

***European Communities – Measures Affecting the Approval and  
Marketing of Biotech Products***

***(DS291, DS292, DS293)***

***Second Written Submission  
by the European Communities***

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**Table of cases cited in this submission**

<b>Short Title</b>	<b>Full Case Title and Citation</b>
<i>Argentina – Textiles and Apparel</i>	Panel Report, <i>Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items</i> , WT/DS56/R, adopted 22 April 1998, as modified by the Appellate Body Report, WT/DS56/AB/R, DSR 1998:III, 1033
<i>Chile – Price Band System</i>	Appellate Body Report, <i>Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products</i> , WT/DS207/AB/R, adopted 23 October 2002
<i>EC – Asbestos</i>	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/AB/R, adopted 5 April 2001
<i>EC – Hormones</i>	Appellate Body Report, <i>EC Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
<i>EC – Poultry</i>	Panel Report, <i>European Communities – Measures Affecting the Importation of Certain Poultry Products</i> , WT/DS69/R, adopted 23 July 1998, as modified by the Appellate Body Report, WT/DS69/AB/R, DSR 1998:V, 2089
<i>EC – Poultry</i>	Appellate Body Report, <i>European Communities – Measures Affecting the Importation of Certain Poultry Products</i> , WT/DS69/AB/R, adopted 23 July 1998, DSR 1998:V, 2031
<i>Japan – Agricultural Products II</i>	Appellate Body Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277
<i>Japan – Apples</i>	Appellate Body Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/AB/R, adopted 10 December 2003
<i>US – Certain EC Products</i>	Appellate Body Report, <i>United States – Import Measures on Certain Products from the European Communities</i> , WT/DS165/AB/R, adopted 10 January 2001
<i>US – Wool Shirts and Blouses</i>	Appellate Body Report, <i>United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India</i> , WT/DS33/AB/R and Corr.1, adopted 23 May 1997, DSR 1997:I, 323

**I. INTRODUCTION**

1. In this submission the European Communities responds to the arguments made by the Complainants in their first written submissions, their oral statements to the first meeting of the Panel and their answers to the questions of the Panel and of the European Communities. It is not the intention of the European Communities to repeat the arguments it has already set out and which it maintains in full.
2. The first two groups of claims made by the Complainants are cross-linked and many legal issues arising in this case are potentially relevant for several claims. Accordingly, the European Communities will first discuss the legal issues in general terms in Section II (Horizontal Issues) and then address each of the categories of claims brought by the Complainants (in Sections III – V). The factual issues that are contested between the parties will be discussed where relevant for the legal discussion.
3. The European Communities will not here summarise in full the legal and factual arguments which it makes in this Second Written Submission. Nevertheless, a few general points are in order.
4. First, the Communities cannot but be struck by the way in which the Complainants have sought to avoid engaging with the facts on the individual applications. Their case is based solely on the alleged existence of some general “moratorium.” If they are unable to persuade the Panel that such a “moratorium” exists, their entire case collapses. Yet they have not been able to identify a single act of the European Communities which reflects a decision to apply a moratorium. There is none. So their case necessarily turns on their ability to demonstrate that the totality of acts and omissions relating to the applications made between 1998 and 2003 amount, in some collective way, to a “moratorium.” The European Communities fails to see how the Panel can decide whether these acts or omissions amount to a moratorium without assessing each one individually. The central point is that this case turns on the facts.

5. The European Communities will not at this stage go into detail with regard to all the factual issues that divide the parties. These will be addressed throughout this submission in the relevant sections. Nevertheless, it is appropriate to point out that there are sharp differences between the parties on the facts, and that these have to be decided by the Panel. Article 11 of the DSU states that it is a function of the panel to make “an objective assessment of the facts of the case.”
6. In these cases the factual issues assume very great significance. Any decision taken by the Panel could be taken as expressing a general view as to the merits or demerits of GMOs and GM products. The European Communities considers that this would be most unfortunate. For example, if the Panel were to proceed to identify the existence of a ‘moratorium’ without looking at the decisions and actions taken in relation to each application for authorisation it will, in effect, be taken as expressing the view that the reasons for seeking additional information, or determining the precise conditions to be attached to any authorisation, lack scientific or other justification. The Panel would be deciding that the scientific basis for the Communities’ change of legislation, or the new scientific understanding, or the new international developments, had no merit. In the European Communities’ view, the only way to avoid such a consequence must be for the Panel to consider each application on its own merits and in the context of its particular factual circumstances. That necessarily means assessing the scientific views which may have caused a delay in decision-making. And that must require an independent assessment of the scientific and technical facts. The European Communities addresses this issue in more detail in its submission of 22 July on the appointment of scientific and technical experts, in which it explains the reasons why it considers it to be imperative that the Panel not proceed without appointing such experts.
7. Second, the individual assessment of each application – including its timetable – necessarily requires a proper consideration of the scientific and technical issues which have been raised in relation to that application. This is why the Communities fails to understand how the Panel could proceed without independent expertise to assess the merits or demerits of the particular scientific or technical claims. In this regard, the Communities notes the contradictory position adopted

by the Complainants on various scientific and technical matters. This confirms the need for independent expertise. Such expertise touches on issues of fact and law: it is self-evident that the definition of a toxin or a contaminant, for example, in the *SPS Agreement* is both a matter of interpretation and a point on which scientific expertise is required.

8. Third, the Communities notes that each of the Complainants dips into other international instruments when it suits their purposes. This confirms that the issues faced by the Panel have to be taken in their broader context. That context includes other relevant international instruments, which reflect the view of the international community as to the appropriate way to proceed on decision-making in relation to GMOs and GM products. The European Communities submits that a failure by the Panel to have regard to this broader context will risk undermining the legitimacy of the WTO system. The Panel should therefore not accede to the Complainants arguments that this case may be decided in “clinical isolation” from the rules of public international law more generally.
9. As requested by the Panel, the European Communities will be making a separate identification of the scientific and technical nature that divide the parties in a separate submission on the terms of reference for scientific and technical experts on 22 July.

## **II. HORIZONTAL ISSUES**

### *A. Burden of Proof*

10. The first legal issue to which the European Communities wishes to draw the Panel’s attention is the burden of proof. The concept is a basic one which is relevant in all legal proceedings. In this case it is fundamental for the correct development and adjudication of the case. The decision as to which party has the burden of proving a fact or claim may appear straightforward. Actually, it is a delicate one and, in many previous instances, has been critical for the result of the case. In the current case, there has been no discussion so far of the issue of burden

of proof. However, as was evident both in the first written submissions and during the first meeting of the Panel with the parties, the parties strongly disagree on a number of factual and legal issues. Several of these issues are at the core of this dispute (existence of general moratorium, undue character of delays, etc.). One of the features of this case is that the Complainants seek to avoid the complex, difficult and controversial issues, and seek to obtain from the Panel a finding based on the assumption that the risks posed by all the GMOs and GM products that are the subject of these proceedings is clear and established, and that the only reason why they have not all been approved is that the European Communities has “suspended” its approval procedures and imposed a “moratorium.” The Complainants therefore deliberately do not discuss the risks posed by each of the products and do not describe the procedural activity that is going on in respect of each application. It has been left to the defendant to draw attention to these issues. But that does not mean that it has the burden of proof. It remains for the Complainants to prove in respect of each of the applications that the absence of risk has been established and that no useful further investigation into the risks is being undertaken.

11. The European Communities is sure that, when the Panel is called upon to deliver its ruling, it will decide correctly to whom to allocate the burden of proof and whether this has been fulfilled or not. However, in order to assist the Panel in this judgement, the European Communities will recall here the basic principles underlying the distribution of the burden of proof. In the sections below on the individual claims it will, where necessary, indicate with more precision the outstanding specific elements that a correct distribution of the burden of proof will have to take into account.
12. The case-law of panels and the Appellate Body on the issue of the burden of proof is consistent. It is clearly reflected in the *EC – Hormones* Appellate Body report, which states:

The initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that *prima facie* case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency.<sup>1</sup>

13. According to this statement at least two consequences can be established: first, the party that invokes the existence of a certain situation bears the burden of proving it; second, (and this appears somewhat less clear to the applicants) in order to shift the burden, a *prima facie* case must first be established.

14. It is clear and accepted by the Appellate Body in *US – Shirts and Blouses* that:

precisely how much and precisely what kind of evidence will be required to establish such a presumption will necessarily vary from measure to measure, provision to provision, and case to case.<sup>2</sup>

15. However, the establishment of the *prima facie* case cannot be reduced to a mere assertion of the existence of a situation, without further supporting evidence submitted by the party making the claims. This would go against the general rule expressed in *EC – Hormones* and is contrary to common sense, as pointed out by the Appellate Body in its *US – Shirts and Blouses* report:

we find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof.<sup>3</sup>

16. Finally, this approach establishes also the sequence that the Panel has to follow in its analysis: it is only when the *prima facie* case is made by one party that the burden of proof shifts to the other one; consequently, a panel has to verify first if the Complainants have established a *prima facie* case in relation to each of the their claims and only then can it move on to ascertain whether the other party has refuted it.

17. This was very clearly expressed in *EC – Hormones* where the Appellate Body stated that:

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<sup>1</sup> Appellate Body Report, *EC – Hormones*, para. 98.

<sup>2</sup> Appellate Body Report, *US – Wool Shirts and Blouses*, page 14.

the Panel should have begun the analysis of each legal provision by examining whether the United States and Canada had presented evidence and legal arguments sufficient to demonstrate that the EC measures were inconsistent with the obligations assumed by the European Communities under each Article of the *SPS Agreement* addressed by the Panel, i.e., Articles 3.1, 3.3, 5.1 and 5.5. Only after such a *prima facie* determination had been made by the Panel may the onus be shifted to the European Communities to bring forward evidence and arguments to disprove the complaining party's claim.<sup>4</sup>

18. In this case, almost all the evidence at the basis of the case has so far been provided by the European Communities. The European Communities has been and remains willing to respond to the Panel's requests for information and explanation. However, it wishes to stress that this cannot amount to a shift in the burden of proof (or more precisely of the burden of persuasion).
19. As shown below, the Complainants often try to support their claims on the basis of assertions alone. This approach can hardly be reconciled with the rules that discipline the burden of proof in WTO dispute settlement procedures. The Complainants have the burden of proof. If they fail to prove their claims (as so far they have), these must be dismissed.

*B. Risk Assessment and the role of Scientific Opinions*

20. The European Communities makes a number of points on the approach that the Complainants take to the concept of "risk assessment" and the role of scientific opinions in this case.

**1. The meaning of "risk assessment" in the *SPS Agreement***

21. As the European Communities explained in its responses to the questions from the Panel, the term "risk assessment" in the *SPS Agreement* has to be understood in the broad sense of "risk analysis" as defined by the Codex and other international instruments. Risk assessment therefore encompasses three different aspects: (1)

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<sup>3</sup> *Ibidem*, page 14.

<sup>4</sup> Appellate Body Report, *EC – Hormones*, para. 109.

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risk assessment in the narrow sense, i.e. as a “scientifically based process”<sup>5</sup>, and (2) risk management, and (3) risk communication.<sup>6</sup>

22. This conclusion follows from the definition of risk assessment given in paragraph 4 of Annex A to the *SPS Agreement*. It also follows from paragraphs 2 and 3 of Article 5 of the *SPS Agreement*, which state that

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

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

23. These provision make it clear that in making an assessment of the risks, Members are entitled, and indeed obliged (“Members shall”), to take into account not only scientific but also economic and regulatory considerations. The list of factors to be taken into account in making an “assessment of the risks” is not exhaustive.
24. On the basis of the replies given to question 48 (f) of the Panel, it would seem that Argentina takes the view that a positive risk assessment in the narrow sense will automatically lead to a market authorisation. Argentina does not seem to accept that risk management considerations may be part of an approval procedure. The European Communities considers that this is manifestly wrong in the light of the above arguments.
25. The United States and Canada, on the other hand, seem to agree that at least some risk management considerations must be taken into consideration in an approval

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<sup>5</sup> See European Communities’ response to question 2 of the Panel.

<sup>6</sup> Since the term “risk assessment” is used in the *SPS Agreement* in this wider sense, the European Communities will also use it in this sense in this submission (except where the context otherwise implies).

procedure. The United States applies a “necessity” requirement, although it does not explain what it means by this. Canada takes the position that management considerations may only apply with regard to risks that are identified based on relevant scientific evidence.<sup>7</sup>

26. The European Communities disagrees with Canada. It submits that the “necessity” of risk management (and risk communication) considerations must be assessed on the basis of a broader conception of relevant factors. Particular risks can only be assessed and potentially identified in the risk assessment process on the basis of the available scientific information *at the time of the assessment*. Scientific knowledge may not be sufficient to clearly identify the risk.<sup>8</sup> Moreover, risks may become known or relevant at a later stage, and only in the light of new scientific knowledge or information. In this way the precautionary approach (or principle) becomes highly relevant. It assists in addressing new products and new traits, where scientific understanding is still developing. Prudent governments as risk managers and regulators are entitled to develop and apply appropriate safeguards to protect citizens and the environment. They are entitled to adopt risk management options, for example an appropriate general surveillance scheme, which are able to detect and identify any negative impact that was unforeseen or unidentified in the initial process of risk assessment. This approach is entirely consistent with international developments.

## **2. Risk assessment and the role of scientific opinions**

27. The Complainants generally seek to rely on the theory that “favourable” scientific opinions of their own scientific committees inevitably mean that the European Communities is bound to authorize products. This position is flawed in a number of respects.

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<sup>7</sup> See Canada’s and the United States’ response to question 48 (f) of the Panel.

<sup>8</sup> For instance, the risk management option taken by the USDA to withdraw any trace, even present in minute amounts – less than 1% – of the Starlink product from the market, which has had tremendous negative economic impact – was said to be based on non compliance with the regulations (lack of consent to the use of the product as a food), not on an identified risk. There was still at the time an ongoing risk assessment process in relation to the Cry protein, but that risk management decision was merely based on non-compliance. It was not based on an identified risk – especially considering the minute amounts of the substance in some instances.

28. First, scientific opinions are part of the risk assessment in a narrow sense, i.e. the scientifically based process of (a) hazard identification (b) hazard characterisation (c) exposure assessment and (d) risk characterisation. As seen above, the risk assessment in the narrow sense is only one of three dimensions of the risk analysis/assessment in the wider sense, that a regulator bases its decision on. Risk management and risk communication considerations are assessed by the regulator itself and not by those who deliver the scientific opinion. Thus, the Complainants are effectively claiming that the European Communities should authorize GMOs and GM products after only an incomplete risk assessment. As regards Canada and the United States this position is clearly inconsistent with the above view that risk management considerations may enter the approval process.
29. The inconsistency may be explained by the fact that in North America, it is often the case that the same body is responsible for conducting an assessment of the risks and the preparation of the management options or final decision. This body therefore has responsibility for conducting the entire risk analysis (risk assessment, risk management and risk communication) and for formulating the measure. In the European Communities, by contrast, these functions are distributed between different and independent bodies that constantly interact (as explained by the European Communities in answer to question 86 from the Panel).
30. Second, scientific opinions are not binding. As explained elsewhere there are several scientific committees with different mandates and at different levels in the European Communities.<sup>9</sup> In case of scientific disagreement, the opinions of the EC scientific committees do not overrule other scientific opinions. There is no obligation in SPS law – or indeed in any WTO law – for a regulatory power to effectively delegate to a single scientific committee only. This becomes particularly relevant in a federal or quasi-federal regulatory context.
31. Third, scientific opinions are limited in scope and, therefore, often do not conclude the risk assessment process, even in a narrow sense. The science on GMOs being in constant evolution, new risk considerations sometimes arise spontaneously and

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<sup>9</sup> See European Communities' response to questions 17 and 86 of the Panel.

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change the scope of the risk assessment. As has been explained, in the period relevant to these proceedings, this has been the case.<sup>10</sup>

32. Therefore, being a process of complex interaction with multiple actors (several risk assessment bodies and several risk managers or regulators at “federal” and “sub-federal” level), the process of addressing risk/scientific issues, which are unresolved or new, may require the authorities to go back for a further assessment by an independent scientific body that had issued an earlier positive opinion, much later in the process of analysing a particular application.

*C. The SPS Agreement*

**1. The scope of the SPS Agreement**

33. The Complainants assert in general terms that all the matters before the Panel are within the scope of the *SPS Agreement*.<sup>11</sup> The European Communities has explained why it disagrees. In particular, it has explained in great detail why this is not the case, with supporting documentation by reference to (1) the scope of the *SPS Agreement*;<sup>12</sup> (2) the risks and matters before the panel (that is, the matters that were or are under scrutiny in the various authorisation procedures, or that motivated the Member State provisional measures);<sup>13</sup> (3) which of these risks and matters fall within the scope of the *SPS Agreement* and which do not, and why;<sup>14</sup> and (4) how to analyse measures or delays that fall partially within the scope of the *SPS Agreement* and partially outside it.<sup>15</sup> For the most part, with the exception of the points dealt with below, the Complainants have not responded at all to any of these detailed points. That is consistent with the Complainants’ misconceived “broad brush” attempt to focus exclusively on an alleged measure referred to as a

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<sup>10</sup> See factual part of the European Communities’ first written submission as well as its response to question 18 of the Panel.

<sup>11</sup> First written submission of the United States, paras 74 to 80, paras 134 and 135, paras 154 to 166; first written submission of Canada, paras 148 to 174, para 257, and paras 370 to 385; first written submission of Argentina, paras 36 to 63, paras 204 to 210, and paras 461 to 472.

<sup>12</sup> First written submission of the European Communities, paras 388 to 414.

<sup>13</sup> First written submission of the European Communities, paras 39 to 63 and paras 339 to 360.

<sup>14</sup> First written submission of the European Communities, paras 415 to 433 and 578.

“general moratorium”, but which does not exist, is not a measure, and is not definitive. The Complainants have decided for strategic reasons not to look at the facts in each individual case.

34. The European Communities will first respond to the various arguments made by the Complainants which seek to extend the scope of the *SPS Agreement* so that it covers all aspects of the matters before the Panel. It will then discuss the consequences of the mixed nature of the matters before the Panel.

(a) Exhaustive nature of Annex A.1, first para, *SPS Agreement*

35. The United States asserts that the list of risks or matters subject to the *SPS Agreement* is not exhaustive, referring to the word “include” in Annex A.1, second paragraph of the *SPS Agreement*.<sup>16</sup> That argument is easily rebutted. That paragraph concerns the scope of the *SPS Agreement* in terms of the form of the measure, not its material scope. The material scope of the *SPS Agreement* is determined by Annex A.1, first paragraph of the *SPS Agreement*. That provision does not contain the word “include.”

(b) Relevance of international standards

36. In determining the scope of the *SPS Agreement*, reference has been made to Codex Standard 192 (additive), Codex Standard 193 (contaminant, toxin), the IOE definition of disease, and the IPPC definition of pest. The Complainants are inconsistent among themselves, and individual Complainants are internally inconsistent. They rely on the definitions in other international instruments when it suits their case. When those definitions are inconvenient, however, they assert that the “common and ordinary” meaning of the words in the *SPS Agreement* should prevail, without reference to other international instruments. This is totally unacceptable. It is generally asserted that there are no binding international law

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<sup>15</sup> First written submission of the European Communities, paras 434 to 452. See also generally first oral statement of the European Communities, paras 45 to 49.

<sup>16</sup> First oral statement of the United States, para 40.

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- instruments of relevance to this dispute, with the possible exception of the IPPC.<sup>17</sup> Codex Standard 193 is said to be “informative” but not “determinative”<sup>18</sup>, and not to “necessarily govern” the interpretation of the *SPS Agreement*.<sup>19</sup> The IPPC definition of pest is said to be relevant but not dispositive.<sup>20</sup>
37. The European Communities considers that the “common and ordinary” meaning approach advocated, in some instances, by the Complainants, to the exclusion of the international definitions, would not be sufficient. The Panel should look to the international definitions. The Complainants’ attempts to interpret the various relevant terms by reference to one or other meaning indicated in one or other dictionary will not assist at arriving at an agreed result. It is perverse given the availability of the international definitions.
38. The meaning of the word “contaminants” in the *SPS Agreement* provides an illustration. The European Communities recalls that there are several references to the Codex in the *SPS Agreement*.<sup>21</sup> In particular, Article 3(3) *SPS Agreement* contains an express and clear obligation on Members (there must be scientific justification) applying measures which result in a higher level of protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations. These are defined in the *SPS Agreement* as including the Codex.<sup>22</sup> The Codex definition of contaminant is a “standard” (Codex Standard 193, rev 1, 1995) within the meaning of the Codex and thus also the *SPS Agreement*. It necessarily follows – and the Complainants cannot seriously dispute this point - that at least for the purposes of Article 3(3) *SPS Agreement*, Codex Standard 193 is effectively incorporated by reference into the *SPS Agreement*, being part of an express obligation binding all WTO Members. In other words, for the purposes of Article 3(3) *SPS Agreement*, Codex Standard 193 determines the content of an obligation that binds WTO Members, as if it were written into the *SPS Agreement*.

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<sup>17</sup> Complainants’ response to question 4 of the Panel.

<sup>18</sup> United States’ response to question 3 of the Panel.

<sup>19</sup> United States’ response to question 27 of the Panel.

<sup>20</sup> United States’ response to questions 32 and 34 of the Panel.

<sup>21</sup> *SPS Agreement*: sixth recital; Article 3(4); 12(3); Annex A.3(a).

<sup>22</sup> *SPS Agreement*, Annex A.3(a).

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39. In these circumstances, the European Communities considers that Codex Standard 193 cannot be ignored for the purposes of determining the scope of the *SPS Agreement*. First, if that would be so, it would allow a Member, otherwise caught by the obligation in Article 3(3) of the *SPS Agreement*, to easily avoid that obligation, taking its measure outside the scope of the *SPS Agreement* by simply re-defining the concept of “contaminant” more narrowly. That would not be consistent with the object and purpose of the relevant provisions. Second, there is a very strong interrelationship between Annex A.1 *SPS Agreement* and Codex Standard 193, both provisions setting out definitions or standards (which are very similar types of provision<sup>23</sup>). There must be a strong presumption that the word “contaminant” used in the definition or standard set out in Annex A.1 *SPS Agreement* has the same meaning as the word “contaminant” used in the Codex definition or standard expressly integrated by reference into the text of Article 3(3) *SPS Agreement*. Third, strong contextual support for that view is provided by the sixth recital of the *SPS Agreement*, according to which one of the objectives of the *SPS Agreement* is to further the use of, *inter alia*, Codex standards, including Codex Standard 193. Fourth, further strong contextual support is provided by Article 12(3) *SPS Agreement*, which refers to the objective of securing from, *inter alia*, the Codex, the best available scientific and technical advice for the administration of the *SPS Agreement*, in order to ensure unnecessary duplication of effort. It may fairly be presumed that, in Codex Standard 193, the Codex has already formulated and articulated its best scientific and technical advice as regards the definition of the concept “contaminant.” Fifth, all the Complainants agree about the relevance of the IPPC definition of pests, without explaining why the position should be any different as regards the Codex.<sup>24</sup> For all these reasons, the European Communities disagrees with the United States assertion that the Codex is irrelevant for the purposes of interpreting the *SPS Agreement*.
40. The European Communities takes the same position in relation to the other international standards referred to.

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<sup>23</sup> Canada agrees that Codex Standard 193 contains a definition – see Canada’s response to the Panel’s questions, para 40.

<sup>24</sup> See generally the Parties’ response to question 32 of the Panel.

(c) Additives

41. The Panel should reject the United States assertion that antibiotic resistance genes are additives.<sup>25</sup> That does not correspond to the normal meaning of the word additive, as it is used, for example, in the Codex. According to the Codex definition, an additive is a substance which is added to “food.” The United States attempts to stretch the interpretation of the term “additive” in order to cover also “substances” which are “added” to “plants” (including for reasons that are totally unrelated to any sought characteristics of food) and which may find their way into “food.” The approach of the United States contradicts the universally accepted definition of “additive” and would result in an undue expansion of such concept. Furthermore, the United States proposed definition of “additive” would encompass any gene, whether introduced by recombinant DNA technology or by conventional breeding. In addition, genes are not “substances” within the meaning of Codex Standard 192, they are instructions for the creation of substances.

(d) Contaminants

42. The Complainants disagree amongst themselves as to the correct meaning of the word “contaminants” in the Codex and in Annex A.1 (b) of the *SPS Agreement*. They also disagree on whether or not a foreign gene in a GMO is a contaminant within the meaning of either of those provisions.<sup>26</sup> The United States admits that a foreign gene in a GMO is not a contaminant within the meaning of the Codex (it does not explain why), but does not answer the Panel’s question as regards the *SPS Agreement*. Canada, on the other hand, asserts that a foreign gene in a GMO could be a contaminant within the meaning of the Codex, but also does not answer the Panel’s question as regards the *SPS Agreement*. Argentina puts forward yet another view, asserting that a foreign gene is generally a contaminant within the meaning of both provisions. Only the European Communities has set out a detailed, plausible and true explanation : a foreign gene intentionally introduced into a plant through genetic modification techniques is not a contaminant within the meaning of either provision. The disarray of the Complainants on this point -

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<sup>25</sup> United States’ response to question 40 of the Panel.

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- and the paucity of their arguments - confirm that the position of the European Communities is the correct one. At any rate, in the opinion of the European Communities, it strongly indicates that the Panel would not be in a position to find against the European Communities without first seeking scientific or technical expert advice on this issue. The European Communities is certain that such advice would confirm its position.
43. As to the United States' suggestion that there is no special relationship between the definition of "contaminant" in Annex A.1 of the *SPS Agreement* and the Codex definition of "contaminant, the European Communities refers to its preceding observations in relation to international standards.
44. The Panel should reject Canada's assertions that the "unintended effects" of transgenes intentionally added to plants can lead to the characterisation of such transgenes as "contaminants. First, Canada offers no explanation of what it means by the term "unintended effects." Second, Codex Standard 193 is not concerned with what the effects of a contaminant might be. A contaminant might have many different types of effects, none of which are enumerated or considered in Codex Standard 193. Rather, Codex Standard 193 is concerned with defining what a contaminant is. Third, Annex A.1 *SPS Agreement* defines the scope of the *SPS Agreement* by reference to measures applied to protect against certain risks in connection with certain products, not by reference to "effects." The definitions in Annex A.1 cannot be made dependent on "effects" because that would turn the *SPS Agreement* on its head. The definitions are meant to be objective criteria to determine the material scope of SPS obligations, such as the requirement to base measures on a risk assessment. It is only after such assessment has been conducted, as required by the *SPS Agreement*, that the precise "effects" of a given substance will often become apparent. Fourth, what Canada actually appears to refer to is *undesirable* effects, not *unintended* effects. It is perfectly possible for an undesirable effect (or side effect) to be intentionally accepted, if considered justified by the primary objective. That does not render the effect unintentional or accidental in the sense indicated in the Codex definition of contaminant. Perhaps the first time a specific procedure is performed (the insertion of a foreign gene)

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<sup>26</sup> See generally the Parties' response to question 27 of the Panel.

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there might be some unanticipated side effect, which might, at that time, be described as “unintentional.” However, if the GMO is deliberately re-produced, indeed with a view to mass commercialisation, in the full knowledge of the side effect, that side effect can no longer be described as “unintentional.” There is a deliberate and intentional decision to promulgate the GMO, with the side effect included. This is confirmed by the United States in the context of the issue of antibiotic resistance, by the use of the word “intentionally.”<sup>27</sup>

45. The Panel should also reject Canada’s assertions concerning the phrase in Codex Standard 193 “as a result of the production ... of such food.” These words refer 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. In any event, these phrases do not enlarge the definition of the concept of “contaminant”, but rather restrict it, insofar as it is only substances present in food as a result of the operations enumerated in the definition that will be caught by the definition.

(e) Toxins

46. Similarly, the Complainants disagree amongst themselves on the meaning of the word “toxin” in Annex A.1 *SPS Agreement*.<sup>28</sup> The United States puts forward a wide definition (“any substance which, when introduced into or absorbed by a living organism, destroys life or injures health”), capable of encompassing, for example, a lead bullet. On this basis, the United States asserts that a food allergen is a toxin. Contradicting this, Canada states that a food allergen is not a toxin. Argentina’s position also differs: it asserts that the risks arising from food allergens and toxins are “comparable.” The European Communities fails to see how the Panel can disagree with the European Communities, and agree with the Complainants, at least without seeking scientific or technical expert advice, when the Complainants cannot even agree amongst themselves. The European Communities is confident that independent scientific or technical expert advice

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<sup>27</sup> United States’ response to question 40 of the Panel, at para 61.

will confirm that its position is the correct one. Furthermore, the European Communities continues to disagree with the proposition that Codex Standard 193 is irrelevant to the issue of what is a toxin.

47. The Complainants continue with the careless assumption that it would be sufficient for them to establish that the risk concerns a “toxin” for that risk to fall within the scope of the *SPS Agreement*. That is wrong as a matter of law. Annex A.1(b) of the *SPS Agreement* refers to toxins in foods, beverages and feedstuffs. Toxic characteristics of seeds or crops, or effects on non-target organisms, do not therefore fall within that provision, when the GMO does not fall within the concept of “food, beverage or feedstuff.”<sup>29</sup> The Complainants have not responded at all to this point. This observation applies with equal force to “additives” and “contaminants.”

(f) Diseases and disease-carrying or disease-causing organisms

48. Canada considers that allergens are not disease-causing organisms. The United States and Argentina do not reply to the Panel’s question on this point, and by their silence thus appear to agree with Canada.<sup>30</sup>
49. The outstanding disagreement between the parties in relation to the words “diseases, disease-carrying organisms or diseases-causing organisms” would thus appear to relate only to the issue of antibiotic resistance. This is dealt with below.

(g) Pests

50. The European Communities is pleased to note that Canada and, even more remarkably, in view of its general attitude to non-WTO texts, the United States, accept the relevance of the IPPC definition of “pests.”<sup>31</sup> The European Communities has also set out its views in answer to question 32 from the Panel but

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<sup>28</sup> See generally the Parties’ responses to questions 3 and 28 of the Panel.

<sup>29</sup> First written submission of the European Communities, para 398.

<sup>30</sup> See generally the Parties’ response to question 3 of the Panel.

<sup>31</sup> See responses to question 32 of the Panel.

- stresses two points for present purposes. First, a pest must be a living organism and cannot be simply modified DNA. Second, for an organism to be a pest, it must cause injury to plants.
51. Thus not any “undesirable cross-breed”, as the Panel put it in question 32, can be considered a pest. In particular a cross-breed that harms biodiversity is not a pest. Nor is cross-breed that harms micro-organisms, animals or the environment.
52. The Panel should reject the Complainants’ submissions concerning insecticidal resistance. The problem does not relate to the entry, establishment or spread of a pest, but rather to the genetic make-up of an existing pest, which is already present and established. It therefore falls outside the scope of the *SPS Agreement*.
53. The Complainants assert that the prejudicial effects of insecticidal GMO crops on non-target organisms means that such GMO crops are “pests”, and for that reason within the scope of Annex A.1(d) of the *SPS Agreement*.<sup>32</sup> The Panel should reject that assertion. In the context of such crops, the pest is the target insect, not the crop itself.

(h) Human, animal and plant life or health

54. The European Communities would point out that a measure can only fall within the defined scope of Annex A.1 if it is applied to protect human, animal or plant life or health. If the underlying concern falls outside the scope of that phrase, it does not fall within the *SPS Agreement*. The Complainants wrongly assume that all the concerns arising in the present case fall within the scope of the *SPS Agreement*, which is simply not true.
55. For example, the effects of the relevant GMO on non-living components in the environment, such as biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material, clearly fall outside the scope of the *SPS Agreement*. This is precisely one of the concerns indicated in the

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<sup>32</sup> See generally the Complainants’ response to question 77 of the Panel.

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- relevant EC GMO legislation,<sup>33</sup> and one which some Member States have referred to as requiring further assessment.
56. The same comment may be made with respect to micro-organisms or micro-flora which do not affect human, animal or plant life or health. They do not themselves fall into the category “human, animal or plant.” There are, for example, micro-organisms that are specialized in biophysical or biochemical processes in the soil, and which do not interfere with other superior organisms, but which are nevertheless part of the ecological equilibrium. To the extent that the introduction of GMO products would affect such micro-organisms, measures applied to protect against such risks do not fall within the defined scope of the *SPS Agreement*.
57. The negotiating history of the *SPS Agreement* confirms that it was intended to have a precisely limited scope. The earliest definitions of “SPS measure” were very general. They were refined as negotiations continued so as to limit the scope of the agreement.
58. Of particular note are the discussions that took place on whether environmental risks should be covered. Those that opposed this stressed that environmental risks were of a different nature and that rules designed for SPS measures would not necessarily be appropriate for environmental risks.<sup>34</sup> It would appear that this view ultimately prevailed. The *SPS Agreement* does *not* cover *all* measures aimed at the protection of human, animal or plant life or health. While early drafts included very broad and general language (e.g. Draft Agreement of 28 June 1990: “*Any measure relating to an agricultural product which is designed or operates to protect human, animal or plant life or health*”), later drafts introduced references to specific risks in order to better define the coverage of the agreement (e.g. Draft texts of October 1990). Eventually, the generic reference to the protection of life and health was dropped, and the scope of the agreement had to be determined

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<sup>33</sup> See, for example, Directive 2001/18/EC, section C2.1, sixth indent, and items II.A.11(f) and IV.B.15 in Annex IIIA, and D11 in Annex IIB.

<sup>34</sup> See, for example, 15 October 1990, Report by the Chairman of the SPS WG to the Negotiating Group on Agriculture (MTN.GNG/NG5/WGSP/6): “*In a handful of areas, however, distinct differences in views remain to be reconciled. These include: (a) Scope of the agreement – Should measures taken for the protection of animal welfare and of the environment, as well as of consumer interests and concerns, be defined as sanitary and phytosanitary measures and disciplined under this agreement ?*”

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exclusively on the basis of the specific risk situations identified in Annex 1 (cf. Draft text of November 1990: “*SPS measure - Any measure applied: [description of risks]*”).

59. The *SPS Agreement* does not cover measures for the protection of the environment *as such*, or based on consumer concerns, moral grounds etc.<sup>35</sup> There were intensive debates on this issue, and the negotiating history shows that in the end the majority views were accepted (that is, the *SPS Agreement* covers only the specific matters identified in the definitions).

(i) Antibiotic resistance

60. The Panel should reject the Complainants assertions on the question of antibiotic resistance.<sup>36</sup>
61. It should be stressed at the outset that the issue of antibiotic resistance is relevant both as regards human life or health, and animal or plant life or health. Therefore, these two aspects must both be analysed in turn.
62. With regard to human life or health, it is obvious that Annex A.1(a) *SPS Agreement* does not apply, because it concerns only animal or plant life or health.
63. On the other hand, Annex A.1(b) concerns human life or health, but only in connection with risks arising from additives, contaminants, toxins or disease-causing organisms in foods and beverages. The European Communities has explained at length why antibiotic marker genes are not “additives” within the meaning of Annex A.1(b) *SPS Agreement*. Otherwise, there are three important considerations that must be taken into account. First, the word “causing” is crucial for the interpretation of Annex A.1. The common and ordinary meaning of this provision is that there is a direct causal relationship between the object of the

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<sup>35</sup> The same conclusion is found in a GATT Secretariat’s Background Paper on the proposed Agreement on Sanitary and Phytosanitary Measures (16 April 1993): “*Measures for environmental protection, per se, or to protect the welfare of animals, are not covered by the proposed SPS Agreement. However, this in no way means that such measures are “GATT illegal”, but only that they are not considered as sanitary and phytosanitary measures subject to the rules of the proposed SPS Agreement.*”

<sup>36</sup> See generally the Complainants’ response to questions 40 and 41 of the Panel.

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measure and the disease. That required causal relationship is absent in the present case. The object of the measure is antibiotic resistance. Antibiotic resistance marker genes or, for that matter, food produced from genetically-modified plants containing antibiotic resistant markers, do not cause disease. The United States admits this, by arguing that even if antibiotic resistance marker genes do not cause disease, they “contribute” to the spread of disease. This is insufficient for the purposes of the *SPS Agreement*, which uses the word “causing.” Second, the antibiotic resistance issue is not limited to preserving the effectiveness of antibiotics *vis à vis* disease-causing organisms in foods, beverages or feedstuffs. The concern is much wider than that. Antibiotics are used to treat infections that originate other than from foods, beverages or feedstuffs. For this reason alone the risks are at least partly outside the scope of the *SPS Agreement*.<sup>37</sup> Third, the word “organism” (i.e. “disease-causing organism”) is problematic. The common and ordinary meaning of this provision is that it applies to measures that are directed against or at organisms. The measures in this case are directed at plant DNA. Plant DNA is not an organism.

64. Annex A.1(c) deals specifically with human life or health, but it concerns “animals, plants or products thereof” rather than risks arising from certain substances or organisms “in foods, beverages or feedstuffs.” As stated above, the issue of antibiotic resistance is not limited to preserving the effectiveness of antibiotics *vis à vis* disease-causing organisms in foods, beverages or feedstuffs, as antibiotics are used to treat infections that originate other than from foods, beverages or feedstuffs. Furthermore, antibiotic resistance may be developed through ways other than the uptake of food or feed by humans or animals. Indeed, it is recognised that an important factor may be the persistence of plant-derived DNA in the environment during crop cultivation and harvesting, and in soil residues. Therefore, there is concern about the development of antibiotic resistance in connection with “plants” as such. However, Annex A.1(c) is very clear in referring to situations where diseases are “carried by” plants, which is obviously not the case here as the GM plants containing antibiotic markers are not

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<sup>37</sup> The use of the word “foods” in the final sentence of para 101 of the United States response to question 77 from the Panel nicely illustrates the point, since that is a risk that is narrower than that actually under consideration.

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themselves the pathway of a disease. The Complainants do not even attempt to discuss this issue in their replies to the Panel's questions.

65. With regard to animal life or health, the analysis under Annex A.1(b) is unchanged. The words “diseases” and “disease-carrying organisms” in Annex A.1(a) do not alter the analysis – if the measures do not concern disease-causing organisms, still less do they concern diseases or disease-carrying organisms. It is not entirely clear whether or not the words “entry, establishment or spread” apply to the word “pests.” The grammatical structure of Annex A.1(a) suggests not. Such language is often used in relation to pests. That is how the words are used, for example, in Annex A.1(c) and (d) – and the words are absent from Annex A.1(b), which also refers to “disease-causing organisms.” Even assuming that the words “entry, establishment or spread” would also apply to the words “diseases, disease-carrying organisms or disease causing-organisms”, that would not alter the analysis, since the basic required causal link would still be missing. In any event, Annex A.1(a) does not apply to human life or health. For this reason alone, the overall conclusion must necessarily therefore remain the same: the antibiotic resistance issue must necessarily fall, at least in part, outside the defined scope of the *SPS Agreement*.

(j) Mixed acts

66. The question of how to deal with acts adopted in the municipal jurisdiction of a WTO Member that contain measures applied to protect against the risks defined in the *SPS Agreement*, as well as other measures, is an important threshold issue which the Panel will have to decide.<sup>38</sup> The Panel must consider this problem in a systematic and complete manner, following through the implications of the different lines of reasoning, because it has consequences for precisely what findings and recommendations the Panel could possibly make, or what any possible implementation could possibly involve. There are basically only two models: the “split” model; and the “monolithic” model.

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<sup>38</sup> See generally the Complainants' responses to question 49 of the Panel.

67. The Complainants disagree between themselves on what the right approach should be.<sup>39</sup> The United States appears to advocate the monolithic approach: if a measure falls partly under the *SPS Agreement*, a WTO Panel can limit its examination to that agreement and it must disregard all other aspects (and possible justifications) of the measure. By contrast, Canada considers the difference between the two models “semantic” and irrelevant to the issues before the Panel.
68. There is nothing in the *SPS Agreement* or in any other WTO Agreement that obliges the European Communities or any other Member to refrain from adopting in their domestic jurisdictions single acts, incorporating two or more measures regulated by more than one WTO Agreement or provision. The Complainants have invoked no WTO provision in this respect. This is the way in which the relevant Community legislation is structured, and the Complainants are at pains to insist that they do not attack that legislation “as such.” 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.
69. The Panel must reject the United States’ assertion that the European Communities has not explained how the Panel must trace the demarcation line. The European Communities has explained very clearly that the Panel must follow the precise definition contained in Annex A.1 of the *SPS Agreement*. To the extent that an act contains a measure applied to protect against the risks defined in Annex A.1 of the *SPS Agreement* it falls within the *SPS Agreement*; the rest falls outside the scope of the *SPS Agreement*. A final conclusion on such act as a whole can only be taken after examining all the relevant WTO provisions or agreements.
70. The Complainants disagree on the correct interpretation of Article 1.5 of the *TBT Agreement*. The United States and Argentina assert that it quite clearly resolves the issue. Canada asserts that it does not assist in resolving the issue. In the view of the European Communities, Article 1.5 of the *TBT Agreement* does not support the “monolithic” approach. It does not mean that an act that contains both an SPS measure and a TBT measure 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

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<sup>39</sup> See generally the Complainants’ responses to question 49 of the Panel.

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, in this model, there would appear to be no limitation as to the relationship between the two sets of considerations. 99 % of an act might be a TBT measure and 1 % 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. That cannot be right.

71. This is not what Article 1.5 of the *TBT Agreement* means. Rather, that provision is a jurisdictional conflict rule. The methods used to delimit the scopes of the *SPS Agreement* and the *TBT Agreement* are different. The scope of the *SPS Agreement* is defined in Annex A.1 by reference to measures applied to protect against certain enumerated risks. The scope of the *TBT Agreement* contains no such provision. As a consequence, it is perfectly possible to imagine a single measure that, at the same time, falls within the scope of the *SPS Agreement* and within the scope of the *TBT Agreement*. In that situation, Article 1.5 of the *TBT Agreement* means that such a measure falls to be considered only under the *SPS Agreement*. If the scope of the *TBT Agreement* would also have been defined by reference to measures applied to protect against certain enumerated risks – different from those under the *SPS Agreement* – then there would have been no need for such a conflict rule, other than to deal with residual ambiguity in the drafting. This 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*.
72. In a sense, the key issue is what constitutes a “measure.” In the opinion of the European Communities there are, typically, two key elements to a measure: the operative part and the explanation. The operative part of a measure is that part which “bites” – it contains the direction or instruction or rule, often formulated in mandatory language. The explanation contains the reasons for the measure. The WTO agreements typically contain provisions relating to the explanation or

reasons in a measure, and the *SPS Agreement* is no exception. This is common sense. These two elements in a measure cannot be considered in isolation. It is often impossible to assess whether or not a measure is consistent with the WTO without knowing the reasons why it is adopted or maintained. Consequently, the measure consists of both the operative part, and the reasons, *which form an inseparable whole*.

73. This observation applies with particular force in the context of the *SPS Agreement*, because the scope of the *SPS Agreement* is defined by reference to the *reasons* for which a measure is applied, not the effects of that measure. That is the approach adopted in the *SPS Agreement*, and all the Parties are bound by it as a matter of law.
74. We turn now to Canada’s assertion that the point is “purely semantic.” The European Communities does not agree. For ease of understanding one can consider the position in relation to a specific act, such as, for example, the Austrian marketing ban on the insecticidal maize Bt-176 (the same principles apply to all the matters before this Panel). We assume (as we must for the purposes of the discussion) that the Panel finds that this act is maintained for reasons that fall partly within the scope of the *SPS Agreement* (such as the risk to human health from increased use of insecticides and the consequent presence of residues in food or beverages), and partly for other reasons (such as the antibiotic resistance issue), which we assume, only for the sake of argument, is covered by the *TBT Agreement*.
75. In this situation, if what the Complainants seek is a finding that the prohibition on maize Bt-176 *is* an SPS measure, and the Panel would make such a finding, then the Panel would commit an error of law. The act is not itself an SPS measure. It contains or includes an SPS measure (i.e. a prohibition to protect against risks set out in Annex A.1(b) of the *SPS Agreement*). But it also contains or includes a TBT measure (i.e. a prohibition aimed at limiting the risk of emergence of antibiotic-resistant pathogens). To find that the TBT measure, because it is in the same act as an SPS measure, is itself transformed into an SPS measure, would be an error of reasoning and of law.

76. Thus, the most that the Panel could properly find, in this situation, is that the act *includes* an SPS measure. Assuming (only for the purposes of the present discussion) that the Panel then goes on to find that the SPS measure in the act is inconsistent with the *SPS Agreement*, then the Panel’s recommendation could only be that the European Communities take the measures necessary to bring the SPS measure in the act into conformity with the *SPS Agreement*. The Panel would not be in a position to lawfully make any recommendation in relation to the act as a whole, unless it has also considered and made findings in relation to the measures in the act that fall outside the scope of the *SPS Agreement*. Consequently, when it would come to implementation, the European Communities would be under an obligation to bring the SPS measure into conformity with the *SPS Agreement*, but not under any obligation to remove the *act*.
77. The European Communities has the impression that the Complainants’ objective is to rush this Panel into a generalised and imprecise set of findings and recommendations, which would raise serious questions in the context of implementation. Their arguments in relation to the so-called “general moratorium” are the best example. In their hasty rush to get there they would brush aside all the legal and scientific or technical issues – ducking the issues today – leaving the real problems unresolved (at least until the matter reaches the Appellate Body). For the Complainants, it seems that this Panel is merely a procedural inconvenience along the way.
78. The European Communities recalls that the function of this Panel is to make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements. It is also the function of the Panel to make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements. The Panel must consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution.<sup>40</sup>

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<sup>40</sup> DSU, Article 11.

79. The European Communities considers that the approach that Canada appears to have in mind would not be consistent with the function of this Panel. Although it is for the complaining party to decide what matter to place before a Panel, the Panel must make an objective assessment of that matter, also in the light of the facts and legal arguments placed before the Panel by the defending Member. That assessment includes the facts as well as the issues of what are the relevant agreements and whether or not they are applicable, and in conformity with the relevant agreements. The Panel must assist the parties in developing a mutually satisfactory solution. Putting off the key issues would not be a satisfactory solution.

## **2. Article 2 and Article 5.7 SPS Agreement**

80. Article 2.2 of the *SPS Agreement* contains an express cross-reference to Article 5.7 of the *SPS Agreement*. A cross-reference may be a technique of drafting economy, used to avoid unnecessary repetition, but it has material legal effects. The effect here is that the text of Article 5.7 is incorporated by reference into the text of Article 2.2. Articles 2.2 and 5.7 of the *SPS Agreement* must therefore be read together – placing one provision alongside the other. In fact, in order to grasp the correct interpretation, it is helpful to actually set out the text of the two provisions together :

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except [that]

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

81. By virtue of the incorporation by reference of the text of Article 5.7 into Article 2.2, the text of Article 5.7 is part of Article 2, which is entitled “Basic Rights and

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- Obligations.” Thus, read in the context of Article 2, the text in Article 5.7 of the *SPS Agreement* sets out basic rights and obligations, of equivalent status to the other basic rights and obligations set out in Article 2 of the *SPS Agreement*.
82. The comma after the word “evidence” in Article 2.2 of the *SPS Agreement* is significant. It means that the words that follow the comma exclude all of the words up to and including the word “evidence.” If the drafters had intended only to exclude the words “and is not maintained without sufficient scientific evidence” it would have been necessary for them to omit the comma – which they chose not to do. This is entirely logical. A concept of “necessity” is already referred to in Article 2.1 and is in any event built into the text of Article 5.7 of the *SPS Agreement*, because a Member may only act provisionally, and only on the basis of available pertinent information. If available pertinent information indicates the possibility of a breach of what a legislator considers an appropriate level of protection, as in the present case, then a provisional measure to preserve the situation would by definition be “necessary” within the meaning of Article 2.2 of the *SPS Agreement*. Similarly, provisional measures are based on scientific principles, because they are based on the need to allow sufficient time for sufficient scientific evidence to be collected.
83. The European Communities has explained why it considers the relationship between the text of Article 2.2 and the text of Article 5.7 to be one of exclusion, not exception,<sup>41</sup> particularly in the light of the Appellate Body’s jurisprudence, referred to by the Panel. The Complainants disagree among themselves on this point, and their arguments are confused and unclear. As the European Communities observed in its oral statement, the United States agrees with the European Communities, and the United States has not stated that it has changed its mind. Argentina agrees that the relationship is one of exclusion, but asserts that in order to establish exclusion the four substantive conditions of Article 5.7 must be met – a position that the European Communities considers logically incoherent. Whether or not a measure falls within the scope of the *SPS Agreement* does not

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<sup>41</sup> See generally the first written submission of the European Communities, paras 579 to 594; the European Communities’ response to question 110(c) of the Panel; and the Complainants’ response to question 50 of the Panel.

and cannot depend on whether or not it is consistent with one or other substantive provisions of that Agreement. The situation is no different as regards Article 5.7 of the *SPS Agreement*.

84. Canada asserts that Article 5.7 operates as an exception to Article 2.2 of the *SPS Agreement*, attempting to distinguish the present case from earlier cases decided by the Appellate Body on the grounds that there is no “conceptual similarity” and that those cases are “irrelevant.” The European Communities does not agree. Article 3.1 *SPS Agreement* refers to a level of protection based on international standards; Article 3.3 to a higher level of protection *if there is scientific justification*. The structure of these articles is thus conceptually similar to Articles 2.2 and 5.7 of the *SPS Agreement*, which refer to definitive measures, and provisional measures *if justified by the paucity of scientific evidence*. Just as the Appellate Body has found that the absence of scientific justification establishes an inconsistency with Article 3.3, and not that the relevant applicable provision becomes Article 3.1; so this Panel must conclude that *if it were true* that there is sufficient scientific evidence, the provisional measure in question would be inconsistent with Article 5.7, and not that Article 2.2 would become the relevant applicable provision. Precisely the same analysis applies with regard to Article 2.4 of the *TBT Agreement*, which is structured conceptually in the same way, referring to international standards, and to different standards *if justified according to the substantive conditions of Article 2.4*.
85. Having established that the relationship between Articles 2.2 and 5.7 of the *SPS Agreement* is one of exclusion, the final step is to identify the demarcation line. As the European Communities has explained, it considers that the demarcation line is between definitive and provisional measures, and would add the following to the comments it has already made.
86. First, the European Communities would draw the Panel’s attention to the Appellate Body Report in *Japan-Apples*, para 179, cited with approval by the United States, and particularly to the words :

The first requirement of Article 5.7 is that there must be insufficient scientific evidence. When a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether “relevant scientific evidence is insufficient.” (emphasis added)

87. These words clearly indicate that the exclusionary demarcation line between Articles 2.2 and 5.7 of the *SPS Agreement* is based on whether or not the measure is provisional. The Community legislation and the national implementing legislation, as well as the measures themselves, the Court of Justice of the European Communities, and even the Complainants state or claim that the measures are provisional. The European Communities agrees. The provisional nature of the measures must be motivated by the insufficiency of the scientific evidence, but that does not alter the fact that the defining characteristic of an Article 5.7 measure is that it is provisional.

88. Second, the European Communities would draw the Panel’s attention to the statement at para 89 in the Appellate Body Report in *Japan-Agricultural Products II*, repeated at para 176 of the Appellate Body Report in *Japan-Apples* :

Whenever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7.

89. The Appellate Body was referring, *inter alia*, to the requirement that “relevant scientific evidence is insufficient.” Thus, the Appellate Body has repeatedly stated that *if it were true* that relevant scientific evidence is sufficient, the consequence is that there is a breach of Article 5.7 of the *SPS Agreement*, not that Article 2.2 of the *SPS Agreement* somehow becomes the relevant provision. The Appellate Body has therefore repeatedly confirmed that the exclusionary demarcation line between Articles 2.2 and 5.7 of the *SPS Agreement* is *not* the sufficiency or insufficiency of scientific evidence.

90. Third, the European Communities would draw the Panel’s attention to the statement at para 89 in the Appellate Body Report in *Japan-Agricultural Products II* :

These four requirements are clearly cumulative in nature and are equally important for the purposes of determining consistency with this provision.

91. This statement confirms: (1) that the requirements are cumulative; and (2) that they are of equal importance and hence that no one of them has a special role to play in terms of the exclusionary demarcation line with Article 2.2; and (3) that these requirements are relevant to the question of consistency with Article 5.7, not to the question of the exclusionary demarcation line with Article 2.2.
92. Fourth, the European Communities would observe that provisional measures continue to be subject to the requirements of Article 2.3 of the *SPS Agreement*. They may not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members; and measures may not be applied in a manner that would constitute a disguised restriction on international trade.
93. Fifth, on the question of whether or not the Member State measures are provisional, Canada now states that this has been asserted but not demonstrated. Apart from the fact that the European Communities has no burden of proof in this respect, and the fact that Canada offers no evidence or even assertion to the contrary, this is simply not true. The European Communities has explained in great detail, with supporting material, that the measures are provisional, in the light of the relevant Community and national legislation, the measures themselves, the European Court of Justice, and even the Complainants' own statements. The European Communities is at a loss to understand why Canada believes that stating that something it has itself asserted or claimed has not in fact been demonstrated will advance its case.

### **3. Article 5.7 and the rest of Article 5 *SPS Agreement***

94. Once the text of Article 5.7 of the *SPS Agreement* is considered in the appropriate context, that being Article 2.2, into which it is incorporated by reference, under the title "Basic Rights and Obligations", as well as its place in Article 5, its relationship with the other provisions of Article 5 becomes clearer. Articles 5.1 to 5.6 of the *SPS Agreement* clearly apply, in accordance with the basic rights and obligations set out in Articles 2.2 and 2.3: a definitive measure, in circumstances where there is sufficient scientific evidence, based on a risk assessment, based on

an appropriate level of protection, applied consistently, and not more trade restrictive than required. Article 5.8 is a procedural provision of no consequence to the present discussion. As Canada itself has forcefully made the point, there is no logical or textual connection to be made between Article 5.7 and these provisions.<sup>42</sup>

95. In this respect, the European Communities would draw the attention of the Panel to the position within Article 5 of the provision relating to provisional measures (Article 5.7). This structure strongly supports the observations that the European Communities has already made concerning the relationship between Articles 2.2 and 5.7. The fact that Article 5.7 is positioned after Articles 5.1 to 5.6 of the *SPS Agreement* confirms its nature as a special regime applying specifically to provisional measures to the exclusion of Article 5.1 to 5.6. If it were to only exclude Article 5.1, one would expect it to come after Article 5.1.
96. In fact the conditions that would lead to a provisional measure being taken and the requirements that Article 5.7 imposes on them, render the terms of Articles 5.5 and 5.6 just as inappropriate for provisional measures as Article 5.1. Articles 5.2 and 5.3 make clear that the risk assessment and establishing the appropriate level of protection (that is, according to the definition in Annex A.4, the acceptable level of risk) go hand in hand. Until an acceptable level of risk has been established Articles 5.5 and 5.6 cannot apply.
97. The United States refers to a passage in the Appellate Body Report in *Japan-Apples* that confirms this analysis.<sup>43</sup> The Appellate Body, quite rightly, juxtaposed the provisions of Articles 5.1 and 5.7 of the *SPS Agreement*, observing that the concept of “insufficiency” in Article 5.7 must mean insufficient for the purposes of a risk assessment. This reflects the basic difference between the situation in which a definitive measure is adopted on the basis of a risk assessment and sufficient scientific evidence; and the situation in which a provisional measure is adopted. The same juxtaposition may be made between Articles 2.2 and 5.7 of the *SPS Agreement*.

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<sup>42</sup> Canada’s response to question 50(c) of the Panel, at para 115.

<sup>43</sup> United States’ response to question 50(a) of the Panel.

98. This does not mean that provisional measures are not subject to a full set of controls under the *SPS Agreement*. They must comply with the requirements of Article 5.7, as well as with Articles 2.1, 2.3 and 2.4 of the *SPS Agreement*, with which Article 5.7 has equal status. In fact, these provisions contain rules and obligations that are analogous to those set out in Articles 5.1 to 5.6, adapted appropriately to the provisional measures scenario.
99. Thus, Article 5.1 requires an assessment, as does Article 5.7, first sentence; Article 5.1 refers to human, animal or plant life or health, as does Article 5.7, *via* the reference to the term “sanitary or phytosanitary measures” defined in Annex A.1; Articles 5.1 and 5.7 both refer to international standards; Articles 5.2 and 5.3 sets out certain matters that must be taken into account in a risk assessment, the equivalent phrase in Article 5.7 being “available pertinent information”; the consistency requirements of Article 5.5 have an equivalent in the first sentence of Article 2.3; and the trade effect rules in Article 5.4 and 5.6 have an equivalent in the word “necessary” in Article 2.1 and in the second sentence of Article 2.3. Tracing these relationships, it becomes clear that there are two “parallel universes”, one for definitive measures and the other for provisional measures, but each of which follows the same basic structure and contains an equivalent gamut of rules – adapted according to whether the circumstances involve a definitive measure or a provisional measure.

#### **4. Article 5.1 SPS Agreement**

100. In the light of the preceding remarks, it may be confirmed, as the European Communities has already explained, that Article 5.1 of the *SPS Agreement* is not relevant to this case: provisional or temporary measures fall to be considered under Article 5.7 of the *SPS Agreement*; and delays are to be considered in accordance with Annex C.
101. Even if Article 5.1 would be considered relevant, the European Communities would draw the Panel’s attention to the words “as appropriate to the circumstances.” As the European Communities has explained, and as the Appellate Body has confirmed, those words indicate an important degree of flexibility,

whether in relation to the Member State measures, or in relation to the alleged product specific delays.

102. In truth, in relation to the alleged product specific delays, there is no “measure” within the meaning of Article 5.1. If anything, the “measure” that blocks the relevant GMO products for the time being is the EC GMO legislation itself, insofar as it requires products to obtain authorisation before commercialisation. The Complainants have not attacked that legislation “as such.” In any event, that legislation does provide for risk assessments, taking into account risk assessment techniques developed by the relevant international organisations (the Complainants have not alleged otherwise), and that is precisely the process in which the European Communities is currently engaged.
103. Finally, the European Communities would recall once again that, contrary to what the Complainants appear to believe, the obligation under Article 5.1 of the *SPS Agreement* is only that measures be “based on” an assessment. This does not mean that the assessment itself necessarily automatically dictates the terms of the legislative measure to be adopted. Just because there is an obligation, if a measure is adopted, to base that measure on a risk assessment, it does not necessarily follow that, following a first risk assessment, a legislative measure, identical to what is contained in the risk assessment, must immediately and automatically be adopted. This would fundamentally change the nature of the obligation set out in Article 5.1.

## **5. Article 5.5 SPS Agreement**

104. The European Communities has explained in detail why it considers that Article 5.5 is not relevant to this case: delays fall to be assessed under Annex C of the *SPS Agreement* and provisional measures (whether the Member State measures or the alleged temporary “standstill or moratoria” - which do not in fact exist) under Article 5.7 (see the preceding comments on the relationship between Articles 5.7 and the rest of Article 5). Naturally, this does not mean that a Member is entitled to behave in an arbitrary or unjustified manner – Article 2.3 of the *SPS Agreement* provides the necessary discipline in this respect.

105. Indeed, the rule in Article 2.3 of the *SPS Agreement* is sufficiently sophisticated to regulate the relatively straightforward matter of whether or not to adopt or maintain provisional measures. In this respect, the European Communities has explained that in circumstances where the problem relates to a matter which is unknown, a typical legislative reaction may be a temporary or provisional ban on imports or marketing. Under the Community system, like that of many other Members, in the absence of an authorisation the relevant product cannot be lawfully imported or marketed. As long as there is delay, there is no authorisation. The Member State safeguard measures also consist of provisional import or marketing bans. In short, the situation is essentially binary – either there is an authorisation or, for the time being, there is not. The rule in Article 2.3 of the *SPS Agreement* is sufficiently sophisticated to regulate that relatively simple dichotomy.
106. The Complainants accept that under the *SPS Agreement* it is permissible for a Member State of the European Communities to have a different level of protection compared to that applying elsewhere in the European Communities.<sup>44</sup> The Complainants are wrong however, when they assert that, in the context of the safeguard measures, the Member States are applying the same level of protection as at Community level. They are applying a level of protection that reflects their own particular circumstances. Whether that is compatible with Community law is irrelevant to the matter before this Panel. The Complainants recognise this. Contrary to what Argentina asserts, the fact that the Member States are applying a higher level of protection was made clear in the first written submission of the European Communities.
107. In any event, in the context of Article 5.5 of the *SPS Agreement*, WTO Members must necessarily enjoy more flexibility in cases where they lack the elements to assess the nature or the extent of a risk. Indeed, a comparison with other situations – something which is at the heart of Article 5.5 of the *SPS Agreement* - becomes more difficult if each situation cannot be precisely defined or evaluated. Thus, in these circumstances, consistency with Article 5.5 of the *SPS Agreement* can only

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<sup>44</sup> See the Complainants' response to question 38(b) of the Panel.

be considered taking into account the degree of flexibility that must necessarily be present in that provision.

## **6. Article 5.6 SPS Agreement**

108. The European Communities has explained in detail why it considers that Article 5.6 is not relevant to this case: delays fall to be assessed under Annex C of the *SPS Agreement* and provisional measures under Article 5.7 (see the preceding comments on the relationship between Articles 5.7 and the rest of Article 5). This does not mean that a Member is entitled to adopt a measure that is more trade restrictive than necessary – Articles 2.1 and 2.3 of the *SPS Agreement* regulate that point.

109. In any event, as in the case for Article 5.5 of the *SPS Agreement*, WTO Members enjoy more flexibility in cases where they lack the elements to assess the nature or the extent of a risk. Indeed, it is difficult to calibrate a measure if the extent of the risks or the availability or effectiveness of protection measures remains unclear. Consequently, “least trade-restrictiveness” can only be considered in a manner that takes into account such flexibility. In any event, the European Communities would stress that the only argument of the Complainants is that authorisation of the GMOs would be a less restrictive alternative - but this point is entirely linked to the issues of risk and the level of acceptable risk.

## **7. Article 5.7 SPS Agreement**

110. The Complainants assert that there is no relationship between the acceptable level of risk - or the analogous concept in the context of provisional measures - on the one hand, and the question of whether or not relevant scientific evidence is insufficient on the other hand. The European Communities does not agree.

111. In the first place, it would be incorrect to suggest that the concept of the acceptable level of risk – or an analogous concept – is irrelevant to the interpretation and application of Article 5.7 of the *SPS Agreement*. As explained above, in the context of provisional measures, it may well be that a full risk assessment has yet

to be completed and that the level of acceptable risk has yet to be finally determined by the legislator. However, as the Appellate Body has pointed out, the concept of sufficiency in Article 5.7 is relational, and must therefore refer to the level of acceptable risk – or the analogous concept – that is, the matters of concern to the legislator.

112. Consider the case in which several Members are considering whether or not to admit to their territory, for the first time, a particular product, such as a certain type of apple. One recently published scientific opinion suggests, for the first time, that the apple may carry a disease that harms a certain type of pear when it is growing. A second recently published scientific opinion suggests that the apple does not carry the disease.
113. The different legislators in the different Members are confronted with the need to decide whether or not to authorise imports of the apple or adopt provisional measures. It is self-evident that their decisions will depend on the particular circumstances in which they find themselves. The potentially affected pear might not grow at all in one Member, for climatic reasons. In another Member the disease might already be widespread. Yet another Member might be the centre of origin of the pear. For another Member the pear might be a critical cash crop. And so on. On the basis of such factors, and others like them, Members will determine what their appropriate level of protection - or the analogous concept in the context of provisional measures - should be, and take a view on what measures are appropriate. For Members where the pear does not grow or the disease is widespread, the appropriate level of protection - or the analogous concept in the context of provisional measures - might be lower, provisional measures unjustified, and the science sufficient to justify authorisation. For Members which are the centre of origin of the pear or for which the pear is a critical cash crop, the appropriate level might be higher, and provisional measures justified, in the light of the insufficiency of the scientific evidence.
114. To put the point another way, science is essentially about measuring past fact and postulating about future risk. Insufficient scientific evidence means uncertainty, which in turn generates risk. It would be entirely artificial to suppose that there is

some kind of magic moment at which the available science become sufficient for *all purposes*. Rather, the actions of a legislator, whether definitive or provisional, in response to the available science, are a function of what that particular legislator is concerned about.

## **8. Article 2.3 SPS Agreement**

115. As the European Communities has explained, Article 2.3 of the *SPS Agreement* applies to measures, and is therefore irrelevant to any consideration of alleged delay.
116. Article 2.3 refers to a situation in which identical or similar conditions prevail between Members. The basic idea is that if a particular disease, for example, would be present in two exporting Members, the importing Member should treat them equally. The Complainants have not even alleged that identical or similar conditions prevail between their own territories and the territory of some other Member. Nor have they even alleged that the European Communities actually discriminates between WTO Members in respect of its treatment of GMOs. Nor have the Complainants alleged that any such discrimination would be arbitrary or unjustifiable. There is therefore no basis for any finding of a breach of Article 2.3 of the *SPS Agreement*. In any event, the European Communities deals with the GMO issue in an even-handed way, that does not discriminate between different WTO Members.
117. Article 2.3 of the *SPS Agreement* also refers to discrimination between the territory of the importing Member and that of other Members. The basic idea here is that if a disease, for example, would be present both in part of the territory of the importing Member, and on the territory of an exporting Member, the importing Member should respond to the risks arising without arbitrary or unjustifiable discrimination. Similarly, in relation to this provision, the Complainants have neither asserted nor established any inconsistency with the *SPS Agreement*. The fact that, within the European Communities, there may have been some temporary

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disagreements in the past, does not mean that the European Communities has done anything other than respond to the GMO risks in an even-handed way, that does not arbitrarily or unjustifiably discriminate *vis a vis* other WTO Members.

118. Article 2.3 of the *SPS Agreement* also states that measures should not be applied in a manner which would constitute a disguised restriction on international trade. As the European Communities has explained, the present case does not involve any disguised restriction on international trade. The present case concerns the ongoing general discussions within the European Communities about how to respond to the risks posed by GMOs, whatever their origin, any trade effects being entirely incidental. It is a basic right of the European Communities, pursuant to Article 2(1) of the *SPS Agreement*, to take sanitary and phytosanitary measures (and thus, if that provision would be considered relevant to delays, to delay), including anything necessary to ensure, definitively or provisionally, the appropriate level of protection determined by the relevant legislator

*D. The TBT Agreement*

119. The Complainants seem to attribute rather limited importance to the *TBT Agreement* in this dispute. They all assert that the Panel can resolve all the issues before it by reference only to the *SPS Agreement*. The United States has made no claim regarding the *TBT Agreement*.<sup>45</sup> Canada and Argentina have made no claim as regards the alleged general moratorium and the *TBT Agreement*; but have claimed, in the alternative, that the alleged product specific marketing delays are inconsistent with Articles 2.1, 2.2, (5.1.1 Argentina only), 5.1.2, 5.2.1 (and 5.2.2 Argentina only) of the *TBT Agreement*; and that the Member State measures are inconsistent with Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*.<sup>46</sup> The European Communities has explained that the Member State measures are not inconsistent with the *TBT Agreement*,<sup>47</sup> and in doing so has commented in general terms on the meaning of various provisions of that agreement, notably the concept

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<sup>45</sup> First written submission of the United States, footnote 156.

<sup>46</sup> First written submission of Canada, paras 322 to 367; and paras 473 to 505. First written submission of Argentina, paras 377 to 450; and paras 547 to 593.

<sup>47</sup> First written submission of the European Communities, paras 641 to 663.

of technical regulation. The European Communities also claims that the product specific applications do not give rise to any inconsistency with the *TBT Agreement*.

120. In this section the European Communities addresses various issues relating to the *TBT Agreement*, and responds to certain statements that have been made by Argentina and Canada which may be of relevance to the Panel’s analysis of the claims before it.

**1. The meaning of the term “technical regulation”**

121. The European Communities commented in its first written submission on the meaning of the term “technical regulation” in the *TBT Agreement*. In particular, it pointed out that the Member State measures are not technical regulations. However, the EC GMO legislation may be considered to be technical regulations within the meaning of the *TBT Agreement*. On this point, therefore, the European Communities agrees with the Complainants.
122. The observations of the European Communities in respect of Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*, as regards the safeguard measures, apply *mutatis mutandis* as regards the alleged product specific delays. The safeguard measures are not “technical regulations” within the meaning of the *TBT Agreement*. And the alleged product specific delays are also not “technical regulations” within the meaning of the *TBT Agreement*. This emerges particularly clearly from paras 325 to 330 of Canada’s first written submission. Having asserted that the alleged product specific delays are “technical regulations”, Canada proceeds to analyse whether or not they meet the requirements set out in the definition in the *TBT Agreement*. In doing so, however, Canada simply abandons any attempt to discuss the alleged “product specific marketing bans” themselves, and reverts instead to an analysis of the EC legislation (which it elsewhere categorically states it is not attacking “as such”). Changing the subject of the analysis half way through a legal argument renders that argument manifest nonsense. This is self-evident. Also, Canada’s responses to the Panel’s questions

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are illogical.<sup>48</sup> It is simply impossible to understand how an alleged delay – that is, silence or inaction – could lay down mandatory product characteristics, in the sense provided for in the *TBT Agreement*. As a consequence, Articles 2.1 and 2.2, which contain obligations concerning the technical regulation itself, do not apply to the product specific applications.

## **2. Article 2.1 *TBT Agreement* – the issue of likeness**

123. The European Communities has explained why it considers that Article 2.1 of the *TBT Agreement* could apply only to technical regulations, and that neither the Member State measures nor the alleged product specific delays are technical regulations. The Panel should therefore reject Canada’s claim that the European Communities has acted inconsistently with that provision.
124. The Panel should in any event reject the assertions made by Canada in its response to question 69 from the Panel and by Argentina in response to question 57 from the Panel. These Complainants do not attribute any meaning to the words “in respect of technical regulations”, and do not therefore put forward an acceptable interpretation of that provision. Once likeness is properly understood (as relating to products within the field of application of the technical regulation), it is clear that in the present case there is no less favourable treatment.
125. In any event, as the European Communities has explained elsewhere, GMOs and GM products are not like products to conventional products, and for this reason also the European Communities cannot be considered to have acted inconsistently with Article 2.1 of the *TBT Agreement*.

## **3. Article 2.2 *TBT Agreement***

126. The only thing capable of being a technical regulation in the present case is the general EC GMO legislation – neither the Member State measures nor the alleged general or specific “moratoria or “suspensions” are technical regulations. The general EC GMO legislation is not a matter before this Panel. It is only the

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<sup>48</sup> Canada’s responses to questions 10 and 65 of the Panel.

application of that legislation that might possibly be considered before the Panel. However, in this respect, the Complainants have not established that any *application* of the EC legislation – that is any authorisation or Member State safeguard measure – is more trade restrictive than necessary.

127. Canada argues that the “product specific marketing bans” are more trade restrictive than necessary. However, the prohibition on marketing, pending authorisation is the very essence of the GMO legislation – not an application of it. That is to say, before any application has even been filed or considered, the general legislation provisionally prohibits marketing without authorisation.
128. In truth, what the Complainants would actually have to establish in order to make their case is that the *delays* are more trade restrictive than necessary. In order to do that they would have to show that the European Communities has taken longer than necessary to conduct the investigations that it considers necessary. But this the Complainants do not do. By presenting the measures as a “product specific marketing ban” Canada is effectively trying to take a short cut, transforming what is in reality the provisional absence of a final decision into an alleged measure.
129. The Panel should reject Argentina’s assertion that there is an obligation to conduct a risk assessment under Article 2.2 of the *TBT Agreement*.<sup>49</sup> That provision refers to no such obligation. In any event, the European Communities is currently in the process of assessing the risks in order to decide whether to authorise these products. The European Communities fundamentally disagrees that it has been demonstrated that there is no risk associated with the relevant products.<sup>50</sup>
130. The European Communities does not agree with Canada and Argentina’s analysis of Article 2.2 of the *TBT Agreement*, which breaks that provision down into three components.<sup>51</sup> In particular, the European Communities does not agree with the gloss that these Complainants place on that provision, according to which the legitimate objective must actually be fulfilled. There is no such obligation in Article 2.2 of the *TBT Agreement*. According to the terms of that provision, it

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<sup>49</sup> First written submission of Argentina, para 407.

<sup>50</sup> First written submission of Argentina, para 408.

<sup>51</sup> First written submission of Canada, para 338; first written submission of Argentina, para 405.

would be sufficient if a measure would be adopted *in pursuit of* the fulfilment of a legitimate objective. Whether or not the objective is actually fulfilled in fact is irrelevant, provided that the measure contributes or is capable of contributing to that objective.

131. The Panel also should reject Canada’s assertion that :

the scientific opinions of the EC’s own experts indicate that the protection of “human health or safety, animal or plant life or health, or the environment” would have been achieved regardless of whether the measure had been put in place.<sup>52</sup>

132. The relevant opinions contain no such statement. Canada’s assertion fails to take into account the fact that the national legislators’ different appreciation of the appropriate level of protection (acceptable level of risk), or its equivalent in the context of provisional measures, may have been different from that of the Commission or the Council.

133. For similar reasons the Panel should reject the assertions made in paras 405 to 414 of Argentina’s first written submission. Contrary to what Argentina asserts, the European Communities is neither avoiding risk assessment, nor making decisions not based on a risk assessment. It is in the process of considering the pending applications. Furthermore, Article 2.2 of the *TBT Agreement* does not even use the precise words “risk assessment.” In any event, the relevant scientific opinions do not contain the statements presented by Argentina. They do no more than reflect the questions posed at the time, and are themselves qualified in a number of respects. Those opinions may or may not be sufficient for the Commission or the Council, and may at the same time be insufficient for the Member States. There is no “absolute ban” – the applications are still pending.

#### **4. The meaning of “conformity assessment procedure”**

134. The European Communities does not agree with the assumption by Canada and Argentina that the EC GMO legislation constitutes a conformity assessment procedure, and thus that its application is subject to Article 5 of the *TBT*

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<sup>52</sup> First written submission of Canada, para 345.

*Agreement*. In the opinion of the European Communities a conformity assessment procedure does not exist where there is room for the exercise of discretion, or the weighing of complex and to some extent conflicting considerations. It rather relates to the situation in which precise criteria have already been laid down, and it is simply a question of verifying whether or not a specific product meets those objective and precise criteria (such as weight, dimension, material composition, strength, electrical resistance, and so on).

### **5. Article 5.1.1 TBT Agreement**

135. In the light of the preceding observations, the European Communities does not agree that Canada and Argentina have demonstrated the relevance of Article 5.1.1 of the *TBT Agreement*. Furthermore, the European Communities does not agree that the rule described in Article 5.1.1 of the *TBT Agreement* is necessarily identical to any rule set out in the *SPS Agreement*. Article 5.1.1 of the *TBT Agreement* is specifically concerned with the question of “access” to the system, whereas Article 2.3 of the *SPS Agreement* is rather concerned with the question of arbitrary or unjustifiable discrimination. In any event, there is no inconsistency with the provisions of Article 5.1.1 of the *TBT Agreement* in this case, since there has been no “less favourable treatment” of GMO products, within the meaning of that provision.

### **6. Article 5.1.2 TBT Agreement**

136. The European Communities agrees with Canada that the word “necessary” in Article 5.1.2 of the *TBT Agreement* is relational.<sup>53</sup> However, Canada does not draw the correct conclusion for this case. The European Communities does not agree that, in the circumstances of this case, there is any inconsistency with that provision.<sup>54</sup> Because authorisations sought by the applications that are the subject of this case are for the *release into the environment* of GMOs, the risks have a

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<sup>53</sup> First written submission of Canada, paras. 357 and 359 and responses by Canada to Panel’s question number 70, para 154.

<sup>54</sup> See Canada’s response to question 70 of the Panel.

character of irreversibility that makes a stricter approach necessary than would be the case for reversible risks.<sup>55</sup>

### **7. Article 5.2.1 TBT Agreement**

137. The European Communities does not agree with Canada and Argentina’s interpretation of Article 5.2.1 of the *TBT Agreement* – and certainly does not agree that, in the circumstances of this case, there is any inconsistency with that provision. The words and phrases “as expeditiously as possible” and “without undue delay” are simply different. They have different context associated with them. And they are in agreements that have different objects and purposes, and different drafting histories. As abstract terms, it is not possible to simply assert that their meanings coincide in all respects, or that one term entirely covers the other. No doubt there may be an important degree of overlap between them, but that does not make them synonyms. On the contrary, one can only suppose that the drafters of the different agreements used different words and phrases for a reason. It is not possible to say whether or not one phrase is “stricter” than the other in all cases – the outcome in any specific case would depend on all the facts, and have to be considered on a case-by-case basis.

138. Besides, in this case both Canada and Argentina have failed to identify the exact meaning of “as expeditiously as possible.” And they have not discharged their burden of proving, with regard to the specific facts of each specific product application, any moment at which the European Communities has acted “as expeditiously as possible.”<sup>56</sup>

### **8. Article 5.2.2 TBT Agreement**

139. The European Communities does not agree with Argentina’s assertions concerning Article 5.2.2 of the *TBT Agreement*. Insofar as this provision applies at all (which is highly doubtful for the reasons already explained) the standard rules governing

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<sup>55</sup> See also the European Communities’ response to question 113 of the Panel.

<sup>56</sup> See, below, the detailed analysis of the Complainants’ factual claims with regard to each product-specific application, as well as the arguments on burden of proof (Sections III.A.1 and III.A.2(a)).

the processing period of authorisations are a matter of public record, and would be communicated to an applicant on request. Argentina has not demonstrated that any relevant application was not promptly examined; nor that any applicant has not been informed in a precise and complete manner of all deficiencies; nor that the results of any assessment have not been transmitted as soon as possible; nor that the competent authorities have done other than to proceed as far as practicable; nor that any applicant has not been informed of the stage of the procedure, upon request. In these circumstances, there is simply no basis for finding that the European Communities has acted inconsistently with this provision.

*E. The GATT 1994*

140. To the extent that the *SPS Agreement* and the *TBT Agreement* are not applicable to the risks or “measures” contested by the Complainants, their claims will fall to be considered under the GATT 1994. Also, as explained in its first written submission, the European Communities considers that Article XX GATT 1994 may in any event be relevant. However, as regards to the claims raised under the GATT 1994, Argentina and Canada have presented no new arguments since their First written submissions. As a consequence, the European Communities has nothing further to add on these issues.
141. It cannot avoid remarking, though, that several of the Panel’s questions deal with issues of a substantive and factual nature that are at the basis of any determination of “likeness” of GMO and non-GMO products.<sup>57</sup> The responses of the Complainants and of the European Communities to these questions differ substantially. As a consequence, the European Communities considers that, should the Panel wish to address the issue of “likeness” of GMO and non-GMO products, it could not do so without seeking the expert advice of scientists on these issues.
142. The European Communities will comment further on the specific scientific points which remain controversial in its submission of 22 July.

*F. WTO and other international agreements*

143. The European Communities maintains its position as set forth in its oral presentation and in its responses to the questions, that the Panel is bound to follow the approach set forth in *US-Shrimp*.<sup>58</sup> The Panel is required to interpret the relevant rules of WTO law consistently with other rules of international law that may be relevant to these proceedings. In response to Question 4 from the Panel the Communities set out its view that the 1992 Convention on Biological Diversity and its 2000 Biosafety Protocol “are relevant to this case”, and that the provisions of *inter alia* the Codex Alimentarius Commission and other equivalent standards are relevant to these proceedings as *inter alia* “international standards, guidelines and recommendations” within the meaning of Articles 3 and 5, Annex A point 3, of the *SPS Agreement* and Article 2 of the *TBT Agreement*.
144. The European Communities notes that in their answers to the Panel’s Question 4 none of the Complainants disavow the approach taken by the Appellate Body in *US-Shrimp*. However, they are then inconsistent in the consequences which follow. The United States concludes that there are no binding international law instruments which are relevant. However, it then appears to concede that the terms of the Codex may be relevant to interpretation of the *SPS Agreement*, in accordance with customary rules of international law (see response to Question 27 from the Panel). Even more inconsistently, it then relies on the definition of “pest” in the 1997 International Plant Protection Convention (at Article II(1)), a provision which it “does consider relevant in this context” (see response to Question 32 from the Panel, at para. 46). The United States also relies on the IPPC in its response to the Panel’s Questions 34 and 77. This indicates that the United States is entirely inconsistent in its approach, picking and choosing between those conventions which it likes or dislikes.
145. For its part, in response to Question 4, Canada seems to consider that the *International Plant Protection Convention, 1979* may be the only binding international law instrument relevant to this case. However, it then proceeds in

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<sup>57</sup> See questions 23-25, 30-31 of the Panel.

<sup>58</sup> See First written submission of the European Communities, paras. 453 et seq.

Question 27 to rely on the Codex in its construction of the *SPS Agreement*. Like the United States, there is no consistency in the position adopted by Canada. Both feel able to pick and choose amongst the various instruments unfettered by any generally applicable guiding principle of relevance or applicability.

146. As regards Argentina, in response to Question 4, it concludes that there are no binding international instruments which are relevant to the case. However, it too then accepts the relevance of the IPPC (see answer to Panel's Question 32), a position which is entirely consistent with the approach taken by the Appellate Body in *US-Shrimp*. The European Communities notes that Argentina does not argue that that decision of the Appellate Body was wrongly decided (see response to Question 2 of the European Communities to Argentina).

147. In summary, none of the Complainants disagrees with the approach taken by the Appellate Body in *US-Shrimp*. As regards the relevance and applicability of international instruments, they provide inconsistent answers as amongst themselves. Having proposed that no international instruments are relevant, Argentina and the United States proceed on the basis of the relevance of an international convention which is not yet in force where it suits their purposes. All three Complainants appear also to accept the relevance of the Codex. The European Communities considers that there is no objection on the part of any party to the application of the approach taken in *US-Shrimp*. This necessarily means that the Panel is free to consider the international instruments referred to by the European Communities.

#### *G. Mootness*

148. The European Communities notes that all parties agree, albeit for opposite reasons, that the issue of mootness is not relevant as regards the alleged moratorium. The Complainants claim that that measure is still in existence, while the European Communities states that it has never actually existed.

149. However, mootness is relevant for the product specific claims, where product applications have been withdrawn or have been decided after the establishment of

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the Panel.<sup>59</sup> The former is the case with regard to six of the products<sup>60</sup> that the Complainants have listed, the latter with regard to Bt 11 (Food Use) and, as of 20 July, with regard to NK 603 (Release into the Environment). The Complainants do not contest this.<sup>61</sup>

150. There is a necessity, therefore, to address the points of legal disagreement between the parties regarding mootness.
151. The European Communities has taken the view that if a measure is no longer in existence, the Panel should not rule on it.<sup>62</sup> The Complainants seem to adopt the opposite view and hold that the Panel should rule on such measures. Remarkably, the Complainants have made no attempt to explain why WTO Panels are prevented from applying a legal principle that is recognised in jurisdictions around the world and commonly applied by international tribunals, including the International Court of Justice. The European Communities firmly believes that the WTO dispute settlement system is *not* an exceptional case, a sort of “rara avis”, impermeable to the application of such a basic jurisdictional principle. It has discussed the relevant provisions of Article 3 of the DSU in support of its position. The European Communities believes that the first issue that the Panel should address is precisely this one: whether or not the WTO dispute settlement mechanism is in such way exceptional as to prevent the operation of “mootness.”
152. Furthermore, the Complainants’ position is not supported by the case law that the Complainants rely upon. Canada and Argentina refer to the case *Chile – Price Band System* which concerned a measure that was modified in the course of the proceedings.<sup>63</sup> The Appellate Body decided to look at the measure not as it was at

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<sup>59</sup> On the other hand, as has been pointed out in the European Communities’ response to question 7, where product applications were no longer pending before the Community authorities *at the time of the establishment of the panel*, the Complainants’ actions are simply inadmissible. There can be no Community decisions on those products, and this was true at the time of panel establishment, at the time of the consultations, and even before. Thus, the issue is not one of mootness, but one of lack of material object of the dispute *ab initio*.

<sup>60</sup> These are Monsanto Roundup Ready Corn GA 21 (C/ES/98/01), Monsanto MaisGuard & Roundup Ready MON810 & GA21 (C/ES/99/02), Monsanto/Syngenta Roundup Ready sugar beet (C/BE/99/01), Stoneville BXN cotton (C/ES/99/01), Bayer Liberty Link Soybean (Food Use) and Monsanto/Syngenta Roundup Ready sugar beet (Food Use).

<sup>61</sup> See European Communities’ response to question 7 of the Panel.

<sup>62</sup> *Ibidem*.

<sup>63</sup> See Complainants’ response to question 7 of the Panel.

the time of the establishment of the panel, but as it had been modified. It found that the modified measure came within the terms of reference of the panel because those terms identified the measure by including “regulations and complementary provisions and/or *amendments*” [emphasis added].<sup>64</sup> It is in order to support this decision that the Appellate Body quoted the need to “secure a positive solution to the dispute.” As is evident, the case is fundamentally different from the present case and does not offer any conclusion as regards the question of measures that cease to exist. If anything, it supports the view that the Panel, in order to secure a positive solution to the dispute, must take into account developments of the measure since the date of Panel establishment.

153. The United States refers to the case *India – Autos*. The panel, in that case, did indeed take the view that it would be entitled, on the basis of its terms of reference, to look at a measure that was not in existence any longer.<sup>65</sup> Significantly, however, the panel in *India - Autos* also made it clear that it would not make any recommendation in relation to expired measures. The panel stated

If only as a matter of logic, there can be no sense in making such a recommendation if a Panel is of the view that the violation at issue has ceased to exist when its recommendation is being made. [footnote omitted] The Panel does not believe that Articles 11 and 19 of the DSU should be interpreted to demand that a panel must make a formalistic statement that a measure needs to be brought into compliance when it is faced with factual and legal arguments that this is no longer the case and must do so without being entitled to resolve those contentions.<sup>66</sup>

154. The approach in that case is supported by the Appellate Body’s statement in *US – Certain EC Products*, where it observed that

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<sup>64</sup> Appellate Body Report *Chile – Price Band System*, at para. 135. Note also that the Appellate Body also emphasized the fact that all parties agreed to its approach. *Ibidem*, at para. 143 last sentence.

<sup>65</sup> However, following an examination of the facts, the panel reached the conclusion that the measure was still in existence. It based itself on the fact that “*while the framework governmental measure which initially led to the signature of the MOUs may have ceased to "operate", the MOUs themselves have remained in existence*”, and India had “*in particular confirmed that "it is not the intention of India to release the car manufacturers from the commitments they have assumed under the MOUs as a result of imports of SKD/CKD kits prior to 1 April 2001"*” (Report of the Panel, *India – Autos*, at para.7.28). Once again, therefore, the situation in that case was fundamentally different from the situation in the present case.

<sup>66</sup> Report of the Panel, *India – Autos*, para. 8.25.

there is an obvious inconsistency between the finding of the Panel that 'the 3 March Measure is no longer in existence' and the subsequent recommendation of the Panel that the DSB request that the United States bring its measure into conformity with its WTO obligations. The Panel erred in recommending that the DSB request the United States to bring into conformity with its WTO obligations a measure which the Panel has found no longer exists.<sup>67</sup>

155. The European Communities, therefore, submits, in the alternative, that in the unlikely event that the Panel were to decide that it should make findings on measures that are not longer in existence, it should not make any recommendations in respect of those measures.

### **III. THE COMPLAINANTS' CLAIMS**

#### *A. Product-specific delays*

156. The Complainants claim that there is a failure to apply the approval system in respect of a number of specific applications. They characterise this as a suspension. According to the Complainants, these acts constitute at the same time a violation of certain substantive provisions of the *SPS Agreement* and of its Article 8 and Annex C, as well as of provisions of the *TBT Agreement* and of the GATT.
157. The Complainants, however, have failed to identify for each and every product-specific application the instances in which this “failure to apply or suspension” has materialised. In the odd instances where they have chosen to address the facts, they do so on the basis of misrepresentation or omission of the facts, failing also to explain in cogent and clear terms the basis on which they conclude that such behaviour is contrary to WTO law. The Complainants proceed on the basis of general assertion unsupported by any serious analysis.
158. Thus, Argentina alleges that the delays in the processing of the applications/notifications result from the moratorium, but fails to specify what

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<sup>67</sup> Report of the Appellate Body, *US – Certain EC Products*, para. 81.

- exactly the delays are.<sup>68</sup> It prefers to refer constantly to a generic “suspension since 1998 of the approval procedures”, or to the treatment of “biotech products before and after 1998.”<sup>69</sup> At times, it limits itself to indicating the overall time elapsed for the consideration of the product-specific applications<sup>70</sup> or to providing limited comments on them.<sup>71</sup> Assertion is no substitute for analysis.
159. Canada alleges in general terms that “the *moratorium* has directly impeded the operation of the approval process for specific biotech products.”<sup>72</sup> However, it describes only in summary terms a number of developments in the product-specific applications at issue in this case, both in its first written submission<sup>73</sup> and in the table annexed to its replies to questions from the Panel.<sup>74</sup> In both cases it has not been able to identify any delay beyond the overall time which has passed in respect of consideration of these products. Its analysis then boils down to generalised assertions, claiming that “x” number of years are “excessive” or “patently excessive.”<sup>75</sup> This approach is totally unsatisfactory. With a broad brush the detailed consideration of individual products, and the associated scientific and risk-related concerns are swatted away without the benefit of any detailed review of the facts.
160. The United States’ account of the facts related to the product-specific applications is limited to a small number of paragraphs in its first written submission, which discuss the facts by categories of products,<sup>76</sup> and to the table annexed to its replies to questions from the Panel.<sup>77</sup> As with the other Complainants, the United States seeks to prove its claims on the product-specific applications by mere assertion that a *de facto* moratorium has been put in place.

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<sup>68</sup> See, for example, first written submission of Argentina, para. 313; Argentina’s response to question 46 of the Panel.

<sup>69</sup> First written submission of Argentina, Sections II.B and II.C.

<sup>70</sup> First written submission of Argentina, Section II.C.1.c.

<sup>71</sup> Oral statement of Argentina, Section IV.

<sup>72</sup> First written submission of Canada, para. 254.

<sup>73</sup> First written submission of Canada, Section III.C.

<sup>74</sup> See Canada’s response to question 47 of the Panel, table in Annex.

<sup>75</sup> First written submission of Canada, paras. 293-295.

<sup>76</sup> First written submission of the United States, paras. 48-56.

<sup>77</sup> See United States’ response to question 47 of the Panel, table in Annex I.

161. The Complainants' discussion of the legal claims is generic and disconnected from any analysis of the specific facts in specific cases. It is therefore necessary to revisit the facts. In this section the European Communities will proceed first to redress the few factual points discussed by the Complainants so far and then to examine the legal issues specifically linked to the product-specific applications.

**1. Factual issues**

(a) The individual product-specific applications/notifications

162. As mentioned, the Complainants provide only a few specific arguments in relation to a limited number of the product-specific applications which are at issue in this dispute. Of these, several concern applications that have been withdrawn or, as in the case of Bt11 and, as of 20 July 2004, of NK603, brought to a conclusion by way of approval. Claims concerning those applications are not properly before the Panel: if the withdrawals took place before the Panel was established, the Panel has no jurisdiction on them, if they took place subsequently they have become moot.<sup>78</sup> Therefore, the European Communities will make no further comment on them. They are outside the scope of this dispute. The European Communities will limit its rebuttal submission to the small number of individual applications which remain outstanding. It is the Communities' position that for all those products in respect of which no specific comments have been made, the Complainants consider that all time spans in the chronologies submitted by the European Communities do not constitute delay or, if they do, that they are justified.

*i) Bayer oilseed rape (FALCON GS40/90) – C/DE/96/05*

163. The United States is the only Complainant that has brought a claim with regard to the application for Bayer oilseed rape FALCON GS40/90. Its only factual allegation on this product is that the Commission "refused" or "failed" to submit a

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<sup>78</sup> See above para. 149.

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draft measure to the Regulatory Committee for a vote.<sup>79</sup> The United States is plainly mistaken.

164. As the chronology contained in Exhibit EC-062 clearly shows, the Commission launched a voting procedure in the Regulatory Committee on 29 June 1999. The Committee met twice on this dossier, on 29 October 1999 and on 9 March 2000. It did not vote because it came to the conclusion that further information was needed on the assessment of the effect of the newly expressed protein on the biogeochemical cycle and the food chain as well as the likelihood of spreading.<sup>80</sup> Soon after that, the applicant modified the scope of the notification. Since then, the application has proceeded with further submissions by the applicant of additional information. This information concerns *inter alia* the Stewardship program and analysis and consequent requests for clarification by the lead Competent Authority. The application has been dealt with on an entirely proper basis.

ii) *Bayer hybrid oilseed rape (MS8/RF3) – C/BE/96/01*<sup>81</sup>

165. Bayer hybrid oilseed rape (MS8/RF3) is within the terms of reference of both Canada and the United States.

166. Canada alleges a “7.5 year delay in processing the application”<sup>82</sup> and adds just a few more comments on specific steps of the procedures. In particular, Canada claims that:

- the product application was *not* put to a vote of the Regulatory Committee;
- there was “imposition” of the “interim approach” on the applicant.

167. The United States limits its factual allegations to the point that the Commission “refused” or “failed” to submit a draft measure to the Regulatory Committee for a vote.<sup>83</sup>

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<sup>79</sup> See, respectively, first written submission of the United States, para. 50; and United States’ response to question 47 of the Panel, table in Annex I.

<sup>80</sup> See also the further questions raised during the Regulatory Meeting by the Italian Competent Authority (Exhibit EC-062, attachment 24bis).

<sup>81</sup> See detailed chronology (Exhibit EC-63).

<sup>82</sup> See Canada’s response to question 47 of the Panel, table in Annex.

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168. The claims relating to the vote in the Regulatory Committee are plainly wrong. Both Canada and the United States fail to consider the submission of COM Decision XI/565/97-rev2 to the vote of the Regulatory Committee by written procedure, on 29 June 1999.<sup>84</sup> This voting procedure in the Regulatory Committee required extensive exchanges on the proposed Stewardship plan, as well as the updated environmental risk assessment, involving the Commission, the Member States, and the applicant through the lead Member State. This lasted for more than 6 months. The Committee then met with the applicant on 29 October 1999 and again to consider this dossier on 9 March 2000. It did not proceed to any vote because of the scientific issues raised by Italy with regard to “the effects of the transgenic product on the biogeochemical cycles and on food chains” and to outcrossing.<sup>85</sup>
169. As for the “imposition” of the “interim approach” on the applicant, Canada fails to mention that the applicant volunteered to meet the requirements of the revised EC legislation,<sup>86</sup> and submitted further information following requests by the Competent Authorities (for instance on 10 November 1999, 25 February 2000, 13 November 2000, 5 June 2001).
170. Furthermore, both Canada and the United States fail to address and comment on the numerous risk assessment and risk management issues that were discussed and advanced during this period and that are described and documented in the European Communities’ submissions. The initial issue of stewardship for post marketing guidance and monitoring was raised by the Scientific Committee for Plants in its initial recommendations, during the summer of 1999. Thereafter, further risk assessment and risk management issues remained to be fully addressed at the Community level, both in relation to the old rules and the new legislative developments.<sup>87</sup>

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<sup>83</sup> See, respectively, first written submission of the United States, para. 50; and United States’ response to question 47 of the Panel, table in Annex I.

<sup>84</sup> See chronology in Exhibit EC-063.

<sup>85</sup> Fax from the Italian Competent Authority of 14 March 2000 (Exhibit EC-063, attachment 21bis).

<sup>86</sup> Letter from PGS/AgrEvo of 3 August 1999 (Exhibit EC-063, attachment 18bis).

<sup>87</sup> In June 1999, the Council reached a political agreement on a common position for the new revised framework Directive, later to become Directive 2001/18/CE, on the basis of the European Parliament vote in first reading. This legislative intermediate agreement already introduced new issues to be

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171. To take just a few examples,<sup>88</sup> a significant amount of new information was provided by the applicant between August 1999 and January 2003 to cover issues which had been identified by the authorities as having been inadequately addressed in the application. These concerned issues such as traceability and labelling of the product, post market monitoring plans and management of long term herbicide resistance and environmental impact issues, and in particular, almost two years of exchanges with the applicant in order for it to develop and submit appropriate detection and identification methodologies, including availability of reference material. These are all proper risk assessment and risk management issues. Any disagreement on that point should be resolved by independent experts.
172. Another factor that the Complainants have chosen to ignore is that significant new risk information, which is fully relevant to this application and requires appropriate risk assessment and management considerations, has recently been made public. This new information relates to the impact of herbicide regimes associated with the cultivation of GM herbicide tolerant oilseed rape, on farmland biodiversity, and population dynamics and life cycles in the farming ecosystem (risk issues which obviously go beyond the scope of risk assessment under the *SPS Agreement*).<sup>89</sup>
173. The application is proceeding. Nevertheless, a number of risk management issues relevant for the authorities are still pending. These include agreed and harmonised methodologies for detection and identification of the product.

*iii) Trifolium/Monsanto/Danisco Roundup Ready fodder beet  
(A5/15) – C/DK/97/01*

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addressed in the forthcoming procedures, including on expanding the risk assessment scope, for instance on delayed or indirect impacts, or on agricultural practices, and on expanding risk management provision – compulsory risk management plans covering both SPS and non SPS issues, expanded obligations regarding risk management issues relevant for TBT etc....

<sup>88</sup> All these examples are documented in the chronology contained in Exhibit EC-063 and in its attachments.

<sup>89</sup> See Exhibit EC-063, attachment 45, and Exhibits EC-038, EC-039 and EC-040.

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174. Only the United States has brought a claim with regard to Roundup Ready fodder beet (A5/15). However, both Canada and the United States claim that the “Commission failed to submit measure for vote by Regulatory Committee.”<sup>90</sup>
175. From a procedural perspective, the European Communities maintains that Canada cannot submit arguments in relation to a product-specific application that is outside the Panel’s terms of reference, with regard to its claims relating to the product-specific applications. The question of the Panel that generated the table was a precise one, addressed to each of the Complainants, and mentioned “each of the relevant individual product applications.” The European Communities contests that Canada can now revert to product-specific applications that are outside its terms of reference as “relevant individual product applications” to prove its case. The jurisdiction of the Panel in the individual cases of Argentina, Canada and the United States is limited to the measures that were covered by the individual requests for establishment of the Panel. In the case of Canada, the second measure covered by its request for the Panel is “the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I.”<sup>91</sup> As the Panel held in its Preliminary ruling, this means that the Canadian claim on the product-specific applications regards only the four specific products identified in Annex I to the Canadian panel request,<sup>92</sup> i.e. Bayer oilseed rape (MS1/RF1), Bayer hybrid oilseed rape (MS1/RF2), Bayer hybrid oilseed rape (MS8/RF3) and Monsanto Roundup Ready oilseed rape (GT73). In the case brought by Canada, all other product-specific applications are outside the terms of reference of the Panel and any argument made by Canada in relation to them has to be disregarded.
176. From a substantive point of view, the claim is plainly wrong. The Regulatory Committee met first to consider this application on 29 October 1999. However, it reached no vote because of requests for outstanding additional information.<sup>93</sup> The

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<sup>90</sup> United States’ response to question 47 from the Panel, table in Annex I; and Canada’s response to question 47 from the Panel, table in Annex. See also first written submission of the United States, para. 50.

<sup>91</sup> WT/DS292/17 of 8 August 2003.

<sup>92</sup> Preliminary ruling by the Panel on the consistency of the Complaining Parties’ Panel requests with Article 6.2 of the DSU, 8 April 2004.

<sup>93</sup> See chronology in Exhibit EC-064.

United States simply ignores that this product application was the subject of objections by no less than 10 of the 15 Member States. These were based on issues such as insufficient data on the molecular analysis of the insert, on residues, on primary metabolites and on characteristics of intestinal animal microbial flora (data collected from feeding studies performed with GM fodder beets treated with glyphosate and its conventional counterpart), monitoring strategy of gene dispersal in seed-producing countries and possible effects of herbicide residues on animal health.<sup>94</sup> The United States also fails to mention that some of these objections have intervened after the opinion of the Scientific Committee<sup>95</sup> and that the matters which are still under discussion all relate to scientific and technical issues (event-specific detection method, quantitative detection method and validation, monitoring, etc.).

*iv) Monsanto Bt Cotton (531) – C/ES/96/02*

177. Bt Cotton (531) is within the terms of reference of Argentina and the United States. Argentina claims that the procedure under Directive 90/220 has been “stalled” since 11 February 1999 and that the one under Directive 2001/18/EC, initiated on 16 January 2003, “has not progressed since.” As of April 2004, Argentina identifies an overall delay of 7 years and 4 months and of 6 years from the opinion of the Scientific Committee.<sup>96</sup> The United States alleges that the Commission “refused to” or “failed to submit to Council” after the absence of outcome in the Regulatory Committee and that the notification was “indefinitely suspended as of February 11, 1999.”<sup>97</sup>
178. Canada submits one comment on this product. The European Communities maintains the position it has expressed with regard to Roundup Ready fodder beet (A5/15).<sup>98</sup>

<sup>94</sup> See objections by the Member States as documented in the chronology (Exhibit EC-064, attachments 6-10 and 13-22).

<sup>95</sup> See fax from Italian Competent Authority of 14 March 2000 and letter from applicant with additional data (Exhibit EC-064, attachment 34).

<sup>96</sup> First written submission of Argentina, para. 331, and oral statement of Argentina, para. 45-47.

<sup>97</sup> First written submission of the United States, paras. 49-50; and United States’ response to question 47 from the Panel, table in Annex I.

<sup>98</sup> See, above, Section III.A.1(a)(iii).

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179. On the substance, Argentina and the United States report only some facts of the case. They present a partial account, conveniently neglecting those which do fit their broad brush approach acclaiming a generalised moratorium. They fail to mention, for example, that on 22 (not 11) February 1999 the Regulatory Committee failed to reach a qualified majority because a number of Member States maintained objections.<sup>99</sup> These related, in particular, to the presence of an antibiotic resistance gene used as marker within the GM construct, the possible non-target effects on beneficial insects, and the sufficiency of the monitoring plan to analyse indirect effects of Bt cotton, for example on the food web. These are all legitimate scientific concerns. They cannot be ignored or brushed off without detailed consideration.
180. After the no vote in the Regulatory Committee, Monsanto finally provided the required additional information on 25 July 2001 i.e. 29 months later. This related to molecular characterisation, safety assessment and analysis of flanking regions.<sup>100</sup> The translation of the material provided was not made available until and 18 February 2002, i.e. nearly 7 months later.<sup>101</sup> If there was a three year delay it was for reasons lying within the sphere of the applicant, indicating that responses of the kind required cannot be made overnight.
181. Even after it was resubmitted under Directive 2001/18/EC, the application still contained an incomplete monitoring plan.<sup>102</sup> The European Communities cannot be responsible for the lack of diligence or failings of an individual applicant. The Complainants cannot make generalised assertions without dealing properly with individual cases. The Panel cannot decide this dispute without deciding on the facts of each and every application, as this case shows.

v) *Monsanto Roundup Ready cotton (RRC1445) –  
C/ES/97/01*

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<sup>99</sup> See outcome of written procedure and statements from Austria and the UK (Exhibit EC-065, attachment 21bis).

<sup>100</sup> Letter of Monsanto (Exhibit EC-065, attachment 22).

<sup>101</sup> Letter of Monsanto (Exhibit EC-065).

<sup>102</sup> Letters of Lead Competent Authority and of NCB of 1 August and 2 October 2003 (Exhibit EC-065, attachments 24 and 25).

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182. As for Bt Cotton (531), Roundup Ready cotton (RRC1445) is within the terms of reference of both Argentina and the United States. Argentina equally claims that the procedure under Directive 90/220 “stalled” since 11 February 1999 and that the one under Directive 2001/18/EC, initiated on 16 January 2003, “has not progressed since.” As of April 2004, Argentina identifies an overall delay of 6 years and 9 months and of 6 years from the opinion of the Scientific Committee.<sup>103</sup> The United States alleges that the Commission “refused to” or “failed to submit to Council” after the absence of outcome in the Regulatory Committee, and that the notification was “indefinitely suspended as of February 11, 1999.”<sup>104</sup>
183. Canada, by the same token, submits a comment on this product. The European Communities maintains the position it has expressed with regard to Roundup Ready fodder beet (A5/15).<sup>105</sup>
184. On the substance, the comments are similar to those developed under Bt Cotton (531) (see, above, Section III.A.1(a)(iv)). Also in this case, both Complainants fail to mention that on 22 (not 11) February 1999 the Regulatory Committee failed to reach a qualified majority because a number of Member States maintained objections.<sup>106</sup> These related, in particular, to the long-term effects of herbicide tolerant crops on the environment, to the presence of an antibiotic resistance gene used as marker within the GM construct, residue-limits levels, and to the effects on biodiversity of changes in herbicide tolerant crop management.
185. Once resubmitted under Directive 2001/18/EC, the application nevertheless still contains an incomplete monitoring plan that is further delaying the procedure.<sup>107</sup> The Competent authorities are still awaiting the information from the applicant. Once again, any delay which has occurred is entirely legitimate and related to risk assessment and management considerations.

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<sup>103</sup> First written submission of Argentina, para. 330, and oral statement by Argentina at the First Meeting of the Panel with the Parties, para. 48-50.

<sup>104</sup> First written submission of the United States, paras. 49-50; and United States’ response to question 47 from the Panel, table in Annex I.

<sup>105</sup> See, above, Section III.A.1(a)(iii).

<sup>106</sup> See outcome of written procedure and statements from Sweden, Austria and the UK (Exhibit EC-066, attachment 20bis).

<sup>107</sup> Letters of Lead Competent Authority and of NCB of 1 August and 2 October 2003 (Exhibit EC-066, attachments 22 and 23).

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vi) *Amylogene Starch potato - C/SE/96/3501*

186. The United States is the only party to bring a claim with regard to this product, for which it alleges an indefinite suspension of the procedure by the Commission refusing “to submit draft measures to the Regulatory Committee.”<sup>108</sup> The history of this dossier is rather different from the others.
187. First submitted in 1996, the dossier was found to be incomplete by the lead Competent Authority, a fact admitted by Amylogene itself. It took two years to complete. It was circulated to the other Member States in 1998, receiving a number of comments and five objections.<sup>109</sup> Once submitted to the Scientific Committee for an opinion, this took more than three and a half years to consider the dossier, as nine different requests for additional information were made.<sup>110</sup>
188. By the time the Scientific Committee had been able to render its opinion, however, it was clear that the application had to be resubmitted under Directive 2001/18/EC. The applicant did this on 17 January 2003. Since that date the procedure is proceeding in accordance with the new legislation. The 60-day period for comments/objections/requests for further information started from the date of circulation of the assessment report (4 May 2004) and ended on 3 July 2004. Comments and objections raised by Member States concern the post-market monitoring plan, the feeding studies, the antibiotic resistance marker gene, etc. Comments and objections will be transmitted to the applicant for appropriate follow-up. If, further to the response of the applicants, Member States maintain their objection, the matter will be referred to EFSA.
189. The procedure is not - and has never been - suspended. The allegation by the United States to that effect is entirely without substance.

vii) *Bayer winter oilseed rape (Liberator pHoe6/AC) –  
C/D/98/06*

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<sup>108</sup> First written submission of the United States, para. 50; and United States’ response to question 47 from the Panel, table in Annex I.

<sup>109</sup> See Exhibit EC-067, attachments 2-4 and 6-11.

<sup>110</sup> See Exhibit EC-067, attachments 13, 14, 20, 22, 23, 25-28.

190. Winter oilseed rape (Liberator pHoe6/AC) is only within the terms of reference of the United States, which alleges, similarly to the previous product, an indefinite suspension of the procedure by the Commission refusing “to submit draft measures to the Regulatory Committee.”<sup>111</sup>
191. Again, the specific facts of the case are much more complex than the United States would like to admit:
- at Community level, the dossier received a number of comments and requests for further information and was finally subject to objections by eight Member States, mainly regarding the insufficiency of data on molecular characterisation and compositional analysis and the insufficient evaluation of long term environmental effects;<sup>112</sup>
  - the Scientific Committee posed a number of questions to the applicant and took around 16 months to consider this dossier, during which the applicant submitted further information on five occasions;
  - following the Scientific Committee’s recommendation for an agreed code of practices for field management and a research programme,<sup>113</sup> the applicant did not present any proposal and, indeed, did not make contact with the lead Competent Authority until the lead Competent Authority, in November 2002, sent it a letter to point out that the dossier would have to be up-dated by January 2003 under Directive 2001/18/EC;
  - the applicant submitted an updated dossier in January 2003 and the lead Competent Authority requested additional information on molecular characterisation and on the post marketing monitoring plan. While the former was submitted in October 2003, the lead Competent Authority is still awaiting the latter.

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<sup>111</sup> First written submission of the United States, para. 50; and United States’ response to question 47 from the Panel, table in Annex I.

<sup>112</sup> See Exhibit EC-068, attachments 14-20, 22, 24.

<sup>113</sup> See Opinion of the SCP (Exhibit EC-068, attachment 25).

192. The European Communities cannot be held responsible for delays that are caused by the lack of diligence or the failings of an individual applicant.

*viii) Syngenta glufosinate tolerant and Bt resistant (Bt-11)  
corn – C/F/96/05-10*

193. The application for Bt resistant (Bt-11) corn is only included in the United States' term of reference. The Complainant alleges that its consideration was "indefinitely suspended because the Commission refused to submit draft measures to the Regulatory Committee."<sup>114</sup>

194. Once again, the European Communities has to stress the complete absence of any serious factual analysis on the part of the United States. The United States in particular ignores the fact that:

- After the notification was submitted in 1996, the lead Competent Authority requested further additional information on substantial equivalence, use of the herbicide on the plants, allergenicity of the truncated synthetic CryIA(b) protein, environmental risk assessment, insect resistance management, molecular characterisation of the Bt11 line, use of antibiotic (Ampicillin) resistance gene as a marker, and on the experimental data used by the notifier to reach its conclusions. This request led to a number of exchanges between the notifier, the lead CA and the French advisory Committee throughout 1996 and 1997, and up to the end of 1998;
- at Community level, several Member States requested additional information and eight of them maintained objections based on insufficient information on the use of the herbicide, ecological effects on non target organisms, insect resistance management and monitoring, feed safety, and labelling;<sup>115</sup>

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<sup>114</sup> First written submission of the United States, para. 50. See also United States' response to question 47 of the Panel, table in Annex I.

<sup>115</sup> See Exhibit EC-069, attachments 1-9.

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- the Scientific Committee recommended a monitoring plan, and the proposal by the applicant remains unsettled.<sup>116</sup>
195. As this account of the specific facts of this case shows, this application is not – and has never been – suspended.
196. The dossier is currently with EFSA. Outstanding issues related to the post-market monitoring plan have still to be resolved. A discussion between EFSA and the applicant is scheduled for 1<sup>st</sup> September 2004. EFSA is expected to finalise its opinion soon after.

*ix) Monsanto Roundup Ready oilseed rape (GT73) –  
C/NL/98/11*

197. Both the United States and Canada have brought a claim on the application for Roundup Ready oilseed rape (GT73). For both Complainants, this product-specific application represents one of the rare cases where they have been able to quantify a delay. However, the two Complainants disagree as between themselves on the facts.
198. For Canada, the difference between the total time for the initial assessment of the lead Competent Authority and the time taken by the applicant to respond to the questions is 13 months, whereas for the United States it is 32 months. Further, whilst Canada allocates 20 months to resolve issue of confidentiality, the United States considers that the issue was resolved in 10 months.<sup>117</sup> Canada also claims that the total time for review by other Member States has been 8 months rather than the 105 days as established in the European Communities' legislation. In its first written submission, Canada alleges an overall 6 year delay since the submission of the notification.<sup>118</sup>

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<sup>116</sup> See objections by Member States under Directive 2001/18/EC (See Exhibit EC-069, attachments 11-21).

<sup>117</sup> United States' response to question 47 of the Panel, table in Annex I; and Canada's response to question 47 of the Panel, table in Annex.

<sup>118</sup> First written submission of Canada, para. 93.

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199. In this product-specific application, the clock stopped<sup>119</sup> on the first day of the notification because the lead Competent Authority immediately upon receipt of the notification sent out a request for additional information on molecular characterisation and *gox*-gene.<sup>120</sup> From that date to 13 December 2002, when Monsanto complemented its application under Directive 2001/18/EC, there was a continuous exchange of correspondence between the lead Competent Authority and the applicant, which the European Communities has documented in its previous submissions.<sup>121</sup> This period of time was entirely dedicated to resolving scientific and technical issues, such as molecular characterisation and feed safety.
200. As regards the issue of confidentiality, it was at the request of Monsanto that the discussion on these issues was undertaken.<sup>122</sup> The European Communities cannot be responsible for any slippage in the timetable which follows a request made by an applicant.
201. Once complemented under Directive 2001/18/EC, this application moved immediately from the Member State to the Community level. This indicates that all the relevant steps had been completed, and is flatly inconsistent with the notion that a moratorium was in place. At the Community level objections arose on the basis of insufficient data for molecular characterisation, feeding studies, post-market monitoring plan, allergenicity, detection/identification methods, etc.
202. With regard to Canada's comment that the total time for review by other Member States has been 8 months rather than 105 days as established in the European Communities' legislation, the European Communities wishes to stress that according to Article 15.1 of Directive 2001/18/EC, any time spent to request and obtain further information from the notifier is not counted in the 60 + 45 day period.<sup>123</sup> Thus, in this case, as the first requests for additional information were filed on 25 March 2003, the time count, even under EC law, is of 60 days from the date of circulation of the assessment report.

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<sup>119</sup> On the meaning of "clock-stop", see Response by the European Communities to question 82 of the Panel, para. 217.

<sup>120</sup> See Exhibit EC-070, attachment 1.

<sup>121</sup> See Exhibit EC-070, attachments 1-10, 14, 16, 20.

<sup>122</sup> See Exhibit EC-070, attachments 11-13, 15, 17-19, 21-22.

<sup>123</sup> See flowchart on Directive 2001/18/EC in Exhibit EC-118.

203. ESFA granted a favourable opinion for the placing on the market of the GT73 oilseed rape on 11 February 2004. A draft proposal for the placing on the market of the GT73 oilseed rape product was discussed within the Regulatory Committee under Article 30 of Directive 2001/18/EC on 16 June. The Committee did not deliver an opinion. In accordance with Article 5(4) of Decision 1999/468/EC the Commission is thus going to transmit the draft proposal to the Council which will have three months to act.

*x) Bayer Liberty Link soybeans (A2704-12 and A5547-127)  
– C/BE/98/01*

204. This product-specific application is within the terms of reference of both Argentina and the United States. Argentina limits its factual arguments to identifying an overall delay of 5 years and 8 months since the submission of the notification.<sup>124</sup> Oddly enough, it did not mention this product-specific application in its Oral Statement. The United States limits also its factual arguments to say that this notification was delayed at the Member State level.<sup>125</sup>

205. Neither the United States nor Argentina make any attempt whatsoever to address the actual facts of this product-specific application. In particular, they choose to ignore the fact that:

- the notification was incomplete with regard to molecular characterisation, compositional analysis, toxicity, allergenicity, herbicide use, residue behaviour and that an intense exchange of correspondence, as well as meetings, have taken place uninterruptedly from the notification by PGS on 28 September 1998 well into 2001;<sup>126</sup>
- that the application procedure was suspended by the lead Competent Authority twice, because on 24 September 1999 the applicant submitted a notification of

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<sup>124</sup> First written submission of Argentina, para. 330, and oral statement of Argentina at the First Meeting of the Panel with the Parties, paras. 48-50.

<sup>125</sup> First written submission of the United States, para. 51; and United States' response to question 47 of the Panel, table in Annex I.

<sup>126</sup> See Exhibit EC-71, attachments 1-14.

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the same product for the same uses in Portugal.<sup>127</sup> The applicant finally withdrew its double notification in January 2003 when it complemented the dossier under Directive 2001/18; and

- that, under Directive 2001/18/EC, the lead Competent Authority has been waiting for completion of the dossier by the applicant since its request for additional information on 25 February 2003.<sup>128</sup>

*xi) Bayer Liberty Link oilseed rape (T45 X Topas 19/2)  
(stack) - C/GB/99/M5/2*

206. Only the United States has brought a claim with regard to the application for Liberty Link oilseed rape (T45 X Topas 19/2). As for Liberty Link soybeans (A2704-12 and A5547-127), the United States limits its factual arguments to say that this notification was delayed at the Member State level.<sup>129</sup>

207. Once again, the United States chooses to ignore the basic facts of this product-specific application. In particular, it does not mention or consider that, after a request for substantial revision and clarification of the dossier by the lead Competent Authority in December 1999,<sup>130</sup> the applicant did not get back to the lead Competent Authority on this dossier for almost two years. The applicant provided some up-dated documents in January 2003, but not the full dossier. The Applicant finally re-submitted a full dossier only in March 2004 by withdrawing the pending notification and submitting a new notification a few days later.<sup>131</sup> Once again, the Communities cannot be responsible for delays arising at the instigation of the applicant.

*xii) Pioneer/Dow AgroSciences Bt corn CryIF (1507) –  
C/NL/00/10*

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<sup>127</sup> See first written submission of the European Communities, paras. 261-263; and Exhibit EC-71, attachments 15-16 and 20-21.

<sup>128</sup> See acknowledgement of receipt by lead CA and request for missing information (Exhibit EC-71, attachment 24).

<sup>129</sup> First written submission of the United States, para. 51; and United States' response to question 47 of the Panel, table in Annex I.

<sup>130</sup> See advice of UK Scientific Committee (Exhibit EC-072, attachment 5).

<sup>131</sup> See Exhibit EC-072, attachments 6-13.

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208. The application concerning import and processing of Bt corn Cry1F (1507) is analyzed by the United States in paragraph 51 of its first written submission. It claims that “although the applicants provided answers to all of the questions raised by the sponsoring Member States, the Member States nonetheless delayed and ultimately suspended consideration or failed to approve these products under Directive 90/220.”<sup>132</sup>
209. The United States misrepresents the facts:
- This application was submitted in November 2000. The lead Competent Authority identified a number of issues, such as molecular characterisation, allergenicity and toxicity of CRY1F, and labelling, which were insufficiently or inappropriately addressed in the application. The submission of additional information and replies to questions on the part of the applicant continued well into 2003, even after the application had been complemented on the basis of Directive 2001/18/EC<sup>133</sup>.
  - On two different occasions, the applicant required an extension of the time granted by the lead Competent Authority to submit further data or information.
  - Once the application reached the Community level, a considerable number of objections were raised by the Member States,<sup>134</sup> including on environmental effects, monitoring plan, molecular characterisation, sampling and detection methods, allergenicity and toxicity.
  - The application is currently with EFSA. Outstanding issues related to the post-market monitoring plan have still to be discussed with the applicant. A meeting between EFSA and the applicant is scheduled in September.
210. The actual facts demonstrate that contrary to the US claim there was neither a suspension of consideration nor a failure to approve this product.

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<sup>132</sup> First written submission of the United States, para. 51; and United States’ response to question 47 of the Panel, table in Annex I.

<sup>133</sup> See Exhibit EC-074, attachments 1-13.

<sup>134</sup> See Exhibit EC-074, attachments 18-27 and 30-36.

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*xiii) Pioneer/Dow AgroSciences Bt corn Cry1F (1507) –  
C/ES/01/01*

211. Similarly to the previous application, the United States mentions the application concerning the cultivation of the Bt corn Cry1F (1507) in paragraph 51 of its First written submission. Also in this case, it claims that “although the applicants provided answers to all of the questions raised ..., the Member States nonetheless delayed and ultimately suspended consideration or failed to approve these products under Directive 90/220.”<sup>135</sup>
212. Pioneer notified this product in July 2001, i.e. after the adoption of Directive 2001/18 setting new standards for the review of the applications. The United States correctly remarks that there were some requests for additional information. These requests were dealt with by the applicant during the following 12 months (17 July 2002 - last letter under the Directive 90/220).<sup>136</sup> Shortly after the application was updated, the lead Competent Authority submitted the assessment to the Commission. Presently the product is at the stage when the objections raised by particular Member States are to be responded to or commented on by the notifier.<sup>137</sup>

*xiv) Monsanto Roundup Ready corn (NK603) – C/ES/00/01*

213. Roundup Ready corn (NK603) is within the terms of reference of both Argentina and the United States.
214. Canada also submits comments on this product. The European Communities maintains the position it has expressed with regard to Roundup Ready fodder beet (A5/15).<sup>138</sup>
215. Argentina identifies an overall delay of 3 years and 8 months, and a delay of 1 year and 3 months since the submission of the update under Directive

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<sup>135</sup> First written submission of the United States, para. 51; and United States’ response to question 47 from the Panel, table in Annex I.

<sup>136</sup> See Exhibit EC-075, attachments 1-3.

<sup>137</sup> See Exhibit EC-075, attachments 8-19.

<sup>138</sup> See, above, Section III.A.1(a)(iii).

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- 2001/18/EC.<sup>139</sup> The United States limits its factual arguments to the claim that this notification was delayed at Member State level because it took the lead Competent Authority 12 months instead of 90 days for the completion of its assessment.<sup>140</sup>
216. Also in this case, the facts are blurred by a superficial description. In particular, the Complainants choose to ignore that the notification that Monsanto submitted in August 2000 was incomplete and therefore not considered as received until January 2001. This is the date from which any count of time elapsed must start. 44 days afterwards the clock was stopped<sup>141</sup> because the Scientific Committee of the lead Competent Authority requested additional information on issues such as molecular characterisation, nutritional composition, and environmental impact.<sup>142</sup> Exchanges with the applicant on these issues continued until the summer of 2002, when the applicant began to complement the dossier under Directive 2001/18/EC.
217. After receipt of all elements necessary under the new legislation, the lead Competent Authority submitted the dossier to the Commission in January 2003. Since then the application has proceeded smoothly and, although several Member States have maintained objections based on their own risk assessments,<sup>143</sup> a decision on its authorisation is due to be adopted by the Commission on 20 July 2004.

*xv) Monsanto Roundup Ready corn (GA21)*

218. The application for Roundup Ready corn (GA21) under Regulation 258/97 is within the terms of reference of both Argentina and the United States.

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<sup>139</sup> First written submission of Argentina, para. 332, and oral statement of Argentina at the First Meeting of the Panel with the Parties, para. 45-47.

<sup>140</sup> First written submission of the United States, para. 51; and United States' response to question 47 of the Panel, table in Annex I.

<sup>141</sup> On the meaning of "clock-stop", see European Communities' response to question 82 of the Panel, para. 217.

<sup>142</sup> See request of additional information by the Spanish National Biosafety Committee (Exhibit EC-076, attachment 1).

<sup>143</sup> See objections from various Member States (Exhibit EC-076, attachments 11, 13-14, 16-20, 23-32).

219. Canada also submits comments on this product. The European Communities maintains the position it has expressed with regard to Roundup Ready fodder beet (A5/15).
220. As far as the specific factual comments are concerned, Argentina's only claim is that, notwithstanding the opinion of the Scientific Committee, no authorisation has been yet granted.<sup>144</sup> The United States identifies three problematic junctures in this application's procedure:<sup>145</sup>
- at Member State level, a delay of 10 months instead of 90 days for the lead Competent Authority to complete its assessment;
  - at Community level, a delay of 17 months for the Scientific Committee on Plants to render its opinion, and
  - the refusal/failure by the Commission to submit the measure to the Regulatory Committee in February 2000.
221. With regard to the argument by Argentina, the European Communities has already explained at length the value of the opinion of its Scientific Committees in the overall economy of the European Communities' approval procedures for GMOs in its replies to the questions from the Panel.<sup>146</sup> Furthermore, as already mentioned, there is a difference between risk assessment and risk management.<sup>147</sup>
222. As for the United States' claims, the European Communities notes the failure to engage with the real facts. The United States willingly ignores the fact that the 18 months spent at Member State level were due to the incompleteness of the dossier initially submitted by Monsanto and to the need for additional scientific data.<sup>148</sup>

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<sup>144</sup> Oral statement of Argentina at the First Meeting of the Panel with the Parties, para. 55.

<sup>145</sup> First written submission of the United States, para. 54; and United States' response to question 47 of the Panel, table in Annex I.

<sup>146</sup> See, in particular, European Communities' response to question 17 of the Panel.

<sup>147</sup> See, above, Section II.B.

<sup>148</sup> See, Exhibit EC-091, attachments 1-6.

223. Similarly, at Community level, the Scientific Committee on Food found that the dossier did not contain sufficient information concerning substantial equivalence and toxicity testing.<sup>149</sup>
224. Finally, the European Communities does not understand the claim that the Commission refused/failed to submit the measure to the Regulatory Committee in February 2000. At that time, the dossier had just arrived at Community level and the Commission could not submit it to the Regulatory Committee without circulating it first to the Member States and, as appropriate, requiring the opinion of the Scientific Committee. As these are requirements of European Communities' law which are not contested by the Complainants, the European Communities invites the Panel to reject this argument.
225. At present, the European Joint Research Centre is working on the validation of a detection method for this product. After the validation of the detection method, the Commission will submit a draft Decision concerning the authorisation of the product for an opinion to the relevant Regulatory Committee.

*xvi) Bayer Liberty Link soybeans*

226. Both Argentina and the United States have presented claims with regard to the application for Bayer Liberty Link soybeans under Regulation 258/97.
227. The only factual argument of Argentina is an overall delay of 5 years and 8 months and of 1 year and 3 months since the application was submitted.<sup>150</sup> As in the case of the application for release into the environment of Bayer Liberty Link soybeans, Argentina fails to mention this product-specific application in its Oral Statement. The United States alleges that the Member State has “refused to forward” the application to the Commission and that its review is not completed.<sup>151</sup>

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<sup>149</sup> See Request of 24 April 2001 (Exhibit EC-091, attachment 17).

<sup>150</sup> First written submission of Argentina, para. 333.

<sup>151</sup> First written submission of the United States, para. 55; and United States' response to question 47 of the Panel, table in Annex I.

228. Again, the Complainants choose to ignore the simple fact that the applicant was requested to provide additional information on substantial equivalence and presence of transgenic pat DNA and pat protein by the Belgium Biosafety Council in April 1999,<sup>152</sup> and on issues such as nutritional and biochemical characterization and toxicity of the transgenic plant by the Greek and Italian authorities in June and July 1999.<sup>153</sup> All three requests for additional information have remained, to this date, mostly unanswered, notwithstanding the reminders sent by the lead Competent Authority.<sup>154</sup>
229. On 6 July 2004, BayerCrop Science withdrew its application. The European Communities therefore considers that this product-specific application has become moot.

*xvii) Pioneer/Dow AgroSciences Bt corn Cry1F (1507)*

230. The product application for Bt corn Cry1F (1507) under Regulation 258/797 is only within the terms of reference of the United States.
231. The Complainant alleges in its first written submission that “the Member States refused to forward [the application] to the Commission.”<sup>155</sup>
232. Again, the United States claim is factually inaccurate. If the Panel looks at the chronology for this product it will see that there was no refusal to forward the application. There were requests for further information by some of the Member States and the lead Competent Authority on labelling, monitoring, molecular characterisation, and event specific detection methods. A request for information is not a refusal.<sup>156</sup>
233. Once clarified, in November 2003 the application was assessed and sent to the Commission by the Dutch competent authority. As some Member States had

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<sup>152</sup> See letter of 28 April 1999 (Exhibit EC-093, attachment 1).

<sup>153</sup> See requests of 7 June and 21 July 1999 (Exhibit EC-093, attachments 5-6).

<sup>154</sup> See letters of 10 May 1999 and of 28 April 2004 (Exhibit EC-093, attachments 3 and 9).

<sup>155</sup> First written submission of Argentina, para. 55.

<sup>156</sup> See Exhibit EC-095, attachments 1-9.

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raised objections,<sup>157</sup> the risk assessment was not completed under Regulation 258/97. Therefore the application will now be considered by EFSA under Regulation 1829/2003.

*xviii) Monsanto MaisGuard & Roundup Ready (MON810 & GA21) corn (stack)*

234. The United States, which is the only Complainant to have presented a claim in regard to the application for MaisGuard & Roundup Ready (MON810 & GA21), acknowledges that the delays are caused by the applicant.<sup>158</sup> The European Communities takes note of the fact that with regard to this product-specific application the claim is no longer live.

*xix) Monsanto Roundup Ready corn (NK603)*

235. The product-specific application for Roundup Ready corn (NK603) under Regulation 258/797 is within the terms of reference of both Argentina and the United States.
236. Canada also submits comments on this product. The European Communities maintains the position it has expressed with regard to Roundup Ready fodder beet (A5/15).<sup>159</sup>
237. Argentina's only factual comment is that an overall delay of 3 years has elapsed.<sup>160</sup> The United States identifies, at Member State level a delay of 14.5 months instead of 90 days for the lead Competent Authority to complete its assessment.<sup>161</sup>
238. Again, the United States ignores the fact that the 18 months spent at Member State level were due to the incompleteness of the dossier initially submitted by

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<sup>157</sup> See Exhibit EC-095, attachments 10-16.

<sup>158</sup> See United States' response to question 47 of the Panel, table in Annex I.

<sup>159</sup> See, above, Section III.A.1(a)(iii).

<sup>160</sup> First written submission of Argentina, para. 332.

<sup>161</sup> European Communities' response to question 47 of the Panel, table in Annex I.

Monsanto (missing references) and to the need for further data on molecular characterisation and compositional analysis.<sup>162</sup>

239. EFSA granted a favourable opinion for the placing on the market of foods and food ingredients derived from NK603 maize on 25 November 2003. Following the validation of a detection method by the JRC, the Commission submitted a draft authorisation Decision to the Standing committee on Food Chain and Animal Health for an opinion on 30 April 2004. The Committee did not deliver, by qualified majority, an opinion on the draft submitted by the Commission. Pursuant to Article 13(4)(b) of Regulation (EC)N°258/97. In accordance with Article 5 of Council Decision 1999/468/EC, the Commission was required to submit to the Council a proposal relating to the measures to be taken, the Council having 3 months in which to act by a qualified majority. The proposal was adopted by the Commission on 24 June 2004 and transmitted to the Council on 13 July. As the Council did not reach a qualified majority on the proposal on 19 July 2004, the Commission will adopt a decision on the authorisation of NK603 derived products by the end of October 2004.

(b) The time element

240. The above excursus through the product-specific applications clearly demonstrates that nothing like a failure to apply (or a suspension) of the approval system exists or has ever existed.
241. The Complainants have failed to engage with the facts. The claims relating to the general moratorium and to product-specific delays collapse when the specific facts of each case are considered. This is why the Complainants' strategy is to avoid dealing with individual applications, or looking at the scientific and risk assessment related reasons which have arisen in each case. Instead they apply a superficial attempt to reduce the whole case to a generalised and indiscriminate *moratorium*. The Panel should resist the approach which they are being asked to follow. The Panel is required to consider the treatment of each application on its merits.

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<sup>162</sup> See Exhibit EC-096.

242. The specific facts of the specific cases demonstrate that any generalisation is misplaced because each application has its own specificities. In particular, the analysis of the facts show clearly that there are no “concerted acts and omissions that stall applications at key decision making stages in the approval process regardless of the scientific evidence demonstrating the safety of the product.”<sup>163</sup> The time taken for each product-specific application is documented as being used in respect of the following activities:

- (a) To allow review by an organ of the European Communities on the basis of the requirements established by the EC legislation;
- (b) To allow debate between the applicant, the Member States (both as Competent Authorities and in the Regulatory Committee), and the Commission on scientific and/or technical issues;
- (c) To address efforts to deal with risk management concerns (elaboration of monitoring requirements, adequate agricultural practices, etc.) as well as risk communication (labelling, etc.);
- (d) To respond to delays voluntarily caused by the applicant and not attributable to the European Communities (multiple notification; insufficient data; bad quality of the data (e.g. molecular data); time to compile requested information or data etc.).

(c) The scientific and technical nature of the reasons for the delays

243. The activities involved in the assessment of GMOs are scientifically and technically justified. Therefore, should the Panel have any doubt on whether the time which has elapsed for each product-specific application was necessary and justified to address scientific and technical issues, the Communities’ submits that independent scientific and technical advice must be sought. Plainly there is a dispute between the parties on this factual issue.

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<sup>163</sup> Oral statement of Canada, para. 16.

244. The independent expertise is needed to determine whether the time actually used in the specific cases to address the actual issues which arose was “undue.”
245. Relevant issues include the development (by the applicant and/or the authorities) and the analysis (by the authorities) of strictly risk management issues, falling outside the competence of risk assessors and risk assessment opinions, such as availability of detection and identification methodologies, post market monitoring plan to address potential long term environmental or ecological impact, or management of agricultural changes in agronomic practices due to a change in the spectrum of herbicide used caused by the cultivation of GMOs. Any scientific advice should also refer to the scientific and technical knowledge as existing at the time the issues arose.
246. The European Communities will elaborate further on the specific technical and scientific issues which arise in this case in its submission of 22 July.

## **2. Legal issues**

247. The factual analysis above requires a further discussion of a number of legal issues, such as whether the Complainants have discharged their burden of proving the facts that are at the basis of their claims; under which WTO Agreement should the facts of this cases be assessed; which substantive provisions of the *SPS Agreement* apply to the facts of this case; which periods of time should actually be considered as “delays” in the specific facts of each application; and which reasons would compel the Panel to consider that any delays which may have occurred are “undue.”

### **(a) Burden of proof**

248. As noted above,<sup>164</sup> it is for the Complainants to establish a *prima facie* case. With regards to the facts on which a case is based, the Appellate Body has consistently held that

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<sup>164</sup> Section II.A.

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the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof thereof.<sup>165</sup>

249. The constant case-law of panels and the Appellate Body has followed this approach. This is reflected in the Panel's decision in *Argentina – Textiles*:

Concerning the issue of what one may call the "burden of proof", the Appellate Body has confirmed the GATT practice whereby

...c) it is for the party asserting a fact to prove it.<sup>166</sup>

250. In the present case, it is clear from the above factual analysis of the product-specific applications that the Complainants have failed to substantiate their claims with any proof of the facts. Their factual arguments are at best generic (general suspension, general failure, overall time elapsed, stalled/delayed at Member State level, etc.). In some cases the Complainants get their facts wrong (Commission's failure to submit proposal to Regulatory Committee, imposition of interim approach, indefinitely suspended, etc.). Assertion is not a substitute for a rigorous presentation of the actual facts.

251. The Complainants also tend to standardise their arguments and repeat them for several product-specific applications without looking at the individual facts. The best example of this artificial categorisation is to be found in the first written submission of the United States.<sup>167</sup> In just four paragraphs the United States presents the facts for the 39 product-specific applications covered by its request for the establishment of the Panel. Any analysis of the specific and actual activities that have taken place in each specific case, as well as of any reason underlying them, is missing.

252. The Panel has asked Canada to "address in more detail at what stage in the relevant procedure 'delays' arose and why they are considered 'undue'."<sup>168</sup> In reply, Canada provides the table annexed to its replies to the questions of the Panel. In this, as well as in all other submissions, Canada generally fails to

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<sup>165</sup> Appellate Body Report, *US - Wool Shirts and Blouses*, p. 14.

<sup>166</sup> Panel Report in *Argentina – Textiles*, para. 6.35.

<sup>167</sup> Working Procedures for the Panel, adopted on 17 March 2004, para. 4.

<sup>168</sup> Question 63 of the Panel to Canada.

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indicate which period of time should be considered a delay and, in all cases, why the delay would be considered unjustified in the specifics of each application.

253. In the very few cases where a delay has been identified, the Complainants disagree among themselves on the length of that delay. Often, the dates chosen by the Complainants are random.<sup>169</sup> In no case are they documented, or supported by hard evidence.
254. In all cases, all Complainants fail to address and comment on the numerous risk assessment and risk management issues that were discussed and advanced in the course of the specific proceedings.<sup>170</sup> These are described and documented in the European Communities' submissions, they are ignored by the Complainants. All those issues should have been known to the Complainants before the initiation of these proceedings, through their contacts with applicant companies.<sup>171</sup> Regrettably, it appears that the Complainants do not have available to them the information that would have enabled them to "exercise their judgement as to whether action under these procedures would be fruitful" in accordance with Article 3.7 of the DSU. The European Communities regrets the unwillingness of the Complainants to engage in meaningful consultations prior to requesting the establishment of a panel.<sup>172</sup>
255. In the light of all this, the European Communities hereby requests the Panel to find that the Complainants have not discharged their burden of proving the facts that are at the basis of their claims on the product-specific applications.

(b) Applicable law

256. The second issue which arises from the analysis of the individual product-specific applications is that of the applicable law: under which WTO Agreement should

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<sup>169</sup> See, for instance, the dates referred to in Sections III.A.1(a)(iv), (v), and (ix) above.

<sup>170</sup> See, for instance, first written submission of the United States, para. 139.

<sup>171</sup> See for instance Canada's letter to the Panel of 18 June 2004: "In preparing its case, it has been necessary for Canada to consult with the companies whose applications for approval of biotech products have been stalled by the EC moratorium, or whose products are subject to the EC Member States national bans".

<sup>172</sup> See European Communities' response to questions of the Panel in the context of the preliminary ruling procedure, paras. 4-7 and Exhibits EC-001 to EC-005.

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these facts be assessed? Is it the *SPS Agreement*, or the *TBT Agreement*, or the GATT 1994, or a combination of these instruments ? The European Communities submits that differential timing of individual steps in each specific application procedure may originate with considerations within the scope of different and/or multiple WTO provisions.

257. On this point, the Complainants have followed different approaches.
258. Argentina takes the simplistic way of considering that all relevant risks fall within the scope of Annex A of the *SPS Agreement*. It avoids the substance of the issue, which it does not bother to discuss.<sup>173</sup>
259. Canada has a more labyrinthine approach. On the one hand, it accepts that an approval procedure that qualifies as an SPS measure can also be applied “to protect against non-SPS risks.”<sup>174</sup> On the other hand, however, it asserts that “it is not the reason for the delay but the nature of the approval procedure that determines whether Annex C applies.”<sup>175</sup> The sweeping conclusion of this reasoning is intended to prevent the Panel from examining any non-SPS justification for delay under any WTO provision other than Annex C of the *SPS Agreement*.
260. The United States simply considers that the burden of proving the justifications and their being outside the scope of the *SPS Agreement* was on the European Communities. Apart from this interesting inversion of the burden of proof, the United States seems to agree with Canada that as long as the approval procedure is an SPS measure, consideration of all risks, even of those which are outside the *SPS Agreement*, falls under Annex C.<sup>176</sup>

i) *Mixed delays*

261. The Communities proceeds on the basis that the Panel finds that an act has not been adopted partly for reasons that fall within the scope of the *SPS Agreement*,

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<sup>173</sup> Argentina’s response to question 48(a) from the Panel.

<sup>174</sup> Canada’s response to question 48(a) from the Panel, para. 92.

<sup>175</sup> Canada’s response to question 35(b) from the Panel, para. 64.

<sup>176</sup> United States’ response to question 48(a) from the Panel, para. 73.

- and partly for reasons that are covered, for example, by the *TBT Agreement*. The analysis to be applied to “mixed delays” is the same as that to be applied to mixed acts.<sup>177</sup> Action and inaction are two different sides of the same coin.
262. The Communities submits that the Panel cannot lawfully find that the delay is in all respects “undue delay” within the meaning of Annex C of the *SPS Agreement*, and recommend that the European Communities adopt the outstanding act. That is because the outstanding act may be partly an SPS measure and partly a TBT measure. And under the *TBT Agreement* it may be that the European Communities has acted and continues to act “as expeditiously as possible” within the meaning of Article 5.2.1 of the *TBT Agreement* – in other words, that there is still time to run under the *TBT Agreement*.
263. Furthermore – and on this point there is a difference with the position in relation to mixed acts – the Panel cannot split and isolate the SPS delay. It cannot make a discrete finding that there has been “undue delay” within the meaning of Annex C of the *SPS Agreement*, without taking into account the position under the *TBT Agreement*. That is because the approvals systems in the European Communities make no provision for two different acts (one SPS measure and one TBT measure). They require a single act addressing both measures. The Complainants do not attack the European Communities system “as such” and must therefore be taken to have accepted this aspect of it. As long as the TBT issue lawfully remains open, the SPS measure lawfully remains unadopted, and *vice versa*.
264. In this situation, therefore, the Panel must take into account the situation under the *TBT Agreement*. If the Panel finds that, under the *TBT Agreement*, the European Communities acted as expeditiously as possible, then there can be no breach of the *TBT Agreement* and no breach of the *SPS Agreement*. To find, in relation to mixed delay, that the European Communities has acted inconsistently with its WTO obligations, the Panel must find both “undue delay” within the meaning of Annex C of the *SPS Agreement* and a failure to act “as expeditiously as possible” within the meaning of Article 5.2.1 of the *TBT Agreement*. Absent one or the other, there is no breach.

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<sup>177</sup> See, above, Section II.C(j).

ii) Classification of reasons for delays

265. Moving a step further in the analysis of which provision actually applies to the specific facts of each specific application, the European Communities sets out in the table below the concerns that have arisen in respect of various product-specific applications at issue in this case,<sup>178</sup> together with the relevant WTO Agreement or Agreements that covers them. This matrix only applies to the issues identified in the context of the approval procedures for the GMO that are the subject of the claims. It is not intended to address the same issues with respect to GMOs in general, and does not purport to be exhaustive.

Type of risks/safety/other issues	SPS	TBT	GATT
<i>Identification of the GMO and application data provided :</i>			
Molecular characterization	X	X	X
Detection of the modification	X	X	X
Quality/extent of data	X	X	X
<i>Issues related to human life or health :</i>			
Antibiotic resistance genes		X	X
Toxicology	X		X
Allergenicity		X	X
Substantial equivalence	X	X	X
Compositional analysis	X	X	X
Feeding studies	X		X
Horizontal gene transfer – health		X	X
<i>Issues related to Bt toxin :</i>			
Bt toxins issues	X	X	X
<i>Agro-environmental issues :</i>			
Herbicide and agriculture management	X	X	X
Impact of agricultural practices on the environment	X	X	X
<i>Environmental issues</i>			
Impact on biodiversity	X	X	X
Long term ecological effect	X	X	X
Horizontal gene transfer	X	X	X
<i>Other legitimate and economic concerns</i>			
Impact on genetic resources	X	X	X

<sup>178</sup> This list is taken from the table submitted by the European Communities as Exhibit EC-154bis.

266. It is clear from this matrix that the Panel is faced with a significant number of “mixed risks/safety concerns” issues. In almost all cases, all three Agreements are applicable because the regulatory concern which is engaged is relevant (i) in part for annex A of SPS, and (ii) in part for environment, “human safety” or other legitimate concerns (TBT), and (iii) in part for human, animal or plant life or health, or the conservation of natural exhaustible resources (GATT). For example, a risks assessment dealing with the impact of a given GMO on biodiversity would cover:

- (a) potential pest risks to the wild flora, i.e. an SPS concern; and
- (b) the potential negative impact on animals other than from pests, disease or feedstuff (such as a predator insect eating another insect because it is itself growing better on a diet of Bt maize), i.e. a GATT and TBT concern; and
- (c) the potential negative impact on the environment (say non-pest non-disease micro-organisms or other environmental component of biodiversity outside human, animal or plant life or health, such as the ecological complexes referred to in the definition of the Convention on Biodiversity), i.e. a TBT or GATT concern.

*iii) Conclusion*

267. In the light of this analysis, it is clear that the superficially neat approach of the Complainants is inconsistent with the WTO Agreements. It is also overly simplistic. First, and as explained above, the approval procedure itself – which is not contested by the Complainants – does not only address SPS concerns. And, second, because disregarding the concerns actually addressed in the specific application procedures in effect ignores the approach of Annex A.1 of the *SPS Agreement*. This requires an approach based on a clear and closed list of measures applied to protect against risks originating from specific entities – i.e. some organisms, pests, additives, contaminants, toxins, diseases – in specific “situations” – i.e. entry, establishment or spread of pests or disease organisms, presence in food, beverage or feedstuffs, disease carried by animals or plants. It

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would blur the very distinction that the drafters of the WTO Agreements have decided to operate by creating three different Agreements: SPS, TBT and GATT.

(c) The SPS Agreement

i) *Provisions on development v. provisions on application of SPS measures*

268. With regard to the operation of the *SPS Agreement*, the parties disagree on the applicability of the substantive provisions of this Agreement to the facts of this case. The Panel has addressed a specific question on this issue to all parties. The United States has basically refused to answer. It claims that the question raises “broad systemic issues that it is not necessary to address in order to resolve this dispute.”<sup>179</sup> Argentina<sup>180</sup> and Canada<sup>181</sup> maintain their position on the concurrent applicability of the various SPS provisions invoked also by recurring to the alleged existence in Article 8, second part, of an obligation to “otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.”

269. The European Communities has explained that the *SPS Agreement* contains two types of provisions, those disciplining the development of the sanitary or phytosanitary measure and those dealing with its application.<sup>182</sup> Challenging, as the Complainants do, the way in which applications for authorisation are dealt with is a challenge against the application of a sanitary or phytosanitary measure. Thus, among the various provisions which the Complainants allege to have been violated, only Article 8 together with Annex C of the *SPS Agreement* can be applied to the facts of this case. Articles 2.2, 2.3, 5.1, 5.5 and 5.6, on the contrary, all contain obligations concerning the development of a sanitary or phytosanitary measure (i.e. the SPS measure itself), not its application and therefore they do not apply.

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<sup>179</sup> United States’ response to question 37 from the Panel, para. 55.

<sup>180</sup> Argentina’s response to question 37 from the Panel.

<sup>181</sup> Canada’s response to question 37 from the Panel, para. 68.

<sup>182</sup> See first written submission of the European Communities, section III.C.2.

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270. As far as the argument construed under Article 8, second part, of the *SPS Agreement* is concerned, it is plainly wrong. Article 8 reads:

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

271. As already mentioned,<sup>183</sup> Article 8 contains two distinct legal provisions. In its first part (up to the word “foodstuff”), it submits “the operation of control, inspection and approval procedures” to the provisions of Annex C. In the second part, it makes clear that the procedures themselves (not their operation) have to be in conformity and must respect all other provisions of the *SPS Agreement*. Far from reinforcing the “catch-all” theory followed by the Complainants, Article 8 confirms the distinction operated by the wording of Article 1 of the *SPS Agreement* that SPS measures “shall be developed and applied in accordance with the provisions of this Agreement” (emphasis added).

272. This distinction between provisions on development and on application of measures is not without its purpose. It addresses two different regulatory needs arising at two different points in time: the need to ensure the creation of procedures which respect certain parameters and the need to ensure the management of these procedures according to other parameters. Other Agreements within the WTO family adopt the same approach. In the GATT, for instance, a number of provisions deal with the substance whilst others, such as Article X:3, address procedural issues. The Appellate Body has clearly explained that “to the extent that the laws, regulations, decisions and rulings themselves are discriminatory, they can be examined for their consistency with the relevant provisions of the GATT 1994.”<sup>184</sup> However, when the legal action is directed against “the *substantive content* of the rules themselves, and not to their *publication or administration*, that [action] falls outside the scope of Article X of the GATT 1994.”<sup>185</sup> Similarly, the *Agreement on Rules of Origin* has a specific

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<sup>183</sup> Canada’s response to question 37 from the Panel, para. 68.

<sup>184</sup> Appellate Body Report, *EC – Bananas*, para. 200.

<sup>185</sup> Appellate Body Report, *EC – Poultry*, para. 115.

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Part II that deals with the “disciplines to govern the application of rules of origin”, as opposed to Part I which establishes the definition of rules of origin.

*ii) Alleged violations of Article 8 and Annex C*

273. With regard to the issues at stake in this case that concern Article 8 and Annex C of the *SPS Agreement*, all parties appear to agree that:

- a violation of obligations set out in Annex C of the *SPS Agreement* simultaneously represents a violation of Article 8 of the *SPS Agreement*;<sup>186</sup>
- not every delay is a violation of Article 8 and Annex C, it has to be “undue”;<sup>187</sup>
- both the “justification for” and the “duration of” the delay are relevant to determine whether the delay is undue.<sup>188</sup>

274. Substantial disagreement exists, however, as to the manner in which to determine the point at which the lapsing of time becomes a “delay,” as well as the circumstances in which a delay has become “undue.”

◆ From a lapse in time to delay

275. As demonstrated above<sup>189</sup>, the Complainants invariably do not identify in the specific facts of each application which periods of time should actually be considered as “delays.” Similarly, they have not been forthcoming or clear in identifying what constitutes a “delay” in general terms. Canada is the only party that has attempted a few definitions. In particular, it has submitted that the lapsing of time becomes a “delay” when:

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<sup>186</sup> First written submission of Argentina, para. 294; first written submission of Canada, para. 297; first written submission of the European Communities, para. 470. It also appears implicit in the approach followed by the United States in its first written submission, Section IV.B.2.b.

<sup>187</sup> Argentina’s response to question 35(b) from the Panel; Canada’s response to question 35(b) from the Panel, para. 60; United States’ response to question 35(b) from the Panel, para. 53.

<sup>188</sup> Canada’s response to question 35(b) from the Panel, para. 61; first written submission of the European Communities, para. 479.

<sup>189</sup> See Sections III.A.1(a) and (b).

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- it is an “‘unjustifiable’ and ‘excessive’ ‘hindrance’ in undertaking or completing an approval procedure”;<sup>190</sup>
  - standard times established in national legislation are being exceeded;<sup>191</sup>
  - processing time for approval in other jurisdictions is shorter (this criterion is, however, relevant but not dispositive).<sup>192</sup>
276. The European Communities believes that the assessment of when a period of time becomes a delay is a matter of fact to be established on a case-by-case basis. In particular, in the case of approval procedures for novel products, each specific product presents characteristics and specificities that are peculiar to it. These also vary according to the specific habitat/environment in which the product is going to be produced and marketed.<sup>193</sup> The question of time cannot, therefore, be separated from the scientific issues associated with an individual product.
277. It follows that it is wrong for Canada to assert that, if a product has been previously approved in other jurisdictions, the processing time for those approvals is also relevant. That may be the case, but not necessarily, depending on the particular facts of each case.
278. It also follows that the time limits in the legislation setting up the approval procedure cannot be but “standard”, i.e. average, indicative. Nowhere is it said in the *SPS Agreement* that Members must always abide by the standard processing periods foreseen in their legislation, as the Complainants claim. In this regard, the Communities notes the flexibility inherent in the Biosafety Protocol, where the drafters plainly recognised the need to take into account the facts on a case-by-case basis. Similarly, Annex C does not even impose on Members an obligation to have such periods established by legislation. Its paragraph 1(b) only requires Members to publish the standard processing period or to communicate to the

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<sup>190</sup> First written submission of Canada, para. 238.

<sup>191</sup> Canada’s response to question 35(b) from the Panel, para. 62.

<sup>192</sup> Canada’s response to question 35(b) from the Panel, para. 62.

<sup>193</sup> For example, the United States Environmental Protection Agency (EPA) has prohibited plantings of transgenic Bt cotton in parts of Arizona, Southern Florida and Hawaii where conditions might be more favourable for cross-breeding between Bt cotton and wild cotton. The concern was that giving wild cotton a Bt producing gene would increase the chances of it becoming an invasive plant.

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applicant the anticipated processing period. The purpose of this provision is one of transparency and is not linked in any way to the concept of “undue” in paragraph 1(a).

279. The European Communities’ legislation contains an indication of standard processing times for the different stages of the procedure. At the same time however, it has a built-in flexibility to take into account steps in the procedure whose exact timing cannot be foreseen and, therefore, standardised. Thus, any period of time during which further information is awaited from the applicant, or during which the scientific committee is analysing the dossier, or during which the Council is supposed to take a decision, is not taken into account.<sup>194</sup>

◆ Possible justifications

280. As seen above in the analysis of the factual claims, the Complainants have not given any reason to explain why the Panel should consider that any delays which may have occurred are “undue.” The Communities notes that the Panel – rather than the Complainants - has taken the trouble to identify a number of possible justifications for procedural delays. This is clear from a question to the Complainants.<sup>195</sup> The Claimants responses to the circumstances suggested by the Panel are often contradictory.

281. Below, the European Communities will analyse each suggested justification in the light of the responses given by the Complainants to the Panel:<sup>196</sup>

- (a) ***The delay is caused by risk considerations which do not fall within the scope of Annex A of the SPS Agreement:*** Argentina and the United States deny that any of the risks at issue in the product-specific applications falls outside the *SPS Agreement*, and in this way avoid answering the question. Canada, on the contrary, agrees in principle that risk considerations outside the scope of Annex A of the *SPS Agreement* can constitute justifications for procedural delays. The European Communities has dwelt at length on the

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<sup>194</sup> See flowcharts on EC notification and approval procedures (Exhibits EC-118, EC-119, EC-120).

<sup>195</sup> Question 48 of the Panel.

<sup>196</sup> Responses of Argentina, Canada and the United States to question 48 of the Panel.

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issue of mixed delays, both above and in earlier submissions. The European Communities considers that any time spent assessing risks that are covered by other WTO Agreements is to be: (i) assessed on the basis of these Agreements, and (ii) is also justified under Annex C, point 1(a), of the *SPS Agreement*.

- (b) ***The delay has been voluntarily accepted by the applicant:*** Argentina and the United States consider that applicants have no other choice but to accept any further behaviour of the authorising authority and that therefore, this cannot constitute a justification for a delay. According to Canada, by contrast, any “voluntary” commitment should be assessed in the same manner as a delay caused by a legislative or regulatory amendment. The European Communities disagrees with all Complainants. In its submission, whenever an applicant has accepted a delay, such as in the case of the voluntary implementation of the so-called interim approach, it must be deemed to have accepted as justified the reasons that lay behind these changes.<sup>197</sup> Nothing would have, in fact, prevented an applicant from complaining about such delays. The EC legislation foresees the possibility of administrative and judicial remedy, before national courts and ultimately the ECJ, but none has been sought.
- (c) ***The delay is caused by the entry into force of new legislation with stricter requirements:*** Argentina contests that an “imminent” rather than an “effective” legislation can have any consequence. Canada, on the contrary, recognises that, subject to reasonable limits, this can be considered a justification for procedural delays. The United States appears implicitly to agree with Canada. The European Communities concurs with Canada that the entry into force of new legislation which foresees stricter requirements to protect human, animal and plant life or health or the environment, may constitute a justification for procedural delays. This is the case of the

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<sup>197</sup> As with regard to the United States’ claim that the European Communities has not proven that any delay was actually accepted by the applicants, the European Communities considers this nothing more than one of the usual attempts by the United States to reverse the burden of proof. It also shows the ignorance by the United States of the chronologies of the individual product-specific applications

legislative changes to the regulatory framework for the approval of GMOs. Legislative changes were necessary to address a number of changes in scientific knowledge and, therefore, a different awareness of the risks at stake. These legislative changes at the EU level were entirely consistent with international developments.

- (d) ***The delay is not attributable to a Member (e.g. caused by the applicant)***: all parties agree that in this case the delay would be justified.
- (e) ***The delay is necessary to ensure compliance with existing legislation and relevant international standards (e.g., Codex Principles; see Exhibit EC-44)***: Argentina tautologically submits that if a delay is caused by the need to ensure compliance with existing legislation and relevant international standards the result of it should be a decision of approval or rejection, but not a delay. The United States considers that the question of ensuring compliance with national legislation is not dispositive of whether a delay is “undue”; whilst Canada recognises that if the “existing legislation” is the one establishing the approval procedure itself, then compliance with it is certainly a justification. The European Communities agrees with Canada. However, in the course of a specific approval procedure, delays can be caused also by compliance with other relevant legislation than the one establishing the approval procedure itself, for instance legislation on traceability and labelling. Such delays are also justified. In the specifics of the case at issue, as the Complainants do not contest the requirements of the overall EC GMO legislation, any time spent to conform to such legislation must be considered justified.
- (f) ***The delay is caused by efforts to elaborate monitoring requirements, adequate agricultural practices and similar efforts to manage SPS risks***: Argentina contests this justification on the basis of the fact that, if a risk assessment exists, the authorisation must be granted. The European Communities disagrees with Argentina. As explained at length in its

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submitted by the European Communities, in which all the applicants’ voluntary commitments are clearly indicated and annexed.

submissions,<sup>198</sup> risk assessment and risk management are two distinct phases of the risk analysis process and have related but different aims. In particular, according to the Codex definition, risk management is “the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.” Thus, risk management decisions do not necessarily mirror the risk assessment conclusions but have to determine the policy decisions on the basis of such conclusions. Article 5.1 of the *SPS Agreement* recognises this when it requires SPS measures to be “based” on a risk assessment rather than to “conform” to it. In any case, Argentina fails to note that in this case it is often the very risk assessment body that has recommended, or even imposed as conditions for a favourable opinion, monitoring and similar requirements.<sup>199</sup> Canada agrees with the European Communities when it considers the elaboration of risk management tools to be “a legitimate component of the approval procedure.” However, Canada qualifies its position by arguing that the risks to be managed have to be “identified based on relevant scientific evidence.” The European Communities has already addressed these arguments above.<sup>200</sup> Here it notes that, in its legislation on GMOs, certain risk management measures are to be proposed by the applicant and must be submitted already with its notification, thus independently from any risk assessment determination.<sup>201</sup> As this requirement of the EC legislation has not been contested by Canada, the European Communities understands that Canada considers it as being based on “relevant scientific evidence.” Canada thus appears to concur with the European Communities that the scientific evidence and the risk assessment on which an approval has to be based are not only the ones respectively considered or rendered by a given Scientific Committee but all those which are available at the time the final decision on approval is taken.

<sup>198</sup> See, above, Section II.B and European Communities’ response to question 2 from the Panel, para. 9.

<sup>199</sup> See, for example, the SCP’s opinions on Bayer oilseed rape FALCON GS40/90, on Bayer oilseed rape MS8/RF3, on Roundup Ready fodder beet A5/15, and on Bt Cotton 531; first written submission of the European Communities, para. 204, 211, 218 and 224.

<sup>200</sup> See above, para. 25 and 26.

<sup>201</sup> See Article 13, paragraph 2(e), of Directive 2001/18/EC, with regard to monitoring plans.

282. In addition to these justifications, the European Communities submits that delays in approval procedures can also be justified by (g) the analysis of scientific and technical issues, and (h) risk communication matters such as labelling. In neither case is delay to be considered “undue.”
283. Last but not least, the European Communities would like to draw the Panel’s attention to the fact that, in its response to Question 48 from the Panel the United States reverses the burden of proof. It states that the European Communities has not shown that the delays in its application procedures were caused by any of the possible reasons identified by the Panel. The United States here fails to engage with the facts and the detailed chronologies submitted for each product-specific application by the European Communities. In this regard, the European Communities wishes to recall that in accordance with the constant jurisprudence of panels and of the Appellate Body<sup>202</sup> it is for the United States to prove the violation which it asserts. It is for the United States, as the party invoking a violation of Annex C, point 1(a), to identify specific delays in the single product-specific applications and to prove that these were “undue.”

(d) The TBT Agreement

284. For a rebuttal of the claims related to the *TBT Agreement*, the European Communities refers the Panel to the horizontal section above.<sup>203</sup>

(e) GATT 1994 – Articles III:4 and XX

285. As mentioned above, the European Communities notes that there has been no discussion of this claim by the Complainants at the first meeting of the Panel with the Parties or in the replies to the questions of the Panel and so has nothing to add to its First written submission.
286. In general terms, it restates its defence that, in the unlikely event that the Panel should find that any delay in a product-specific application is inconsistent with any

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<sup>202</sup> See above, Section II.A.

<sup>203</sup> See above, Section II.D.

of the provisions invoked by the Complainants, the actions are nevertheless justified under Article XX of the GATT.<sup>204</sup>

*B. The alleged “general suspension” or “general moratorium”*

**1. Measures at issue**

287. The Complainants’ arguments on the alleged general moratorium have become even more obscure in the light of the Complainants’ statements at the first hearing. Their replies to the questions put by the Panel and the European Communities do not provide any material clarification. It is still not possible to ascertain precisely what the Complainants mean by the term “moratorium.” Nor is it possible to identify with any degree of precision the precise acts or omissions on the part of the Communities to which the term is said to refer. The Communities also notes that the approach taken by the Complainants is contradictory and inconsistent.
288. This Panel is being invited by the Complainants to identify the existence of a measure which is alleged to be a moratorium, and to decide the entire case on that basis. This is notwithstanding the Complainants’ evident inability to identify a single decision on the part of the Communities which reflects such a moratorium. In the circumstances, if the Panel is to identify a violation of WTO law through this so-called “moratorium” - and for the European Communities to bring its actions into compliance with its WTO obligations - the Panel must define with absolute precision what the “moratorium” consists of and what the measure at issue is. Contrary to what the Complainants state, this is not a question of implementation. It is the very subject-matter of the dispute. Identifying a “moratorium” is a mixed question of fact and law lying at the heart of the dispute.
289. In general terms a moratorium may be defined as “a postponement or deliberate temporary suspension of some activity.”<sup>205</sup> “Suspension” is the “action to suspend.” To “suspend” is defined as “putting a stop to, esp. temporarily, ceasing

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<sup>204</sup> See first written submission of the European Communities, Section III.G.

<sup>205</sup> The New Shorter Oxford English Dictionary, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 1828

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- from the execution or performance of, desisting from, ceasing temporarily, deferring dealing with.”<sup>206</sup>
290. A measure that is a moratorium must therefore be shown to be a “plan or course of action”<sup>207</sup> to suspend a procedure. Alternatively, as the Panel itself has put it, it must be “a decision not to decide.” The process of decision-making is temporarily stopped with the effect that applications are no longer being considered.
291. On the basis of the facts which the European Communities has put before the Panel it is clear that there has been no such decision attributable to the European Communities. There may be expression of individual opinion associated with specific persons, or views of individual member States. But the Communities itself has not taken any such decision. There has been no moratorium adopted by the European Communities in the case of GMOs in the period between 1998 and 2003. There is no moratorium in place now. Every application is decided on its own merits, against the background of proposed and actual new legislation and changes in scientific knowledge and understanding, including risk assessment and risk management. This is clear from a number of features.
292. First, even though EC legislation was being revised in the period 1998 to 2001, in order to put in place more comprehensive and stricter legislation to take account of new scientific understanding and international developments, the procedure of considering existing applications was never suspended to await the entry into force of that legislation. Instead, as set out above in the section on product-specific delays, the existing applications continued to be assessed and were the subject of decision-making procedures. Those applications that had reached an advanced stage were treated on the basis of an “interim approach” which sought to anticipate the new Community legislation, in particular as regards certain risk management requirements. The Panel will now recognise that there were a number of particularly complex issues, which required an extensive exchange between the competent authorities and the applicants and which cost a considerable amount of time. The Complainants appear to contest the manner in which this effort of taking

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<sup>206</sup> The New Shorter Oxford English Dictionary, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3162

<sup>207</sup> The New Shorter Oxford English Dictionary, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 1726

- the procedures forward was engaged but the fact remains that there was no suspension of the process.
293. Second, during the period in question the new legislation has entered into force and the above period of transition has ended (i.e. in the case of Directive 2001/18 well before the establishment of this Panel). The application procedures are now proceeding in accordance with the requirements of that Directive, giving effect to the considerations which took place in the period between 1998 and 2003. While the application procedures, in some cases, may have suffered important delays during the transition period, they are now proceeding normally. The Complainants may not agree with one or the other position or decision taken by individual players or instances in these application procedures, but it is evident that at no time was there a suspension of the process, either formally or informally.
294. The Complainants seek to avoid the consequences of this fact in a number of ways. On the one hand, they avoid engaging with the issue of what the moratorium is. Instead, they dwell on its effects,<sup>208</sup> or its “victims,”<sup>209</sup> or its “expressions,”<sup>210</sup> or its results,<sup>211</sup> and so on. As regards the issue of statements of certain individuals, the European Communities refers to its comments in the first written submission. Suffice it to say that all these statements refer to or comment on a fact which the European Community does not contest, i.e. that there have not been any market authorisations for a given period of time other than the market authorisations granted pursuant to the simplified procedure under the Novel Foods Regulation. The “absence of a decision,” however, is not the same thing as a “decision not to decide.”
295. More generally, however, the Complainants attempt to obtain a factual and legal ruling against the European Communities based on their description of a factual situation that allegedly is the effect, result or consequence of a presumed moratorium. That attempt is artificial and simplistic. It seeks to replace legal and factual analysis with mere assertion. The responsibility of WTO members arises

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<sup>208</sup> See for example Canada’s response to question 45 of the Panel.

<sup>209</sup> See Canada’s response to question 63 of the Panel.

<sup>210</sup> See Argentina’s response to question 5 of the Panel.

<sup>211</sup> See Oral Statement of the United States at para. 42.

only on the basis of measures which have been taken. Responsibility cannot arise from (alleged) effects, or results or consequences. The task of the Panel is to identify the measure, and to do so precisely and accurately. Panels do not rule on effects without establishing the existence of a measure for which the WTO member is responsible. The question of what measure caused an observed effect cannot be left open.

296. On the other hand, the Complainants try to get around the fact that there is no suspension of the procedure by reinventing the definitions and meaning of the terms “moratorium” and “measure.” The issue now is no longer that of a suspension of the approval process, but that of a “blockage at key stages in the process.” Blockage, *nota bene*, in that context, according to the Complainants, does not mean that a product application gets stuck at a particular decision-making stage. Indeed, the product applications have moved from one stage to the next as is obvious even from the tables presented by Canada and the United States in their replies to the Panel’s questions (which the European Communities otherwise considers to be fundamentally flawed)<sup>212</sup> let alone from the detailed chronologies that the European Communities has provided. Blockage rather means that developments are not always going the way the Complainants would like them to go. For example, a competent authority may take longer than foreseen in the legislation, or consultation among Member States is dragging on, or a Regulatory Committee does not vote in favour, or the Council is unable to find a qualified majority, or information has not been provided by an applicant. According to the Complainants any of these matters are to be treated as part of a scheme of “concerted acts and omissions”, by which the European Communities is “giving effect to the moratorium.”
297. Quite apart from the factual errors contained in the above tables, the European Communities objects in strong terms to the legal approach taken by the Complainants, which is highly problematic in a number of respects.

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<sup>212</sup> As explained in detail in Section III. A.1 the facts presented in this table are not accurate. Moreover, for the purposes specifically of proving a “moratorium” that applies *across the board*, it does not suffice to address only a limited selection of product applications.

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298. First, the Complainants present as a measure, i.e. as a plan or course of action, the most diverse reactions of different players in relation to different applications. Even if one were to accept a theory that “concerted acts and omissions” could collectively constitute a measure,<sup>213</sup> it is still necessary to prove that (a) there is a plan or course of action, a *design*, which is being followed, and (b) that it is being followed as *de facto* binding by all players involved. Such proof requires evidence, and this has not been provided by the Complainants. The Complainants already fail the first hurdle. They describe the most diverse actions, which only have one thing in common, namely that from the Complainants’ point of view they are not scientifically justified. What is more, they conveniently leave out all others that do not fit the picture.
299. Second, the “acts and omissions” presented are part of an internal decision-making process and as such do not have external legal effect. What has legal effect and is, therefore, challengeable is the final outcome of the decision-making procedures, and only that.<sup>214</sup> By the same token, if there is no act or final outcome of the decision-making procedure, what can be attacked is a failure to act, but only if it is possible to identify in WTO law a positive obligation to act. In this case the only positive obligation is to act without undue delay. The European Communities have comprehensively and effectively demonstrated that when one looks at each individual application there has been no undue delay, generally or individually.
300. The strategy adopted by the Complainants is obvious. Attacking an alleged “measure” in the way they have avoids the need to address the individual merits of each application. It may also offer the possibility of greater control on the implementation side. The Panel should resist these attempts to entirely dissolve the concept of a “measure” for convenience sake.
301. In conclusion, the European Communities submits that there is no measure or measures which individually or collectively may be treated as a moratorium.

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<sup>213</sup> As the European Communities has pointed out in its first written submission (paras. 566 et s.), it is established case law that a practice as such does not constitute a challengeable measure. “Concerted acts and omissions”, if anything, would have to be considered a practice.

<sup>214</sup> In the case law of the European Court of Justice this is well established see for example In Case T-326/99, *Nancy Fern Olivier v. Commission and EMEA*, decision of the 18 December 2003, at paras. 51 et s.

**2. The issues the Panel would have to address if there were a measure**

302. Should the Panel, however, take the view that there is a measure, it would have to consider a number of issues, most of which the European Communities has already discussed elsewhere in this submission.
303. First, if the Panel were to adopt the view that there is a measure it would have to determine whether the measure was in existence at the time of the establishment of the Panel and if so, whether it still is in existence. The first is a question of subject-matter jurisdiction, the second a question of mootness. As the European Communities has explained elsewhere, if the delays that occurred in the approval procedures before (and because of) the adoption of the new legislation were to be seen as a measure, that measure would have ended with the entry into force of that legislation, namely with the entry into force and application of Directive 2001/18 as of January 2003.<sup>215</sup> The measure, therefore, would not have been in existence at the time of the establishment of the Panel.
304. Second, if the Panel were to take the view that there is a measure (in existence and not moot) it would, as with regard to any other measure adopted in the context of a GMO approval procedure, have to determine to what extent that measure comes within the scope of the *SPS Agreement*. The European Communities refers to its comments in section II.C.1. of this submission as well as in its first written submission.<sup>216</sup>
305. Third, to the extent that the Panel were to examine the measure under the *SPS Agreement* it would have to address it under Article 5.7 of that *Agreement*, as the measure would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence. The European Communities refers in this respect to its arguments on the issue of burden of proof.<sup>217</sup>
306. Fourth and to the extent that the measure does not fall under the *SPS Agreement* the Panel would need to consider whether it is a technical regulation falling under

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<sup>215</sup> See response of the European Communities to question 7 of the Panel.

<sup>216</sup> First written submission of the European Communities, paras. 388 et s.

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the *TBT Agreement* or whether Article III:4 of the GATT 1994 would be applicable.

307. Fifth and finally, to the extent the Panel were to examine the measure under the *TBT Agreement* or the GATT 1994, it would have address the question of possible justification under Article XX GATT 1994.
308. As has been argued in the relevant sections in part II of this submission, expert advice is needed on a number of these issues.

C. *The EC Member State Safeguard Measures*

**1. Facts and legal argument before the Panel**

309. The United States asserts that the European Communities' detailed explanations as to the Member States' safeguard measures are "vague and cryptic." It claims that it cannot "discern ... what reasons the EC is referring to."<sup>218</sup> The European Communities does not deny that its submissions are lengthy. Perhaps under constraints of time the United States has not found it too easy to read the repeated and clear cross references in the First written submission of the European Communities.<sup>219</sup>
310. To assist the United States, the European Communities offers the following example in respect of one Member State's safeguard measures. It is the measure adopted by Austria in relation to the insecticidal GM maize Bt-176.<sup>220</sup> One of the reasons for the Austrian safeguard measure is the issue of antibiotic resistance.<sup>221</sup> Austria's concern is that the antibiotic resistance marker gene might be transferred to bacteria in the human gut, and that this might eventually reduce the effectiveness of antibiotics used in medicine.<sup>222</sup> This issue falls, at least in part,

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<sup>217</sup> See first written submission of the European Communities, paras 595 et s. as well as, in this submission section II.A.2.

<sup>218</sup> First oral statement of the United States, para 54.

<sup>219</sup> Repeated above in the section of this rebuttal relating to the *SPS Agreement*.

<sup>220</sup> First written submission of the European Communities, para 347 and footnote 254.

<sup>221</sup> First written submission of the European Communities, para 348.

<sup>222</sup> First written submission of the European Communities, paras 48 to 50.

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outside the scope of the *SPS Agreement*.<sup>223</sup> Therefore, some of the reasons for the Austrian safeguard measure fall outside the scope of the *SPS Agreement* and, in relation to these reasons, the Austrian safeguard measure cannot be considered inconsistent with the *SPS Agreement*.<sup>224</sup> To further assist the United States, the European Communities attaches a table summarising the overall situation. In each case reference may be made to the same sections of the First written submission of the European Communities as are indicated above.

311. The European Communities refers to its additional submission concerning the scientific issues, where these matters are further developed.

## **2. The concerns of the Member States**

312. The Panel asked the United States to explain its position in relation to the concerns cited by the Member States.<sup>225</sup> The United States answered that question by reference to what it alleges “the Member State measures cite” – which is something different. The United States thereby changed the terms of reference of the Panel’s question, and thus failed to respond to the question actually posed. What is or is not expressly referred to in the Member State measures themselves is not the point. Those measures are in some cases relatively succinct, as is often the case with provisional measures. The United States knows perfectly well that they do not contain more than a summary or indication of the issues. The United States deliberately selects what it knows to be a narrow presentation of the issues, as part of its general strategy to force as much as it possibly can into the scope of the *SPS Agreement*.

313. A true appreciation of the Member State concerns emerges from a fair and complete consideration of the histories of each of these measures, and the procedural steps leading up to, and following, their adoption. What is relevant are not just the concerns that resulted in the adoption of these measures, but also the concerns that cause the Member States to maintain these measures. Indeed, the

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<sup>223</sup> First written submission of the European Communities, para 432.

<sup>224</sup> First written submission of the European Communities, para 578.

<sup>225</sup> United States response to question 77 from the Panel.

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Community legislation expressly provides an opportunity for the Member States to explain to the Commission the reasons for which such measures are maintained, and that is typically done both in writing, as well as orally, in the meetings of the various relevant committees. In these proceedings the European Communities is responsible for these Member State measures, and the European Communities has explained in detail to the Panel and the Complainants the true scope of the concerns that resulted in these measures being adopted and maintained. They are summarised in the attached table. The European Communities has also explained in detail which of these concerns fall within the scope of the *SPS Agreement*, and which do not, and why. The United States has not properly or fully responded to these explanations, but rather has simply attempted to change the underlying terms of reference.

314. As regards Bt-176 and the other insecticidal crops, the European Communities has explained in the section of this rebuttal relating to the *SPS Agreement* that it does not agree that the GMO crop itself is a “pest” within the meaning of Annex A.1(a) of the *SPS Agreement*. The European Communities has similarly explained why the antibiotic resistance marker gene is not an “additive” within the meaning of the *SPS Agreement*, and why the antibiotic resistance issue must necessarily fall, at least in part, outside the scope of the *SPS Agreement*. The United States assertion that, in the specific case of insect resistance, necessitating the use of other insecticides, the crop becomes the pest, is wrong. This matter is covered by the *SPS Agreement* insofar as it concerns the threat to human or animal health from risks arising from increased residues in food, beverage or feed due to increased use of insecticides. It is not covered by the *SPS Agreement* insofar as it concerns the effects on wild fauna or other effects on human health such as effects due to increased exposure of operators or bystanders.<sup>226</sup>

315. As regards herbicide tolerance, the European Communities agrees that part of the measures falls within the *SPS Agreement*.<sup>227</sup> As regards the increased use of herbicides in relation to the introduction of a herbicide tolerant GM crop, the European Communities agrees that the threat to human health falls partly within

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<sup>226</sup> First written submission of the European Communities, paras 428 and 430.

<sup>227</sup> See generally first written submission of the European Communities, paras 419 to 424.

the *SPS Agreement* – but Annex A.1(b), not Annex A.1(d). The same is true of the threat to animal health. The threat to wild flora and fauna, however, falls outside the scope of the *SPS Agreement*.

316. The European Communities strongly disagrees with the response of the United States to question 73 from the Panel. The first issue here is whether or not measures taken to protect humans from allergic reaction to a substance that happens to be a toxin for insects falls within or outside the *SPS Agreement*. The United States is wrong to assert that such a measure falls within the scope of the *SPS Agreement*. For such a measure to fall within the scope of the *SPS Agreement*, it would have to protect humans from the substance *as a toxin*, not as an allergen. The very concept of “toxic” is a relational one, requiring an analysis of how the toxic thing and the protected thing interact, *in terms of toxicity*. The view of the United States would appear to be that as soon as any thing would be toxic for any human, animal or plant, any measure taken to protect any other human, animal or plant from *any threat of whatever kind* posed by that thing would be within the *SPS Agreement*. That is incorrect. A heavy bar containing highly toxic concentrations of lead might be the subject of sanitary or phytosanitary measures. That does not mean that legislation designed to prevent such a bar from being physically used as a weapon falls within the scope of the *SPS Agreement*. The second issue is that, in much the same way, concerns about occupational exposure are not covered by concerns about the presence of a substance in food.

### **3. Provisional nature of the measures**

317. The European Communities refers to the section of this rebuttal relating to the *SPS Agreement*, where it has explained the relationship between Article 5.7 and the other provisions of the *SPS Agreement*. All the Complainants originally stated that the Member State measures are provisional measures, and the European Communities agrees with that assessment.

### **4. Level of protection and sufficiency of science**

318. The European Communities refers to the section of this rebuttal relating to the *SPS Agreement*, where it has explained the relationship between Article 5.7 and the other provisions of the *SPS Agreement*, and specifically how the different levels of protection sought by different legislators may affect the view they take about whether or not the available scientific evidence is insufficient.

#### **IV. CONCLUSIONS AND REQUEST FOR SEPARATE FINDINGS**

319. In the light of the preceding observations, the European Communities refers to and re-iterates the conclusions set out in its first written submission, as supplemented by its oral statement and its response to the Panel's questions.

320. The European Communities would also recall that at this stage of the proceedings it remains clear that the Complainants allege different facts and make different claims, and accordingly the European Communities requests the Panel to make separate and specific findings and recommendations for each Complainant. The European Communities does not consider at this stage that separate Panel reports for each of the three cases are essential.

**LIST OF EXHIBITS**

EC-155      Table summarising the position in relation to the Member State measures,  
as set out in the first written submission of the European Communities.