argues that potential risks to animal or plant life or health would be the result, not of the spread of resistant target organisms, but of steps taken to prevent the spread of resistant target organisms, *i.e.*, of the change in the use of pesticides. We accept that injury to animals or plants could be a direct result of the pesticide use. Nonetheless, as we have said, any injury to animals or plants would be an indirect result of the entry, establishment or spread of resistant insects. Without the development of resistance in the target (or non-target) organisms, the more harmful pesticide use would not be necessary. We therefore consider that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target (or non-target) organisms *qua* relevant pest. We note that this view is also consistent with the aforementioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.267 The European Communities further argues that potential risks to animal or plant life or health would in any event not arise from the "establishment" or "spread" of the target organisms, given that the target organisms already existed, but from a change in the characteristics, or the genetic make-up,

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[414] Annex II.D.2.4 of Directive 2001/18.

[415] *Ibid*.

[416] We note that in addressing the issue of resistance in target or non-target organisms all Parties have been assuming that the resistant organisms would be controlled through the use of more or different pesticides and that this could adversely affect wild flora and/or fauna.

of the target organisms. We are not persuaded by this argument. In our view, there could be a legitimate concern that the target (or non-target) organisms would establish or spread. Indeed, were it otherwise, there would be no need to proceed to any change in the control of the resistant insect populations. Moreover, if, as the European Communities asserts, the resistant target (or non-target) insects had characteristics or a genetic make-up different from previous generations of these insects, it would seem that this might be the difference that would allow the resistant insect populations to become established or spread.

effects on non-target organisms and biogeochemical cycles

7.268 Before leaving the issue of "pests", we need to address whether other potential adverse effects than the ones we have already considered could also be viewed as effects of GMOs *qua* "pests" on animal or plant life or health. We note in this respect that Directive 2001/18 specifies that adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these"[417], which in turn include adverse effects of the release of GMOs on non-target organisms.[418] Similarly, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed environmental impact resulting from direct and indirect interactions of [GM plants] with non-target organisms (also taking into account organisms which interact with target organisms) [...]".[419] Furthermore, Directive 2001/18 refers to possible adverse "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material"[420], and "[p]ossible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of GMO release(s)".[421]

7.269 Having regard to effects on non-target organisms, we consider that to the extent that GM plants may result in changes in animal or plant populations (including in target organism populations), this may increase or decrease the food available for particular non-target animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce, etc. These effects would thus impact on the genetic diversity of an ecosystem, including populations of species.[422] In our view, by causing harm to the life or health.[423] In our view, by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of

[417] Annex II.C.2.1 of Directive 2001/18.
[418] Annex IIIA.IV.B.12 of Directive 2001/18.
[419] Annex II.D.2.5 of Directive 2001/18.
[420] Annex II.C.2.1 of Directive 2001/18.
[421] Annex II.D.2.8 of Directive 2001/18.
[422] We recall the comment of one of the experts advising the Panel, Dr. Andow, that "[...]of all of the potential environmental risks of transgenic Bt crops, it can be said that resistance in the target pests is a real, tangible risk, while risks associated with gene flow and risks to non-target organisms are mostly only potential risks" (Annex H, para. 96). Dr. Andow further indicated that "[to] my knowledge there are no reports of adverse effects on soil micro- or macro-flora or fauna separate from those in the UK-FSE trials. Nor are there any reports of adverse effects on soil dwelling bacteria, algae, or protozoa. However, to my knowledge there have not been any studies of any of these possible effects. The Panel should not infer that the absence of information implies an absence of effect." (Annex H, para. 174)
[423] Even if it were considered that adverse effects on genetic diversity of ecosystems, including populations of species, would not be damage to the life or health of these populations and hence would fall outside the scope of Annex A(1)(a), these effects could in our view be considered to constitute "other damage" within the territory of a Member and hence would fall within the scope of Annex A(1)(d).

Annex A(1).[424] We note that in relation to potential adverse impacts on plant life or health, this view is consistent with Annex 3 of ISPM No. 11. Annex 3 states that LMOs may be considered as "pests" if they are associated with adverse effects on non-target organisms, including "effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)". In the light of these elements, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect the life or health of non-target organisms, whether animals or plants, from risks arising from the entry, establishment or spread of GM plants *qua* "pests".

7.270 Regarding effects on biogeochemistry, it is useful to distinguish between direct and indirect potential effects of GMOs. To the extent that GMOs might affect the life or health of non-target soil microfauna or –flora, Directives 90/220 and 2001/18 could, as we have indicated earlier, be considered as measures applied to protect the life or health of soil microfauna or –flora from risks arising from the entry, establishment or spread of GM plants *qua* "pests".[425] To the extent that GMOs might adversely affect soil microfauna or –flora, or nitrogen-fixing bacteria, and this would have an adverse effect on the life or health of other plants or animals, we think Directives 90/220 and 2001/18 could be considered as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of GM plants *qua* "pests".[426]

7.271 We note that Directive 2001/18 also specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs".[427] The European Communities has argued that the use of GM crops as opposed to conventional crops may have adverse effects on the agro-ecological environment and on biodiversity. In this context, the European Communities has referred to research on the effect, if any, that the management practices associated with genetically modified herbicide tolerant crops might have on farmland wildlife, when compared with weed control used with non-GM crops.[428]

7.272 The concern referred to by the European Communities pertains to changes in weed control practices – specifically, changes in herbicide use – that may be associated with the introduction of herbicide tolerant GM crops.[429] In relation to this scenario, there is no doubt in our minds that the

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[424] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36.

[425] We understand that such direct risks may arise, for example, through the exposure of soil microfauna to Bt toxins in the roots of Bt-producing GM plants, or through the decomposition and absorption into the soil of other transgenes.

[426] We note that in relation to potential adverse impacts on plant life or health, this view is consistent with Annex 3 of ISPM No. 11, which refers to effects on soil fauna and microflora, and nitrogen-fixing bacteria, which might result in a phytosanitary impact. International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36.

[427] Paragraph 9 of Annex II.D.2. of Directive 2001/18.

[428] UK Department for Environment Food and Rural Affairs, "GM crops: Effects on farmland wildlife", October 2003 (Exhibit EC-38). These studies are referred to as the "Farm Scale Evaluation".

[429] The European Communities addresses specifically changes in herbicide use, and has not provided any information about other potential changes in weed control practices related to the introduction of GM crops as compared to non-GM crops.

weeds against which the herbicide is used qualify as "pests" within the meaning of Annex A(1).[430] The herbicide use, for its part, constitutes a pest control measure. In the scenario posited by the European Communities, potential risks to the environment, including to non-target organisms such as farmland wildlife, would be the result of a change in weed control practices, *i.e.*, the application of a herbicide, the increased application of a herbicide, or the application of a different, more harmful herbicide. Indirectly, however, any environmental risks would be the result of the entry, establishment or spread of the relevant weeds. Given this, we consider that risks to the environment 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. We note that this view is consistent with the previously mentioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.273 Regarding the link to GM plants, we note that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from a change in management practices in the wake of the introduction of herbicide tolerant GM plants. Based on the evidence before us, we understand that herbicide tolerant GM plants are linked to the herbicide to which they are tolerant. Indeed, the herbicide-tolerance trait of these GM plants is the reason why these plants have been genetically modified in the first place. In other words, these GM plants have been developed so that farmers can use the relevant herbicide to protect the plants against competition from particular weeds. Moreover, the herbicide to which GM plants are tolerant has been developed to help control and/or eradicate the relevant weeds. Thus, it is clear that, *via* the relevant herbicide, the GM plants in question are also linked to the weeds, and hence the pests, to be controlled.

7.274 As the GM plants, the herbicide and the weeds are interlinked in the aforementioned ways, 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 the environment from risks arising indirectly from the entry, spread or establishment of weeds. Also, we recall our earlier statement 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.

7.275 In the light of the foregoing, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects on the environment which involve adverse effects on the life or health of non-target organisms (animals and plants) and which arise from the management techniques associated with GMOs, we consider that the Directives can be viewed as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".[431]

"diseases, disease carrying organisms or disease-causing organisms"

7.276 The **European Communities** notes that the World Organization for Animal Health (OIE) defines a disease as: "the clinical and/or pathological manifestation of infection".[432] A GMO is not infected or an infection, and is not, in itself, a disease, a disease-carrying organism, nor generally considered a disease-causing organism.

[430] We note that a particular herbicide may target a specific weed or a broad spectrum of weeds. For simplicity, we hereafter refer to "weeds" in the plural.

[431] We will consider this scenario further as part of our discussion of Annex A(1)(d) below.

[432] *International Animal Health Code*, 2002.

7.277 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 degree as to produce or threaten to produce detectable illness or disorder".[433] 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)".[434] 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".[435]

7.278 The European Communities contends that GMOs *per se* are neither infected nor infections, nor diseases, nor disease-carrying or disease-causing organisms. We note that we do not need to determine in the abstract whether GMOs are diseases, disease-carrying organisms, etc. Rather, we need to determine whether the adverse effects which might arise from the deliberate release of GMOs into the environment and which Directives 90/220 and 2001/18 seek to avoid are covered by Annex A(1). In this regard, we note that Directive 2001/18 specifies that potential adverse effects of GMOs include disease to animals and plants, and altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors.[436] Directives 90/220 and 2001/18 thus seek to prevent GM plants from introducing or spreading diseases, and from altering the susceptibility of animals or plants to pathogens, which might facilitate the introduction or spread of disease-causing organisms (that is, pathogens) or create new disease-carrying organisms (vectors). In the light of this, we think that Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising from the entry, establishment or spread of diseases, disease-carrying organisms (*e.g.*, vectors) and disease-causing organisms (*e.g*, pathogens).

antibiotic resistance marker genes

7.279 The **European Communities** observes that the risks of concern regarding antibiotic resistance marker genes (hereafter "ARMG") are that the ARMG could be transferred from the plant to bacteria in the digestive tract of humans or animals, and that this might negatively impact on the use of antibiotics in clinical or veterinary medical treatments. The European Communities argues that it is not the plant DNA, but a separate pathogen, that causes the disease; the plant DNA merely contributes to the development of antibiotic resistance, and therefore such effects fall outside of the scope of the *SPS Agreement*. Another concern, according to the European Communities, relates to the risk that persistence of plant-derived DNA in soil residues could transfer antibiotic resistance to microbial pathogens which would otherwise be treatable by the antibiotic at issue if the pathogens should infect and cause disease in humans or animals.

7.280 The **United States** argues that it is not necessary for plant DNA to be an organism for measures taken to protect against any increased risk of antibiotic resistance to fall within the scope of the *SPS Agreement*. Concerns relating to effects of plant DNA are essentially concerns about the potential effects of the altered plant, which is an organism within the scope of Annex A(1)(a). The text of this provision requires only that the measure be adopted to protect against the risks…arising from the establishment or spread of diseases…or disease-causing organisms. The United States notes

[433] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 698.
[434] *See* http://www.who.int/docstore/peh/Vegetation_fires/Health_Guidelines_final_AnnC.pdf.
[435] *Ibid*.
[436] Annex II.C.2.1 of Directive 2001/18.

that for an animal infected with the pathogen that would ordinarily be treated with the antibiotic to which the pathogen had become resistant, the transfer of the resistance gene would contribute to the establishment and spread of disease--the disease caused by the now resistant pathogen—a risk that clearly falls within Annex A(1)(a). If an altered plant contributes to the spread of the disease, a measure taken for the purposes of controlling such a plant is a measure taken to protect against the 'risks arising from the spread of...disease-causing organisms." The fact that the altered plant is not the sole cause of the disease does not change this conclusion.

7.281 The **Panel** considers that the concern raised by the European Communities relates to the potential transfer to pathogens of ARMG present in certain GMOs. If pathogens were to become resistant to certain antibiotics in this manner, this might lessen the effectiveness of medical treatments involving these antibiotics and hence might pose a risk to the life or health of animals infected with the resistant pathogen.[437]

7.282 The European Communities argues that neither the GM plant nor the ARMG can be considered a disease-causing organism. We find it unnecessary to take a position on whether the GM plant or the ARMG could be viewed as a disease-causing organism within the meaning of Annex A(1). We are satisfied that even if the GM plant or the ARMG were not viewed as a "disease-causing organisms" in and of themselves, the pathogen which develops resistance to the antibiotic in question could be regarded as a "disease-causing organism" for the purposes of Annex A(1).

7.283 Having regard to Directives 90/220 and 2001/18, we recall that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that potential adverse effects of GMOs include "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".[438] In the light of this, we think that Directives 90/220 and 2001/18 can be considered as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, the Directives can, in our view, be considered as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer.

7.284 We recognize, as we have done earlier, that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs. We have also pointed out earlier, however, that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from the transfer to pathogens of genes conferring antibiotic resistance. The potential risks to animal life or health which are at issue in the situation we are considering would be the direct or indirect result of pathogens which have or might become resistant to antibiotics due to the transfer of genetic material from a GM plant containing an ARMG.

[437] We note, however, that according to the experts advising the Panel, the risk of transferral of the antibiotic resistance marker gene is negligible. Dr. Nutti, for example, described the steps that would be necessary for such a transfer to occur, and stated that "[t]here have been numerous experiments aimed at evaluating the possibility of transfer of plant DNA to microbes and mammalian cells. To date, there are no reports that marker genes in plant DNA transfer to these cells." (Annex H, para. 1123) Dr. Andow stated that "[t]o my knowledge, all reports have not found adverse effects on flora or fauna from antibiotic resistance genes or gene products. Extensive studies on nptII did not find any adverse effects, and found that any undetected adverse effects would likely be several orders of magnitude smaller than naturally occurring phenomena." (Annex H, para. 175)

[438] Annex II.C.2.1 of Directive 2001/18.

Hence, there is a rational relationship between controlling the release into the environment of GM plants containing an ARMG and the purpose of protecting animal life or health from risks arising from the entry, spread or establishment of disease-causing organisms and diseases. Also, we recall 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 GM plant containing an ARMG to be released into the environment – need itself be the disease-causing organism, or the disease, which gives rise to the risks from which the measure seeks to protect.

Preliminary conclusions concerning Annex A(1)(a)to the SPS Agreement

7.285 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II.C.2.1 of Directive 2001/18, the following fall within the scope of Annex A(1)(a) of the *SPS Agreement*:

– disease to animals and plants including toxic, and where appropriate, allergenic effects[439];
– effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these;
– altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
– compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;
– effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

This does not exclude, however, that, depending on the circumstances, some of these potential adverse effects may also fall within the scope of other sub-paragraphs of Annex A(1).

7.286 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following fall within the scope of Annex A(1)(a), while recognizing that, depending on the circumstances, some may also fall within the scope of other sub-paragraphs of Annex A(1):

– likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
– any selective advantage or disadvantage conferred to the GMHP;
– potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
– potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
– possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;

[439] We address potential allergenic effects below, in the context of our analysis of Annex A(1)(b) and in footnote 495.

– possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
– possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Annex A(1)(b) to the *SPS Agreement*: Protection of human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs

7.287 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.

"foods, beverages or feedstuffs"

7.288 The **European Communities** notes that a food is something that is intentionally ingested by a human for nutritional purposes; a beverage is something that is drunk; and a feedstuff is something that farmed animals are intentionally permitted to ingest for nutritional purposes. Annex A(1)(b) does not encompass products that are not "foods, beverages or feedstuffs". A GM seed to be used in agriculture is not a "food, beverage or feedstuff". It is destined to be planted in the ground, not eaten by humans or fed to animals. Therefore, according to the European Communities, a GM sowing seed cannot fall within Annex A(1)(b). Similarly, a crop or plant is not in itself necessarily a food. It may be processed into something that becomes a food, but that does not make the crop or plant itself a food. A GM crop or plant does not therefore necessarily fall within sub-paragraph (b). However, the European Communities notes that Annex A(1)(b) may cover the risk of a modified gene in food, beverages or feedstuffs causing disease in humans or animals.

7.289 The European Communities further argues that a crop or plant is not necessarily a "feedstuff" for animals – that depends on whether or not it is destined for such use, and whether or not the crop will first be processed. Finally, the impact of a GMO on wild flora and fauna does not fall within sub-paragraph (b), because it does not relate to foods, beverages or feedstuffs. The GM crop is not a "feedstuff" vis-à-vis the pest. The same is true in respect of non-target organisms, since the crop is not a "feedstuff" vis-à-vis such organisms.

7.290 The **Complaining Parties** argue that "foods, beverages or feedstuffs" encompass genetically modified plants intended for use in foods, including processed foods. The gene or DNA which is inserted into a GM plant can be considered to be an additive or a disease-causing organism. Proteins which are expressed due to the changes generated during genetic modification can be considered to be contaminants or toxins depending upon their food safety effects.

7.291 The **Panel** notes that the common definition of a "food" is a substance taken into the body to maintain life and growth.[440] 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

[440] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 1001.

defined as fodder[441], and "fodder" is defined as "food for cattle, horses, etc., and more specifically as dried food, as hay, straw, etc., for stall-feeding".[442]

7.292 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[443], 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.

"additives"

7.293 The **United States** claims that certain types of genes, such as the ARMG, fall within the definition of an additive under the *SPS Agreement*. According to the United States, this is further supported by the Codex definition of an additive, which does not exclude genetic inserts or constructs added to food crops.[444] Thus, consistent with the Codex definition, the ARMG is a component of the food from the biotech plant; is not normally consumed as a food by itself; is not normally used as a typical ingredient of the food; and is intentionally added to the plant (and thus the food from the plant), for a technological purpose in the manufacture of the food. Protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within Annex A(1)(b). For the same reason, products that contain ARMG are also covered by the *SPS Agreement*.

7.294 **Canada** considers that an ARMG is a "substance" in the basic sense of that term, and nothing in the Codex definition would exclude the possibility that an ARMG could be considered an additive.

7.295 The **European Communities** notes that the Codex provides a relevant definition for the purposes of determining the meaning of "additive" in Annex A(1)(b). Codex defines an additive as a substance which is added to "food", not a substance which is added to plants and which may find its way into food. The European Communities argues that the GMO products relevant in this dispute are not "additives" within the Codex definition. Nor is a gene an additive – whether introduced by recombinant DNA technology or by conventional breeding. Genes are not substances, but rather instructions for the creation of substances.

7.296 According to the European Communities, the definition of "additive" proposed by the United States would encompass any gene, whether introduced by recombinant DNA technology or by conventional breeding. Furthermore, the European Communities argues that the risks of concern regarding ARMG fall outside of the scope of the *SPS Agreement*. In particular, ARMG or food produced with GM plants which contain ARMG do not cause disease.

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[441] *Ibid*., p. 937.
[442] *Ibid*., p. 997.
[443] The Panel recalls its view that the *SPS Agreement* explicitly covers risks to wild fauna and distinguishes neither among categories of animals (such as insects, birds, and mammals) nor between "target" and "non-target" species.
[444] Art. 2a, Codex Procedural Manual 14th edition (Reference A), p. 43.

7.297 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".[445] 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."[446]

7.298 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".[447] 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.

7.299 We note that the Codex definition of "food additives" refers to additions made "in the manufacture" of the food in question or at subsequent stages of food production. In the present dispute, the Panel considers that "food" encompasses GM plants that are eaten as such or processed into products that are eaten. We note that the concept of "manufacture" does not fit well with the first situation where plants are grown for food purposes (*e.g.*, sweet maize for fresh consumption). As we see it, the farmer cannot add substances to a plant for a technological purpose in the same way that a manufacturer can add substances to a food product for a technological purpose (*e.g.*, colouring to match the flavour of a yoghurt). If farmers wish to add a substance of the relevant type, we think they effectively have to do so at the stage of developing and producing the seeds of the plant. Therefore, we think that in the special case of "plant production", substances intentionally added at the stage of seed development and production could be reasonably considered to be substances added in the manufacture of the food plant, if the substances are present in the harvested plant as a component or affect the characteristics of the harvested plant.

7.300 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).[448] 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

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[445] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 25.

[446] Codex Procedural Manual 14th edition (Reference A), p. 43. The same definition of an additive is contained in Section 2(a), Codex General Standard for Food Additives (Codex Stan 192-1995) (Rev.6-2005).

[447] *Concise Oxford Dictionary*, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1429.

[448] It is useful to recall that the Appellate Body has established that for an SPS measure to be "based on" an international standard the measure need not necessarily "conform to", or comply with, that standard. Appellate Body Report, *EC – Hormones*, para. 163. Therefore, even if the meaning and scope of the term "additives" as it appears in the *SPS Agreement* and in the Codex standard did not correspond exactly, it would still be possible for Members to "base" their SPS measure on the Codex standard.

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.[449] Looking at the text of Annex A(1)(b), we note that it broadly, and simply, refers to "additives" "in foods". The ordinary meaning of the term "additives" read in the context of Annex A(1)(b) does not suggest that for an added substance to qualify as an "additive" in a food, the substance needs to have been added at a particular stage prior to the consumption of the food in question.

7.301 In the light of the foregoing, the Panel is of the view that genes, intentionally added for a technological purpose to GM plants that are eaten or being used as an input into processed foods, can be considered "additives in foods" within the meaning of Annex A(1)(b). This should not be construed to mean, however, that all genes of a plant that is eaten or being used as input into processed foods could be classified as "additives".

7.302 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".[450] The Parties disagree whether ARMG should be considered as "additives" within the meaning of Annex A(1)(b).

7.303 Based on the explanations given by the Parties, we understand that ARMG are genes used in genetic engineering to detect whether cells into which another foreign gene is inserted have actually taken up that gene.[451] While the ARMG are needed only in the genetic engineering process, the marker genes remain in the GM plant. We recognize that ARMG may not be the kinds of substances that are normally considered to be "additives", *e.g.*, they do not enhance the flavour, appearance or preservation of a product. However, the ARMG is deliberately added in the production of a GM product that is consumed as food, for a specific technological purpose (*e.g.*, to permit the tracing of successful gene transfers), is a component of the GM plants which are processed into food products and remains in the product that is finally consumed. In the light of this, we are of the view that in the context of an approval procedure assessing the safety of specific food products ARMG may be considered to constitute food "additives" within the meaning of Annex A(1)(b).

7.304 We note that the potential adverse effect referred to in Directive 2001/18 is primarily associated with the transmission of antibiotic resistance from the marker genes present in GM plants to the digestive gut of animals or humans. The concern is that this might result in humans or animals developing antibiotic resistance.[452] The development of antibiotic resistance can be considered a risk to human or animal life or health, in that it may compromise the effectiveness of medical or veterinary treatments for diseases. Any potential increase in the population of antibiotic resistant bacteria could also facilitate the dissemination of infectious diseases, as antibiotic treatment would not be effective in stopping the spread of such diseases. Another potential risk is that new reservoirs of diseases could

[449] We find instructive in this regard the provisions of Article 1.1 of the *TBT Agreement*. Article 1.1 provides that "[g]eneral terms for standardization and procedures for assessment of conformity shall normally have the meaning given to them by definitions adopted within the United Nations system and by international standardizing bodies taking into account their context and in the light of the object and purpose of this Agreement".

[450] Annex II.C.2.1 of Directive 2001/18.

[451] For example, we understand that scientists attach these ARMG to the gene which they are seeking to introduce into plant cells. After these linked genes have been inserted into plants, the plant cells are grown in a substance which has been treated with the antibiotic. Only cells which contain the antibiotic resistance, and thus the gene of interest, will survive.

[452] *See supra*, para. 7.303.

be created in humans or animals where resistant bacteria have failed to be eliminated by antibiotic treatments. In the light of this, Directives 90/220 and 2001/18 can, in our view, be considered as measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs.

"contaminants"

7.305 The **European Communities** argues that concerns related to higher levels of toxins or contaminants in food, beverages or feedstuffs as a result of increased use of herbicides due to the introduction of herbicide-resistant crops may fall within Annex A(1)(b) of the *SPS Agreement*. However, the European Communities argues that a foreign gene intentionally introduced into a plant through genetic modification techniques is not a contaminant within the meaning of either Annex A(1)(b) of the *SPS Agreement* or the Codex General Standard for Contaminants and Toxins in Food (hereafter, Codex Standard 193). The Codex defines a contaminant as:

> "any substance *not intentionally* added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination."[453]

7.306 The European Communities maintains that both the GMOs and the proteins produced by the GMOs with which this case is concerned will be intentionally present in food. Thus they cannot fall within the Codex definition of contaminant.

7.307 Finally, the European Communities argues that the phrase in Codex Standard 193 "as a result of the production … of such food" refers to the process of food production, not to the more fundamental process of genetic engineering or design. Similarly, the common and ordinary meaning of the words "crop husbandry" refers to what happens on the farm, not what happens in the laboratory. Furthermore, if the Codex definition of contaminant covered any substance unintentionally present as a result of the production of the plant, and included the modification created by gene transfers, or the resulting protein, then most genes and proteins in conventional plants would be "contaminants".

7.308 **Canada** considers that the modification or reaction created by gene transfer, or the expressed protein, could be considered a "contaminant" as that term is defined in Codex Standard 193. While the insertion of the transgene is intentional, that insertion may have unintended effects, one of which could be the creation or expression of an unintended substance. This unintended substance could be considered a contaminant, rather than the transgene itself.

7.309 Furthermore, Canada argues that Codex Standard 193 sets out guidelines for the establishment of the maximum level and guideline levels for contaminants in food or feed, a process that requires an assessment of the "effects" of a contaminant on human and animal health. Codex Standard 193 recognizes that there may be substances that fall within the Codex definition of "contaminant" but are nonetheless excluded from the scope of the Codex Standard because they have "no public health significance".[454] Accordingly, whether a substance falls within Codex Standard 193

[453] Art. 1.2.3, Codex General Standard for Contaminants and Toxins in Food (Codex Stan 193-1995) (Rev.1-1997) (emphasis added).

[454] *Ibid.*, p. 1, Art. 1.2.2. Moreover, Standard 193 provides on p. 3:

is closely tied to the risks to public health associated with that substance, or in other words, the "effects" of the substance.

7.310 Canada notes that the Codex definition requires that the substance must be "present in food as a result of production". One of the examples of production cited is "operations carried out in crop husbandry." Crop husbandry includes the development of seeds. Much of modern crop husbandry is carried out both on the farm and in the laboratory, as an interactive, iterative process between scientist and farmer. Regardless of where selective breeding activities take place, these activities are part of crop husbandry. According to Canada, it therefore logically follows that an unintended substance arising from the genetic modification or reaction by gene transfers is "present in food as a result of production". This type of unintended substance could be considered a "contaminant" for the purposes of Codex Standard 193.

7.311 **Argentina** argues that the gene transfers used in the development of agricultural biotechnology products could generate effects similar to "contaminants".

7.312 The **Panel** notes that the common meaning of a contaminant is "a substance which pollutes, corrupts or infects".[455] 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 above-mentioned 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.[456]

7.313 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.

7.314 The European Communities argues, based on the Codex definition of the term "contaminant", that a protein unintentionally expressed as a result of a genetic modification of a plant should not be considered a "contaminant". The European Communities considers that for the unwanted substance

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> When there are indications that *health hazards* may be involved with consumption of foods that are contaminated, it is necessary that a risk assessment is made. When *health concerns* can be substantiated, a risk management policy must be applied, based on a thorough evaluation of the situation. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish maximum levels or other measures governing the contamination of foods. In special cases, it may also have to be considered to give dietary recommendations, when other measures are not sufficiently adequate to exclude the possibility of *hazards to health*. (emphasis added)

[455] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 499.

[456] Codex Procedural Manual, 14th Edition, (Reference A), Rome, 2004, pg. 43.

to qualify as a "contaminant", it would need to be present as a result of the production of the food, and not as a result of the genetic engineering, or the design, of the plant which is used as an input into the processed food. It is correct that the Codex definition of "contaminants" refers to substances which are present in food as a result of the production (including operations carried out in crop husbandry) of the food in question. We recall, however, that we are concerned here with GM plants that are eaten or used as inputs into processed foods. It seems to us that in circumstances where a substance would be created or expressed unintentionally in the process of cultivation of GM plants, *i.e.*, in the process of the production of the plants, it can be reasonably said that the relevant substance is present in the food "as a result of the production" of that food. In any event, the Codex definition is not dispositive of the meaning of the term "contaminant" as it appears in Annex A(1)(b).[457] Annex A(1)(b) broadly, and simply, refers to "contaminants" "in foods". It does not suggest that for a substance present in food to qualify as a "contaminant", the substance needs to have been added at a particular stage prior to the consumption of the food in question.

7.315 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[458] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[459] The Parties have not addressed how contaminants in food or feedstuffs could give rise to disease and hence health problems in humans or animals. To the extent that such risks exist, we think that Directives 90/220 and 2001/18 could be considered as measures applied to protect human or animal life or health from risks arising from contaminants in foods or feedstuffs, namely from proteins unintentionally produced in GM plants which are eaten or used in the production of food or feedstuffs.

7.316 We note the European Communities' argument that the introduction of herbicide-resistant GM crops might lead to a higher level of contaminants, specifically herbicide residues, in foods or feedstuffs, inasmuch as the herbicide-resistance of GM crops might allow for and entail an increased use of herbicides in the field.[460] We would agree that the term "contaminants" in Annex A(1)(b) could encompass herbicide residues present in foods or feedstuffs, and that they may pose risks to human or animal life or health.[461] It is not clear to us from reading Directives 90/220 and 2001/18 whether they are applied, *inter alia*, to avoid disease to humans or animals resulting from herbicide residues in GM plants used as food or feedstuff. To the extent they could be so applied, however, we would agree that the Directives can be seen as measures applied to protect human or animal life or health from risks arising from pesticide residues, and hence contaminants, in GM plants used as or in foods or feedstuffs.

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[457] We have addressed earlier, in the context of our discussion of the term "additives", the fact that the *SPS Agreement* in provisions other than Annex A(1) refers to "international standards".

[458] Annex II.C.2.1 of Directive 2001/18.

[459] Annex II.D.2.7 of Directive 2001/18.

[460] We recall that one of the experts advising the Panel, Dr. Snow, noted that "[a]pplication rates of glufosinate and glyphosate are expected to increase greatly if these herbicide-tolerant crops are adopted by farmers". (Annex H, para. 1115)

[461] The United States has pointed out, for instance, that pesticide residues in biotech crops might conceivably have allergenic effects and thus present dietary risks.

"toxins"

7.317 The **European Communities** notes that a toxin can be defined as "a poisonous substance produced during the metabolism and growth of certain micro-organisms and some higher plant and animal species."[462] The European Communities considers that the unintentional production of a poisonous substance during the metabolism and growth of either GM or non-GM plants may be considered as a toxin in the context of Annex A of the *SPS Agreement*. However, the toxic characteristics of seeds or crops, or their effects on non-target organisms, do not fall within SPS Annex A(1)(b) unless the GMO is a "food, beverage or feedstuff."

7.318 The European Communities maintains, furthermore, that the potential toxins created as a result of the *intentionally* introduced specific genetic modification would not be covered by Annex A of the *SPS Agreement*. For example, the toxic effect of an insecticidal crop on the target pest itself cannot fall under Annex A(1)(b), since it is not possible to seek to kill target pests and at the same time seek to protect the life and health of those very same pests.

7.319 The **United States** argues that one food safety-related concern regarding all new plant varieties, developed through modern biotechnology or otherwise, is the unintentional production of a toxin in the food. Toxins introduced into foods by way of biotech or conventional breeding are encompassed by the term "toxins" in the context of Annex A(1)(b). There is nothing in the *SPS Agreement* to indicate that "risks arising from … toxins … in foods, beverages or feedstuffs" should not apply to risks arising from toxins that are in food as a result of breeding changes introduced into the food plant.

7.320 **Canada** agrees that the genetic modification of a plant might unintentionally result in the production of a toxin. The same is true of products from traditionally-bred plants. Canada argues that, apart from potential effects on non-target organisms, the "toxic characteristics of seeds or crops" are only assessed if these products are used for human or animal consumption, not, for example, when these products are for industrial purposes (*e.g.* the oil from oilseed rape used in lubrication or as crude oil).

7.321 The **Panel** notes that common definitions of a "toxin" are "a poison produced by a micro-organism or other organism and acting as an antigen in the body"[463] or "any poisonous antigenic substance produced by or derived from micro-organisms, which causes disease when present at low concentration in the body"[464]. 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."[465] 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."[466] 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".[467] We note that these definitions do not suggest that toxins

[462] *See* http://www.biology-online.org/dictionary.asp as of 15 June 2004.

[463] *Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1517.

[464] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 3312.

[465] Codex Standard 193 – 1995, General Standard for Contaminants and Toxins in Foods, (Rev.1-1997), p. 1.

[466] *Ibid*, p. 1.

[467] FAO Glossary of Biotechnology for Food and Agriculture, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) (FAO, Rome, 2001), p. 285.

in foods are inherently substances which have been unintentionally added to foods.[468] 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.

7.322 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 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.[469] We note that in the present case, the European Communities does not argue that Directives 90/220 and 2001/18 are measures applied to protect target pests, such as insects, from risks arising from the release into the environment of pesticide-producing GM plants.

7.323 We agree with the Parties that a poisonous substance which is produced during the metabolism or growth of a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We also agree with the European Communities that for an SPS measure to be covered by Annex A(1)(b), the toxin which gives rise to risks for human or animal life or health would have to be present in "foods, beverages or feedstuffs". However, we recall that a GM plant which is grown in a field may be eaten as food by wild fauna.[470]

7.324 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[471] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[472] In the light of this, Directives 90/220 and 2001/18 can, in our view, be considered as measures applied to protect the life or health of humans or animals (not including target organisms) from risks arising from toxins produced in GM plants which are foods or feedstuffs.

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[468] We note that the Codex definition of "mycotoxins" refers to the unintentional presence in food of the microfungi, not the unintentional presence of the toxins they may produce.

[469] We refer in this context to our previous discussion of potential risks to animal or plant health arising from the development of resistance in target insects to the insecticide produced by GM plants.

[470] If a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms even if the non-target organisms do not eat the GM plant, or parts thereof, *e.g.*, through exposure other than through ingestion as food, we think the GM plant might qualify as a "pest" within the meaning of Annex A(1)(a).

[471] Annex II.C.2.1 of Directive 2001/18.

[472] Annex II.D.2.7 of Directive 2001/18.

allergens

7.325 The **European Communities** notes that genetic modification may lead to the production of novel proteins or to the increased production of known proteins which may induce an allergic reaction. According to the European Communities, an allergen is defined as "pertaining to antigens that induce an allergic response in an organism or any substance that can cause an allergy."[473] Allergenic responses are only provoked in certain individuals that exhibit sensitivity to the allergen. On the other hand, a toxin is "a poisonous substance produced during the metabolism and growth of certain micro-organisms and some higher plant and animal species."[474] Hence, according to the European Communities, a food allergen cannot be considered to be a toxin. The European Communities argues that it is questionable to describe allergies as diseases; they are better described as medical conditions. In addition, the risk is not so much that the GMO will cause an allergy (which would already be present in the subject), but that it would provoke the allergic reaction.

7.326 The European Communities further notes that potential allergenic effects arising from GM plants may occur as a result of exposure other than through food. Consequently, the issue of allergenicity is not confined to food safety. Rather, the potential presence of allergens in the environment as a result of the release of GM plants may be considered a broader environmental issue, not included in the scope of Annex A(1) of the *SPS Agreement*.

7.327 The **United States** argues that the concern that a biotech product might lead to an allergic reaction on the part of consumers, *e.g.*, concerns regarding allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, falls within the definition of Annex A(1)(b). An allergen would generally fall within the definition of a toxin. A "toxin" is generally defined as "a poison."[475] A "poison" is in turn defined as "any substance which, when introduced into or absorbed by a living organism, destroys life or injures health….".[476] Food allergens clearly fall within the description of a substance that "destroys life or injures health". According to the United States, the allergenicity concern relating to the products at issue in this dispute is that a protein produced in the plant could be allergenic. Or in other words, it is a substance that "destroys life or injures health," or a "poisonous substance," produced during the metabolism and growth of a plant.

7.328 The United States maintains that one exception to this general rule is that when the allergen is itself a pesticide residue, or is a component of a pesticide residue, it would fall within the definition of a contaminant, pursuant to footnote 4 of Annex A(1). Any dietary risks that pesticide residues of GM crops might present would be "risks arising from ... contaminants in foods," including the risk of an allergic reaction from consuming the food.

7.329 The United States argues, in addition, that Annex A(1)(b) is not restricted to dietary risks, but includes any measure taken to protect human or animal life or health from "risks arising from ... toxins ... in foods ... or feedstuffs." Measures taken to protect against occupational exposures from the Bt toxin in the GM plants would fall within this description.

7.330 **Canada** claims that in the context of biochemistry, a "toxin" is defined as "any of the various poisonous substances produced by certain plant and animal cells, including bacterial toxins,

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[473] The European Communities notes that antigens are defined as substances that are recognized by the immune system and induce an immune reaction.

[474] *See* http://www.biology-online.org/dictionary.asp [last visited on 15 June 2004].

[475] *The Compact Oxford English Dictionary*, Oxford University Press, 1971, 24th Printing, p. 2224.

[476] *Ibid.*, p. 3367.

phytotoxins and zootoxins."[477] "Toxic" means "relating to a harmful effect by a poisonous substance on the human body by physical contact, ingestion, or inhalation".[478] A "poison" can be defined as "a substance that in relatively small doses has an action that either destroys life or impairs seriously the functions of organs or tissues".[479] Hence, Canada argues that for the purposes of the *SPS Agreement*, allergens in food and feedstuffs can be considered toxins because allergens, in some circumstances, can destroy life or impair seriously the functions of organs or tissues for people with immunological sensitivities to that allergen.

7.331 **Argentina** also argues that the risks arising from a food allergen are comparable to the risks arising from "toxins" or "disease-causing organisms". Allergens, toxins and disease-causing organisms all pose risks to health, even if allergens may affect just a sub-set of the population, instead of the population as a whole. Argentina agrees that a measure to protect humans against occupational exposures from Bt toxins in corn, which is consumed as either a food or feedstuff, is subject to the *SPS Agreement* since Annex A(1)(b) does not specify or restrict the mode of exposure.

7.332 The **Panel** observes that the Complaining Parties address the concern regarding potential allergic responses to GMOs in the context of Annex A(1)(b). It is our understanding from the evidence provided by the Parties that allergic responses are primarily associated with the ingestion of products consisting of or containing GMOs, rather than through contact with the GM plant *per se*. However, the European Communities has also argued that an allergic reaction could potentially result from exposure to an allergen produced by a GM plant other than through the ingestion of that plant as or in a food. We will address this concern in the context of our discussion of Annex A(1)(c).

7.333 Turning to allergenicity as a food safety concern, we note that Annex A(1)(b) is silent on whether risks arising from allergens produced in GM plants which are used as or in foods or feedstuffs are covered. Food allergenicity concerns were certainly widely known by Members at the time the *SPS Agreement* was drafted. While the absence of a reference to allergens in Annex A(1)(b) might conceivably reflect a deliberate choice to exempt food allergenicity risks from the scope of the *SPS Agreement*, equally, the absence of a reference to allergens could mean that allergens were considered to be covered by the text of Annex A(1)(b). The Complaining Parties in fact argue that allergens could be subsumed within the category of "toxins" or "disease-causing organisms". Below, we will examine whether allergens in foods or feedstuffs could be considered to fall within the category of "toxins".

7.334 The term "allergen" is commonly defined as "a substance that causes an allergic reaction".[480] The term "allergic" is defined as "of, caused by, or relating to an allergy"[481], 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"[482]. 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

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[477] *McGraw-Hill Dictionary of Scientific and Technical Terms*, 6th ed. (New York: McGraw-Hill), p. 2168. Canada notes that this definition of toxin applies only in the context of biochemistry. In other contexts, "toxin" might be interpreted differently, *e.g.*, mercury may be a considered a toxin although it is not produced by a living organism.

[478] *Ibid*, p. 2168.

[479] *Ibid*, p. 1626.

[480] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 35.

[481] *Ibid*.

[482] *Ibid*.

FAO Glossary of Biotechnology for Food and Agriculture, which describes an allergen as "an antigen that provokes an immune response".[483]

7.335 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.[484] 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.

7.336 As noted, the 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"[485], or as "a substance that through its chemical action is able to kill, injure, or impair an organism"[486].

7.337 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.[487] 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.

7.338 We have pointed out earlier that in the specific context of this dispute, allergens would be proteins generated through the expression of genes in GMOs. It is useful to clarify, therefore, that we do not purport to suggest that "toxins" within the meaning of Annex A(1)(b) necessarily need to be proteins. Poisonous substances other than poisonous proteins may qualify as "toxins".

7.339 We have stated above that allergens are substances which cause a damaging immune response by the body in humans or animals which have become hypersensitive to that substance. The fact that

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[483] FAO Glossary of Biotechnology for Food and Agriculture, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) (FAO, Rome, 2001),p. 8.

[484] In the context of GM foods, one of the experts advising the Panel, Dr. Nutti, indicated that "in this case [allergens] are a sub-category [of toxins] because they are proteins. The allergens are always protein." (Annex J, para. 1172) Dr. Nutti further noted that: "If you go to the Codex [Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants], when you go to the annex "Assessment of possible allergenicity", you see all newly expressed proteins produced by GMOs. As far as GMOs are concerned when you go to look for allergens you are looking for the proteins." (Annex J, para. 1188)

[485] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1105.

[486] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 777.

[487] We note that the United States, with reference to H.A. Sampson, "Food allergy Part 1: Immunopathogenesis and Clinical Disorders", Journal of Allergy and Clinical Immunology, Vol. 103:00. 717-728, May 1999, has defined anaphylaxis as a sudden and severe reaction characterized by a sudden drop in blood pressure and breathing difficulties that may be fatal.

a food allergen does not present a risk to all human beings or animals does not, in our view, mean that it cannot qualify as a "toxin" in foods or feedstuff within the meaning of Annex A(1)(b). 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.[488] 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.[489]

7.340 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[490] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[491] In the light of this, to the extent that Directives 90/220 and 2001/18 seek to protect humans and animals from allergenic effects of GM plants used as or in foods, the Directives can, in our view, be considered as measures applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs.

"disease-causing organisms"

7.341 **Canada** and **Argentina** argue that the kind of food allergens which might be produced by GMOs could also be viewed as "disease-causing organisms" within the meaning of Annex A(1)(b). **Argentina** also argues that the risk arising from the mass consumption of products containing ARMG, which may lead to the development of bacteria resistant to antibiotics, falls within the definition given in Annex A(1)(b). According to Argentina, therefore, a measure based on such concerns is a measure aimed at protecting human and animal health from the risks arising from diseases and disease-causing organisms in foods, beverages and feedstuffs.

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[488] It is useful to point out in this context that food safety regulations establishing maximum residue levels for pesticides or veterinary drugs, or regarding the approval of the use of certain food additives, are frequently established to ensure the protection of the health of those segments of the population considered to be most vulnerable to the potential health risk, for example, infants, pregnant women or the elderly. The Codex Standard for Food Additives, for example, provides that: "Where the food additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the food additive by consumers in those groups." (Codex Stan 192-1995, Rev.5-2004.) Furthermore, specific standards have been developed with respect to special groups of consumers, such as the Codex Standard for Processed Cereal-based Foods for Infants and Children, Codex Stan. 74-1981 (amended 1985, 1987, 1989, 1991), FAO, Rome.

[489] Regarding effects on trade, we note that our view that protection of vulnerable sub-populations from food allergens falls within the scope of the *SPS Agreement* does not imply that products containing such allergens should be prohibited. Adequate protection might be achieved through a requirement that food products containing known allergens be labelled so that the susceptible population is informed of their content.

[490] Annex II.C.2.1 of Directive 2001/18.

[491] Annex II.D.2.7 of Directive 2001/18.

7.342 The **Panel** recalls that it has already found that the food allergens at issue in this dispute can be considered as "toxins" within the meaning of Annex A(1)(b), and therefore it is not necessary to address whether they could, in addition, be considered as "disease-causing organisms" within the meaning of Annex A(1)(b). Similarly, we have already found that ARMG could, in the case at hand, be considered to be "additives" within the meaning of Annex A(1)(b). Therefore, we do not find it necessary to address whether they could also be considered as "disease-causing organisms".

Preliminary conclusions concerning Annex A(1)(b)to the *SPS Agreement*

7.343 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following fall within the scope of Annex A(1)(b) of the *SPS Agreement*:

– "disease to humans including allergenic or toxic effects"
– "altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors"
– "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".

This does not exclude, however, that, depending on the circumstances, some of these potential adverse effects may also fall within the scope of other sub-paragraphs of Annex A(1).

7.344 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following falls within the scope of Annex A(1)(a), while recognizing that, depending on the circumstances, it may also fall within the scope of other sub-paragraphs of Annex A(1):

– possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

Annex A(1)(c) to the *SPS Agreement*: protection of human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread or pests

7.345 We now turn to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(c) of the *SPS Agreement*. The Parties have addressed Annex A(1)(c) in connection with the issue of the potential allergenicity of GMOs and GMO-induced increased use of pesticides, hence we analyse these issues under corresponding headings.

allergenic effects of GMOs unrelated to consumption as food

7.346 We first turn to analyse the issue of the potential allergenic effects of GMOs which are not used as or in foods.

7.347 The **European Communities** notes that potential allergenic effects arising from GM plants may occur as a result of exposure other than through food. Consequently, the issue of allergenicity is not confined to food safety. Rather, the potential presence of allergens in the environment as a result of the release of GM plants may be considered a broader environmental issue, not included in the scope of Annex A(1) of the *SPS Agreement*.

7.348 The **United States** argues that measures taken to address risks from occupational or residential exposure to biotech plants, such as possible allergic reactions in farmers applying Bt microbial pesticides, would generally fall within paragraph 1(c), as measures "to protect human life or health [...] from risks arising from [...] the establishment or spread of pests."

7.349 The **Panel** recalls that it has addressed the issue of the risks arsing from the potential of GMOs to produce food allergens above in the context of its analysis under Annex A(1)(b). What is at issue here is the potential of GMOs to produce allergenic effects in persons working, or otherwise coming into contact, with GMOs.

7.350 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.[492]

7.351 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. As a result, we do not believe that GM plants which have been harvested could not be considered to be "pests" if they cause harm to the health of humans who may be handling them during harvesting, transport or processing.

7.352 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects".[493] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the [GM plant] and persons working with, coming into contact with or in the vicinity of the [GM plant] release(s)".[494] We think that by controlling the release of GMOs into the environment to avoid effects of this kind, Directives 90/220 and 2001/18 serve to avoid the entry, spread or establishment of allergenic GMOs. In the light of this, we consider that Directives 90/220 and 2001/18 can be

[492] In our view, the ordinary meaning of the term "pest" as it is used in the context of Annex A(1)(c) does not suggest that for a plant to qualify as a "pest", it necessarily needs to cause harm to the health of each and every person coming in contact with it. This view is consistent with our interpretation of the term "toxin" in Annex A(1)(b).

[493] Annex II.C.2.1 of Directive 2001/18.

[494] Annex II.D.2.6 of Directive 2001/18.

appropriately viewed as measures applied to protect human life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests".[495]

possible health effects from increased herbicide use associated with GMOs

7.353 The **European Communities** argues that negative effects of the use of herbicides on human health do not fall within Annex A(1)(c) because the herbicide is not a "disease carried by animals, plants or products thereof" and because the risk arises even if the GM plant is not a pest. Negative effects on human health from the consumption of pesticide residues might, however, fall within the scope of Annex A(1)(b).

7.354 The **Panel** understands the European Communities to argue that the introduction of herbicide-resistant GM plants might entail use of herbicides in the field when no herbicides were previously used, increased use of herbicides or use of different herbicides, and that this might in turn cause harm to human health. We further understand the EC argument to be that the relevant harm 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.[496] Thus, according to the European Communities, a change in weed control practices – specifically, changes in herbicide use – which may be associated with the introduction of herbicide tolerant GM crops might have adverse effects on human health, *e.g.*, for workers applying them in the field.

7.355 As an initial matter, we note that the European Communities has not explained why such potential health effects might arise. As noted by us earlier, it is our understanding that before a plant protection product can be used on any crop cultivated within the European Communities, the use of the product on the relevant crop is subjected to an assessment for safety. Therefore, it would seem that if herbicides used in conjunction with herbicide tolerant GM crops have been approved for use, and if they are applied in accordance with any conditions that may have been attached to their approval, such application should not normally be harmful to human health. Having said this, it 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.

7.356 We note that the scenario posited by the European Communities – that a change in weed control practices associated with the introduction of herbicide tolerant GM crops might have adverse effects on human health – is very similar to another scenario we have already considered, namely the scenario in which a change in weed control practices associated with the introduction of herbicide tolerant GM crops might have adverse effects on the environment. Accordingly, our analysis parallels that of the latter scenario.

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[495] We recall that Directive 2001/18 also specifies that potential adverse effects of GMOs include "disease to animals including allergenic or toxic effects". It would appear, therefore, that Directives 90/220 and 2001/18 could also be applied to prevent GMOs from producing allergenic effects resulting from exposure of animals to GMOs other than as or in a food. For completeness, we note that in this situation the GMOs could be viewed as "pests" in relation to susceptible animals. Accordingly, we think that if applied to prevent such effects, Directives 90/220 and 2001/18 may be appropriately viewed as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests". As such, they would be covered by Annex A(1)(a).

[496] We recall that in the context of our analysis under Annex A(1)(b) we have addressed a similar argument relating to the possibility of the increased use of herbicides leading to a higher level of contaminants, specifically herbicide residues, in GM plants used as or in foods or feedstuffs.

7.357 Thus, also in 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.

7.358 Regarding the link to GM plants, we note that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including indirect effects on human health, such as effects occurring through a change in management practices in the wake of the introduction of herbicide tolerant GM plants.[497] As we have observed earlier, herbicide tolerant GM plants are linked to the herbicide to which they are tolerant. Moreover, the herbicide to which GM plants are tolerant has been developed to help control and/or eradicate the relevant weeds. Thus, it is clear that, *via* the relevant herbicide, the GM plants in question are also linked to the weeds, and hence the pests, to be controlled.

7.359 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 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.

7.360 In the light of the foregoing, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects on human health which arise from changes in management practices associated with the introduction into the environment of GMOs, we consider that the Directives can be viewed as measures applied to protect human life or health from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".[498]

Preliminary conclusions concerning Annex A(1)(c) to the *SPS Agreement*

7.361 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following falls within the scope of Annex A(1)(c) of the *SPS Agreement*:

– "disease to humans including allergenic or toxic effects".

This does not exclude, however, that, depending on the circumstances, this potential adverse effect may also fall within the scope of other sub-paragraphs of Annex A(1).

7.362 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following falls within the scope of Annex A(1)(c):

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[497] *See* the introductory paragraph of Annex II of Directive 2001/18, which defines "indirect effects" as "effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management".

[498] We made a similar point above in relation to the situation where target organisms, notably insects, develop resistance to a pesticide. We said there that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms.

– possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

Annex A(1)(d) to the *SPS Agreement*: Prevent or limit other damage within the territory of a Member from the entry, establishment or spread of pests

7.363 We turn, finally, to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(d) of the *SPS Agreement.* In order for us to determine whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(d), we need to consider in particular the meaning and scope of the term "other damage" used in Annex A(1)(d) and address whether certain potential effects of GMOs could be said to give rise to "other damage".

"other damage"

7.364 The **United States** maintains that the term "other damage" means damage other than damage to animal or plant life or health, or to human life or health. This could include, for example, property damage by pests. However, nothing in the *SPS Agreement* excludes other non-life or non-health damage to plants, animals or humans caused by pests.

7.365 **Canada** observes that the ordinary meaning of the term "damage" is "harm done to a thing […]; *esp.* physical injury impairing value or usefulness."[499] The context of the term "damage" suggests that "damage" means the injurious or harmful potential biological and economic consequences that result from the occurrence of an event. The use of the term "other" suggests that the type of damage contemplated in Annex A(1)(d) is distinct from the damage to animal or plant life or health and human life or health arising from the entry, establishment and spread of pests that fall within the scope of Annex A(1)(a*)* and (c), respectively. Canada recalls its argument that the terms "animal" and "plant" are defined broadly in the *SPS Agreement*.[500] According to Canada, many of the risks to biodiversity or the environment cited by the European Communities fall within the risks to animal and plant life or health contemplated by Annex A(1)(a). Canada does not consider that plants, animals, or humans can be "damaged" unless there is damage to their "life or health"; it would be inconsistent with the object and purpose of the *SPS Agreement* to extend the definition of damage to plants, animals or humans to include so-called damage that is not based on injury or harm to their life or health. In this particular context, reduced yield of a crop, as a result of competition from a pest such as a weed, would be considered impairment to the health of the crop plant.

7.366 According to Canada, "other damage" is not limited to damage sustained by plants, animals or humans but includes damage from the entry, establishment or spread of pests to the functioning of the environment or the ecosystem taken as a whole, independent of damage to the life or health of specific plants or animals. This would include, for example, damage resulting from ecosystem destabilization and from control, eradication or management programs that would be needed if a pest were introduced, and impacts of such programs (*e.g.* pesticides…) on biological diversity. Other examples include environmental and other undesired effects of control measures; the capacity of a pest to act as a vector for other pests; significant effects on designated environmentally sensitive or protected areas; significant changes in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling etc.); effects on human use (water quality, recreational uses, tourism, animal

[499] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 1, p. 588.

[500] *See* paras. 7.205 and 7.215.

grazing, hunting, fishing); and costs of environmental restoration. Canada argues that this view is supported by the relevant international standard for analysing the risks associated with pests, including LMOs.[501]

7.367 **Argentina** maintains that the concept of "other damage" in Annex A(1)(d) refers to the prevention of situations not listed in paragraphs (a), (b) and (c) and related to pests. Examples of such "other damage" include concerns related to the fitness of plants, animals or humans. Argentina considers that the broader ecological consequences of a GM plant that grows where it is not wanted also constitute "other damage" caused by the "entry, establishment or spread of pests". Concerns regarding cross-contamination of other organisms by biotech products likewise fall under Annex A(1)(d). Measures to prevent or minimize adverse effects related to excessive population increase of a GM plant in the environment or to competitive advantage of the GMOs in relation to unmodified organisms also fall within the scope of Annex A(1)(d) of the *SPS Agreement*. While in Argentina's view, the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is by negatively affecting wild flora and/or fauna, Argentina considers that the scope of Annex A(1)(d) is sufficiently broad to encompass any possible other damage to biodiversity or the ecological balance.

7.368 The **European Communities** considers that the term "other damage" covers damages arising from the entry, establishment or spread of a pest other than damage to the "life or health" of humans, animals and plants. The European Communities maintains that it is commonly accepted that the words "other damage" refer to economic damage. This includes, for example, a reduction in the value of a crop whose quality is reduced because of damage by a pest that does not threaten the life or health of the plant. However, the European Communities observes that "other damage" is expressly linked only to the risks arising from the entry, establishment or spread of a "pest". Since the European Communities argues that a GMO is not a pest unless it is growing in the wrong place and/or at the wrong time, this provision cannot be used to bring all measures applied to protect against damage to ecology or the environment arising from the introduction of a GMO under the scope of the *SPS Agreement*. In particular, according to the European Communities the effects of GMOs on non-living components in the environment, such as biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material, are among the concerns identified in the EC legislation which clearly fall outside the scope of the *SPS Agreement*.[502]

7.369 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.

7.370 The residual category of "other damage" is potentially very broad.[503] In our view, "other damage" could include damage to property, including infrastructure (such as water intake systems,

[501] International Standard for Phytosanitary Measure No. 11, Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks", FAO, Rome, 2004 (adopted April 2004), pp. 23-24.

[502] The European Communities notes, for example, Section C2.1, sixth indent in Annex II, and items II.A.11(f) and IV.B.15 in Annex IIIA, and D11 in Annex IIIB, of Directive 2001/18.

[503] We note that the text of Annex A(1)(d) refers to "other damage within the territory", and not to "other damage to humans, animals or plants". We therefore see no basis in the text of Annex A(1)(d) for construing the term "other damage" so as to encompass only other damage to humans, animals or plants. It is clear, however, that only damage from the entry, establishment or spread of "pests" can qualify as "other damage" within the meaning of Annex A(1)(d).

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"[504], or "a loss or harm resulting from injury to person, property, or reputation"[505]. 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).

7.371 We note that damage to plant, animal or human life or health may entail consequential economic damage. Governmental measures protective of the life or health of plants and animals are sometimes taken precisely to avoid such adverse economic consequences. We therefore agree with Canada that measures taken, *e.g.*, to protect cultivated crops against weeds which might enter a field and out-compete and crowd out the cultivated crops, thus reducing crop yield, might be appropriately regarded as measures falling within the scope of Annex A(1)(a) rather than as measures falling within the scope of Annex A(1)(d). This view is consistent with the fact that Annex A(1)(d) omits reference to "diseases". Obviously, the entry, establishment or spread of diseases may, *inter alia*, lead to economic damage in the territory of a Member.[506] However, in the case of a disease, economic damage would be the result of the damage the disease causes to plant, animal or human life or health. The same is not necessarily true for a pest. We recall in this respect that the term "pest", as we interpret it, refers, not just to an animal or plant which is destructive of animals, plants or humans, or which causes harm to the health of other animals, plants or humans, but also to an animal or plant which causes other harm. It is therefore understandable that Annex A(1)(d) specifically and separately addresses measures applied to control damage other than damage to plant, animal or human life or health.[507]

7.372 In addition to physical damage to property or economic damage, we consider that the concept of "other damage" is also susceptible of encompassing damage to the environment other than damage to the life or health of living organisms (*i.e.*, animals or plants). We note in this regard Argentina's argument that the concept of "other damage" might encompass damage to "biodiversity". Dictionaries define "biodiversity" as "the variety of plant and animal life in the world or in a particular habitat"[508]

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[504] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 361.

[505] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 252.

[506] This is recognized in the aforementioned Article 5.3, which, to recall, refers to "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".

[507] We note in passing that there may be situations where a pest gives rise to damage to the life or health of other animals or plants without this necessarily being considered a reason for applying a measure to protect the life or health of these other animals or plants. For instance, the affected other animals or plants might themselves be pests. However, the pest in question may, in addition and at the same time, give rise to economic damage which is different and separate from the damage it causes to the life or health of other animals or plants. That economic damage may be considered a reason for applying a measure to limit the pest. Thus, as this example shows, the mere fact that a pest gives rise, *inter alia*, to potential damage to the life or health of other animals or plants does not mean that any measure applied to combat that pest is automatically or exclusively covered by Annex A(1)(a).

[508] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Oxford University Press, 1999), p. 135.

or "biological diversity in an environment as indicated by number of different species of plants and animals"[509]. The *Glossary of Biotechnology for food and agriculture* defines "biodiversity" as "[t]he variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems".[510] We deduce from the aforementioned definitions that damage to "biodiversity" implies damage to living organisms. Accordingly, we are not persuaded that the term "other damage" in Annex A(1)(d) includes damage to "biodiversity" as such. However, as we have noted earlier, a measure applied to prevent damage to "biodiversity" may qualify as a measure applied to protect animal or plant life or health from the kind of risks referred to in Annex A(1)(a) and (b).

7.373 Turning now to consider Directives 90/220 and 2001/18, we note that Directive 2001/18 specifies that potential adverse effects of GMOs include "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition or organic material".[511] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GMO plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s)".[512] We have already indicated that to the extent GMOs might affect the life or health of soil microfauna or -flora, the concern would be that GMOs might act as pests and, as such, give rise to risks to animal or plant life or health. In other words, this would be a concern falling within the scope of Annex A(1)(a). Likewise, if GMOs were to have effects on soil micro-organisms and this were to pose risks to the life or health of other animals or plants, we think this would be a concern that GMOs might act as pests which indirectly give rise to risks to animal or plant life or health.

7.374 The European Communities argues that concerns regarding effects of GMOs on biogeochemistry also include concerns about effects on non-living components in the environment, such as the recycling of carbon and nitrogen through changes in soil decomposition of organic material. In the European Communities' view, such concerns are outside the scope of the *SPS Agreement*. We are not persuaded by this argument. To the extent that GMOs might cause damage to (as opposed to mere changes in) geochemical cycles, such that there would be damage to the environment other than damage to living organisms, we think such environmental damage could be considered as "other damage" from the entry, establishment or spread of GMOs *qua* "pests" within the meaning of Annex A(1)(d). In the light of this, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects of GMOs on "non-living components" in the environment, including those which are part of geochemical processes, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" from the entry, establishment or spread of GMOs *qua* "pests".

7.375 We note that Directive 2001/18 also specifies that potential adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment"[513], which include the "potential for excessive population increase" and "competitive advantage of the GMOs"[514].

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[509] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 98.

[510] *FAO Glossary of Biotechnology for food and agriculture*, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) Rome, 2001, p. 30.

[511] Annex II.C.2.1 of Directive 2001/18.

[512] Annex II.D.2.7 of Directive 2001/18.

[513] Annex II.C.2.1 of Directive 2001/18.

[514] Annex IIIA.iv.B.7 and 8 of Directive 2001/18.

Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GMO plants, applicants should provide information on the "[l]ikelihood of the [GMO plant] becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats"; "[a]ny selective advantage or disadvantage conferred to the [GMO plant]"; "[p]otential for gene transfer to the same or other sexually compatible plant species under conditions of planting the [GMO plant] and any selective advantage or disadvantage conferred to those plant species"; "[p]otential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GMO plant] and target organisms, such as predators, parasitoids, and pathogens (if applicable)"; "[p]ossible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the [GMO plant] with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens".[515]

7.376 We have addressed these various adverse effects earlier. All of them relate to potential effects of "pests". In these situations, the GMOs themselves or cross-breeds might act as pests, or target organisms or non-target organisms might become pests, as a result of the release of GMOs into the environment. The Parties have not addressed whether any of the aforementioned types of "pests" could cause damage to the "non-living components" in the environment. We have no basis on which to determine whether this would or would not be possible. Therefore, we simply note that to the extent Directives 90/220 and 2001/18 seek to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health or on geochemical processes, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" from the entry, establishment or spread of "pests".

7.377 We note, furthermore, that Directive 2001/18 also specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs".[516] The European Communities has argued that the use of GM crops as opposed to conventional crops may have adverse effects on the agro-ecological environment and on biodiversity. In this context, the European Communities has referred to research on the effect, if any, that the management practices associated with genetically modified herbicide tolerant crops might have on farmland wildlife, when compared with weed control used with non-GM crops.[517]

7.378 We have addressed the issue of the potential adverse effects on non-target organisms, including farmland wildlife, arising from changes in weed control practices (including changes in herbicide use) that may be associated with the introduction of GM crops in the context of our discussion of Annex A(1)(a). We determined that to the extent Directives 90/220 and 2001/18 are applied to avoid such effects, they can be viewed as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests". To the extent that changes in weed control practices might cause damage to the environment other than damage to the life or health of non-target organisms, we think such damage could be considered as "other damage" resulting indirectly (*i.e.*, via such changes), from the entry, establishment or spread of weeds *qua* "pests" within the meaning of Annex A(1)(d). In the light of

[515] Annex II.D.2.1-5 of Directive 2001/18.
[516] Paragraph 9 of Annex II.D.2. of Directive 2001/18.
[517] UK Department for Environment Food and Rural Affairs, "GM crops: Effects on farmland wildlife", October 2003. These studies are referred to as the "Farm Scale Evaluation".

this, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects arising from management techniques associated with GMOs other than damage to the life or health of non-target organisms, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests".

Preliminary conclusions concerning Annex A(1)(d) to the *SPS Agreement*

7.379 In light of these considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following fall within the scope of Annex A(1)(d) of the *SPS Agreement, e.g.*, to the extent they relate to the protection of "non-living components" in the environment:

– effects on the dynamics of populations of species in the receiving environment;
– effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

7.380 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following fall within the scope of Annex A(1)(d) of the *SPS Agreement, e.g.*, to the extent they relate to the protection of "non-living components" in the environment:

– likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
– any selective advantage or disadvantage conferred to the GMHP;
– potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
– potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
– possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;
– possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
– possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Labelling to indicate presence of GMOs

7.381 Before concluding our examination of Directives 90/220 and 2001/18 under Annex A(1), it is necessary to address the labelling requirements imposed by Directive 2001/18. The Parties did not raise and discuss this issue as part of their arguments on whether Directive 2001/18 falls within the scope of Annex A(1). However, since the issue of labelling requirements is of some significance to our examination below of whether Regulation 258/97 falls within the scope of Annex A(1), consistency requires that we broach the issue as part of our examination of Directives 90/220 and 2001/18.

7.382 Directive 2001/18 provides that the applicant must submit a proposal for labelling. The proposal must include the commercial name of the relevant product containing a GMO, the name of the GMO, and a clear statement that a GMO is present, either on a label or in a document accompanying the product. The competent member State authorities must examine applications for compliance with the requirements of Directive 2001/18, including the labelling requirements. The applicant must not place a GMO on the market unless it has received the written consent of the competent authority and unless it has complied with any conditions required in the consent. The written consent must specify the labelling requirements. In all cases, the statement that a GMO is present must appear on a label or in an accompanying document.[518]

7.383 Furthermore, with regard to GMOs which have been approved for placing on the market, Directive 2001/18 requires member States to take all necessary measures to ensure that at all stages of the placing on the market, the labelling of the relevant GMOs comply with the requirements specified in the written consent.[519] The Directive does not specify the measures which need to be taken by member States in fulfilment of this requirement.

7.384 As we understand it, Directive 2001/18 requires labelling or documentation to indicate the presence of a GMO in cases where the competent authorities have determined, based on available scientific evidence, that the release of the relevant GMO into the environment is safe for both human health and the environment. A requirement to indicate the presence of a GMO in such cases may not at first glance appear to be a measure that would fall within the scope of the *SPS Agreement*. Therefore, we think we should examine whether the labelling requirement in Directive 2001/18 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).

7.385 We recall in this regard that the only stated purpose of Directive 2001/18, besides the approximation of member State laws, is to protect human health and the environment from risks arising from the deliberate release of GMOs into the environment.[520] This is in contrast to Regulation 258/97 (which we will consider below) that makes reference to other purposes, such as not misleading the consumer. In the light of this, we think that if the labelling requirement in Directive 2001/18 is rationally related to the stated purpose of Directive 2001/18, and in the absence of sufficient indications of a different or additional purpose, we may and should presume that the labelling requirement is intended to serve the purpose articulated in the Directive.[521]

7.386 In considering the issue whether the labelling requirement in Directive 2001/18 is rationally related to the stated purpose of Directive 2001/18, we find instructive, among other provisions, those of Article 20 of the Directive. Article 20 addresses situations where after the consent to the placing on the market of a product containing or consisting of a GMO has been given, new information becomes available to competent authorities, from the users of the product or other sources, which could have consequences for the risks of the GMO to human health or the environment. Article 20

[518] Articles 4(4), 13(2)(f) and 19(3)(e) as well as Annex IV of Directive 2001/18. While Directive 90/220 also imposed certain labelling requirements, it did not require a statement to the effect that a GMO is present. Article 11(1) and Annex III of Directive 90/220.

[519] Article 21(1) of Directive 2001/18.

[520] Article 1 of Directive 2001/18.

[521] We note that the 40th preambular paragraph of the Directive states that the presence of a GMO should be indicated on a label or in a document "[i]n order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified". The phrase "appropriately identified" does not indicate that the labelling requirement is applied for the purpose of protecting human health and the environement. But this phrase likewise does not indicate that the labelling requirement is applied for a purpose other than, or additional to, the protection of human health or the environment.

provides that in such situations the consent to the placing on the market may be amended or terminated, depending on the results of a review procedure which is to be conducted when relevant new information becomes available.[522] While the Directive does not specify the precise consequences flowing from a decision to terminate the consent, it is reasonable to assume that the relevant product could no longer be lawfully made available by sellers to third parties, and that measures might be taken to inform the public of the newly discovered risks and to require or encourage users of the product to return it to the seller or to discontinue using it.

7.387 The requirement that the presence of a GMO in a product be explicitly identified on a label or in an accompanying document fits the situation contemplated in Article 20. As pointed out, Article 20 refers, *inter alia*, to situations where new information becomes available, from the users of a product, with regard to the risks of a GMO to human health or the environment after the consent to the placing on the market has been given. 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 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.[523]

7.388 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.[524] 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

[522] We also note that Article 23(1) of Directive 2001/18 requires member States to ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, are applied, including information to the public.

[523] We are mindful of the fact that Directive 2001/18 contains monitoring requirements, *inter alia* to identify the occurrence of unanticipated adverse effects of GMOs on human health or the environment. However, information and data may in some cases be collected and reported through general surveillance practices already implemented for agricultural cultivars other than the GM crop in question. Therefore, users of GM crops may not necessarily associate monitoring with the presence of a GMO. Furthermore, monitoring plans may not always be implemented by those responsible for doing so. We consider that in such cases, by alerting users to the presence of GMOs, labelling to indicate their presence can be presumed to result in consent holders and competent authorities being better informed, or informed more promptly, than they otherwise would be of observations of unanticipated adverse effects of GMOs on human health or the environment.

[524] Accidental dissemination of GM seeds might occur, for instance, as a result of an accident involving a vehicle transporting GM seed bags from the seller to the farmer.

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.[525]

7.389 In the light of the foregoing considerations, we are of the view that there is a rational relationship between, on the one hand, the purpose stated in Directive 2001/18 of protecting human health and the environment and, on the other hand, the particular labelling requirement contained in Directive 2001/18, which applies in cases where a product containing or consisting of a GMO has been found to be safe for human health and the environment. Furthermore, neither in Directive 2001/18 nor in any other piece of evidence before us do we see sufficient indications that the labelling requirement in Directive 2001/18 is intended to serve a purpose different from, or additional to, the purpose Directive 2001/18 says it seeks to achieve, *i.e.*, the protection of human health and the environment.[526]

7.390 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*.[527]

7.391 We have determined above that the labelling requirement in Directive 2001/18 is rationally related to the purpose of protecting human health and the environment. We have also observed that the Panel record does not contain sufficient indications of a purpose different from, or additional to, the protection of human health and the environment. In these circumstances, we think we may and should presume that the labelling requirement is applied to protect human health and the environment from possible unanticipated effects of GMOs. To the extent it 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).[528] Thus, we consider that the labelling requirement in question does not remove Directive 2001/18 from the scope of the *SPS Agreement*.

7.392 We stress that our finding that the labelling requirement in Directive 2001/18 falls within the scope of the *SPS Agreement* does not necessarily imply that the requirement is consistent with the provisions of that Agreement. The consistency of the relevant requirement with the *SPS Agreement* is an issue that is not before us, and so we refrain from expressing a view on it.

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[525] We note that in the case of unexpected, accidental release there could be a need for a rapid response to prevent or limit adverse effects on human health or the environment.

[526] Further elaboration of this point is provided *supra*, at paras. 6.60 *et seq*., in response to a comment made by the European Communities at the interim review stage.

[527] The reference to "labelling requirements *directly related to food safety*" (emphasis added) in the second sub-paragraph of Annex A(1) is in our view intended to provide an example of a labelling requirement which clearly and unambiguously serves one of the purposes identified in Annex A(1). It may be inferred from this reference that some food-related labelling requirements would not be subject to the *SPS Agreement*, *e.g.*, food labelling required to provide quality assurance, volume of contents, or to reflect consumer preferences or moral considerations.

[528] We have addressed earlier how GMOs might give rise to risks falling within the scope of the various sub-paragraphs of Annex A(1), and so we refer to our earlier analysis in this regard.

Conclusions with respect to the purpose of Directives 90/220 and 2001/18

7.393 In our analysis above, we have identified and considered the risks or adverse effects Directives 90/220 and 2001/18 seek to avoid, either by their express terms or according to the European Communities. In relation to all of these risks, we have determined that, in terms of the origin of these risks and their possible consequences, they are risks covered by one or more of the sub-paragraphs of Annex A(1). In the light of this, and since the stated purpose of Directives 90/220 and 2001/18 is to avoid these risks, we are of the view that Directives 90/220 and 2001/18 can be considered as measures which are applied for the purposes identified in Annex A(1)(a) through (d). In other words, we consider that they meet the purpose element of the definition of the term "SPS measure". To that extent, Directives 90/220 and 2001/18 constitute SPS measures.[529]

(ii) Regulation 258/97

7.394 The Panel now turns to examine whether the specific risks or concerns identified in Regulation 258/97 are risks that fall within the scope of the definition of an SPS measure provided in Annex A(1) of the *SPS Agreement*. The Panel recalls that Regulation 258/97 concerns novel foods and food ingredients, including foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220, and foods and food ingredients produced from, but not containing, genetically modified organisms.

7.395 Regarding the purposes for which Regulation 258/97 is applied, we note Article 3(1) of the Regulation, which states that foods and food ingredients falling within the scope of the Regulation must not:

– present a danger for the consumer,
– mislead the consumer,
– differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

7.396 It is important to note that marketing approval is granted only if the novel food or food ingredient for which marketing approval is sought complies with the criteria of Article 3(1) of Regulation 258/97.[530]

7.397 We will determine below for each of the three purposes for which Regulation 258/97 is applied whether that purpose falls within the scope of Annex A(1). The Parties have addressed only some of the purposes of Regulation 258/97 and then only in relatively general terms. We therefore begin our task by setting out the Parties' main arguments on the purposes of Regulation 258/97.

7.398 The **United States** argues that European Communities' biotech approval regime for novel foods is unquestionably an SPS measure. Regulation 258/97 states that "[f]oods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous."[531] According to the United States, the specific risks articulated in the Regulation fall within the definition of an SPS measure under the *SPS Agreement*. For example, concerns that a biotech product might lead to an allergic or toxic reaction on the part of consumers,

[529] We note that we have yet to analyze whether Directives 90/220 and 2001/18 meet the other definitional elements of the term "SPS measure". We will do so once we have considered the purposes of Regulation 258/97.
[530] Articles 6(1) and 6(3) of Regulation 258/97.
[531] Article 3(1) of Regulation 258/97.

e.g., concerns regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, or the presence of toxins or other contaminants in foods containing biotech products, fall within the definition of Annex A(1)(b), which covers measures applied to protect "human or animal life or health" from risks arising from "contaminants" or "toxins" in "foods, beverages or feedstuffs."

7.399 The United States further argues that concerns that widespread consumption of varieties containing ARMG might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of Annex A(1)(b). Such concerns have been characterized as food safety issues. Thus, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs."

7.400 **Canada** argues that the central purpose of Regulation 258/97 is to protect against risks identified in sub-paragraph (b) of Annex A(1) of the *SPS Agreement*, namely, to "protect human or animal life or health […] from risks arising from […] contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". Regulation 258/97 identifies the "protect[ion] of public health" as a justification for adoption of a single safety assessment throughout the European Community.[532] The Regulation further states that "[f]oods and food ingredients falling with the scope of this Regulation must not: present a danger for the consumer" or be "nutritionally disadvantageous."[533]

7.401 Canada observes that Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97.[534] Safety assessments conducted under Regulation 258/97 should include an assessment of contaminants, toxins and disease-causing organisms resulting from the novel elements of the novel food or food ingredient in question. The safety assessment should address only "[c]hemical or microbiological contaminants of novel foods […] specifically related to the novelty […]" and "the presence of microbial toxins and microbial or viral infective agents […] [when] this is a consequence of the novelty."[535] Part XIII of the Commission Recommendation sets out the type of toxicological information that should be included in an assessment for novel foods under Regulation 258/97, including toxicity, mutagenicity and allergenicity studies.[536]

7.402 **Argentina** maintains that the EC approval procedures, including those for novel food under Regulation 258/97, are SPS measures. Argentina recalls that the definition of SPS measures in Annex A(1) explicitly includes "*inter alia* [...] approval procedures [..]". In particular, Argentina notes

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[532] 2nd preambular paragraph of Regulation 258/97.
[533] Article 3(1) of Regulation 258/97.
[534] Commission Recommendation 97/618.
[535] *Ibid.*, Article 5.
[536] *Ibid*, p. 14, Part XIII, which states:

> "This scheme covers the set of toxicological information needed to assess the [novel foods]. The range of scenarios can extend from foods for which substantial equivalence can be established to foods for which substantial equivalence cannot be established and which, therefore, require an appropriate nutritional-toxicological testing program.
>
> If substantial equivalence to a traditional counterpart cannot be established, the safety assessment based on a case-by-case evaluation must consider the following elements:- consideration of the possible toxicity of the analytically identified individual chemical components; toxicity studies in vitro and in vivo including mutagenicity studies, reproduction and teratogenicity studies as well as long term feeding studies, following a tiered approach on a case-by-case basis; studies on potential allergenicity."

that the purpose of the EC regulations for the approval of biotech products is to determine, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. Argentina considers that the risks to which the EC legislation refers, and which have been evaluated by the respective EC scientific committees, are covered by Annex A(1) because both the legislation and the scientific opinions refer to or deal with, *inter alia*, risks such as toxic or allergic effects in humans and animals, the growth of antibiotic-resistant bacteria and cross-contamination.

7.403 The **European Communities** argues that some of the matters addressed by Regulation 258/97 go beyond the risks envisaged and regulated by the *SPS Agreement*. The scope of the *SPS Agreement* depends on the objectives of a measure. Some aspects of Regulation 258/97 fall within the scope of the *SPS Agreement*, but other aspects do not. In particular, the European Communities argues that the GMOs with which this case is concerned are not additives according to the Codex definition for additives.[537] Furthermore, since both the GMOs and the proteins produced by the GMOs are *intentionally* present in food, they cannot be considered to be "contaminants" or "toxins" within the meaning of Annex A(1)(b).

"present a danger for the consumer"

7.404 The **Panel** begins its examination with the first purpose articulated in Regulation 258/97, which is to prevent GMOs used as or in foods from "present[ing] a danger for the consumer". Regulation 258/97 does not elaborate on how it is to be determined whether a product within the scope of the Regulation presents "a danger" for the consumer. Nonetheless, it is clear from the Regulation's preamble that a fundamental objective of the Regulation is to "protect public health"[538] and to ensure that GMOs present in foods are "safe for human health"[539]. We therefore think that the phrase "danger for the consumer" should be understood as referring to a danger for the life or health of the consumer.

7.405 This view is consistent with Commission Recommendation 97/618, which was referred to by Canada. Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97. This Recommendation indicates that, *inter alia*, the following must be assessed:

- critical nutrients, any critical toxicants and anti-nutritional factors;
- potential for toxigenicity and/or pathogenicity of any novel microorganisms;
- potential occurrence of allergic reactions to novel proteins or other constituents of novel foods; and
- potential toxicological effects related to the functions of marker genes (including antibiotic resistance marker genes).[540]

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[537] According to the Codex Procedural Manual, a "[f]ood 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**Error! Bookmark not defined.**" or substances added to food for maintaining or improving nutritional qualities." Codex Procedural Manual, 14th Edition, Reference A, p. 43.

[538] 2nd and 6th preambular paragraph of Regulation 258/97.

[539] 8th preambular paragraph of Regulation 258/97.

[540] Commission Recommendation 97/618, p. 5 *et seq*.

7.406 We note that potential toxic, pathogenic and allergic effects of foods containing or consisting of GMOs all present dangers for the life or health of the consumer. We further note that Article 3(4) of Regulation 258/97 provides a derogation from the regular approval procedure for foods or food ingredients which have been found to be substantially equivalent to existing foods or food ingredients as regards their "composition, nutritional value, metabolism, intended use and the level of *undesirable substances contained therein*" (emphasis added). This makes clear that potential risks to the life or health of consumers could arise from "undesirable substances contained" in foods containing or consisting of GMOs.

7.407 We recall that Annex A(1)(b) brings within the scope of the *SPS Agreement* measures applied "to protect human or animal life or health [...] from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs". We have addressed the meaning and scope of Annex A(1)(b) when we analysed Directives 90/220 and 2001/18. Based on the above considerations, to the extent that Regulation 258/97 seeks to protect consumers from dangerous foods, it may, in our view, be considered as a measure applied to protect the life or health of consumers from risks arising from additives (including antibiotic resistance marker genes), contaminants (*e.g.*, pesticide residues in pesticide-producing or resistant GM plants) or toxins (including allergens) in foods. In other words, we are of the view that the first purpose of Regulation 258/97 is covered by Annex A(1)(b).

"mislead the consumer"

7.408 The second purpose identified in Regulation 258/97 is to avoid that foods containing or consisting of GMOs "mislead the consumer". We note in this regard that Article 8.1 of Regulation 258/97 requires the labelling of food to ensure that the final consumer is informed of:

– any characteristic or food property such as composition, nutritional value or nutritional effects, or the intended use of the food, which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient;
– the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;
– the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns; and
– the presence of an organism genetically modified by techniques of genetic modification.

7.409 We note that marketing approval is granted only if the relevant novel food or food ingredient complies with Article 3(1) of Regulation 258/97, which includes the requirement that the food or food ingredient not mislead the consumer, and if it is labelled in accordance with the above-mentioned requirements of Article 8(1) of the Regulation.[541]

7.410 The Panel recalls that pursuant to Annex A(1) of the *SPS Agreement*, SPS measures include, *inter alia*, "labelling requirements directly related to food safety". The term "food safety" as it is used in the *SPS Agreement* encompasses the safety of such substances as food additives, contaminants (including pesticide residues), etc.[542] Potential health risks arising from such substances are addressed in Annex A(1)(b). Therefore, we consider that labelling requirements related to food safety are labelling

[541] Articles 6(1) and 6(3) of Regulation 258/97.
[542] Annex A(3) specifies the relevant international standards for "food safety", which include Codex standards relating to food additives, pesticide residues and contaminants.

requirements which are applied to protect human health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods.

7.411 Of the four above-mentioned issues on which Article 8(1) requires information to be provided, the second appears to be directly related to food safety (materials which may have implications for the health of certain sections of the population). The first and third issues seem unrelated to food safety (nutritional value or nutritional effects, or the intended use of the food, and on materials which give rise to ethical concerns). The fourth issue relates to information on the presence in a food of a GMO. This information parallels the above-noted labelling requirement in Directive 2001/18. The requirement in Regulation 258/97 is imposed irrespective of whether there is a food safety concern, that is to say, an actual or potential health risk associated with the presence of that GMO in the food in question. Since Regulation 258/97 seeks to ensure that novel foods not mislead the consumer in addition to ensuring that they not present a danger for the consumer, it is reasonable to assume that the requirement that the consumer be informed of the presence of a GMO irrespective of whether there is an associated health risk is at least in part imposed to prevent consumers from being misled. In other words, we consider that, at least in part, Regulation 258/97 requires the identification of the presence of a GMO in a food product in order to ensure that those consumers who have a preference for food not containing or consisting of GMOs are not misled into purchasing food containing or consisting of GMOs.[543]

7.412 We are of the view that to the extent Regulation 258/97 is applied to ensure that novel foods not mislead the consumer, it does not constitute a measure applied to protect the life or health of consumers from risks arising from, *e.g.*, additives or contaminants in foods. Accordingly, we consider that the second purpose of Regulation 258/97 falls outside the scope of Annex A(1).

"nutritionally disadvantageous"

7.413 The third purpose of Regulation 258/97 is to ensure that novel foods, including foods containing or consisting of GMOs, not differ from foods which they are intended to replace to such an extent that their normal consumption would be "nutritionally disadvantageous" for the consumer. We recall that the first purpose of Regulation 258/97 is to prevent novel foods from presenting a "danger" for the consumer. We have to assume, therefore, that the concept of "danger for the consumer", which we have said is linked to the protection of the life or health of the consumer, is distinct and separate from the concept of "nutritional disadvantage for the consumer". Indeed, conceptually, it makes sense to distinguish the two situations. The normal consumption of a novel food may be nutritionally disadvantageous for the consumer if it does not provide the body with nutrients in the right quantity or of the right quality. This fact alone would not mean, however, that the relevant novel food would present a danger for the consumer. To consider a hypothetical example, if oranges were to be genetically modified in such a way that they contained greatly reduced levels of Vitamin C, presumably juice produced from these oranges would likewise be a poor source of Vitamin C. Consumers who normally drank orange juice as an important source of Vitamin C in their diet might be nutritionally disadvantaged if they consumed juice from the genetically modified, low Vitamin C, oranges. However, this nutritional disadvantage could be rectified through the consumption of another source of Vitamin C. Based on these considerations, we are not convinced that the requirement that novel foods not be nutritionally disadvantageous for consumers is intended, as such, to protect the life or health of consumers.

[543] We do not mean to suggest that the absence of information about the presence of a GMO would necessarily lead to consumers being misled. Rather, our statement concerns the reasons for which we consider the European Communities is applying the identification requirement contained in Regulation 258/97.

7.414 The Panel recalls that, Annex A(1)(b) brings within the scope of the *SPS Agreement* measures applied "to protect human [...] life or health [...] from risks arising from additives, contaminants, toxins or disease-causing organisms in foods [...]". We have indicated that, in our view, the requirement in Regulation 258/97 that novel foods not be nutritionally disadvantageous for the consumer is not applied, as such, to protect "human life or health". Therefore, to the extent that Regulation 258/97 is applied to ensure that novel foods are not nutritionally disadvantageous for the consumer, we think it cannot be considered a measure applied to protect the life or health of consumers from risks arising from, *e.g.*, additives or contaminants. In other words, we consider that the third purpose of Regulation 258/97 is not covered by Annex A(1).

Conclusions with respect to the purpose of Regulation 258/97

7.415 In our analysis above, we have identified and considered each of the three separate and independent purposes for which Regulation 258/97 is applied. We have determined that to the extent the Regulation seeks to achieve the first of the three purposes – *i.e.*, ensuring that novel foods not present a danger for the consumer – it may be considered as a measure which is applied for the purpose identified in Annex A(1)(b). In other words, we consider that the first purpose of Regulation 258/97 meets the purpose element of the definition of the term "SPS measure".[544]

7.416 On the other hand, to the extent Regulation 258/97 is applied to achieve the second and third purposes – *i.e.*, ensuring that novel foods not mislead the consumer, and that they not be nutritionally disadvantageous for the consumer – it is not a measure applied for one of the purposes mentioned in Annex A(1). To that extent, the Regulation does not meet the purpose element of the definition of the term "SPS measure". Since the Regulation does not meet one of the constitutive elements of the definition of the term "SPS measure", it follows that Regulation 258/97 is not an SPS measure within the meaning of Annex A(1) to the extent it is applied to ensure either that novel foods not mislead the consumer or that they not be nutritionally disadvantageous for the consumer.

(c) Whether the EC approval procedures are SPS measures in terms of their form and by their nature

7.417 We now turn to analyse whether Directives 90/220 and 2001/18 as well as Regulation 258/97 are "SPS measures" in terms of their form and by their nature.

7.418 The **United States** argues that Directives 90/220 and 2001/18, as well as Regulation 258/97, are "approval procedures" under the *SPS Agreement*. Annex C to the *SPS Agreement* defines "approval procedures", as including, *inter alia*, "procedures for sampling, testing and certification". Because biotech products must be approved before they can be placed on the market,[545] the procedures are analogous to the types of procedures specifically articulated in Annex C, *e.g.*, procedures for certification. As such, the procedures fall within the definition of "approval procedures" provided for under the Annex. *Second*, these procedures are imposed to "ensure" that the requirements of the European Communities' approval legislation for biotech products are met. *Third*, the European Communities' approval legislation is a "sanitary or phytosanitary measure" as defined in Annex A(1) of the *SPS Agreement* because it is applied for the purpose of protecting human, animal, or plant life or health or preventing or limiting other damage within the territory of the Member from certain enumerated risks in Annex A.

[544] We note that we have yet to analyze whether Regulation 258/97 meets the other definitional elements of the term "SPS measure".

[545] *See* Articles 6(8) and 19(2) of Directive 2001/18; Articles 6(4) and 11(5) of Directive 90/220; Article 4(2) of Regulation 258/97.