(d) Overall conclusion

7.1627 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 10.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

E. PRODUCT-SPECIFIC MEASURES

1. Measures at issue

7.1628 In addition to the general *de facto* moratorium on approvals, the Complaining Parties are also challenging a number of product-specific measures. The Panel begins its analysis by setting out the Complaining Parties' general descriptions of the measures at issue and the European Communities' comments in response.

(a) General

7.1629 The **United States** notes that it is challenging the failure by the Commission and the member States to consider for approval certain applications specified in its request for the establishment of a panel. The United States refers to these product-specific measures as "product-specific moratoria". According to the United States, these product-specific moratoria are separate measures from the general moratorium affecting all applications. The United States also notes, however, that they are similar measures in that both refer to the European Communities' failure to consider applications for approval. Also, since the general moratorium applied to all applications, a necessary corollary is that the European Communities also adopted product-specific moratoria on each of the relevant applications specified in the United States' panel request. Accordingly, the evidence and arguments the United States adduced in support of the existence of a general moratorium also establish the existence of the product-specific moratoria, and that the European Communities did not undertake and complete its approval procedures for each individual application without undue delay.

7.1630 **Canada** states that it is challenging the failure by the European Communities to consider or approve, without undue delay, certain applications specified in its request for the establishment of a panel. Canada refers to the failure by the European Communities in this regard as the product-specific marketing bans. Canada contends that the general moratorium and the product-specific marketing bans are closely related, though distinct, measures. The product-specific marketing bans are a direct consequence of the moratorium as applied to individual applications. They are the manifestation of the moratorium in the context of the approval procedures of the four specific products of concern to Canada. Canada's arguments in relation to product-specific marketing bans are intended to focus on the direct and detrimental impact of the moratorium on specific applications.

7.1631 **Argentina** states that it is challenging (i) the suspension by the European Communities of consideration of specified applications for approval, or the failure to consider specified applications for approval as well as (ii) the undue delays in completing the consideration and processing of specified applications. Argentina argues that the product-specific suspension of processing or failure

to consider as well as the undue delay are effects of the application of the *de facto* moratorium to specific applications for approval.

7.1632 The **European Communities** notes that it has considerable difficulty in understanding the difference between the first group of claims by the Complaining Parties relating to the alleged moratorium on approvals and the second group of claims relating to alleged failures to consider for approval specific applications. According to the European Communities, the Complaining Parties' assertions about a "suspension of procedures" or any "failure to consider applications" are assertions about delay.

7.1633 The **Panel** notes that, according to the Complaining Parties, the product-specific measures they are challenging are distinct from the general *de facto* moratorium on approvals. At the same time all three Complaining Parties point out that the product-specific measures are related to the general moratorium on approvals. Based on these statements and the Complaining Parties' arguments, it is our understanding that the product-specific measures are, or arise from:

- specified acts and/or omissions through which the relevant EC entities were giving effect, in the context of particular approval procedures, to their decisions to impose a general moratorium on approvals, or
- specified acts and/or omissions through which relevant EC entities chose to respond, again in the context of particular approval procedures, to the circumstance that other EC entities were imposing a general moratorium on approvals.

7.1634 It should be noted, however, that in their requests for the establishment of a panel, the Complaining Parties have described the product-specific measures in more general terms. Moreover, each Complaining Party has used a somewhat different description. It is therefore useful to address these different descriptions one by one.

7.1635 The United States in its panel request says that the measure at issue is the failure by the European Communities to consider particular applications for approval. It is clear to us that the United States does not contend that the European Communities has not considered the relevant applications at all. In our view, the United States contends that the European Communities has failed to consider the relevant applications for *final* approval. We understand this to be essentially a contention that the consideration of these applications was affected by the general moratorium on final approvals, in the sense that their consideration was either effectively suspended at some point in the approval process or continued at a delayed pace. This understanding would appear to be supported by the fact that when referring to the product-specific measures, the United States speaks of the "product-specific moratoria".

7.1636 Canada in its panel request says that the measure at issue is the failure by the European Communities to consider or approve, without undue delay, the applications mentioned in its request. Thus, unlike the United States, Canada explicitly includes an allegation of undue delays in the consideration and approval of the relevant applications in the definition of the measures being challenged. At the same time, Canada refers to the alleged failure to consider or approve the relevant applications without undue delay as the product-specific marketing bans. Canada claims in this regard that at some point in the approval process each of the relevant applications was subjected by the European Communities to an effective marketing ban. The validity of this claim will be discussed further below. At this stage, it is sufficient to note that we will conduct our examination based on the description of the product-specific measures set out in Canada's panel request.

7.1637 Argentina distinguishes two types of product-specific measures. The first type of product-specific measure is described in Argentina's panel request as the suspension of consideration of, or the failure to consider, particular applications for approval. In our understanding, this type of measure is conceptually the same as the product-specific measures referred to in the United States' panel request. The second type of product-specific measure identified in Argentina's panel request concerns undue delays in finalizing consideration of particular applications for approval. Accordingly, like Canada, Argentina explicitly includes an allegation of undue delays in the consideration of the relevant applications in the definition of the measures being challenged.

(b) Relevant applications

7.1638 As noted above, each of the product-specific measures challenged by a particular Complaining Party relates to a particular application. Below it is indicated (i) how many applications were specified by each Complaining Party and (ii) on how many of these applications the Panel has been requested to offer product-specific findings.

(i) DS291 (United States)

7.1639 The United States in its request for the establishment of a panel stated that the relevant applications are mentioned in Annexes I and II to its request. These two Annexes list a total of forty-one applications. As all forty-one applications are within the terms of reference of this Panel, there are, in principle, forty-one product-specific measures which the United States could seek to challenge. However, in its first written submission, the United States indicated that it is making claims in respect of only twenty-seven applications.[1336] We conclude from this that the United States has abandoned its product-specific claims in respect of the remaining fourteen applications.[1337]

7.1640 According to the United States' first written submission, the twenty-seven applications in respect of which it is pursuing product-specific claims include eighteen which were submitted under Directive 90/220 and were pending under Directive 2001/18 on the date of establishment of this Panel as well as nine applications pending under Regulation 258/97.[1338] Among the nine applications the United States claims were pending under Regulation 258/97, there are two applications which were withdrawn before the Panel was established. They are Transgenic red-hearted chicory (food) and Transgenic green-hearted chicory (food). Evidence provided by the European Communities shows that both were withdrawn by the applicant in May 2003.[1339] We note in this respect that, in a submission made subsequent to its first written submission, the United States stated that it is not requesting findings on applications that were withdrawn prior to the establishment of the Panel.[1340] In the light of this categorical statement, we consider we need not, and hence do not, make findings in respect of the two aforementioned applications concerning transgenic chicory. This means that there are in total twenty-five applications on which the Panel is expected to offer product-specific findings

[1336] US first written submission, paras. 67, 131, 137-138.

[1337] It should be noted that the United States discussed the applications concerning MS1/RF2 oilseed rape and MS1/RF1 oilseed rape (EC-89) under the heading "product-specific moratoria". US second written submission, para. 53. However, the United States also presented arguments relating to its general moratorium claim under that heading. US second written submission, paras. 52-53. Accordingly, we do not understand the United States to have increased the number of measures in respect of which it is making product-specific claims.

[1338] The eighteen applications pending under Directive 2001/18 are identified at paras. 49-51 of the US first written submission; the nine applications pending under Regulation 258/97 are identified at paras. 54-55 of the US first written submission.

[1339] Exhibits EC-97/At. 32 and EC-98/At. 42. The United States also acknowledges this fact. US second written submission, footnote 76.

[1340] US reply to Panel question No. 197, footnote 26.

– eighteen which were pending under Directive 2001/18 and seven which were pending under Regulation 258/97.

7.1641 The eighteen applications which were pending under Directive 2001/18 as of August 2003 comprise those concerning:

- Bt-531 cotton
- RR-1445 cotton
- Falcon oilseed rape
- MS8/RF3 oilseed rape
- RR fodder beet
- Transgenic potato
- Liberator oilseed rape
- Bt-11 maize (EC-69)
- GA21 maize (EC-78) (withdrawn in September 2003)
- MON810 x GA21 maize (withdrawn in September 2003)
- LL soybeans (EC-71) (withdrawn in June 2004)
- LL oilseed rape
- BXN cotton[1341]
- Bt-1507 maize (EC-74)
- Bt-1507 maize (EC-75)
- NK603 maize (approved by Commission in July 2004)
- RR oilseed rape (EC-70) (approved by Commission in August 2005[1342])
- RR sugar beet (withdrawn in April 2004)

7.1642 The seven applications which were pending under Regulation 258/97 as of August 2003 are those concerning:

- GA21 maize (food)
- Bt-11 sweet maize (food) (approved by Commission in May 2004)
- NK603 maize (food) (approved by Commission in October 2004)
- LL soybeans (food) (withdrawn in July 2004)
- Bt-1507 maize (food)
- RR sugar beet (food) (withdrawn in April 2004)
- MON810 x GA21 maize (food)

(ii) DS292 (Canada)

7.1643 Canada's request for the establishment of a panel identifies four applications. They were all submitted under Directive 90/220. As of August 2003, they were either pending under Directive 2001/18 or awaiting the lead CA's written consent to the placing on the market. Canada requests product-specific findings on all four applications. The applications at issue are those concerning:

[1341] According to the European Communities, the application concerning BXN cotton was withdrawn by the applicant after the establishment of the Panel. However, the European Communities has provided no support for this assertion.

[1342] We recall that after the second substantive meeting, on 1 September 2005, the Panel received a letter from the European Communities stating that the Commission had approved the application concerning RR oilseed rape (EC-70) under Directive 2001/18.

- MS1/RF1 oilseed rape (EC-89) (awaiting the lead CA's written consent)
- MS1/RF2 oilseed rape (awaiting the lead CA's written consent)
- MS8/RF3 oilseed rape
- RR oilseed rape (EC-70) (approved by Commission in September 2005[1343])

(iii) DS293 (Argentina)

7.1644 Argentina's request for the establishment of a panel contains an attachment, Annex I, which identifies seventeen applications. It appears that Annex I is intended to illustrate the impact of the general *de facto* moratorium on specific applications as well as to specify the applications in respect of which Argentina is making product-specific claims. Among the seventeen applications referred to in Annex I, there are two which are mentioned twice.[1344] There are four additional applications in respect of which Argentina makes no claims in its submissions.[1345] The eleven remaining applications are the applications on which we think we are requested to make product-specific findings. Of these eleven applications, six were submitted under Directive 90/220. With one exception[1346], they were pending under Directive 2001/18 on the date of establishment of this Panel. Argentina claims that the other five applications were all submitted under Regulation 258/97.

7.1645 The six applications submitted under Directive 90/220 comprise those concerning:

- Bt-531 cotton
- RR-1445 cotton
- GA21 maize (EC-78) (withdrawn in September 2003)
- GA21 maize (EC-85) (withdrawn in June 2001)
- NK603 maize (approved by Commission in July 2004)
- LL soybeans (EC-71) (withdrawn in June 2004)

7.1646 The five applications which Argentina says were submitted under Regulation 258/97 are those concerning:

- Bt-531 cotton
- RR-1445 cotton
- GA21 maize (food)

[1343] We recall that after the second substantive meeting, on 1 September 2005 the Panel received a letter from the European Communities stating that the application concerning RR oilseed rape (EC-70) was approved by the Commission in September 2005. We further note that in the context of presenting its product-specific claims in respect of the application concerning RR oilseed rape (EC-70), Canada also presented arguments on RR oilseed rape (EC-79). *E.g.*, Canada's first written submission, paras. 86-87 and 295. *See also* Canada's reply to Panel question No. 60. The application concerning RR oilseed rape (EC-79) was submitted to France. However, Annex I to Canada's panel request refers only to the application submitted to the Netherlands, which is that concerning RR oilseed rape (EC-70). Accordingly, we will not entertain Canada's product-specific claims in respect of the application concerning RR oilseed rape (EC-79) submitted to France. We consequently offer no product-specific findings on that application.

[1344] This is the case of the applications concerning GA21 maize (food) and LL soybeans (EC-71). Argentina in its submissions to the Panel does not argue that the applications which we consider are mentioned twice are in fact different applications.

[1345] This is the case of the applications concerning GA21 maize (EC-78) (alleged procedure under Regulation 258/97), T14 maize (procedure under Directive 90/220 and alleged procedure under Regulation 258/97) and LL soybeans (EC-81). T14 maize is mentioned in footnote 188 of Argentina's first written submission, but no claim is raised there.

[1346] The application concerning GA21 maize (EC-85) was withdrawn in June 2001.

– NK603 maize (food) (approved by Commission in October 2004)
– LL soybeans (food) (withdrawn in July 2004)

(c) Withdrawn and approved applications

7.1647 The above analysis shows that among the applications in respect of which the Panel is requested to make product-specific findings are applications which were withdrawn either before or after the Panel was established. There also are applications which were approved by the Commission in the course of the Panel proceedings. The European Communities argues that the Panel should not make findings with regard to withdrawn or approved applications. Accordingly, we must decide whether it is appropriate to assess the WTO-consistency of the relevant product-specific measures.

(i) Applications withdrawn before the establishment of the Panel

7.1648 We note at the outset that if an application is withdrawn, this means that the product-specific measure complained of no longer exists. In the case of the application concerning GA21 maize (EC-85), the product-specific measure complained of by Argentina is the alleged "undue delay in finalizing consideration of that application". Once that application was withdrawn, this meant that there no longer was an undue delay in finalizing consideration of that application.

7.1649 As we pointed out earlier, the product-specific measure which relates to the application concerning GA21 maize (EC-85) is within the terms of reference of DS293 (Argentina). Notwithstanding this, the European Communities submits that claims concerning applications withdrawn before the Panel was established are without object and, hence, inadmissible ab initio. In our view, the mere fact that the product-specific measure concerning GA21 maize (EC-85) no longer existed as of the date of establishment of the Panel does not, *ipso facto*, deprive us of our authority to make findings on a measure that is within our terms of reference.[1347]

7.1650 This is also clear from the Appellate Body report in *US – Certain EC Products*. That dispute concerned a measure which was withdrawn almost two months before a panel was established.[1348] The panel considered the measure, offered findings on it and recommended that it be brought into conformity with WTO rules.[1349] The Appellate Body found that the panel should not have made a recommendation regarding a measure that no longer existed.[1350] But the Appellate Body nowhere suggested that the panel erred in making findings regarding that measure.[1351] We recognize that in our case the application concerning GA21 maize (EC-85) was withdrawn more than two years before the Panel was established. However, there is nothing in the DSU to suggest that our jurisdiction, which is established by our terms of reference[1352], is affected by such considerations of time.

7.1651 Having said this, past jurisprudence shows that a panel is not necessarily required to make use of its authority to make findings in respect of measures which were no longer in existence on the date of establishment of a panel. In *Argentina – Textiles and Apparel*, the panel decided not to make

[1347] A different issue (which we do not reach) is whether we have the authority to make recommendations in relation to the product-specific measure in question.

[1348] The panel in that case was established on 16 June 1999, while the measure at issue (the "3 March Measure") ceased to exist on 19 April 1999 when a new measure (the "19 April Action") was adopted.

[1349] Panel Report, *US – Certain EC Products*, para. 7.3.

[1350] Appellate Body Report, *US – Certain EC Products*, para. 81. The Appellate Body in *US – Upland Cotton*, referring to its report on *US – Certain EC Products*, stated that "the fact that a measure has expired may affect what recommendation a panel may make". Appellate Body Report, *US – Upland Cotton*, para. 272.

[1351] *Ibid*., para. 271.

[1352] Appellate Body Report, *Brazil – Desiccated Coconut*, p. 22.

findings on the WTO-consistency of a measure which had been revoked eleven days before the panel was established.[1353] Moreover, as noted by the panel in *US – Gasoline*, "it had not been the usual practice of a panel established under the General Agreement [on Tariffs and Trade 1947] to rule on measures that, at the time the panel's terms of reference were fixed, were not and would not become effective".[1354]

7.1652 We consider that in determining whether to make findings on a measure no longer in existence on the date of establishment of a panel, panels should notably take account of the object and purpose of the dispute settlement system.[1355] Pursuant to Article 3.7 of the DSU, "[t]he aim of the dispute settlement mechanism is to secure a positive solution to a dispute".

7.1653 In the case of the application concerning GA21 maize (EC-85), we are not persuaded that making product-specific findings with regard to that application is necessary to "secure a positive solution to [the] dispute" between Argentina and the European Communities. We note in this regard that there is no agreement between the Parties that it would be useful for us to make findings on the product-specific measure concerning the application in question. Moreover, the application was withdrawn more than two years prior to the establishment of the Panel. Thus, unlike in the *US – Certain EC Products* case where the measure at issue was in force for just over a month, this is a case where Argentina could have presented its claims while the application was still pending.[1356] Finally, we note that the applicant resubmitted the application to another member State and that the resubmitted application – the application concerning GA21 maize (EC-78) – was still pending on the date of establishment of this Panel. We will make findings on the resubmitted application. As a result, we are resolving the dispute between Argentina and the European Communities insofar as it relates to GA21 maize.

7.1654 In the light of these considerations, we will neither examine nor make product-specific findings on the application concerning GA21 maize (EC-85).

(ii) Applications withdrawn after the establishment of the Panel

7.1655 In relation to applications which were withdrawn after the Panel was established, we note that only the United States and Argentina are seeking product-specific findings on applications falling within this category.

7.1656 The **European Communities** argues that the Panel should not address product-specific measures concerning applications which were withdrawn after the Panel was established. According to the European Communities, the issue has become moot and the relevant claims must be considered inadmissible. The European Communities bases its argument on three provisions of the DSU. *First*, Article 3.3 of the DSU states that the basic aim of the dispute settlement system is "the prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements *are being* impaired by measures taken by another Member" (emphasis added). This shows that the purpose of dispute settlement is to address and redress situations that are in actual existence. *Secondly*, Article 3.4 of the DSU provides that

[1353] Panel Report, *Argentina – Textiles and Apparel*, para. 6.15.
[1354] Panel Report, *US – Gasoline*, para. 6.19.
[1355] This approach is consistent with that of the panel in *Chile – Price Band System*, which stated that "[a]lthough we do not consider that the termination of a measure before the commencement of panel proceedings deprives a panel of the authority to make findings in respect of that measure, we would only make findings regarding the provisional safeguard measures in this case if we were to consider this necessary in order to 'secure a positive solution' to the dispute." Panel Report, *Chile – Price Band System*, para. 7.115.
[1356] We note that the application was first submitted in December 1997.

"recommendations or rulings by the DSB shall be aimed at achieving a satisfactory settlement of the matter". This cannot be the case if there is no matter to settle (i.e., if no measure is being applied). *Thirdly*, Article 3.7 of the DSU provides that "before bringing a case a Member shall exercise its judgment as to whether action under these procedures would be fruitful. The aim of the dispute settlement mechanism is to secure a positive solution to a dispute". A case on a measure that is not in existence any longer would be devoid of any purpose and not fruitful. The European Communities also points out that it is a legal principle recognized in jurisdictions around the world and commonly applied by international tribunals, including the International Court of Justice (the "ICJ"), that a tribunal should not rule on a measure no longer in existence.[1357]

7.1657 The **United States** argues that the concept of mootness is of no relevance, since the product-specific measures existed in August 2003, when the terms of reference were set. The United States refers to the panel report on *India – Autos*, which states that "[a] WTO Panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective".[1358] Regarding the European Communities' argument with regard to a "legal principle" concerning mootness, the United States notes that the European Communities failed to mention that GATT and WTO panels in the past considered terminated measures, and that the European Communities failed to explain how such a principle would be consistent with the text of the DSU.

7.1658 **Argentina** argues that the European Communities' statement on mootness is not supported by WTO jurisprudence. Argentina refers to the panel report on *Chile – Price Band System*, wherein the panel stated that "Article 19.1 of DSU does not prevent us from making findings regarding the consistency of an expired provisional safeguard measure".[1359] Argentina also refers to the above-quoted passage from the panel report on *India – Autos*.

7.1659 Subsequently, the **European Communities** clarified its position. It notes that it is not its position that the Panel may not consider product-specific measures concerning applications which were withdrawn after the Panel was established.[1360] But the European Communities remains of the view that such measures are "*sans objet*", and that there is no longer any utility in considering such measures because there does not exist, in respect of such measures, a dispute between the Parties.

7.1660 The **Panel** notes that there is no disagreement among the Parties that the product-specific measures which relate to applications withdrawn after the establishment of the Panel are within the Panel's terms of reference. There also is no disagreement among the Parties that the Panel in principle has the authority to consider measures which ceased to exist after the establishment of the Panel. We agree with both points. In relation to the second point – the authority of panels to consider measures which ceased to exist after the establishment of a panel – we note that the panel in *India – Autos* observed that:

[1357] The European Communities refers to the following ICJ judgments: *Questions of Interpretation and Application of the 1971 Montreal Convention raising from the Aerial Incident at Lockerbie* (Libyan Arab Jamahiriya v. United States of America), Judgment, ICJ Reports 1998, at 131, para 45; *Nuclear Tests* (Australia v. France), Judgment, ICJ Reports 1974, p.272, para 62; and *Border and Transborder Armed Actions* (Nicaragua v. Honduras), Jurisdiction and Admissibility, Judgment, ICJ Reports 1988, p.95, para. 66.

[1358] Panel Report, *India – Autos*, para. 7.26.

[1359] Panel Report, *Chile – Price Band System*, para. 7.124.

[1360] The European Communities nonetheless notes that the Panel should not issue recommendations in respect of such measures.

> "A WTO Panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective."[1361]

7.1661 The Parties disagree on whether the Panel should make use of its authority to make findings on the product-specific measures concerning the withdrawn applications. The European Communities argues that it is no longer useful for the Panel to consider the relevant product-specific measures, and that the Panel should therefore refrain from ruling on these measures. According to the European Communities, this would be consistent with international practice, including that of the International Court of Justice.

7.1662 In considering this issue, we note that previous panels have addressed measures which ceased to exist after the establishment of the panel. The panel in *Indonesia – Autos* stated in this regard that:

> "[I]n previous GATT/WTO cases, where a measure included in the terms of reference was otherwise terminated or amended after the commencement of the panel proceedings, panels have nevertheless made findings in respect of such a measure."[1362]

7.1663 We would agree with the European Communities that it may be appropriate for panels to look to the practice of international tribunals for inspiration, particularly in situations where the WTO agreements, GATT/WTO jurisprudence or practice provide no useful guidance. But we do not find ourselves in a situation of this kind. As is clear from the above remarks, there is specific GATT/WTO jurisprudence and practice to guide us. In these circumstances, we see no need to draw on the jurisprudence of the International Court of Justice.

7.1664 We do not consider that Articles 3.3 or 3.4 of the DSU support the view that we should refrain from making findings on the relevant product-specific measures. In relation to Article 3.3, the European Communities appears to argue that if benefits are no longer "being" impaired by a measure, because the measure has ceased to exist, the Panel should not make findings on it. However, the main objective of Article 3.3 is to emphasise the importance of the *prompt* settlement of situations in which benefits are being impaired by a measure. In our view, it cannot be deduced from this that in situations where benefits are no longer being impaired by a measure, a panel should refrain from making findings on it. We note that pursuant to Article 3.2 of the DSU the dispute settlement system also serves "to preserve the rights and obligations of Members under the covered agreements". We think that it is consistent with this function of the dispute settlement system for a panel to make findings on the WTO-consistency of a measure which has ceased to exist, especially if so requested by one of the parties.

7.1665 Turning to Article 3.4, we note that that provision states that recommendations or rulings by the DSB must be aimed at achieving a satisfactory settlement of the "matter". The European Communities suggests that if a measure has ceased to exist, there is no longer a "matter" to be settled. However, the "matter" to be settled is the matter referred to the DSB for settlement. As is clear from Article 7.1 of the DSU and the Appellate Body report in *Guatemala – Cement I*[1363], the matter referred to the DSB is the matter described by a Complaining Party in its request for the establishment of a panel. Pursuant to Article 6.2 of the DSU, the request for establishment of a panel must identify the

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[1361] Panel Report, *India – Autos*, para. 7.26.
[1362] Panel Report, *Indonesia – Autos*, para. 14.9.
[1363] Appellate Body Report, *Guatemala – Cement I*, para. 72.

specific measures at issue. Applying these considerations to the present case, it is clear that the "matter" to be settled by the DSB in a satisfactory manner includes the product-specific measures identified by the United States and Argentina in their respective panel requests. Therefore, we do not agree that once the relevant product-specific measures ceased to exist, there was, to that extent, no longer a "matter" which could be settled by the DSB.

7.1666 Regarding whether it is useful for the Panel to address the product-specific measures concerning the withdrawn applications, we recall our view that in making that determination, account should notably be taken of the object and purpose of the dispute settlement system, which is to secure a positive solution to a dispute. We note in this regard that there is no agreement between the Parties that it would be useful for us to make findings on the product-specific measures concerning the applications in question. However, the United States and Argentina as Complaining Parties did not say that in view of the withdrawal of the applications in question, they were no longer seeking findings on the product-specific measures concerning these applications. On the contrary, Argentina, for instance, explicitly requested the Panel to offer such findings. Moreover, unlike in the case of the application concerning GA21 maize (EC-85), our findings on other product-specific measures do not resolve the dispute relating to the relevant biotech products. Finally, we note that the applications were withdrawn by the applicants. It is clear, therefore, that this is not a case where the relevant measures were terminated by the responding party in the course of panel proceedings in a good faith effort to resolve the underlying dispute. Thus, we do not consider that if we make findings on the product-specific measures at issue, we would be frustrating efforts undertaken to reach a positive solution to the dispute. In these circumstances, we are unable to agree with the European Communities that it is no longer useful for us to offer findings on the product-specific measures at issue.

7.1667 In the light of the above, the Panel will make findings on the product-specific measures concerning those applications which were withdrawn after the Panel was established.

(iii) Applications approved after the establishment of the Panel

7.1668 The last category of applications to be addressed concerns applications which were approved by the Commission in the course of the Panel proceedings. All three Complaining Parties are seeking product-specific findings on such applications. In our view, applications which were *definitively* approved[1364] in the course of the Panel proceedings may be assimilated, for the purposes of the present inquiry, to applications which were withdrawn in the course of the Panel proceedings. Both categories of applications have in common the fact that the underlying approval procedures were pending on the date of establishment of the Panel, but were subsequently discontinued. The only difference is that in the case of a definitively approved application, the relevant approval procedure was discontinued as a result of action directly attributable to the European Communities. We do not consider that this difference, by itself, warrants a different approach by the Panel. We note in this regard that the European Communities does not argue that the Commission approved applications in order to resolve its dispute with the Complaining Parties in relation to the relevant applications.[1365]

[1364] We use the phrase "definitively approved" to refer to a situation where according to information on our record the applicant may proceed with the placing on the market of the biotech product which is the subject of the approved application.

[1365] The European Communities argues that the approvals of the relevant applications are simply the consequence of these applications having reached the final decision-making stage after being assessed at member State and Community level. EC comments on the Complaining Parties' replies to Panel questions, paras. 62-63.

7.1669 In the light of this, the Panel will make findings also with regard to those product-specific measures that concern applications which were definitively approved in the course of the Panel proceedings. The evidence on record supports the conclusion that two applications – namely, the application concerning Bt-11 sweet maize (food) and the application concerning NK603 maize (food) – were definitively approved in the course of the Panel proceedings. For the other relevant applications approved by the Commission in the course of the Panel proceedings, the record does not allow us to determine whether these applications have been definitively approved, such that they may be placed on the market.[1366] In any event, it is clear from the foregoing that we would offer findings on product-specific measures concerning such applications even if they had been definitively approved after the date of the establishment of the Panel.

(iv) Conclusion

7.1670 In the light of the foregoing considerations, we will offer no findings on the product-specific measure concerning GA21 maize (EC-85) (DS293), but we will make findings on product-specific measures concerning applications which were withdrawn after the Panel was established as well as on the product-specific measure concerning Bt-11 sweet maize (food) (DS291), an application which was definitively approved in the course of the Panel proceedings. However, we will not make any recommendations in the event that we find that the product-specific measures concerning applications which were withdrawn after the Panel was established, or the product-specific measure concerning Bt-11 sweet maize (food) (DS291), are WTO-inconsistent.

2. Claims of inconsistency raised by the Complaining Parties

7.1671 The Complaining Parties have each presented a series of claims of inconsistency in relation to the European Communities' product-specific EC measures they are challenging

7.1672 The **United States** claims that the product-specific EC measures it is challenging are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1367]

(a) Annex C(1)(a) and, consequently, Article 8 of the *SPS Agreement*;

(b) Annex B(1) and, consequently, Article 7 of the *SPS Agreement*;

(c) Annex C(1)(b) and, consequently, Article 8 of the *SPS Agreement*;

(d) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(e) Article 5.5 of the *SPS Agreement*.

7.1673 **Canada** claims that the product-specific EC measures it is challenging are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1368]

[1366] We note in this regard that in relation to the applications concerning NK603 maize (for animal feed use) and RR oilseed rape (EC-70) the record contains no evidence that the relevant lead CA has given its written consent for the placing on the market of these products after they were approved by the Commission under Directive 2001/18.

[1367] The claims are listed in the order in which they were developed in the first written submission of the United States.

[1368] The claims are listed in the order in which they were developed in the first written submission of Canada.

(a) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(b) Article 5.6 and, consequently, Article 2.2 of the *SPS Agreement*;

(c) Article 5.5 and, consequently, Article 2.3 of the *SPS Agreement*;[1369]

(d) Annex C(1)(a) and, consequently, Article 8 of the *SPS Agreement*;

(e) Article III:4 of the GATT 1994;

(f) Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement*.

7.1674 With regard to Canada's claims under the *TBT Agreement*, Canada explained that, if the Panel determines that parts of the relevant product-specific measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, its claims under the *TBT Agreement* are to be considered cumulative rather than alternative.

7.1675 **Argentina** claims that the product-specific EC measures are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1370]

(a) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(b) Articles 5.5 and 5.6 of the *SPS Agreement*;

(c) Annex C(1)(a), (b), (c) and (e) and, consequently, Article 8 of the *SPS Agreement*;

(d) Article III:4 of the GATT 1994;

(e) Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*.

7.1676 As previously indicated, the Panel will make findings in relation to ten product-specific EC measures challenged by Argentina. However, Argentina's claims under Article 8 and Annex C(1) of the *SPS Agreement* and those under Article 5.2 of the *TBT Agreement* concern only eight of the ten "relevant product-specific measures". The two measures which are not the subject of a claim under these provisions are the measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97.

7.1677 We further note that Argentina's claims under the *TBT Agreement* are put forth as alternatives to its claims under the *SPS Agreement*.

7.1678 The **European Communities** argues that none of the product-specific claims presented by the three Complaining Parties is founded, and that it has not acted inconsistently with any of the WTO provisions which are being invoked by the Complaining Parties in respect of any of the product-specific measures.

7.1679 In view of the European Communities' view that all of the Complaining Parties' product-specific claims should be dismissed in their entirety, it is clear that the **Panel** needs to assess the merits of those claims. We will first examine the Complaining Parties' substantive claims under

[1369] Canada's claim under Article 5.5 is put forth as an alternative to its claim under Article 5.6.

[1370] The claims are listed in the order in which they were developed in the first written submission of Argentina.

Articles 5 and 2 of the *SPS Agreement*, and, if appropriate, will go on to examine the transparency claim under Annex B of the *SPS Agreement* and the procedural claims under Annex C of the *SPS Agreement*. Finally, to the extent it is necessary to do so, we will also examine Canada's and Argentina's claims under the GATT 1994 and under the *TBT Agreement*.

3. Consistency of the product-specific measures with Article 5.1 of the *SPS Agreement*

7.1680 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1681 Article 5.1 of the *SPS Agreement* provides:

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

7.1682 The **United States** argues that like the general moratorium, to the extent the product-specific measures – the product-specific moratoria – are preventing the sale or marketing of biotech products, each failure by the European Communities to consider for approval a pending application of a biotech product is an "SPS measure" that is not "based on a risk assessment" as required by Article 5.1. The United States considers that the product-specific moratoria, which, in effect, ban the relevant biotech products from the EC market, are "SPS measures" as defined in Annex A(1) of the *SPS Agreement*. The EC approval regime, including that part of the regime modified by the product-specific moratoria, are plainly "sanitary or phytosanitary" measures. Similarly, the product-specific moratoria, although unwritten, are "measures" under the *SPS Agreement*, just as the general moratorium affecting all products is a "measure" under the *SPS Agreement*. Regarding the requirement that SPS measures be based on a risk assessment, the United States submits that with respect to fourteen of the pending applications, the European Communities has not put forth any risk assessment whatsoever. As for the remaining thirteen applications, the European Communities has undertaken risk assessments but the product-specific moratoria are not based on these assessments.

7.1683 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). According to Canada, the failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans", is not "based on" risk assessments contrary to Article 5.1. While the European Communities has completed risk assessments for each of the four applications, it has failed to base its failure to consider, and approve, these applications on these assessments.

7.1684 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.1 because it is not based on any risk assessments. Argentina points out that there are applications that have not been approved in spite of the fact that member States or the EC scientific committees have conducted risk assessments and the assessments were favourable. In these cases, the requirements of Article 5.1 have not been met because the favourable risk assessment has not been taken into consideration. Other applications have had their processing suspended without any risk assessment having been conducted either by member States or EC scientific committees. In these cases, the requirements of Article 5.1 have not been met because no risk assessment was

performed on account of the suspension of consideration of, or failure to consider, the relevant applications.

7.1685 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties here thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.1 is not applicable to these delays.

7.1686 The **Panel** notes that, by its clear terms, Article 5.1 applies to SPS measures. Accordingly, for a particular product-specific measure to be subject to Article 5.1, it must be an SPS measure. The European Communities contests that the product-specific measures constitute SPS measures within the meaning of Article 5.1. It is therefore necessary to consider this issue.

7.1687 We recall that the Complaining Parties have stated that the product-specific measures they are challenging are related to the general moratorium on approvals. We have observed that based on these statements we understand that the product-specific measures are, or arise from:

- specified acts and/or omissions through which the relevant EC entities were giving effect, in the context of particular approval procedures, to their decisions to impose a general moratorium on approvals, or
- specified acts and/or omissions through which relevant EC entities chose to respond, again in the context of particular approval procedures, to the circumstance that other EC entities were imposing a general moratorium on approvals.

7.1688 In relation to the general moratorium on approvals, we have found earlier that the European Communities' decision to apply a general moratorium on approvals was not a decision effectively imposing an across-the-board definitive marketing ban, but a decision concerning the application, or operation, of approval procedures. We also found that the decision in question was not, itself, a measure applied to achieve the European Communities' appropriate level of protection. These findings led us to conclude that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) and Article 5.1.

7.1689 If, as we believe, the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure", logic suggests that the same should be true for the product-specific measures, considering that, in our understanding, they essentially are acts and/or omissions through which relevant EC entities were giving effect to the decision to apply a general moratorium on approvals, or through which they were reacting to the circumstance that other EC entities were imposing a general moratorium.[1371] Notwithstanding the fact that there is a logical link between the general moratorium and the product-specific measures, it is appropriate to examine in more detail whether the latter measures constitute SPS measures within the meaning of Annex A(1) and Article 5.1. As the Complaining Parties have provided slightly different descriptions of the product-

[1371] We recall that in relation to the second category of acts and/or omissions, the Complaining Parties essentially allege that applications were processed at a delayed pace in view of the existence of a general moratorium on final approvals until certain conditions were met.

specific measures of which they are complaining, we examine this issue separately for each Complaining Party.[1372]

(a) DS291 (United States)

7.1690 As we have previously noted, the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval. We recall that for a particular measure to be subject to Article 5.1 it must be an "SPS measure". To determine whether the European Communities' alleged failure to consider a particular application for final approval constitutes an "SPS measure", we first look to the definition of that term set out in Annex A(1) of the *SPS Agreement*. According to Annex A(1), SPS measures include "requirements and procedures".

7.1691 Regarding "requirements", we note that failure to consider a particular application for final approval, even if intentional, is not the same thing as a negative final approval decision on that application. Nor does failure to consider for final approval necessarily lead to, or predetermine, a negative final approval decision. Consequently, we are of the view that the European Communities' alleged failure to consider a particular application for final approval would not have imposed a substantive SPS "requirement" within the meaning of the Annex A(1) definition of the term "SPS measure".

7.1692 The United States argues, however, that, in effect, the European Communities' alleged failure to consider particular applications for final approval banned the relevant biotech products from the EC market. We would agree that failure to consider a particular application for final approval would ordinarily result in delays in the completion of the relevant approval procedure. In turn, these delays would have the effect of extending the time-period during which the biotech product in question was subject to the provisional marketing ban flowing from the EC pre-marketing approval requirement. But a failure to consider a particular application for final approval would not have imposed a new ban; a ban was already in place, as a consequence of the pre-marketing approval requirement. In other words, the origin of the provisional marketing ban, including of the effectively extended ban, would not have been the failure to consider the relevant application for final approval, but the EC pre-marketing approval requirement, *i.e.*, the European Communities' substantive decision to ban biotech products until they have been approved.

7.1693 Consistent with the foregoing, we agree that failure to consider a particular application for final approval would have had an impact on how long the provisional marketing ban was in place for the relevant biotech product. Yet we are unable to agree that a failure to consider an application for final approval effectively would have imposed a new marketing ban, and, hence, a negative "requirement", on the biotech product concerned. If the United States had been of the view that the aforementioned impact on the provisional marketing ban resulted in that ban being applied inconsistently with Article 5.1, it was open to it to challenge that ban (*i.e.*, the pre-marketing approval requirement) as the source of the provisional marketing ban. The United States chose not to do so in this case.

7.1694 Regarding "procedures", we note the United States' argument that the European Communities' alleged failure to consider particular applications for final approval "modified" part of the EC approval regime. Since the alleged product-specific measures in question would not, in our view, have imposed any new substantive requirement, we do not think that they would have modified any substantive requirement which is part of the EC approval regime. What remains to be examined, then,

[1372] *See also* our discussion of the Complaining Parties' Article 5.1 claim in Section VII.D.5 above.

is whether the product-specific measures would have modified the relevant EC approval procedures.[1373]

7.1695 Clearly, the European Communities' alleged failure to consider a particular application for final approval would not itself have constituted, or established, a procedure for approving the relevant biotech product or, more to the point, for preventing the final approval of this biotech product. The failure to consider a particular application for final approval also would not have effectively amended the relevant EC approval procedure for the specific biotech product in question. As we have explained in earlier findings on the general moratorium on approvals, the European Communities did not apply a different type of approval procedure. The applications in question continued to be assessed in accordance with the procedure set out in Directives 90/220 and 2001/18, as well as Regulation 258/97. Therefore, we are not persuaded that the alleged failure to consider a particular application for final approval would have "modified" the relevant EC approval procedure. In our assessment, the foregoing also leads to the conclusion that the alleged failure to consider a particular application for final approval cannot be considered a "procedure" within the meaning of Annex A(1).

7.1696 Thus far, we have found that the European Communities' alleged failure to consider a particular application for final approval qualifies neither as a "requirement" nor as a "procedure" within the meaning of Annex A(1). But we have not yet determined in positive terms what is the legal nature of the failure in question. We think the United States' reference to the failure by the European Communities to consider a particular application for final approval should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. In other words, we think that, in essence, the United States is complaining of a particular manner of operating the EC approval procedures in specific cases.

7.1697 In terms of Annex A(1), this means that we are concerned with the application, or operation, of "procedures". As we have said in our earlier findings, while "procedures" as such may according to the Annex A(1) definition constitute SPS measures, the application, or operation, of such procedures does not, itself, constitute an SPS measure within the meaning of Annex A(1). Accordingly, we come to the conclusion that the European Communities' alleged failure to consider a particular application for final approval does not meet all of the constituent elements of the definition of the term "SPS measure" as provided in Annex A(1).

7.1698 Turning now to Article 5.1, we recall our earlier finding that the term "SPS measure" in Article 5.1 should be interpreted to refer to a measure applied for achieving the relevant Member's appropriate level of sanitary or phytosanitary protection. In our view, the European Communities' alleged failure to consider a particular application for final approval would not, itself, have been a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Rather, as we have said, it would have been the application of a particular way of operating the relevant EC approval procedure. As we explained above, the practical effect of the alleged failure to consider a particular application for final approval would have been to extend the time-period during which the relevant biotech product was subject to the provisional marketing ban flowing from the pre-marketing approval requirement. The pre-marketing approval requirement which imposes the provisional marketing ban is a measure applied to achieve the European Communities' level of protection, but that requirement is a separate measure from the European Communities' alleged failure to consider a particular application for final approval. By itself, the

[1373] The relevant approval procedures are set out in Directive 90/220 and its successor, Directive 2001/18, as well as Regulation 258/97.

alleged failure to consider a particular application for final approval would not have achieved or implied a particular level of protection.

7.1699 As the European Communities' alleged failure to consider a particular application for final approval would not, itself, have been a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection, it cannot, in our view, be considered an "SPS measure" within the meaning of Article 5.1.

7.1700 Based on the above considerations, we thus determine that the European Communities' alleged failure to consider a particular application for final approval cannot be considered an "SPS measure" within the meaning of Article 5.1 and Annex A(1). As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged failure to consider particular applications for final approval. In view of this conclusion, we need not continue our analysis of the United States' claim under Article 5.1.

(b) DS292 (Canada)

7.1701 In relation to DS292, we have noted above that Canada is challenging the alleged failure by the European Communities to consider or approve, without undue delay, particular applications of specific interest to Canada. Canada also refers to this failure to consider or approve applications as an effective "product-specific marketing ban".

7.1702 Regarding Canada's reference to an effective product-specific marketing ban, we note that we have already addressed a similar argument of the United States. Thus, we need only recall that we agree that the alleged failure by the European Communities to consider or approve a particular application would have had an impact on how long the provisional marketing ban resulting from the EC pre-marketing approval requirement was in place for the relevant biotech product. But we are unable to agree that the alleged failure to consider or approve an application effectively would have imposed a new marketing ban, and, hence, a negative "requirement", on the biotech product concerned.

7.1703 Instead, similar to what we have said of the measures challenged by the United States, we consider that Canada's reference to the failure by the European Communities to consider or approve a particular application should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. Thus, we think that, in essence, Canada is complaining of a particular manner of operating the EC approval procedures in specific cases.

7.1704 For the same reasons as those we have given in the context of our analysis of the measures challenged by the United States, the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection and hence cannot be considered an "SPS measure" within the meaning of Article 5.1.

7.1705 As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.1.

(c) DS293 (Argentina)

7.1706 In relation to DS293, we note that Argentina makes claims under Article 5 of the *SPS Agreement* regarding all ten applications in respect of which the Panel has decided to offer product-specific findings. We first address the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1707 Argentina challenges under Article 5.1 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1374] under Regulation 258/97.

7.1708 Argentina has provided no evidence of the existence of applications concerning Bt-531 cotton and RR-1445 cotton which were submitted for "approval" under Regulation 258/97. The only evidence provided by Argentina in support of its claim relates to cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed. These products were subject to the simplified procedure set out in Article 5 of Regulation 258/97. As indicated by us earlier, under the simplified procedure, there are no "applications" for the placing on the market of subject products which are then "approved" by member State assessment bodies. Moreover, in its request for the establishment of a panel, Argentina identifies Bt-531 cotton and RR-1445 cotton as a relevant biotech product, but not cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed. Thus, cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed is outside the terms of reference of DS293 (Argentina).

7.1709 In view of the fact that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, we find that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.1 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1710 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings. As noted, Argentina describes the product-specific measures it is challenging under Article 5.1 as the suspension by the European Communities of consideration of, or the failure to consider, particular applications of interest to Argentina.

7.1711 As with the measures challenged by the United States, we are of the view that the measures challenged by Argentina qualify neither as "requirements" nor as "procedures" within the meaning of Annex A(1). Instead, we think Argentina's reference to the suspension of consideration of, or failure to consider, a particular application should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. In other words, we think that, in essence, Argentina is complaining of a particular manner of operating the EC approval procedures in specific cases.

[1374] Argentina's first written submission, paras. 201-202.

7.1712 For the same reasons as those we have given in the context of our analysis of the measures challenged by the United States, the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection and hence cannot be considered an "SPS measure" within the meaning of Article 5.1.

7.1713 As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged suspension of consideration of, or failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.1.

(d) Conclusions

7.1714 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

4. Consistency of the product-specific measures with Article 5.6 of the *SPS Agreement*

7.1715 Canada and Argentina claim that the European Communities has acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1716 Article 5.6 of the *SPS Agreement* provides:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or

> phytosanitary protection, taking into account technical and economic feasibility." (footnote omitted)

7.1717 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). The failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans", is "more trade restrictive than required", contrary to Article 5.6. This is because there is another SPS measure that is reasonably available, taking into account technical or economic feasibility; achieves the European Communities' appropriate level of sanitary and phytosanitary protection; and is significantly less restrictive to trade than the contested SPS measure.

7.1718 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.6. This violation of Article 5.6 results from the fact that there exists another SPS measure that: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the European Communities' appropriate level of sanitary and phytosanitary protection; and (3) is significantly less restrictive to trade than the contested SPS measure.

7.1719 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.6 is not applicable to these delays.

7.1720 The **Panel** will analyse Canada's and Argentina's claim separately.[1375]

(a) DS292 (Canada)

7.1721 In relation to DS292, we note that for a particular measure to be subject to Article 5.6 it must be an SPS measure. We also note that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". Furthermore, we recall that in the context of our earlier analysis of Canada's claim under Article 5.1 we found that the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider or approve a particular application cannot be considered an "SPS measure" within the meaning of Article 5.6.

7.1722 As only "SPS measures" are subject to the provisions of Article 5.6, the provisions of Article 5.6 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.6.

[1375] *See also* our discussion of Canada's and Argentina's Article 5.6 claim in Section VII.D.6 above.

(b) DS293 (Argentina)

7.1723 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1724 Argentina challenges under Article 5.6 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1376] under Regulation 258/97.

7.1725 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.6 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1726 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.1727 We recall that for a particular measure to be subject to Article 5.6 it must be an SPS measure. We also recall that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". Furthermore, we recall that in the context of our earlier analysis of Argentina's claim under Article 5.1 we found that the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the European Communities' alleged suspension of consideration of, or failure to consider, a particular application cannot be considered an "SPS measure" within the meaning of Article 5.6.

7.1728 As only "SPS measures" are subject to the provisions of Article 5.6, the provisions of Article 5.6 are not applicable to the European Communities' alleged suspension of consideration of, or failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.6.

[1376] Argentina's first written submission, paras. 201-202

(c) Conclusions

7.1729 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

5. Consistency of the product-specific measures with Article 5.5 of the *SPS Agreement*

7.1730 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1731 Article 5.5 of the *SPS Agreement* provides:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.[....]"

7.1732 The **United States** argues that the product-specific moratoria, which, in effect, ban the relevant biotech products from the EC market, are "SPS measures" as defined in Annex A(1) of the *SPS Agreement*. The United States argues that like the general moratorium, the product-specific moratoria meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has set forth distinct levels of sanitary protection in "different situations": products produced with biotech processing aids and other biotech products. *Second*, those levels of protection exhibit differences that are "arbitrary or unjustifiable." *Third*, the product-specific moratoria result in "discrimination or a disguised restriction on international trade."

7.1733 **Canada** puts forth its claim under Article 5.5 as an alternative to its claim under Article 5.6. In putting forth the Article 5.6 claim, Canada assumed that the European Communities' appropriate level of protection is a "high level of protection", but not a zero-risk level. However, if this assumption is not correct and the European Communities' appropriate level of protection for the four applications of specific interest to Canada at issue is that reflected by the product-specific marketing bans, namely a zero-risk level, then Canada is of the view that the European Communities has violated Article 5.5 of the *SPS Agreement*.

7.1734 Canada argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). Canada claims that the failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans" meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in "different situations" that are comparable. *Second*, those different appropriate levels of protection are "arbitrary or unjustifiable." *Third*, the measures embodying those differences, the product-specific marketing bans, result in "discrimination or a disguised restriction on international trade".

7.1735 According to Canada, the "comparable" situations above are of the following two kinds: (i) the biotech products whose applications have been stalled as a result of the product-specific marketing bans on the one hand and the biotech products that were approved for commercialization prior to the imposition of the moratorium on the other; (ii) the biotech products whose applications have been stalled as a result of the product-specific marketing bans on the one hand and novel non-biotech products such as those produced by conventional plant breeding techniques on the other.

7.1736 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.5. This is because the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina meets the three distinct and cumulative elements which are required to be demonstrated in support of a claim under Article 5.5: (i) The Member that imposes the measure that is the subject of the complaint must have adopted its own levels of sanitary protection against risks to human, animal or plant life or health in various different situations, which are comparable; (ii) these levels of protection exhibit arbitrary or unjustifiable differences in the treatment of different situations; and (iii) these arbitrary or unjustifiable differences must result in discrimination or a restriction of international trade.

7.1737 According to Argentina, the "comparable" situations are of the following two kinds: (1) biotech products introduced before and after the moratorium; (2) new "non-biotech" products and new biotech products.

7.1738 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.6 is not applicable to these delays.

7.1739 The **Panel** will analyse separately the claim presented by each Complaining Party.[1377]

(a) DS291 (United States)

7.1740 In relation to DS291, we recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular

[1377] *See also* our discussion of the Complaining Parties' Article 5.5 claim in Section VII.D.7 above.

level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of the United States' product-specific claim under Article 5.1 we found that the type of measure the United States is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider a particular application for final approval cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1741 As Article 5.5 in our view implies that the measures complained of are implementing "SPS measures", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged failure to consider particular applications for final approval. In view of this conclusion, we need not continue our analysis of the United States' claim under Article 5.5.

(b) DS292 (Canada)

7.1742 In relation to DS292, we recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of Canada's product-specific claim under Article 5.1 we found that the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider or approve a particular application cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1743 As Article 5.5 in our view implies that the measure complained of is an implementing "SPS measure", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.5.

(c) DS293 (Argentina)

7.1744 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1745 Argentina challenges under Article 5.5 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1378] under Regulation 258/97.

7.1746 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have

[1378] Argentina's first written submission, paras. 201-202.

pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.5 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1747 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.1748 We recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of Argentina's product-specific claim under Article 5.1 we found that the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged suspension by the European Communities of consideration of, or the failure to consider, a particular application cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1749 As Article 5.5 in our view implies that the measures complained of are implementing "SPS measures", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged suspension of consideration of, or the failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.5.

(d) Conclusions

7.1750 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

6. Consistency of the product-specific measures with Article 2.2 of the *SPS Agreement*

7.1751 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1752 Article 2.2 of the *SPS Agreement* provides:

> "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 as provided for in paragraph 7 of Article 5."

7.1753 **The United States** claims that, as the basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1, the product-specific measures – the product-specific moratoria – are also inconsistent with Article 2.2, because they are not based on risk assessments as required by Article 5.1 and Annex A, paragraph 4.

7.1754 **Canada** argues that Articles 5.1 and 5.6 can be viewed as a specific application of the basic obligation contained in Article 2.2, and a violation of Articles 5.1 and 5.6 can be thus presumed to imply a violation of the more general provision of Article 2.2. Canada is of the view that, as it has already demonstrated that the product-specific marketing bans are not "based on" risk assessments and are therefore inconsistent with Articles 5.1 and 5.6, it can therefore be presumed that the product-specific marketing bans also violate the requirements of Article 2.2.

7.1755 **Argentina** argues that since it has demonstrated that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina is not "based on a risk assessment", it has duly proven that the said suspension does not meet the requirements of Article 2.2.

7.1756 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties here thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 2.2 is not applicable to these delays.

(a) Evaluation

7.1757 The **Panel** notes that the Complaining Parties' claim under Article 2.2[1379] is in the nature of a consequential claim. The Complaining Parties submit that an inconsistency with Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.1. However, we have determined above that Article 5.1 is not applicable to the product-specific measures as defined by the Complaining Parties and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.1 in respect of the relevant product-specific measures. Since the European Communities has not acted inconsistently with Article 5.1, and since the Complaining Parties' claim under Article 2.2 is premised on the existence of a breach of Article 5.1 by the European Communities, the Complaining Parties' claim under Article 2.2 in our view cannot succeed.

7.1758 In relation to DS292, we note that Canada argues in addition that an inconsistency with Article 2.2 also follows by implication from a demonstrated inconsistency with Article 5.6. However, we have reached the same conclusion on Canada's claim under Article 5.6 as we have on Canada's claim under Article 5.1. Accordingly, our reasoning in the preceding paragraph *mutatis mutandis* also applies to Canada's argument based on the alleged inconsistency of the relevant product-specific measures with Article 5.6.

7.1759 In relation to DS293, we recall, in addition, our earlier finding that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 2.2 in relation to these alleged measures.

(b) Conclusions

7.1760 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

[1379] *See also* our discussion of the Complaining Parties' Article 2.2 claim in Section VII.D.8 above.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

7. Consistency of the product-specific measures with Article 2.3 of the *SPS Agreement*

7.1761 Canada claims that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of the product-specific measures it is challenging.

7.1762 Article 2.3 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

7.1763 **Canada** argues that, as the product-specific marketing bans are inconsistent with the European Communities' obligations under Article 5.5, they are, by implication, also inconsistent with the European Communities' obligations under Article 2.3, in accordance with the jurisprudence established by the Appellate Body.

7.1764 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 2.3 is not applicable to these delays.

(a) DS292 (Canada)

7.1765 The **Panel** notes that Canada's claim under Article 2.3[1380] is in the nature of a consequential claim. Canada submits that an inconsistency with Article 2.3 follows by implication from a demonstrated inconsistency with Article 5.5. However, we have determined above that Article 5.5 is not applicable to the product-specific measures as defined by Canada and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.5 in respect of the relevant product-specific measures. Since the European Communities has not acted inconsistently with Article 5.1, and since Canada's claim under Article 2.3 is premised on the existence of a breach of Article 5.5 by the European Communities, Canada's claim under Article 2.3 in our view cannot succeed.

[1380] *See also* our discussion of Canada's Article 2.3 claim in Section VII.D.9 above.

(b) Conclusion

7.1766 In the light of the above, the Panel reaches the following conclusion:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

8. Consistency of the product-specific measures with Article 7 and Annex B(1) of the *SPS Agreement*

7.1767 The United States claims that the European Communities has failed to publish promptly the existence of the product-specific measures the United States is challenging and that the European Communities has thereby acted inconsistently with its obligations under Article 7 and Annex B(1) of the *SPS Agreement*.

7.1768 Article 7 of the *SPS Agreement* provides:

> "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B."

7.1769 Annex B(1) of the *SPS Agreement* provides:

> "Members shall ensure that all sanitary and phytosanitary regulations[1381] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them."

7.1770 The **United States** submits that the product-specific measures it is challenging – the product-specific moratoria – are subject to the publication requirement in Annex B(1). The United States argues that this is for the same reasons which it has provided to establish the applicability of Annex B(1) to the general moratorium. The United States considers that because the European Communities has failed to publish, and, therefore, to publish promptly, the existence of the product-specific moratoria, the European Communities has acted inconsistently with its obligations under Annex B(1) and Article 7.

7.1771 The **European Communities** argues that Article 7 contains procedural obligations (publication) regarding an SPS measure. Thus, the applicability of Article 7 is premised on the existence of an SPS measure. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the measures challenged by the United States are alleged failures to act within a particular timeframe. Thus, the United States is in reality complaining about delay in the completion of specified individual approval procedures. In the European Communities' view, delay of this kind cannot constitute an SPS measure within the

[1381] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

meaning of Annex A(1). Delay is a failure to act in a timely manner. The European Communities deduces from these considerations that the alleged measures are not subject to Article 7.

7.1772 The **Panel** notes that the United States alleges an inconsistency of the product-specific measures identified by it with Annex B(1). The United States uses the alleged inconsistency with Annex B(1) as a basis for a consequential claim of inconsistency under Article 7. Accordingly, we will begin our analysis with the United States' claim under Annex B(1).

(a) "Sanitary and phytosanitary regulations"

7.1773 As we have stated earlier, Annex B(1) applies to "sanitary and phytosanitary regulations" (hereafter "SPS regulations") which have been "adopted". An explanatory footnote to Annex B(1) indicates that the term "SPS regulations" should be understood as meaning "[s]anitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally".

7.1774 It follows from the foregoing that a threshold issue before us is whether the product-specific measures challenged by the United States constitute generally applicable SPS measures which have been adopted. We first examine whether the relevant product-specific measures are "generally applicable".

7.1775 We recall that what the United States is challenging in the case of each of the product-specific measures is an alleged failure by the European Communities to consider a specified application for final approval. As is already clear from our own description of these measures, these measures are product-specific. In other words, each of these measures affects an application concerning a specific biotech product. None of these measures is applicable to all biotech products generally, or at least to all biotech products which fall within the scope of the relevant EC approval procedures and require approval. To that extent, there is thus a clear difference between the product-specific measures identified by the United States and the general moratorium on approvals, which we found was generally applicable inasmuch as it was applicable to all applications which were pending between June 1999 and August 2003.

7.1776 In the light of this, we are unable to agree with the United States that each of the product-specific measures it is challenging is a measure which is "applicable generally". As general applicability is a necessary definitional element of the term "SPS regulations", it is not necessary for us to examine whether the relevant product-specific measures are "SPS measures" and whether they have been "adopted". We therefore find that none of the product-specific measures challenged by the United States is an "SPS regulation" within the meaning of Annex B(1). It follows that the provisions of Annex B(1) are not applicable to these measures.

7.1777 We recall that the United States seeks to establish an inconsistency with Article 7 on the basis of an alleged inconsistency with Annex B(1). As we have found that the provisions of Annex B(1) are not applicable to the product-specific measures challenged by the United States, these measures cannot be inconsistent with these provisions. Under the approach followed by the United States, there can then logically be no inconsistency with Article 7 either, even assuming that Article 7 is applicable to these measures.

(b) Conclusion

7.1778 In the light of the above, the Panel reaches the following conclusion:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

9. Consistency of the product-specific measures with Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*

(a) General

7.1779 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1780 Article 8 of the *SPS Agreement* provides:

> "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."

7.1781 Annex C(1)(a), first clause, of the *SPS Agreement* provides:

> "1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> (a) such procedures are undertaken and completed without undue delay [...]."

7.1782 The Complaining Parties seek to establish an inconsistency with Article 8 on the basis of an inconsistency with Annex C(1)(a), first clause. Article 8 requires, *inter alia*, that Members observe the provisions of Annex C in the operation of their approval procedures. It follows that a failure to observe the provisions of Annex C(1)(a) implies a breach of Article 8. Accordingly, should we conclude that the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, in respect of any of the product-specific measures on which we make findings, we will also conclude that the European Communities has, by implication, also acted inconsistently with the provisions of Article 8.

7.1783 In relation to Annex C(1)(a), first clause, we note that we have addressed the interpretation of this provision in Section VII.D.11 above.[1382] We further note that in accordance with the lead-in to

[1382] We note that like the other Parties, Argentina has addressed the meaning of Annex C(1)(a), first clause. However, Argentina's relevant arguments do not lead us to an interpretation of Annex C(1)(a), first clause, which is different from the one we set out earlier.

Annex C(1) the provisions of Annex C(1)(a) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(a). Therefore, the European Communities was and is required under the provisions of Annex C(1)(a) to "undertake and complete" the approval procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) "without undue delay".

7.1784 We recall that the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval, while Canada is challenging the alleged failure by the European Communities to consider or approve, without undue delay, particular applications. We have observed in this regard that these are essentially challenges to the application by the European Communities of a particular way of operating the relevant EC approval procedures. We also recall that Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications.

7.1785 It is clear to us, therefore, that the type of measure challenged by each of the Complaining Parties could in principle constitute, or lead to, a breach of the European Communities' obligations under Annex C(1)(a), first clause, and that this type of measure can therefore be examined in the light of the provisions of Annex C(1)(a), first clause. Since the Complaining Parties seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), first clause, this conclusion applies also to Article 8.

(b) Deliberate Release – Applications submitted under Directive 90/220 and/or Directive 2001/18

7.1786 We now begin our examination of the approval procedures which were conducted under Directives 90/220 and 2001/18 for the applications identified by the Complaining Parties. Before going further, however, we should briefly address certain issues presented by the application of Annex C(1)(a), first clause, to approval procedures conducted under the aforementioned Directives.

(i) Application of Annex C(1)(a), first clause, to approval procedures begun under Directives 90/220 and continued under 2001/18

7.1787 Each of the relevant approval procedures on which the Panel is making findings was begun under Directive 90/220 but not completed by the date of repeal of Directive 90/220 (17 October 2002). Pursuant to the provisions of Directive 2001/18, applications which were pending on the date of repeal of Directive 90/220 (17 October 2002) became subject to Directive 2001/18 and therefore had to be "complemented" by the applicant in the light of the provisions of Directive 2001/18. If the applicant did so by a specified deadline (17 January 2003), approval procedures were to be undertaken in accordance with the provisions of Directive 2001/18.[1383] For each of the approval procedures here at issue, approval procedures were undertaken under Directive 2001/18 after the applicant had complemented its application.

7.1788 This presents the question whether approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 should be viewed as new approval procedures or as a continuation of the approval procedures which were not

[1383] Article 35 of Directive 2001/18. None of the Complaining Parties questioned the WTO-consistency of Article 35.

completed under Directive 90/220. We have already examined this question in the context of our analysis of the general EC moratorium on approvals.[1384] It is therefore sufficient at this juncture to recall our conclusion that (i) approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 were a continuation of the approval procedures previously conducted under Directive 90/220, and that (ii) an approval procedure begun under Directive 90/220 and continued under Directive 2001/18 constitutes one single approval procedure for the purposes of Annex C(1)(a), first clause.

7.1789 It follows from this conclusion that there is no need, in the context of our inquiry under Annex C(1)(a), first clause, to distinguish between undue delays which may have occurred in the processing of an application under Directive 90/220 and undue delays which may have occurred when the procedure for the same application was continued under Directive 2001/18. Notably, our conclusion means that a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of undue delays which occurred while Directive 90/220 was in force. Likewise, a failure to observe the provisions of Annex C(1)(a), first clause, can also be established on the basis of undue delays which occurred after the entry into force of Directive 2001/18. In either case, the relevant approval procedure would have been unduly delayed, contrary to the requirements of Annex C(1)(a), first clause.

7.1790 Finally, we recall that in Section VII.D we have addressed whether the reason for the general EC moratorium on final approvals could have provided a justification for delays which might have occurred as a result of that moratorium. We have also addressed whether the adoption of Directive 2001/18 could have justified delaying the completion of approval procedures conducted under Directive 90/220 so that as of October 2002 they would become subject to the new provisions of Directive 2001/18. These earlier observations are relevant and applicable also to our examination of the Directive 90/220 (and 2001/18) approval procedures identified by the Complaining Parties.

7.1791 With these general observations in mind, we now proceed with the examination of the individual product-specific measures complained against.

(ii) Falcon oilseed rape (EC-62)

7.1792 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Falcon oilseed rape has been unduly delayed.

7.1793 The **United States** initially argued that the Commission in this procedure did not submit a draft measure to the Regulatory Committee. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission never submitted a draft measure to the Regulatory Committee again. The United States also submits that under the applicable EC legislation, in the absence of action by the Regulatory Committee, the Commission was required to submit a draft measure, whether favourable or negative, to the Council. The United States recalls in this respect that the *SPS Agreement* requires that the European Communities make a decision without undue delay. In this case, the Commission failed to forward a decision to the Council.

7.1794 The United States submits, in addition, that the application concerning Falcon oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that

[1384] *See supra*, paras. 7.1535-7.1536.

although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Falcon oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1795 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter. The Regulatory Committee did not vote on 9 March 2000 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. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.1796 The **United States** responds that the only information that could have been requested at the March 2000 Regulatory Committee meeting was the information requested by Italy concerning the effect of the transgenic product on the biogeochemical cycles and on the food chain and on the spreading of the gene due to the possibility of crossing between the PGM and wild species. The United States points out in this respect that the applicant responded to Italy's request on 30 November 2000 even though, in the Untied States' view, Italy's request was not scientifically justified.

7.1797 The **Panel** begins its analysis by addressing the US argument concerning the Commission's failure to re-convene the Regulatory Committee for a vote on the Commission's draft measure.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1798 The Panel recalls that the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure, and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1799 The Panel also recalls that in November 2000 the applicant provided the additional information which had been requested by Italy. In late May 2001, following a request by the lead CA of April 2000, the applicant clarified certain aspects of its application. According to the lead CA, uncertainty as to these aspects had prevented the Regulatory Committee from voting on the application in March 2000.

7.1800 When the applicant clarified certain aspects of its application in late May 2001, it also submitted additional and updated information to the lead CA. The applicant apparently did so of its own motion. It stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The applicant requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[1385] However, the lead CA did not forward the documents to the other member States and the Commission because it considered that further clarification was necessary.[1386]

[1385] Exhibit EC-62/At. 98.
[1386] Exhibit EC-62/At. 101.

The applicant provided the requested clarification on 30 October 2001.[1387] Towards the end of November 2001, the applicant wrote to the Commission, drawing attention to the additional information and indicating its desire to present the information to the other member States at a meeting of the "working group on herbicide-tolerant crops" scheduled for early December 2001.[1388] The record does not indicate whether this meeting took place.

7.1801 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1802 In approaching this question, the Panel takes note of the following elements. To begin with, by the end of May 2001 the applicant had met all requests for information and clarification conveyed to it in the wake of the March 2000 Regulatory Committee meeting. As noted, however, at the end of May 2001 the applicant also provided additional and updated information to the lead CA. That information was apparently never forwarded by the lead CA to the other member States and the Commission. Nevertheless, the record indicates that the Commission was made aware of its existence in June 2001[1389], inquired about it in September 2001[1390], and also in September 2001 was told by the lead CA that it would be informed about when the applicant would provide the clarification sought by the lead CA[1391]. In November 2001, the Commission was told directly by the applicant that the applicant had provided the clarification requested by the lead CA at the end of October 2001.

7.1803 Furthermore, it is important to remember that the applicant provided the additional information, not pursuant to a requirement flowing from the provisions of Directive 90/220, but in an effort to convince member States to vote in favour of approving its application. Also, the lead CA had not been requested to offer an assessment of the additional information before transmitting it to the other member States and the Commission. Indeed, the lead CA did not purport to undertake an assessment, for it merely asked the applicant for clarification and made suggestions for modifications, to avoid questions from other member States or to "further acceptance" by other member States.[1392]

7.1804 In view of these elements, the Panel considers that at the latest at the end of November 2001, after the applicant had clarified and revised the additional information first submitted in May 2001 and directly approached the Commission in this regard, the Commission could have stepped in and requested the lead CA to forward the additional information to other member States and itself.[1393] At least, the Commission could have done so if, as is likely, it wanted member States to have access to the additional information before re-convening the Regulatory Committee.

7.1805 The Panel notes that in its November 2001 letter to the Commission, the applicant made known its desire to present the additional information to the other member States at a meeting of the

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[1387] Exhibit EC-62/At. 105.
[1388] *Ibid*.
[1389] Exhibit EC-62/At. 101.
[1390] Exhibit EC-62/At. 102 (e-mail from lead CA to applicant).
[1391] Exhibit EC-62/At. 101.
[1392] Exhibit EC-62/At. 98.
[1393] It should be noted that more than five months after the applicant had provided the clarification requested by the lead CA, the latter sought further modifications and additional information. Exhibit EC-62/At. 106. However, as the lead CA was not required to make an assessment of the clarification provided by the applicant before transmitting the new documents to other member States and the Commission, there is no reason to consider that the Commission could not have sought the transmission of these documents to itself and other member States in November 2001.

"working group on herbicide-tolerant crops" scheduled for early December 2001. The European Communities has not explained the mandate of the "working group on herbicide-tolerant crops". There is no indication that this working group played a part in the lead-up to the October 1999 and March 2000 meetings of the Regulatory Committee. At any rate, the fact that the applicant wished to "present" the additional information to the working group does not imply that the applicant did not want the information to be distributed to the other member States until after its presentation.

7.1806 Had the Commission requested the lead CA to forward the additional information towards the end of November 2001, it could have scheduled a meeting of the Regulatory Committee for early 2002, thus giving other member States and itself time to review the additional information. As well, since Directive 90/220 was not repealed until mid-October 2002, there was enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.[1394]

7.1807 In earlier findings, we observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In our view, neither consideration would provide a justification for the Commission's failure to re-convene a Regulatory Committee meeting in early 2002.

7.1808 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission in suspending the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1395] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipates significant member State opposition and regardless of whether there are valid reasons for such opposition.

7.1809 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it may also be noted that the applicant strengthened the Commission's position by supplying new information which it said confirmed that its application was

[1394] In earlier findings on the application concerning Falcon oilseed rape, we noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Even assuming that in this scenario there was not enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force, the Panel does not consider that this would have justified the Commission's failure to re-convene the Regulatory Committee for a vote. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries vis-à-vis other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, the Commission could not have legitimately invoked the June 1999 declaration as a justification for not re-convening the Regulatory Committee in early 2002.

[1395] To recall, the record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

already in accordance with the main provisions of the new Directive 2001/18.[1396] Certainly as of the end of November 2001, after the applicant had clarified and revised the additional information first submitted in May 2001, the Commission therefore had additional arguments for seeking a vote on its draft measure in the Regulatory Committee.

7.1810 Based on the above considerations, the Panel is of the view that at the latest in early 2002 the Commission should have re-convened the Regulatory Committee meeting for a vote on the application concerning Falcon oilseed rape. Accordingly, the Panel concludes that the time actually taken by the Commission to convene a further Regulatory Committee meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long.

7.1811 In addition, we recall that the United States claims that the approval procedure concerning Falcon oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning Falcon oilseed rape after May 2001 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1812 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on a draft measure, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1813 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene a further Regulatory Committee meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Falcon oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Falcon oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1396] It should also be recalled that in November 2000 the applicant provided the additional information which had been requested by Italy. In addition, in late May 2001, following a request by the lead CA of April 2000, the applicant clarified certain aspects of its application.

(iii) MS8/RF3 oilseed rape (EC-63)

7.1814 Two Complaining Parties, the United States and Canada, claim that the completion of the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed.

7.1815 The **United States** initially argued that the progress of the application concerning MS8/RF3 oilseed rape stalled when the Commission refused to submit a draft measure to the Regulatory Committee as required by the approval process. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure, and that after the second attempt the Commission never submitted a draft measure to the Regulatory Committee again. The United States submits that the resulting delay was undue.

7.1816 The United States submits, in addition, that the application concerning MS8/RF3 oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MS8/RF3 oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1817 **Canada** submits that the applicant proposed and continuously revised its risk management measures in response to concerns expressed by member States, the SCP and the Commission. Regardless of these attempts by the applicant, the processing of the application has been delayed, which Canada believes demonstrates that the European Communities was and is intent on blocking the approval of this product for cultivation and is intent on imposing such onerous and unnecessary conditions as to make the importation of the product for processing uneconomical.

7.1818 Canada argues that since the application went to the Community level, member States took approximately 12 months to put forth their objections to the application, and after the SCP issued its positive opinion on the application, the European Communities took another 12 months to address recommendations contained in the SCP opinion, including a monitoring plan. Although the application was discussed at the Regulatory Committee in the summer of 1999, no vote was taken. Canada notes that in August 1999 the applicant proposed to voluntarily agree to meet the requirements of the Council's June 1999 Common Position. On the basis of these commitments, the Commission invited the applicant to present its proposal to the Regulatory Committee in October 1999. However, while the Regulatory Committee again considered the proposal, it failed to hold a vote. Subsequently, the applicant made further proposals as a further attempt to address concerns expressed by member States. However, although the matter went yet again before the Regulatory Committee in March 2000, it failed to hold a vote.

7.1819 Canada also claims that any delay in the completion of the approval procedure following the failure of the Regulatory Committee to adopt the draft measure approving MS8/RF3 oilseed rape in March 2000 should be considered "undue". Canada notes in this regard the efforts made by the applicant to respond to further requests by the lead CA. Canada observes that while the lead CA finally accepted the applicant's proposed post-marketing monitoring plan and agricultural guidelines in May 2002, the European Communities provided no information to explain the delay between May 2002 and early January 2003, when the applicant submitted a further updated dossier under Article 35 of Directive 2001/18.

7.1820 Finally, Canada observes that more than eight years after the application was initially submitted for approval to the lead CA in 1996 and more than six years after the SCP issued its opinion in May 1998, MS8/RF3 oilseed rape remains unapproved either for import and processing or cultivation, despite reasonably available risk management measures. Canada submits that by any reasonable standard, the extraordinary length of time to process this application constitutes "undue delay".

7.1821 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in the Regulatory Committee in June 1999, and the Regulatory Committee met twice on the matter. According to the European Communities, the Regulatory Committee did not vote on 9 March 2000 because Italy raised scientific issues regarding the effects of the product in question on biogeochemical cycles and on food chains and the likelihood of spreading. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.1822 **Canada** notes that Italy's questions had already been addressed in the application dossier and by the SCP. Further, the attempts to raise concerns about impacts of herbicide use on farmland biodiversity inappropriately linked concerns related to herbicide use to approval of a seed variety. Canada notes that: 1) for all other seed varieties, seed approval legislation is distinct from the pesticide approval legislation; 2) herbicide use is one of many factors that may have an impact on farmland biodiversity; and 3) EC member States have actually authorized the use of glufosinate-ammonium for general use as well as for specific use on genetically modified herbicide-tolerant crops. Canada also counters that the European Communities fails to point out that the submission of further information by the applicant was necessary because the information requirements were either unclear or changing.

7.1823 The **Panel** begins its analysis by addressing the United States' and Canada's arguments concerning the Commission's failure to re-convene the Regulatory Committee for a further meeting.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1824 The Panel recalls that the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. No vote was taken on the draft measure at either meeting and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1825 The record does not indicate why the Regulatory Committee did not proceed to a vote on MS8/RF3 oilseed rape at the March 2000 meeting.[1397] One reason may have been a request for information from the Italian CA. Italy transmitted its request to the lead CA on 14 March 2000, and the lead CA then forwarded it to the applicant.[1398] In November 2000 the applicant provided the lead CA with answers to the questions raised by Italy indicating that all the issues raised had been

[1397] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[1398] Exhibit EC-63/At. 87. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

previously addressed by the SCP as well as the update of the application provided by the applicant in November 1999. This communication was also circulated to the other CAs and the Commission.[1399]

7.1826 It should further be noted that in June 2001 the applicant sent a letter to the lead CA which clarified certain aspects of the application, including its scope. There is no indication that this clarification had been requested. However, the applicant's letter noted that following the March 2000 meeting of the Regulatory Committee the clarification appeared necessary.[1400] In a separate letter of the same date, "following the revision of Directive 90/220/EEC", the applicant also submitted updated information to the lead CA, including an updated environmental risk assessment, a post-market monitoring plan, agricultural guidelines, additional information regarding identification and labelling and information for the public concerning the product in question.[1401] The letter stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The letter requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[1402] There is no indication that the lead CA ever forwarded the new documents to the other member States and the Commission. A meeting of CAs was held two weeks after the applicant submitted the additional information, but the Panel has no information about what was discussed at that meeting. It is clear from the record, however, that the lead CA confirmed receipt of the new documents only in July 2001. The lead CA informed the applicant that it had forwarded the documents to the relevant scientific committee of the Belgian Biosafety Council (hereafter the "BBC") for an opinion.[1403] No reason was given for why an opinion had been requested.

7.1827 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1828 In approaching this question, the Panel takes note of the following elements. In November 2000 the applicant had met all requests for information conveyed to it following the March 2000 Regulatory Committee. The additional information was circulated to all CAs and the Commission in December 2000. As noted, however, in June 2001 the applicant provided additional clarification and updated information to the lead CA. The record does not indicate that the Commission was made aware of the existence of the June 2001 information. At the same time, there is nothing in the record to suggest that the Commission was "waiting" for the June 2001 information.

7.1829 Regarding the clarification provided by the applicant in June 2001, we note that if the Commission was not waiting for that clarification, then that clarification could not provide a justification for the Commission's failure to re-convene the Regulatory Committee sometime between December 2000 and June 2001. On the other hand, if the Commission had been waiting for clarification from the applicant, it should have inquired with the lead CA whether the applicant had provided clarification. There is no evidence that the Commission did so.

7.1830 Regarding the updated information also provided by the applicant in June 2001, it is important to remember that the applicant provided that information, not pursuant to a requirement flowing form the provisions of Directive 90/220, but in an effort to convince member States to vote in

[1399] Exhibit EC-63/At. 89 and 90.
[1400] Exhibit EC-63/At. 92.
[1401] Exhibit EC-63/At. 91.
[1402] *Ibid*.
[1403] Exhibit EC-63/At. 93.

favour of approving its application. Also, the lead CA had not been requested to offer an assessment of that additional information before transmitting it to the other member States and the Commission. Notwithstanding this, the lead CA requested an opinion of the BBC. However, it seems that for the BBC, it was not obvious that an opinion was needed. In November 2001, the BBC discussed the information in question. According to the minutes of the internal discussion, "no opinion on the part of the Biosafety Advisory Council was necessary prior to the forwarding of these documents to the European Commission; and in the past such additional information had already been sent straight to the Commission on several occasions."[1404] However, as this was the first time a company had submitted a monitoring plan, agricultural guidelines and public dossier, the BBC "thought it advisable to ask the Biosafety Advisory Council to discuss these documents before forwarding them to the European Commission."[1405] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[1406]

7.1831 We are not convinced that a lead CA assessment of the updated information was required before that information could be transmitted to the Commission and the other CAs, and that the Commission therefore needed to wait for the lead CA's assessment before re-convening the Regulatory Committee. Indeed, we note that in a parallel situation, a different lead CA did not find it necessary to make an assessment of additional information submitted by an applicant to demonstrate that its application was already in line with the main provisions of Directive 2001/18.[1407]

7.1832 In any event, in the approval procedure concerning MS8/RF3 oilseed rape, the applicant replied to the last pending question of the BBC in early May 2002.[1408] The record shows no further developments in this approval procedure until October 2002, when Directive 90/220 was repealed. Thus, there is no indication that the BBC ever provided its opinion on the June 2001 information to the lead CA. Even assuming that the Commission knew about the updated information of June 2001, and even assuming that it was justifiable in principle for the Commission to let the lead CA undertake some assessment of the information, it remained the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to finish its assessment of the updated information and to circulate it together with that information so that a further attempt at completing the approval procedure under Directive 90/220 could be made.[1409]

7.1833 In view of these elements, we consider that if the Commission had sought the circulation of the additional information once the applicant had replied to the last pending question in May 2002, it should have been possible for the information to be circulated promptly and for a Regulatory Committee meeting to be held in the summer of 2002 at the latest. As Directive 90/220 was not repealed until mid-October 2002, we think this would have left enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.[1410]

[1404] Exhibit EC-63/At. 102.

[1405] *Ibid*.

[1406] *Ibid*.

[1407] *See* our earlier analysis of the approval procedure concerning Falcon oilseed rape.

[1408] Exhibit EC-63/At. 108. The applicant also indicated readiness to follow a suggestion by the BBC regarding information to the public, subject to further clarification by the BBC. *Ibid*.

[1409] If the Commission did not know about the updated information submitted by the applicant in June 2001, then the existence of that information could not provide a justification for the Commission's failure to re-convene the Regulatory Committee after December 2000.

[1410] The Commission might have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the

7.1834 In earlier findings, the Panel observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not have achieved the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In the Panel's view, neither consideration would provide a justification for the Commission's failure to re-convene the Regulatory Committee for a third meeting.

7.1835 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission in suspending the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1411] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipates significant member State opposition and regardless of whether there are valid reasons for such opposition.

7.1836 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it should also be noted that if the Commission was aware of the existence of the updated information of June 2001, then that information would have provided it with additional arguments for seeking a vote on its draft measure in the Regulatory Committee. To recall, the applicant submitted the June 2001 information to demonstrate that the application concerning MS8/RF3 was already in accordance with the main provisions of the new Directive 2001/18.

7.1837 Based on the above considerations, the Panel is of the view that at the very latest in the summer of 2002 the Commission should have re-convened the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape. Accordingly, the Panel concludes that the time actually taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was held between March 2000 and October 2002 – was unjustifiably long.

7.1838 In relation to DS291, we recall that the United States claims that the approval procedure concerning MS8/RF3 oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape after November 2001 is consistent with the application of such a measure. In the light of this, and in

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required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Even assuming that in this scenario there was not enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force, the Panel does not consider that this would have justified the Commission's failure to re-convene the Regulatory Committee for a vote. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, the Commission could not have legitimately invoked the June 1999 declaration as a justification for not re-convening the Regulatory Committee.

[1411] The record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1839 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on a draft measure, we do not go on to examine other arguments put forward by the United States and Canada in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1840 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MS8/RF3 oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MS8/RF3 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, the Panel recalls its finding that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long. Based on this finding, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay", the application concerning MS8/RF3 oilseed rape, and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS8/RF3 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iv) RR fodder beet (EC-64)

7.1841 One Complaining Party, the United States, claims that the completion of the approval procedure concerning the RR fodder beet has been unduly delayed.

7.1842 The **United States** initially argued that the Commission in this procedure did not submit a draft measure to the Regulatory Committee. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission never submitted a draft measure to the Regulatory Committee again. The United States also submits that under the applicable EC legislation, in the absence of action by the Regulatory Committee, the

Commission was required to submit a draft measure, whether favourable or negative, to the Council. The United States recalls in this respect that the *SPS Agreement* requires that the European Communities make a decision without undue delay. In this case, the Commission failed to forward a decision to the Council.

7.1843 The United States submits, in addition, that the application concerning RR fodder beet is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR fodder beet is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1844 The **European Communities** argues that contrary to the US argument, the Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter – first on 29 October 1999 and then on 9 March 2000. The Regulatory Committee did not vote on 29 October 1999 due to outstanding requests for information.

7.1845 The **United States** responds that contrary to the European Communities' assertion that there were outstanding requests for information, the applicants had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote during the one and a half years between when the SCP issued its opinion and when the Regulatory Committee finally met. The United States also notes that when the applicants attempted to get a resolution of this matter on 12 July 2000, stating that they had fully addressed all objections raised by member States and requesting the lead CA "to inform all member States that the application was complete and subject to a Community decision"[1412], the European Communities ignored, for six months, the applicant's request.

7.1846 The **Panel** begins its analysis by addressing the US argument concerning the Commission's failure to re-convene the Regulatory Committee for a vote on the Commission's draft measure.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1847 The Panel recalls that, after the SCP issued its favourable opinion with regard to this application on 23 June 1998, the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. No vote was taken on the draft measure at either meeting, and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1848 We also recall that in July 2000 the applicant provided the additional information requested by the Italian CA, as well as data on molecular characterization which were apparently generated at the request of the United Kingdom's CA. The conclusion of the July 2000 letter states that, in the applicant's view, all objections raised by the CAs within the 60-day period provided for in Directive 90/220 had now been fully addressed. We further recall that the lead CA did not forward the new documents to the other CAs. As also noted earlier, the Commission received a copy of the applicant's July 2000 letter.

[1412] Exhibit EC-64/At. 119.

7.1849 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1850 In approaching this question, the Panel takes note of the following elements. To begin with, by mid-July 2000 the applicant had apparently addressed all objections raised by the CAs within the 60-day period provided for in Directive 90/220 and conveyed to the applicant. That information was never forwarded by the lead CA to the other CAs. However, it should be recalled in this respect that in February 2001 the applicant suggested to the lead CA, in view of the "very volatile" EC regulatory context, that it forward the documents after the adoption of Directive 2001/18 (which came in March 2001) and the circulation of a Commission proposal on new EC rules concerning labelling and traceability (which came in July 2001).[1413] The lead CA did not follow the applicant's suggestion.

7.1851 Furthermore, as noted, the Commission received a copy of the applicant's July 2000 letter. It is likely that the Commission wanted the other CAs to have access to the additional information provided in July 2000 before re-convening the Regulatory Committee. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to circulate the additional information provided by the applicant in July 2000 so that a further attempt at completing the approval procedure under Directive 90/220 could be made.

7.1852 In view of these elements, we consider that after July 2000, once the applicant had provided the additional information sought by the Italian CA, or at the latest in the summer of 2001, when the Commission circulated its proposal for new EC rules on labelling and traceability, the Commission could have re-convened the Regulatory Committee for a vote on the application concerning RR fodder beet. Directive 90/220 was not repealed until 17 October 2002. In our view, there was thus enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.

7.1853 In earlier findings, we observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In our view, neither consideration would provide a justification for the Commission's failure to re-convene the Regulatory Committee for a vote prior to the repeal of Directive 90/220.

7.1854 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission's suspension of the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1414] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipated significant member State opposition and regardless of whether there were valid reasons for such opposition.

[1413] *Ibid*.

[1414] To recall, the record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

7.1855 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it may also be noted that the applicant strengthened the Commission's position by supplying supplementary information addressing objections raised by other CAs.

7.1856 Based on the above considerations, the Panel is of the view that at the latest in the summer of 2001 the Commission should have re-convened the Regulatory Committee for a vote on the application concerning RR fodder beet. Accordingly, the Panel concludes that the time actually taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long.

7.1857 In addition, we recall that the United States claims that the approval procedure concerning RR fodder beet was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning RR fodder beet after July 2000 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1858 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on its draft measure, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1859 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR fodder beet for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR fodder beet, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(v) Bt-531 cotton (EC-65)

7.1860 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning Bt-531 cotton has been unduly delayed.

7.1861 The **United States** submits that the application concerning Bt-531 cotton under Directive 90/220 suffered a three-and-a-half-year period of inactivity by EC regulators. From 7 May 1999, after the launch of inter-service consultations on a draft measure to be submitted to the Council, until 12 February 2003, when the lead CA finally circulated the updated application to the Commission, the application was totally ignored by the Commission and lead CA. The United States considers this lengthy delay to be unwarranted and thus undue.

7.1862 The United States points out in this respect that the application in question had received a favourable scientific assessment by the European Community's own scientific committee, the SCP. That certain member States objected in the Regulatory Committee does not justify the Commission's refusal to act on the application. The United States submits that those objections which were explained in statements, notably those by Austria and the United Kingdom, were the subject of detailed scientific consideration in the SCP's positive opinion in July 1998. The United States also notes that there is at any rate nothing to indicate that the Commission undertook any process whatsoever to resolve the member State concerns. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. The United States is therefore of the view that the delay in question was not caused, as the European Communities claims, by a pending request to the applicant for additional information.

7.1863 The United States notes in addition that the EC legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. The United States considers that where the European Communities' own legislation provides timelines, a suspension of the approval procedure without any scientific justification must be considered undue delay.

7.1864 The United States submits, finally, that the application concerning Bt-531 cotton is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-531 cotton is undue. The United States also argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1865 **Argentina** argues that after the Regulatory Committee in February 1999 failed to achieve a qualified majority in favour of approving the application concerning Bt-531 cotton, the Commission refused to submit a draft measure to the Council until the application had to be resubmitted under Directive 2001/18. Argentina submits that this was not due to any action or omission on the part of the applicant. According to Argentina, there notably are no EC documents which specifically requested the applicant to provide additional information. Argentina considers that the delay which it says was caused by the Commission is undue. Argentina argues in this respect that the requirements of legislation not yet in force do not provide grounds for a prolonged failure to process an application. In particular, the application concerning Bt-531 cotton should not have been forced to start the procedure again under the new Directive 2001/18 when the procedure under the old Directive 90/220 had already been in progress for three years. Furthermore, Argentina asserts that there is no scientific evidence to justify the delay after the Regulatory Committee vote. Those member States which in the Regulatory Committee voted against approving Bt-531 cotton ignored the positive scientific opinion of the SCP of July 1998. Moreover, Argentina contests the scientific validity of the statements

offered by some member States in support of their votes inasmuch as these statements do not refute the positive opinion of the SCP.[1415]

7.1866 Argentina singles out another instance of delay which it considers undue. Argentina asserts that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning Bt-531 cotton had been inactive for an additional period of 1 year and 3 months.

7.1867 Finally, Argentina submits that the total time consumed by the procedures under Directives 90/220 and 2001/18, from the time the application was first submitted until April 2004, the date of Argentina's first written submission, has been 7 years and 4 months. In Argentina's view, this delay can in no way be justified in the light of the deadlines stipulated in the relevant EC legislation. Argentina contends that the procedure under Directive 90/220 should normally have been completed within 240 days, which does not include the time during which a CA or the Commission may be awaiting additional information it may have requested or the time needed by an EC scientific committee to issue an opinion ("clock-stop"). Similarly, Argentina contends that under Directive 2001/18, a procedure should be completed within 285 days if no objections to the lead CA's initial assessment are made, and 450 days if objections are made. Again, this does not include the time spent waiting for additional information or for a scientific committee opinion. Argentina asserts that the delay affecting the approval procedure concerning Bt-531 cotton cannot be justified by such "clock-stops".

7.1868 The **European Communities** argues that the Regulatory Committee in February 1999 failed to reach a qualified majority because a number of member States raised scientific concerns which had not been addressed in any of the applicant's previous submissions. The European Communities submits that long after the vote in the Regulatory Committee, on 25 July 2001, the applicant provided the requested additional information, and that the translation of this material was not made available until February 2002. According to the European Communities, if there was a three-year delay after the Regulatory Committee vote, it was because of the time taken by the applicant to provide the requested additional information.

7.1869 Regarding the requirement contained in Article 21 of Directive 90/220 that the Commission "shall, without delay, submit to the Council a proposal relating to the measures to be taken", the European Communities points out that in the *Pharos* case[1416], the European Court of Justice examined an identical requirement to submit a proposal to the Council "without delay" in the context of legislation on the setting of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Regulation 2377/90). The Court stated that nothing in the wording of the relevant provision "suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission".[1417] The Court then went on to point out that the Commission was free to modify its proposal before submitting it to the Council and found that "if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it".[1418] On that basis, the Court found that the Commission, which had taken over eleven months before forwarding a proposal to the Council, had not breached its

[1415] Exhibit ARG-54, p. 3.
[1416] European Court of Justice, Case C-151/98, *Pharos against Commission [1999]* ECR I-8157.
[1417] *Ibid.*, para. 20.
[1418] *Ibid.*, para. 24.

obligation to act "without delay".[1419] The Court pointed to the fact that the matter with which the Commission was confronted was "highly complex and sensitive".[1420] The Court also made it clear that the Commission could not be criticised for having sought additional advice from an EC scientific committee in an effort to prevent its proposal from being rejected by the Council.[1421]

7.1870 Concerning the case at hand, the European Communities argues that the concerns raised by certain member States were all legitimate and scientifically sound. They could not be ignored or brushed off by the Commission without detailed consideration. Moreover, according to the European Communities, in the light of the impending legislative changes, further reflection was necessary before proceeding further. The European Communities submits that this is in line with the jurisprudence of the European Court of Justice.

7.1871 In relation to the delay which occurred after the application was resubmitted under Directive 2001/18, the European Communities submits that the application contained an incomplete monitoring plan. According to the European Communities, the lead CA is awaiting additional information on the post-marketing monitoring plan that it has requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.1872 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Council

7.1873 The Panel begins its analysis by addressing the delay allegedly caused by the Commission. The Panel recalls that on 7 May 1999, the Commission launched inter-service consultations on a draft measure to be submitted to the Council. But at no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council. The United States and Argentina argue that the Commission should have completed its inter-service consultations and submitted a draft measure to the Council before October 2002.

7.1874 It is clear that the preparation by the Commission of a draft measure and its submission to the Council is not a process which necessarily takes more than three years. To begin with, in other approval procedures, the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee, and that some made written statements.[1422] Moreover, as the Panel understands it, the preparation by the Commission of a draft measure to be submitted to the Council is not a process that is fundamentally different from the preparation by the Commission of a draft measure to be submitted to the Regulatory Committee. In the approval procedure here at issue, the Commission prepared a draft measure and launched a vote in

[1419] The Panel notes that the judgement indicates that during the eleven-month period, the Commission initially reconsidered the file for six months and then sought a second scientific opinion. *Ibid.*, para. 32.

[1420] *Ibid.*, para. 26.

[1421] *Ibid.*, para. 27.

[1422] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 sweet maize (food) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

the Regulatory Committee in less than three months.[1423] It may be inferred from these examples that the Commission could in principle have completed its task well before October 2002.

7.1875 The issue thus becomes whether in the specific circumstances of this case the Commission could in fact have completed its task before October 2002. The European Communities argues that the Commission did not need to forward a draft measure to the Council because the applicant took too long to provide information which had been requested of it. The European Communities notes that the applicant did not provide that information until 25 July 2001, and that the translation of this material was made available only in February 2002. However, in its earlier analysis of the approval procedure in question, the Panel found that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant in July 2001. The Panel pointed out that even after the applicant had provided the information, the Commission did not forward a draft measure to the Council, although Directive 90/220 remained in force for another seventeen months, until October 2002. Accordingly, the information provided by the applicant in July 2001 does not justify the Commission's failure to forward a draft measure to the Council.

7.1876 Another argument put forward by the European Communities to justify the Commission's failure to forward a draft measure to the Council relates to the fact that the Regulatory Committee failed to achieve the necessary qualified majority to approve the application concerning Bt-531 cotton and that Austria, Sweden and the United Kingdom, in written statements supporting their votes, expressed certain concerns. The European Communities submits that these concerns were scientifically sound and had not been previously addressed by the applicant, and that they could not, therefore, be ignored or brushed off by the Commission without detailed consideration.

7.1877 As no qualified majority was reached in the Regulatory Committee, the Panel considers that, as a general matter, it was justifiable for the Commission to take some time, as part of its inter-service consultations, to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine, in the light of the results of such an analysis, whether it would be appropriate to modify the Commission's draft measure before it was sent on to the Council, and if so, how.

7.1878 The Panel recognizes that, as a matter of EC law, the Commission's draft measure did not need to obtain a qualified majority in the Council to complete the approval procedure. If the Council had failed to reach a favourable qualified majority, the Commission would have had to adopt its draft measure and hence approve the application concerning Bt-531 cotton.[1424] However, it must be borne in mind that an EC decision to approve the application concerning Bt-531 cotton would have authorized the applicant to market its product in all EC member States. In the light of this, the Commission had good reasons, in the Panel's view, to seek a qualified majority in the Council as this would have enhanced the legitimacy and acceptability of an EC decision to approve the application concerning Bt-531 cotton.[1425] This means that the Commission could take a reasonable period of time to explore ways of modifying its draft measure with a view to increasing the measure's chances of

[1423] Exhibit EC-65/Ats. 48 and 51. The Panel does not express a view as to whether this three-month period was necessary in the circumstances to complete the relevant procedural stage.

[1424] Article 21 of Directive 90/220. If the Council had reached a qualified majority against approving the application, then the application would, however, have had to be rejected.

[1425] It should also be recalled that the Complaining Parties did not question the design of the approval procedure set out in Directive 90/220 (or its successor, Directive 2001/18), and in particular the fact that member States vote on applications. If the Commission were obliged to press on immediately, preventing it from taking into account the votes and views expressed by member States, it would undermine the European Communities' ability to operate its approval procedure as designed.

being accepted by the Council by a qualified majority.[1426] It does not mean that the Commission could simply wait for the majorities in the Council to change enough to allow the Commission's original draft measure to be accepted by a qualified majority. The obligation imposed on the European Communities is to complete its approval procedures without undue delay. This obligation may at times require the Commission to complete an approval procedure even if it does not have the (qualified) majority support of the Council.

7.1879 How much time is to be accorded to the Commission for the purpose of reconsidering a draft measure which did not obtain a qualified majority in the Regulatory Committee can only be determined in the light of the circumstances of each case.

7.1880 Turning, then, to the circumstances of this case, the European Communities asserts that the concerns identified in the written statements by Austria, Sweden and the United Kingdom had not been addressed by the applicant before. The Panel is unable to agree with this assertion. As pointed out by the United States, the concerns referred to in the statements by the three member States were addressed in the SCP opinion of July 1998.[1427] At any rate, the record does not indicate that after the Regulatory Committee vote, the Commission or the lead CA sought additional information from the applicant in an effort to allay these concerns.

7.1881 Even if it were assumed that during its inter-service consultations the Commission was undertaking its own assessment of the scientific validity of the specific concerns expressed with a view to supporting its draft measure with scientific arguments[1428], it is well to recall that the SCP was able to undertake a comprehensive scientific assessment of the application concerning Bt-531 cotton in little over three months' time.[1429] The Panel also notes that the European Communities does not assert that the concerns raised by the member States in question presented either new or particularly complex scientific problems.

7.1882 Another circumstance invoked by the European Communities is the fact that Directive 90/220 was being revised at the time. According to the European Communities, a period of time for reflection was therefore needed before proceeding further. To recall, the Commission in this case launched its inter-service consultations on a draft measure to be submitted to the Council in May 1999. At the end of June 1999, the Council reached a political agreement – the Common Position – on the proposal to amend Directive 90/220, but Directive 2001/18, the Directive amending Directive 90/220, was not adopted until March 2001 and did not enter into force until October 2002. Thus, the Commission started its inter-service consultations almost three-and-a-half years before the entry into force of Directive 2001/18. In the light of this, even accepting that the Commission could take some time to reconsider its draft measure, the Commission's failure to forward a draft measure to the Council cannot be excused on the grounds that there was not enough time to complete the approval procedure while Directive 90/220 was still in force.[1430]

[1426] The Panel recalls once more that in other approval procedures the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee.

[1427] Exhibit EC-65/At. 47, paras. 6.2.1 and 6.3.3-6.3.4. The Panel notes that Sweden voted in favour of the Commission's draft measure and that Sweden's statement suggests that its concerns were met.

[1428] The European Communities did not specifically assert that it was undertaking a scientific assessment of the concerns in question; it merely implied that the Commission embarked on a "detailed consideration" of these concerns.

[1429] Exhibit EC-65/Ats. 43 and 47.

[1430] In its earlier findings on the application concerning Bt-531 cotton, the Panel noted that the Commission had reason to believe that due to the "blocking minority" of the Group of Five countries in the

7.1883 Furthermore, the fact that some member States and segments of public opinion may have considered that Directive 90/220 was no longer adequate and may have voiced opposition to further approvals under that Directive 90/220 did not, in the Panel's view, provide a justification for the Commission to delay the approval procedure in question until new legislation had been put in place. The EC legislator allowed Directive 90/220 to remain in force and hence applicable until October 2002. Moreover, if the Commission saw a need to respond to concerns about perceived inadequacies inherent in Directive 90/220, there were other courses of action open to it. Thus, the Commission could in the first instance have sought voluntary commitments from the applicant. Alternatively, it could have proposed that the application be approved subject to conditions. In this respect, it is worth noting that Directive 90/220 provided additional safeguards if new information on risks of Bt-531 cotton had become available after its EC-wide approval.[1431] In such an event, a member State could, pursuant to Article 16, provisionally restrict or prohibit the marketing of Bt-531 cotton. Finally, if in fact the Commission had been of the view that the risks arising from the marketing of Bt-531 cotton could not be adequately assessed or managed under Directive 90/220, it could arguably have sought the rejection of the application, subject to the right of the applicant to submit the application for reconsideration under the revised Directive, once it entered into force.[1432]

7.1884 Based on the above considerations, the Panel is of the view that in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long.

7.1885 Regarding DS291, we recall that the United States claims that the approval procedure concerning Bt-531 cotton was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure concerning Bt-531 cotton to the Council is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1886 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Council, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Council, it would have to adopt the draft measure it submitted to the Council. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force.

[1431] The Commission usually made this point in its decisions approving applications. *See, e.g.*, Exhibit ARG-35 ("[w]hereas Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks of the product becomes available").

[1432] The fact that such a final decision might possibly have been challenged by the applicant before an EC court would obviously not have been a legitimate reason for not completing the approval procedure.

Conclusions

7.1887 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-531 cotton for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-531 cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning Bt-531 cotton without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vi) RR-1445 Cotton (EC-66)

7.1888 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning RR-1445 cotton has been unduly delayed.

7.1889 The **United States** submits that the application concerning RR-1445 cotton was delayed for nearly four years under Directive 90/220 by EC regulators. The United States submits that from 22 February 1999, after the failure of the Regulatory Committee to reach a decision, and despite the launch of inter-service consultations on a draft measure to be submitted to the Council starting 7 May 1999, the application was totally ignored by the Commission and lead CA until is was re-submitted under Directive 2001/18 on 16 January 2003. The United States considers this lengthy delay to be unwarranted and thus undue.

7.1890 The United States points out in this respect that the application in question had received a favourable scientific assessment by the SCP. In the United States' view, the fact that certain member States objected in the Regulatory Committee does not justify the Commission's refusal to act on the application. The United States submits that those objections which were explained in statements, notably those by Austria, Sweden and the United Kingdom, were the subject of detailed scientific consideration in the SCP's positive opinion in July 1998. None of the member States objecting at the Regulatory Committee stage offered any competing risk assessment or scientific evidence for their objections, nor did they identify any specific inadequacies in the SCP review. The United States also notes that there is at any rate nothing to indicate that the Commission undertook any process

whatsoever to resolve the member State concerns. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. The United States is therefore of the view that the delay in question was not caused, as the European Communities claims, by a pending request to the applicant for additional information.

7.1891 The United States notes in addition that the EC legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. The United States considers that where the European Communities' own legislation provides timelines, a suspension of the approval procedure without any scientific justification must be considered undue delay.

7.1892 The United States submits, finally, that the application concerning RR-1445 cotton is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR-1445 cotton is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years

7.1893 **Argentina** argues that after the Regulatory Committee in February 1999 failed to achieve a qualified majority in favour of approving the application concerning RR-1445 cotton, the Commission refused to submit a draft measure to the Council until the application had to be resubmitted under Directive 2001/18. Argentina submits that this was not due to any action or omission on the part of the applicant. According to Argentina, there notably are no EC documents which specifically requested the applicant to provide additional information. Argentina considers that the delay which it says was caused by the Commission is undue. Argentina argues in this respect that the requirements of legislation not yet in force do not provide grounds for a prolonged failure to process an application. In particular, the application concerning RR-1445 cotton should not have been forced to start the procedure again under the new Directive 2001/18 when the procedure under the old Directive 90/220 had already been in progress for three years. Furthermore, Argentina asserts that there is no scientific evidence to justify the delay after the Regulatory Committee vote. Those member States which in the Regulatory Committee voted against approving RR-1445 cotton ignored the positive scientific opinion of the SCP of July 1998. Moreover, Argentina contests the scientific validity of the statements offered by some member States in support of their votes inasmuch as these statements do not refute the positive opinion of the SCP.

7.1894 Argentina identified another instance of delay which it considers undue. Argentina asserts that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning RR-1445 cotton had been inactive for an additional period of 1 year and 3 months.

7.1895 Finally, Argentina submits that the total time consumed by the procedures under Directives 90/220 and 2001/18, from the time the application was first submitted until April 2004, the date of Argentina's first written submission, has been 6 years and 9 months. In Argentina's view, this delay can in no way be justified in the light of the deadlines stipulated in the relevant EC legislation. Argentina contends that the procedure under Directive 90/220 should normally have been completed

within 240 days, which does not include the time during which a lead CA or the Commission may be awaiting additional information it may have requested or the time needed by an EC scientific committee to issue an opinion. Similarly, Argentina contends that under Directive 2001/18, a procedure should be completed within 285 days if no objections to the lead CA's initial assessment are made, and 450 days if objections are made. Again, this does not include the time spent waiting for additional information or for a scientific committee opinion. Argentina asserts that the delay affecting the approval procedure concerning RR-1445 cotton cannot be justified by such "clock-stops".

7.1896 The **European Communities** argues that the Regulatory Committee in February 1999 failed to reach a qualified majority because a number of member States raised scientific concerns which had not been addressed in any of the applicant's previous submissions. These related in particular to the long-term effects of herbicide tolerant crops on the environment, to the presence of an antibiotic resistance marker gene, residue-limit levels and to the effects on biodiversity of changes in crop management.

7.1897 Regarding the requirement contained in Article 21 of Directive 90/220 that the Commission "shall, without delay, submit to the Council a proposal relating to the measures to be taken", the European Communities points out that in the *Pharos* case[1433], the European Court of Justice examined an identical requirement to submit a proposal to the Council "without delay" in the context of legislation on the setting of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Regulation 2377/90). The Court stated that nothing in the wording of the relevant provision "suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission".[1434] The Court then went on to point out that the Commission was free to modify its proposal before submitting it to the Council and found that "if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it".[1435] On that basis, the Court found that the Commission, which had taken over eleven months before forwarding a proposal to the Council, had not breached its obligation to act "without delay".[1436] The Court pointed to the fact that the matter with which the Commission was confronted was "highly complex and sensitive".[1437] The Court also made it clear that the Commission could not be criticised for having sought additional advice from an EC scientific committee in an effort to prevent its proposal from being rejected by the Council.[1438]

7.1898 Concerning the case at hand, the European Communities argues that the concerns raised by certain member States were legitimate and scientifically sound. They could not be ignored or brushed off by the Commission without detailed consideration. Moreover, according to the European Communities, in the light of the impending legislative changes, further reflection was necessary before proceeding further. The European Communities submits that this is in line with the jurisprudence of the European Court of Justice.

7.1899 In relation to the delay which occurred after the application was resubmitted under Directive 2001/18, the European Communities submits that the application contained an incomplete

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[1433] European Court of Justice, Case C-151/98, *Pharos against Commission [1999]* ECR I-8157.
[1434] *Ibid.*, para. 20.
[1435] *Ibid.*, para. 24.
[1436] The Panel notes that the judgement indicates that during the eleven-month period, the Commission initially reconsidered the file for six months and then sought a second scientific opinion. *Ibid.*, para. 32.
[1437] *Ibid.*, para. 26.
[1438] *Ibid.*, para. 27.

monitoring plan. According to the European Communities, the lead CA was awaiting additional information on the post-marketing monitoring plan that it had requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.1900 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Council

7.1901 The Panel recalls that, following the failure of the Regulatory Committee to reach a decision, on 7 May 1999 the Commission launched inter-service consultations on a draft measure to be submitted to the Council. But at no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council. The United States and Argentina argue that the Commission should have completed its inter-service consultations and submitted a draft measure to the Council before October 2002.

7.1902 It is clear that the preparation by the Commission of a draft measure and its submission to the Council is not a process which inherently takes more than three years. To begin with, in other approval procedures, the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee, and that some made written statements.[1439] Moreover, as the Panel understands it, the preparation by the Commission of a draft measure to be submitted to the Council is not a process that is fundamentally different from the preparation by the Commission of a draft measure to be submitted to the Regulatory Committee. In the approval procedure here at issue, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in four months after receipt of the SCP opinion.[1440] It may be inferred from these examples that the Commission could in principle have completed its task well before October 2002.

7.1903 The issue thus becomes whether in the specific circumstances of this case the Commission could in fact have completed its task before October 2002. The European Communities argues that the Commission was not able to forward a draft measure to the Council because the applicant took too long to provide information which had been requested of it. The European Communities notes that the applicant did not provide that information until 25 July 2001, and that the translation of this material was made available only in February 2002. However, in our earlier analysis of the approval procedure concerning RR-1445 cotton, we found that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant in July 2001. We pointed out that even after the applicant had provided the information, the Commission did not forward a draft measure to the Council, although Directive 90/220 remained in force for another seventeen months. Accordingly, the information provided by the applicant in July 2001 in our view does not justify the Commission's failure to forward a draft measure to the Council.

[1439] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 sweet maize (food) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

[1440] Exhibit EC-66/Ats. 44 and 46. The Panel does not express a view as to whether this four-month period was necessary in the circumstances to complete the relevant procedural stage.

7.1904 Another argument put forward by the European Communities to justify the Commission's failure to forward a draft measure to the Council relates to the fact that the Regulatory Committee failed to achieve the necessary qualified majority to approve the application concerning RR-1445 cotton and that Austria, Italy, Sweden and the United Kingdom, in written statements supporting their votes, expressed certain concerns. The European Communities submits that these concerns were scientifically sound and had not been previously addressed by the applicant, and that they could not, therefore, be ignored or brushed off by the Commission without detailed consideration.

7.1905 As no qualified majority was reached in the Regulatory Committee, the Panel considers that, as a general matter, it was justifiable for the Commission to take some time, as part of its inter-service consultations, to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine, in the light of the results of such an analysis, whether it would be appropriate to modify the Commission's draft measure before it was sent on to the Council, and if so, how.

7.1906 The Panel recognizes that, as a matter of EC law, the Commission's draft measure did not need to obtain a qualified majority in the Council to complete the approval procedure. If the Council had failed to reach a favourable qualified majority, the Commission would have had to adopt its draft measure and hence approve the application concerning RR-1445 cotton.[1441] However, it must be borne in mind that an EC decision to approve the application concerning RR-1445 cotton would have authorized the applicant to market its product in all EC member States. In the light of this, the Commission was entitled, in the Panel's view, to try to obtain a qualified majority in the Council as this would have enhanced the legitimacy and acceptability of an EC decision to approve the application concerning RR-1445 cotton.[1442] This means that the Commission could take a reasonable period of time to explore ways of modifying its draft measure with a view to increasing the measure's chances of being accepted by the Council by a qualified majority.[1443] But the Commission could not simply wait for the majorities in the Council to change enough to allow the Commission's original draft measure to be accepted by a qualified majority. The obligation imposed on the European Communities is to complete its approval procedures without undue delay. This obligation may at times require the Commission to complete an approval procedure even if it does not have the (qualified) majority support of the Council.

7.1907 How much time is to be accorded to the Commission for the purpose of reconsidering a draft measure which did not obtain a qualified majority in the Regulatory Committee can only be determined in the light of the circumstances of each case.

7.1908 Turning, then, to the circumstances of this case, the European Communities asserts that the concerns identified in the written statements by Austria, Italy, Sweden and the United Kingdom had not been addressed by the applicant before.[1444] The Panel is unable to agree with this assertion. Austria and the United Kingdom expressed concerns arising from the antibiotic resistance marker

[1441] Article 21 of Directive 90/220. If the Council had reached a qualified majority against approving the application, then the application would, however, have had to be rejected.

[1442] It should also be recalled that the Complaining Parties did not question the design of the approval procedure set out in Directive 90/220 (or its successor, Directive 2001/18), and in particular the fact that member States vote on applications. It is arguable that if the Panel effectively were to require the Commission to press on immediately, preventing it from taking into account the votes and views expressed by member States, it would undermine the European Communities' ability to operate its approval procedure as designed.

[1443] The Panel recalls once more that in other approval procedures the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee

[1444] The statements are provided in Exhibit EC-66/At. 57. Italy voted in favour of the Commission's draft measure in the Regulatory Committee.

gene, which according to Dr. Squire had been explicitly addressed in the SCP assessment.[1445] The concern identified by Italy was to ensure that the herbicide residues were within the limits established by other EC legislation, which according to the Panel's understanding is not a concern related to the safety of RR-1445 cotton *per se*. Only the general concerns raised by Sweden and the United Kingdom regarding long-term effects of herbicide tolerant crops on the environment were not, according to Dr. Andow fully addressed by the SCP with regard to RR-1445 cotton.[1446] However, Dr. Andow indicated that the long-term experiments suggested by Sweden were not feasible and that the concerns identified could best be addressed in a monitoring plan, but that the necessity of a monitoring plan could not be determined from the objections as submitted. At any rate, the record does not indicate that after the Regulatory Committee vote, the Commission or the lead CA sought additional information from the applicant in an effort to allay these concerns.

7.1909 Even if it were assumed that during its inter-service consultations the Commission was undertaking its own assessment of the scientific validity of the specific concerns expressed with a view to supporting its draft measure with scientific arguments[1447], it is well to recall that the SCP was able to undertake a comprehensive scientific assessment of the application concerning RR-1445 cotton in little over three months' time.[1448] The Panel also notes that the European Communities does not assert that the concerns raised by the member States in question presented either new or particularly complex scientific problems.

7.1910 Another circumstance invoked by the European Communities is the fact that Directive 90/220 was being revised at the time. According to the European Communities, a period of time for reflection was therefore needed before proceeding further. To recall, the Commission in this case launched its inter-service consultations on a draft measure to be submitted to the Council in May 1999. At the end of June 1999, the Council reached a political agreement – the Common Position – on the proposal to amend Directive 90/220, but Directive 2001/18, the Directive amending Directive 90/220, was not adopted until March 2001 and did not enter into force until October 2002. Thus, the Commission started its inter-service consultations almost three-and-a-half years before the entry into force of Directive 2001/18. In the light of this, even accepting that the Commission could take some time to reconsider its draft measure, the Commission's failure to forward a draft measure to the Council cannot be excused on the grounds that there was not enough time to complete the approval procedure while Directive 90/220 was still in force.[1449]

7.1911 Furthermore, the fact that some member States and segments of public opinion may have considered that Directive 90/220 was no longer adequate and may have voiced opposition to further approvals under that Directive 90/220 did not, in the Panel's view, provide a justification for the Commission to delay the approval procedure in question until new legislation had been put in place. The EC legislator allowed Directive 90/220 to remain in force and hence applicable until October 2002. Moreover, if the Commission saw a need to respond to concerns about perceived inadequacies inherent in Directive 90/220, there were other courses of action open to it. Thus, the Commission

[1445] Annex H, para. 468.

[1446] Annex H, paras. 443-448.

[1447] The European Communities did not specifically assert that it was undertaking a scientific assessment of the concerns in question; it merely implied that the Commission embarked on a "detailed consideration" of these concerns.

[1448] Exhibit EC-66/Ats. 40 and 43.

[1449] In its earlier findings on the application concerning RR-1445 cotton, the Panel noted that the Commission had reason to believe that due to the "blocking minority" of the Group of Five countries in the Council, it would have to adopt the draft measure it submitted to the Council. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force.

could in the first instance have sought voluntary commitments from the applicant. Alternatively, it could have proposed that the application be approved subject to conditions. In this respect, it is worth noting that Directive 90/220 provided additional safeguards if new information on risks of RR-1445 cotton had become available after its EC-wide approval.[1450] In such an event, a member State could, pursuant to Article 16 of Directive 90/220, provisionally restrict or prohibit the marketing of RR-1445 cotton. Finally, if in fact the Commission had been of the view that the risks arising from the marketing of RR-1445 cotton could not be adequately assessed or managed under Directive 90/220, it could arguably have sought the rejection of the application, subject, perhaps, to the right of the applicant to submit the application for reconsideration under the revised Directive, once it entered into force.[1451]

7.1912 Based on the above considerations, the Panel is of the view that in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long.

7.1913 Regarding DS291, we recall that the United States claims that the approval procedure concerning RR-1445 cotton was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1914 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Council, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.1915 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR-1445 cotton for final approval, and that this resulted in "undue delay"

[1450] The Commission usually made this point in its decisions approving applications. *See, e.g.*, Exhibit ARG-35 ("[w]hereas Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks of the product becomes available").

[1451] The fact that such a final decision might possibly have been challenged by the applicant before an EC court would obviously not have been a legitimate reason for not completing the approval procedure.

in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR-1445 cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning RR-1445 cotton without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vii) Transgenic potato (EC-67)

7.1916 Only one Complaining Party, the United States, claims that the completion of the approval procedure concerning the Transgenic potato has been unduly delayed.

7.1917 The **United States** argues that after the Transgenic potato received a favourable opinion from the SCP, the Commission failed to submit a draft measure to the Regulatory Committee, with the consequence that the consideration of this application was suspended until the application was resubmitted under Directive 2001/18.

7.1918 The United States submits, in addition, that the application concerning the Transgenic potato is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning the Transgenic potato is excessive and unjustified and, hence, undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1919 The **European Communities** points out that the SCP in this procedure took more than three and a half years to assess the Transgenic potato. The European Communities submits that when the SCP issued its opinion in July 2002, Directive 2001/18 was about to enter into force and it was clear that the application had to be updated in the light of the new Directive.

7.1920 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1921 The Panel recalls that the SCP issued a favourable opinion on 18 July 2002. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In fact, it seems that unlike in other approval procedures[1452], the Commission in this procedure did not even launch inter-service consultations on a draft measure. In October 2002,

[1452] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.

Directive 90/220 was repealed. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1922 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes very long. In some approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in slightly less than three months.[1453] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application a little less than three months after EFSA issued its opinion.[1454]

7.1923 In the case of the approval procedure concerning the Transgenic potato, the SCP issued its opinion almost exactly three months before Directive 90/220 was repealed. The Panel understands the European Communities to argue that in these circumstances, the Commission did not need to submit a draft measure to the Regulatory Committee. This argument presents the issue whether the Commission could justifiably have reached the conclusion that three months would be insufficient to approve the application concerning the Transgenic potato.

7.1924 In its earlier findings, the Panel found that before the Transgenic potato could be approved, a number of procedural steps remained to be undertaken and completed. The Commission had to prepare a draft measure and submit it to the Regulatory Committee; the Regulatory Committee had to meet and vote on the draft measure; in the event of a favourable vote in the Regulatory Committee, the Commission had to adopt its draft measure; and finally, the lead CA had to give its written consent so that the product could be placed on the market. Directive 90/220 does not stipulate specific deadlines for any of these procedural steps.

7.1925 As pointed out above, the record shows that in one particular approval procedure, the Commission was able to obtain a Regulatory Committee vote less than three months after EFSA issued its opinion. If in the approval procedure concerning the Transgenic potato the Commission had proceeded with a sense of urgency, it might thus have succeeded in obtaining a Regulatory Committee vote in slightly less than three months.[1455] If the Commission's draft measure had achieved a qualified majority, the approval procedure would then have had to be completed within a matter of a few days.

7.1926 The record does not provide confirmation that this would have been possible. Regarding the adoption by the Commission of its own draft measure, the approval procedure concerning Bt-11 sweet maize is of interest, although that procedure was conducted under Regulation 258/97. In that procedure, the Commission took close to a month to adopt its own draft measure after the Council failed to achieve a qualified majority.[1456] Regarding the written consent to be given by the lead CA, the Panel finds informative the provisions of Article 18(2) of Directive 2001/18 according to which the lead CA must give its written consent, transmit it to the applicant and inform the other member States and the Commission thereof "within 30 days following the publication or notification of the [Commission's] decision [to adopt its draft measure]". While, as noted, Directive 90/220 stipulates no such deadline, the aforementioned steps were also to be completed under that Directive.[1457] It is

[1453] The Commission launched inter-service consultations on 4 September 1998 and launched a vote in the Regulatory Committee on 26 November 1998. Exhibit EC-65/Ats. 48 and 51.

[1454] EFSA issued its opinion on 25 November 2003 and the Regulatory Committee voted on the Commission's draft measure on 18 February 2004. Exhibit EC-76/Ats. 70 and 72.

[1455] The United States has submitted no evidence or argument to show that the Commission could have completed this task in substantially less time.

[1456] Exhibit EC-92/At. 81.

[1457] Article 13(4) of Directive 90/220.

reasonable to infer from the thirty-day deadline set out in Article 18(2) that the relevant steps could not invariably be completed in just a few days. Notwithstanding the foregoing, it may be assumed that if both the Commission and the lead CA had proceeded on an urgency basis in view of the exceptional circumstance of the imminent repeal of Directive 90/220, they might well have been able to complete their respective procedural steps in less than a month each. However, the evidence before the Panel is insufficient to support the conclusion that the procedural steps to be completed by the Commission and the lead CA should altogether have taken no more than a few days.

7.1927 In conclusion, based on the evidence on the record, the Panel is not convinced that the approval procedure concerning the Transgenic potato could have been completed in the three-month period preceding the date of repeal of Directive 90/220, and that the Commission should therefore have launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee. Accordingly, the Panel finds that it has not been established that the time actually taken by the Commission to prepare and forward a draft measure – no draft measure was prepared and forwarded between July 2002 and October 2002 – was unjustifiably long.

Total amount of time taken since submission of application

7.1928 The United States also puts forward the argument that the total amount of time during which the application concerning the Transgenic potato was pending is excessive and unjustified and, hence, undue. The application concerning the Transgenic potato was first submitted for approval under Directive 90/220 in August 1996. This means that as of the end of August 2003, the approval procedure had been pending for more than seven years.

7.1929 The Panel agrees with the United States that, in absolute terms, this is a long period of time. However, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long. Indeed, certain delays might be attributable, not to the European Communities, but to the applicant. Other delays might be attributable to the European Communities, but they might be justifiable. In the case of applications which were submitted under Directive 90/220 – and the application concerning the Transgenic potato is one of these – it must also be remembered that in accordance with Article 35 of Directive 2001/18, applications submitted under Directive 90/220, but not approved by October 2002 became subject to Directive 2002/18 and had to be re-assessed by the lead CA. As a necessary consequence, applications which had progressed to an advanced stage in the approval process under Directive 90/220 and then were resubmitted to the lead CA under Directive 2001/18 were pending for long periods of time. Yet despite the fact that Article 35 of Directive 2001/18 resulted in certain approval procedures – including that concerning the Transgenic potato – being delayed, the United States did not question the provisions of Article 35. In these circumstances, it would be incongruous not to take account of the fact that some of the total time taken to assess a relevant application was a direct consequence of the operation of Article 35.

7.1930 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning the Transgenic potato was not completed in less than

three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning the Transgenic potato.[1458]

7.1931 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question had been pending for more than seven years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning the Transgenic potato had already been pending for more than two years and ten months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1459] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning the Transgenic potato was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.1932 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning the Transgenic potato had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

Conclusion

7.1933 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late July 2002 and October 2002 – was unjustifiably long, or that the total amount of time taken by the European Communities up to August 2003 was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning the Transgenic potato for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning the Transgenic potato, the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1458] It is worth recalling, more generally, that the approval procedures which were completed before there was a moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1459] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

(viii) Liberator oilseed rape (EC-68)

7.1934 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Liberator oilseed rape has been unduly delayed.

7.1935 The **United States** argues that after Liberator oilseed rape received a favourable opinion from the SCP the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that this resulted in a two-year delay, since no action was taken on the application until November 2002 when the applicant was requested to provide an update in light of the entry into force of Directive 2001/18. The United States submits that there is no indication of any problem with the application during the two-year gap, nor of any additional information needed for final approval. According to the United States, the two-year delay was therefore undue.

7.1936 The United States submits, in addition, that the application concerning Liberator oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Liberator oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1937 The **European Communities** argues that the SCP opinion on Liberator oilseed rape recommended "an agreed code of practice for field management of the particular modified crop involving the active participation of the applicant to promote best practice by farmers".[1460] The European Communities submits that contrary to what it had done in the parallel dossier on Falcon oilseed rape, the applicant did not present any proposal for a code of practice following the opinion of the SCP and that it did not manifest itself with the lead CA at all until the lead CA in November 2002 sent the applicant a letter reminding it of the need to up-date the application by January 2003. The European Communities submits that it cannot be held responsible for delays that are caused by the lack of diligence or the failings of an applicant.

7.1938 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1939 The Panel recalls that the SCP issued a favourable opinion on 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee until Directive 90/220 was repealed in October 2002. After the repeal of Directive 90/220, on 5 November 2002, the lead CA contacted the applicant to remind it of the need to update the application so that it could be further considered under Directive 2001/18. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1940 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than twenty-two months. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton,

[1460] Exhibit EC-68/At. 88.

the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1461] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion.[1462] It may be inferred from these examples that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.1941 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. The European Communities essentially asserts that its failure to do so is justified in view of the applicant's failure to present a code of practice for the field management of Liberator oilseed rape once the SCP had issued its opinion. However, in its earlier analysis of the approval procedure in question, the Panel found that it was not persuaded that the applicant was supposed to present a proposal for a code of practice, nor that the Commission failed to submit a draft measure to the Regulatory Committee because it was waiting for the applicant to propose a code of practice. The Panel further found that, in any event, the Commission in this case did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee, and that the fact that the applicant did not present a proposal was not an obstacle to the Commission launching such consultations.[1463] Accordingly, the Panel is unable to agree with the European Communities that the applicant's failure to present a code of practice justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002.

7.1942 Separately, it should be noted that the SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. There was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee. In the Panel's assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning Liberator oilseed rape could not be completed while Directive 90/220 was still in force.

7.1943 In its earlier findings on the application concerning Liberator oilseed rape, the Panel noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it the Commission considered it doubtful that there would be enough time in view of anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to legally bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have legitimately invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

[1461] Exhibit EC-65/Ats. 48 and 51.
[1462] Exhibit EC-76/Ats. 70 and 72.
[1463] *See supra*, para. 7.687.

7.1944 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long.

7.1945 In addition, we recall that the United States claims that the approval procedure concerning Liberator oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1946 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1947 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Liberator oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Liberator oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ix) Bt-11 maize (EC-69)

7.1948 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-11 maize (EC-69) has been unduly delayed.

7.1949 The **United States** argues that after the application concerning Bt-11 maize (EC-69) received a favourable opinion from the SCP in November 2000, the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that, under the EC approval system, the next step after the SCP favourable opinion should have been to submit the application for approval by the Regulatory Committee. According to the United States, however, there was no action on the application for two years after the SCP opinion and instead the next entry in the chronology provided by the European Communities is an "evaluation of updates by the lead CA" in October 2002, which is

unexplained and unsupported by any exhibit or attachment. According to the United States, the lengthy delay after the SCP opinion was issued provides compelling evidence of the existence of a general moratorium.

7.1950 The United States submits, in addition, that the application concerning Bt-11 maize (EC-69) maize is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-11 maize (EC-69) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1951 The **European Communities** argues that, after the SCP opinion, further discussions were held between the lead CA, the applicant and the Commission, and they went on until well into 2002. The European Communities notes in this respect that the SCP recommended a monitoring plan, and that the issue of the monitoring plan remained unsettled. The European Communities further points out that in May 2002 the applicant submitted additional information, including supplementary sequence information on the molecular characterization of the Bt-11 line, taking into account the provisions of the new Directive, *inter alia* on monitoring, traceability and labelling.

7.1952 The **United States** responds that the monitoring plan referred to in the SCP opinion is an "Insect Resistance Management" (IRM) plan, and that the SCP never recommended any changes to the applicant's proposed IRM plan. The United States also notes that the only other mention of monitoring was with respect to changes in field populations of non-target insects, but that the SCP did not request a monitoring plan on non-target insects, or note any deficiency in the application. Moreover, the United States argues that nothing in the record indicates that EC regulators ever approached the applicant either to identify a problem or to request additions to the application.

7.1953 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1954 The Panel recalls that in the approval procedure concerning Bt-11 maize (EC-69), the SCP issued a favourable opinion on 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1955 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than twenty-two months. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1464] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion.[1465] It may

[1464] Exhibit EC-65/Ats. 48 and 51.
[1465] Exhibits EC-76/At. 70-72.

be inferred from these examples that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.1956 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. The Panel understands the European Communities to assert that the Commission did not send a draft measure to the Regulatory Committee because, after the SCP opinion, the lead CA, the applicant and the Commission continued discussions on a monitoring plan well into 2002. The Panel also understands the European Communities to assert that the applicant submitted additional information in May 2002, just before the new Directive entered into force.

7.1957 Regarding the monitoring plan, we stated in earlier findings on this approval procedure that we are not persuaded by the European Communities' assertion that the Commission did not submit a draft measure to the Regulatory Committee because the SCP recommended a monitoring plan and the issue remained unsettled. We further found that, in any event, the Commission in this case did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee, and that the fact that the SCP stated that monitoring should be carried out was not an obstacle to the Commission launching inter-service consultations on a draft measure. Accordingly, we are unable to agree with the European Communities that the fact that the SCP recommended a monitoring plan justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002.

7.1958 Regarding the additional information submitted by the applicant in May 2002, we have already observed earlier that this information was apparently voluntarily submitted with a view to updating the application in anticipation of the entry into force of the new requirements contained in Directive 2001/18. There is no evidence that this additional information was submitted at the request of the Commission or the lead CA. In other words, there is no reason to believe that the Commission was waiting for this information. In our view, therefore, the May 2002 information does not justify the Commission's failure to submit a draft measure to the Regulatory Committee between November 2000 and May 2002.

7.1959 Separately, it should be noted that the SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[1466] In our assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning Bt-11 maize (EC-69) could not be completed while Directive 90/220 was still in force.

7.1960 In our earlier findings on the application concerning Bt-11 maize (EC-69), we noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In our view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it the Commission considered it doubtful that there would be enough time in view of

[1466] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. On the other hand, the Commission could have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. Yet, as pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

7.1961 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long.

7.1962 In addition, we recall that the United States claims that the approval procedure concerning Bt-11 maize (EC-69) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1963 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1964 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-11 maize (EC-69) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-11 maize (EC-69), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(x) RR oilseed rape (EC-70)

7.1965 Two Complaining Parties, the United States and Canada, claim that the completion of the approval procedure concerning RR oilseed rape (EC-70) has been unduly delayed.

7.1966 The **United States** argues that this application was delayed at the member State level for more than four years. The United States submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220. More specifically, the United States argues that the total time taken at the member State level for the initial review was 54 months (7 July 1998 to 22 January 2003), of which 12 months were taken by the applicant to respond to questions. The United States asserts that an additional 10 months of the total time taken were spent resolving confidentiality issues in relation to detection methods. Thus, according to the United States, the lead CA in this procedure took 32 months for its review instead of the 90 days referred to in Article 12 of Directive 90/220. The United States considers this delay in completing the approval procedure concerning RR oilseed rape (EC-70) to be undue.

7.1967 The United States notes, in addition, that Denmark, Italy, Belgium, Austria, France and Germany all objected to the lead CA's favourable initial assessment on the grounds that new EC rules concerning the traceability and labelling of biotech products needed to be in place before they could support the approval of any application. The United States submits that this shows an unwillingness to acknowledge the strength of the scientific conclusions reached by the lead CA and opposition to approval regardless of the merits of the application in question. The United States notes, in addition, that Austria and Denmark also objected because in their view issues concerning liability and coexistence remained to be resolved. The United States submits that a desire for rules addressing these issues cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in aspects unrelated to the environment, human or animal health and delay approvals indefinitely, rendering the "no undue delay" discipline meaningless.

7.1968 The United States also points out that the application concerning RR oilseed rape (EC-70) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR oilseed rape (EC-70) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1969 **Canada** notes that in February 2000, the Dutch State Institute for Quality Control of Agricultural Products (RIKILT-DLO), which is responsible for providing scientific opinions relating to feed safety, issued a favourable assessment of RR oilseed rape (EC-70). On 10 January 2001, the Dutch Committee on Genetic Modification (COGEM), which is responsible for providing scientific advice relating to human health and the environment, concluded its assessment with a favourable conclusion. In January 2003, the Netherlands CA published a favourable overall assessment report. Canada submits that the two-year delay by the Netherlands CA in completing its overall assessment report and forwarding it to the Commission is unjustified and excessive.

7.1970 Canada also argues that the total time taken by the Netherlands to review this file was 54 months (7 July 1998 to 22 January 2003). Out of these 54 months, the applicant took a total of 12 months to respond to questions. Another 10 months were used for discussions of the confidentiality status of certain information submitted by the applicant beyond the legal requirements of the approval

legislation then in force. Canada submits that even if the latter period of time were not taken into account in this calculation, the remaining 32 months are in stark contrast to the 90 days foreseen in Directive 90/220 for this procedural step. In Canada's view, it is reasonable to infer from this that in the light of the moratorium, the Dutch authorities were taking a decidedly go-slow approach.

7.1971 Regarding the delay caused by the issue of confidentiality, Canada notes that Annex C(1)(d) of the *SPS Agreement* states that WTO Members shall ensure "the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected […] in such a manner that legitimate commercial interests are protected". Under Article 25 of Directive 2001/18, an applicant is entitled to request that commercially sensitive information be protected, which the applicant in this case did in March 2001. Canada is therefore of the view that delays arising from an applicant seeking to ensure the fulfilment of obligations, both under the *SPS Agreement* and domestic law, relating to the protection of legitimate commercial interests should not be attributed to the applicant.

7.1972 In addition to the foregoing, Canada submits that the failure by the European Communities to approve this product under Directive 2001/18 compounds the already unjustified and excessive delay. Canada submits that repeated, unjustified "road-blocks" that have been imposed by member States resulting in excessive delays – unjustified objections to the lead CA's favourable initial assessment in March 2003, the failure of the Regulatory Committee to obtain a qualified majority at its meeting of 16 June 2004 – demonstrate that the European Communities has violated its obligations under Annex C(1) of the *SPS Agreement*.

7.1973 Regarding member State objections, Canada notes that Denmark, Italy, France, Austria and Belgium raised objections, not on the basis of safety concerns, but on the grounds that approval of the application in question should be suspended pending the adoption of new EC legislation on traceability and labelling. Canada further contends that Denmark (in relation to transport of RR oilseed rape (EC-70)) and Italy (in relation to herbicide use) raised objections outside the scope of the assessment foreseen by Directive 2001/18. Finally, Canada argues that objections were raised which were irrelevant in the light of the scope of the requested approval (*i.e.* for import and processing). Denmark requested that a monitoring plan should include observations on dispersal and gene transfer to oilseed rape and wild relatives.[1467] Likewise, Italy, the United Kingdom, Spain and Austria objected on the basis that a post-market monitoring plan needed to be proposed to assess seed spillage. Canada submits that the European Communities' scientific committee has confirmed repeatedly, and in particular for oilseed rape, that the mere fact of potential dispersal of seeds and gene transfer among domesticated or wild relatives is not *per se* negative for human health or the environment. Moreover, Canada points out that the scope of the approval was for import only, as opposed to planting – a fact that does not normally attract attention to seed spillage, because the imported grain is processed at the port of entry where spillage is controlled in compliance with statutory standards and to avoid economic loss.

7.1974 Canada also argues that the total time for member State review of the lead CA's initial assessment was eight months (22 January 2003 to 6 October 2003) instead of 105 days, the time-period envisaged in Article 15 of Directive 2001/18.

7.1975 Regarding the failure of the Regulatory Committee to obtain a qualified majority at its meeting of 16 June 2004, Canada notes that prior to the vote, EFSA rendered a favourable opinion and that in rendering its favourable opinion, EFSA considered all of the member States' objections in relation to safety issues. Canada considers, therefore, that whatever the rationalization for member

[1467] Exhibit EC-70/At. 26.

States to vote against or abstain from voting, such rationalizations were not justified by science-based health or safety considerations. In Canada's view, it follows that the failure of the Regulatory Committee to approve the application forced additional unwarranted delays.

7.1976 Finally, Canada contends that the length of time it has taken, so far, for this application to move through the approval system – seven years – is, by any reasonable standard, "undue" and therefore a violation of Annex C(1)(a), keeping in mind that it still has not been approved. However, the amount of time this application has languished in the approval procedure is not the sole reason for Canada's claim that the delay has been undue. First and foremost, the European Communities has had in place, since October 1998, an unjustified moratorium on approvals. Furthermore, the refusal to approve the application concerning RR oilseed rape (EC-70) is not based on a risk assessment, despite numerous favourable risk assessments conducted by the European Communities' own scientific committees.

7.1977 The **European Communities** argues that in this procedure there was a continuous exchange of correspondence between the lead CA and the applicant until December 2002, when the applicant updated its application in accordance with the requirements of Directive 2001/18. According to the European Communities, this period of time was entirely dedicated to resolving scientific and technical issues, such as molecular characterisation and feed safety. The lead CA requested additional information on molecular characterization and on certain feed safety aspects, and exchanges regarding these issues continued until the year 2000. After the adoption of Directive 2001/18 in March 2001, the lead CA asked the applicant to provide information on a detection method as required under the new legislation. The applicant requested confidentiality status for the information to be provided. The lead CA initially did not accept the reasons provided for requesting that status and several letters were exchanged on the issue. The lead CA also requested reference material which again triggered a debate on confidentiality. The European Communities notes that these issues were only settled in the autumn of 2002. By that time, Directive 2001/18 had entered into force and the lead CA and applicant worked on up-dating the application according to Directive 2001/18. As regards the issue of confidentiality, the European Communities submits that it was at the request of the applicant that the discussion on these issues was undertaken and that the European Communities cannot be responsible for any slippage in the timetable resulting from a request made by an applicant.

7.1978 The European Communities further points out that once the applicant had provided an update, the application moved immediately to the Community level. A few member States requested additional information and six member States raised objections. The objections related to issues of molecular characterisation (insufficient data), feeding studies, the monitoring plan, allergenicity, detection/identification methods as well as traceability and labelling. Meetings were held with the applicant to settle these issues and the applicant provided additional information. The European Communities contends that the objections raised by member States were based on legitimate and scientifically sound concerns, or regulatory requirements outside the scope of this dispute (traceability and labelling).

7.1979 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.1980 We note that in the approval procedure concerning RR oilseed rape (EC-70), the applicant submitted an application to the lead CA (the Netherlands) on 7 July 1998. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The dossier was forwarded to the Commission with a favourable assessment report on 16 January 2003, after the applicant had provided an updated application in accordance with Directive 2001/18.

7.1981 The United States and Canada assert that the lead CA took too long to complete its assessment. They note that the lead CA took much more time for its own assessment of the application than the 90 days envisaged in Article 12(2) of Directive 90/220.[1468] We consider that this is correct.[1469] However, whether or not the lead CA complied with the 90-day deadline stipulated in Directive 90/220 in our view is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Indeed, legislation of different WTO Members may stipulate deadlines for this type of assessment which are more or less strict. Nevertheless, we consider that the deadline set forth in Directive 90/220 provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under Directive 90/220. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.[1470]

7.1982 In the present case, however, the European Communities contends that all of the time taken by the lead CA until December 2002, when the applicant complemented its application in accordance with the requirements of Directive 2001/18, was necessary to resolve scientific and technical issues.[1471] Since we do not view the fact that the 90-day deadline was exceeded as dispositive, *per se*, we go on to examine whether the lead CA was justified in forwarding an assessment report to the Commission only in mid-January 2003.

7.1983 In its earlier findings on the approval procedure concerning RR oilseed rape (EC-70), the Panel noted its understanding that when evaluating applications for placing on the market, the Netherlands CA notably took into consideration the advice from the COGEM and the opinion of the RIKILT-DLO. In the approval procedure in question, the RIKILT-DLO submitted its favourable opinion in February 2000[1472], and the lead CA advised the applicant in March 2000 in an e-mail that no further technical information for the risk assessment needed to be supplied.[1473] The COGEM did not provide its favourable advice until 10 January 2001.[1474]

7.1984 Regarding the advice from the COGEM, it should be recalled that the COGEM met in September 1998 to discuss the application in question. This led to a request for additional information on molecular characterization, which was transmitted to the applicant also in September 1998.[1475] The applicant provided the requested information in December 1998.[1476] Yet the COGEM did not meet again to discuss the application and the additional information for another two years. The relevant meeting took place in December 2000, a month before the COGEM provided its final

[1468] We recall that the 90 days envisaged in Directive 90/220 do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant.

[1469] For instance, as is clear from Exhibit EC-70, the lead CA was assessing the application between 13 August 1998 and 25 September 1999; between 2 April 1999 and 17 August 1999; and between 18 November 1999 and 21 January 2000 when the RIKILT-DLO appears to have requested additional information (Exhibit EC-70/At. 17). These periods of time, which are but examples, already add up to more than seven months.

[1470] Our remarks concerning the 90-day deadline set out in Article 12(2) of Directive 90/220 are also applicable, *mutatis mutandis*, to the corresponding 90-day deadline set out in Article 14(2) of Directive 2001/18.

[1471] EC second written submission, para. 199.

[1472] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

[1473] Exhibit EC-70/At. 18; Exhibit CDA-132.

[1474] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

[1475] Exhibit EC-70/At. 7.

[1476] Exhibit EC-70/Ats. 9 and 10.

advice.[1477] The record does not support the inference that the COGEM provided its advice only in January 2001 because it needed to resolve scientific or technical issues. Nor is there any indication in the record that the COGEM had other reasons for delaying the provision of its advice. There is therefore no apparent reason why the COGEM could not have provided its advice before or by the time the lead CA informed the applicant by e-mail that no further technical information needed to be submitted, *i.e.*, before or by March 2000.

7.1985 In the light of the foregoing, the Panel considers that at the latest in March 2000 the lead CA could have had all the elements to complete its assessment report. The European Communities notes that the applicant submitted additional information in April and May 2000. It is correct that in the aforementioned e-mail of March 2000 from the lead CA to the applicant, the lead CA also noted that the legal name and registration of the applicant would need to be confirmed, and that the original application would need to be modified to take into account the additional information submitted in the course of the assessment process.[1478] In April 2000, the applicant confirmed its legal name and registration.[1479] And in mid-May 2000, the applicant sent a draft document to the lead CA to indicate how it intended to modify the original application and to ask for comments and suggestions.[1480] The lead CA replied that it would communicate its "findings" as soon as possible, probably within less than a fortnight.[1481] This estimate demonstrates that the document submitted in mid-May 2000 did not call for a lengthy analysis by the lead CA. Moreover, the Panel does not consider that the March 2000 e-mail from the lead CA constitutes a formal request for information which triggered a clock-stop.[1482]

7.1986 If, as the Panel believes, the lead CA could have obtained all necessary elements at least by March 2000, it may reasonably be assumed that the lead CA could have completed its assessment report at the latest 90 days later, *i.e.*, around the end of June 2000. It should be recalled that Article 12(2) of Directive 90/220 requires that "at the latest 90 days after receipt" of an application, the lead CA must, in the case of a favourable assessment, forward the application to the Commission with a favourable opinion. The Panel has already observed in respect of the corresponding 90-day deadline stipulated in Directive 2001/18 that that deadline provides a useful indicator for determining how much time might be needed to complete an member State level assessment. Assuming that 90 days would have been sufficient seems all the more reasonable as by March 2000 the lead CA had already assessed the application for more than the 90 days envisaged in Article 12(2) of Directive 90/220.[1483]

7.1987 Based on the foregoing considerations, the Panel considers that the lead CA could have forwarded its assessment report to the Commission well before the end of 2000 and thus much before

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[1477] Exhibit EC-70/At. 17, p. 2 (in Dutch), Letter of 10 January 2001 by the COGEM to the Netherlands CA, p. 2. *See also* Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5.

[1478] Exhibit EC-70/At. 18.

[1479] Exhibit EC-70/At. 19. In addition, the applicant sent some information which the European Communities acknowledges had already been transmitted to the lead CA. EC reply to Panel question No. 152.

[1480] Exhibit EC-70/At. 21. The Panel fails to see a basis for the European Communities' contention that the relevant draft document was "a new element in the authorization process because it change[d] the terms of the application". Nor does the Panel think that Exhibit EC-70/At. 23 supports the conclusion that the lead CA was still "analys[ing] the update" in November 2000. EC reply to Panel question No. 152.

[1481] Exhibit EC-70/At. 22.

[1482] Indeed, the chronology provided to the Panel by the European Communities does not describe the communication as such, which is in contrast to other entries in the chronology. Exhibit EC-70/At. 18.

[1483] As noted previously and by way of example, the lead CA was assessing the application between 13 August 1998 and 25 September 1999 as well as between 2 April 1999 and 17 August 1999. These periods of time add up to more than 90 days. Exhibit EC-70.

mid-January 2003. This means that, contrary to the European Communities' contention, not all of the time taken by the lead CA up to December 2002 was necessary to resolve scientific and technical issues. Moreover, the lead CA's failure to complete and forward an assessment report before the end of 2000 could not, in the Panel's view, be excused on the basis that there was insufficient time to complete the approval procedure concerning RR oilseed rape (EC-70) while Directive 90/220 was still in force. Directive 90/220 was not repealed until October 2002. There was thus enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of RR oilseed rape (EC-70).[1484]

7.1988 In its earlier findings, the Panel also stated that even assuming that the COGEM could not have provided its advice before January 2001, the Netherlands could still have completed and forwarded its assessment report sooner than it did. Specifically, the Panel noted that when the COGEM provided its advice in January 2001, the lead CA did not complete its assessment report but on 12 March 2001 – the date of adoption of Directive 2001/18 – requested a detection method based on the provisions of Directive 2001/18, even though that Directive did not enter into force until October 2002. The applicant provided a detection method four days later.[1485] However, the applicant requested confidential treatment of the detection method. This resulted in an eight-month exchange with the applicant. As we noted earlier, during that exchange, the lead CA caused delays by not requesting clarification promptly. Our examination focuses on the delays caused by the lead CA during the course of the exchange over confidentiality issues.

7.1989 We begin our examination by recalling relevant facts. In May 2001, the lead CA asked the applicant to reconsider its request for confidential treatment of the detection method it had submitted, or else to provide further substantiation. The lead CA also stated that in the absence of further substantiation by June 2001, it would take a decision with respect to the request.[1486] In September 2001, after providing further clarification at the request of the lead CA and "in order to keep the approval process moving forward", the applicant agreed to disclose the protocol for the detection of RR oilseed rape (EC-70). But the applicant requested that the primer sequences in the protocol remain confidential until the first patent application was published.[1487] In response, the lead CA again sought further substantiation. After receiving additional substantiation, the lead CA in January 2002 granted the request that the primer sequences should be treated as confidential.

7.1990 It is clear from these facts that there was a disagreement between the lead CA and the applicant regarding whether certain information was by nature confidential. Article 19 of

[1484] In its earlier findings on the application concerning RR oilseed rape (EC-70), the Panel noted that the Netherlands could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the Netherlands' failure to forward an assessment report to the Commission. The Netherlands might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

[1485] As Directive 2001/18 was not yet in force on the date of the lead CA's request, the applicant was arguably not obliged, as a matter of EC law, to comply with it. In our view, there can be no doubt in view of the wording of the lead CA's request for a detection method that the applicant was aware that the basis for the request was legislation not yet in force. But there is no indication in the record that the applicant contested the propriety of the request.

[1486] Exhibit EC-70/At. 26.

[1487] Exhibit EC-70/At. 30.

Directive 90/220 provides that in such cases it is for the lead CA to decide, after consultation with the applicant, whether the information should be treated as confidential.[1488] It appears to the Panel that the lead CA was following this procedure. However, it took a long time – eight months – to resolve the issue of the confidentiality status of the relevant information. While the applicant took a total of three and a half months to reply to the several requests for further substantiation, in June 2001 the lead CA waited for more than a month after receiving further substantiation before it followed up with a request for yet more substantiation.[1489] A similar situation arose in September 2001 when the lead CA waited for more than two months before following up with another request.[1490] The substantiation provided by the applicant in June and September 2001 was neither very extensive nor particularly complex.[1491] Moreover, in June and September 2001, there was no apparent reason for the lead CA to consider that there was insufficient time to approve the application before Directive 90/220 was repealed in October 2002. The Panel therefore does not see any justification for the lead CA's failure to follow up more promptly. In the Panel's view, the lead CA's delayed action in response to the June and September submissions of the applicant demonstrates that, contrary to the European Communities' contention, not all of the time taken by the lead CA up to December 2002 was necessary to resolve scientific and technical issues.

7.1991 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) – notably the time spent waiting for COGEM to provide its advice, and the time taken to follow up on substantiation provided by the applicant for its request for confidential treatment of certain information – was unjustifiably long.

7.1992 In relation to DS291, we recall that the United States claims that the approval procedure concerning RR oilseed rape (EC-70) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its assessment is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.1993 In view of our conclusion with regard to the time taken by the Netherlands for its assessment, we do not go on to examine other arguments put forward by the United States and Canada in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.1994 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) was unjustifiably long, and that it can reasonably be inferred from surrounding

[1488] Canada refers to the analogous provisions of Article 25 of Directive 2001/18. However, these provisions were not applicable at the time.

[1489] Exhibit EC-70/At. 28.

[1490] Exhibit EC-70/At. 33.

[1491] The June letter from the applicant is two pages long, that of September is only one page long.

circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR oilseed rape (EC-70) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR oilseed rape (EC-70), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) was unjustifiably long. Based on this finding, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay", the application concerning RR oilseed rape (EC-70), and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning RR oilseed rape (EC-70), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xi) LL soybeans (EC-71)

7.1995 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning LL soybeans (EC-71) has been unduly delayed.

7.1996 The **United States** submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220.

7.1997 The United States also points out that the application concerning LL soybeans (EC-71) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL soybeans (EC-71) is excessive and unjustified and, hence, undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1998 **Argentina** claims that the application was delayed at the member State level for 68 months without a final decision on its approval. Argentina asserts that the European Communities neither processed the application nor conducted the required risk assessment. Argentina argues that there is no scientific justification for the delay, as the "initial reports" were not prepared.

7.1999 The **European Communities** provides three explanations for the delay at the member State level: (1) requests by the lead CA for further information during the period from September 1998 to 2001; (2) procedural problems arising from the fact that the applicant submitted an application for the same product in Portugal; and (3) delays caused by the applicant's lack of response to requests for additional information on 25 February 2003.

7.2000 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2001 We note that in the approval procedure concerning LL soybeans (EC-71), the applicant submitted an application to the lead CA (Belgium) on 28 September 1998. In September 1999, the applicant submitted an application for this same product to Portugal. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The applicant updated the application on 15 January 2003. Also in January 2003, the applicant withdrew the parallel application to Portugal.

7.2002 We recall that in relation to Belgium's assessment of LL soybeans (EC-71) three separate time periods can be usefully distinguished: (1) the time period between the submission of the application to the Belgian CA and the concurrent submission in Portugal; (2) the time period between the submission of the concurrent application in Portugal and the repeal of Directive 90/220; and (3) the time period between the submission of the application under Directive 2001/18 and the applicant's withdrawal of the application.

7.2003 The Panel begins its analysis with the alleged delay at member State level during the period before the parallel application was submitted to Portugal. We recall that in a letter dated 31 March 1999, the Belgian Biosafety Council stated that it was "of the opinion that the file [concerning the application submitted under Directive 90/220] in its present form (with addition of molecular data and after minor corrections) can be passed on to the European Commission with a positive opinion".[1492] Based on the March 1999 advice by the Biosafety Council the Belgian CA on 28 May 1999 asked for more information, including information on molecular characterization, nutritional analysis (concerning the approval procedure for LL soybeans (EC-93)) and herbicide aspects.[1493] The applicant did not respond to the May 1999 request until July 2001.

7.2004 The European Communities provides no justification for the time taken by the lead CA to forward the request for additional information from the Belgian Biosafety Council. While the lead CA as the responsible agency could review the request in order to determine whether it was appropriate to transmit it to the applicant, we are not convinced, in the absence of any justification offered by the European Communities, that two months were needed to review this straightforward request for additional information. Indeed, at an earlier stage in the approval procedure, the lead CA forwarded a similar request from the Biosafety Council within a matter of several days.[1494] We therefore consider that the lead CA could and should have acted more promptly than it did when the Biosafety Council suggested a request for additional information in March 1999.

7.2005 As noted, the applicant did not respond to the lead CA's May 1999 additional request for information until July 2001, *i.e.*, more than two years later. Meanwhile, however, the applicant had submitted an application to Portugal. The time during which a parallel application was maintained concurrently in Portugal contributed to the delayed progress of the application in Belgium. We note in this regard that in a communication to Belgium dated 1 December 2000, the applicant explicitly indicated its intention of maintaining dual applications.[1495] In this letter the applicant also stated it would take all necessary measures to ensure that only one application would circulate at the Community level. On 5 December 2000, the Biosafety Advisory Council of the Belgian CA

[1492] Exhibit EC-71/At. 16.
[1493] Exhibit EC-71/Ats. 17 and 22.
[1494] Exhibit EC-71/Ats. 4 and 5.
[1495] Exhibit EC-71/At. 23.

confirmed the continuation of the evaluation process in Belgium and requested that the applicant forward the questions posed by the Portuguese CA in the approval procedure concerning LL soybeans (EC-81) in order to complete the application dossier in Belgium.[1496] On 5 September 2001, ten months after confirming the continuation of the evaluation process in Belgium, the Belgian CA indicated to the applicant that further evaluation of the application would be suspended until the applicant specified a single country to handle the application.[1497] The applicant responded on 8 October 2001 by asserting the maintenance of double concurrent applications.[1498] No further exchanges appear to have occurred between the applicant and the lead CA until January 2003, when the applicant updated the application submitted to Belgium under Directive 2001/18. While there is no evidence on the record to confirm this, it appears that in view of the applicant's response the lead CA did not further assess the application concerning LL soybeans (EC-71) between October 2001 and January 2003. Thus, the consideration of the application appears to have been suspended as from September 2001 as a result of the applicant's refusal to discontinue one of the two applications submitted under Directive 90/220.

7.2006 We note that the applicant was of the view that Directive 90/220 did not prevent it from filing identical applications to different lead CAs. It nevertheless acknowledged that this approach could give rise to procedural problems, and it therefore indicated that it would withdraw one of the two applications as soon as one of the applications was ready for transmission to the Commission. The Belgian CA appears to have considered that the approach followed by the applicant was either not permitted by Directive 90/220 or otherwise inappropriate.

7.2007 The United States and Argentina did not submit arguments or evidence which would indicate that Belgium's position rested on an incorrect interpretation of Directive 90/220. While Directive 90/220 does not explicitly require that applications be maintained with a single competent authority, it also does not explicitly state that applications may be maintained with more than one competent authority. We note that the issue of parallel applications arose also in the approval procedure concerning Bt-11 maize (EC-80). In that procedure, the lead CA in Spain did not appear to consider this a problem.[1499] On the other hand, it should also be noted that the applicant in the procedure concerning LL soybeans (EC-71) apparently did not contest Belgium's refusal to continue to consider its application.

7.2008 From the information before us, it is not apparent that Belgium's position on this issue, which appears to have led it to suspend consideration of the application concerning LL soybeans (EC-71) under Directive 90/220, was a mere pretext for delaying the consideration of the application. Indeed, Belgium indicated to the applicant that it would continue considering the relevant application if the applicant decided to discontinue the application submitted to Portugal. Furthermore, in applying the provisions of Annex C(1)(a), first clause, we think we must be mindful of Members' limited resources and the consequent need to avoid unnecessary duplication and administrative inefficiencies. Thus, a delay in the consideration of an application which was caused by a Member's refusal to conduct concurrent approval procedures in respect of an identical application does not appear to us to be unjustifiable *per se*. Taking account of these elements, we are not convinced that in the specific circumstances of this case, Belgium's refusal to continue its assessment of the application concerning LL soybeans (EC-71) while the applicant maintained its concurrent application to Portugal resulted in a loss of time which was unjustifiable.

[1496] Exhibit EC-71/At. 24.
[1497] Exhibit EC-71/At. 28.
[1498] Exhibit EC-71/At. 29.
[1499] Exhibit EC-80/At. 12.

7.2009 Regarding the consideration of this application under Directive 2001/18, we note that after the applicant updated its application under Directive 2001/18 (15 January 2003) and withdrew its application in Portugal (27 January 2003), the Belgian CA acknowledged receipt of the updated application and requested further information regarding molecular characterization, detection methods and reference materials. The applicant provided preliminary informal answers regarding information for labelling requirements and detection methods in March 2003. There is no record of further exchanges between the applicant and the lead CA until the applicant withdrew the application in July 2004.

7.2010 The European Communities claims that the delay which occurred after the applicant had provided preliminary informal answers was attributable to the applicant. The record shows that the applicant provided a partial response to the lead CA's request for additional information and indicated that further information would be forthcoming regarding reference samples of genomic DNA for this product. Given the applicant's stated intention of submitting further information to address questions from the lead CA and the lack of arguments addressing this issue from the United States and Argentina, it is reasonable to believe that the lead CA was waiting for the submission of further information. Accordingly, we have no reason to disagree with the European Communities' contention that the delay in question was attributable to the applicant rather than the lead CA.

7.2011 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) – specifically the time taken by the lead CA to forward the request for additional information suggested by the Biosafety Council in March 1999 – was unjustifiably long.

7.2012 In relation to DS291, we recall that the United States claims that the approval procedure concerning LL soybeans (EC-71) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. Our finding that the time taken by Belgium for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long is based on the view that the lead CA could and should have transmitted its May 1999 request for additional information earlier than it did. Thus, our finding above relates to a time period which pre-dates June 1999. In the light of this, we do not consider that we can infer that Belgium's conduct in March, April and May 1999 was a consequence of the general moratorium on approvals which we found was in effect between June 1999 and August 2003.

7.2013 In view of our conclusion above, in relation to DS291 we need to go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Total amount of time taken since submission of application

7.2014 The United States also puts forward the argument that the total amount of time during which the application concerning LL soybeans (EC-71) was pending is excessive and unjustified. The application concerning LL soybeans (EC-71) was first submitted for approval under Directive 90/220 in September 1998. This means that as of August 2003, the approval procedure had been pending for four years and eleven months.

7.2015 The Panel agrees with the United States that, in absolute terms, this is a long period of time for the assessment by the lead CA. However, as we have explained earlier, the mere identification of

the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2016 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL soybeans (EC-71) was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning LL soybeans (EC-71).[1500]

7.2017 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for almost five years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL soybeans (EC-71) had already been pending for almost nine months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that each particular application was affected by it at all stages of the procedure. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1501] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL soybeans (EC-71) was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2018 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning LL soybeans (EC-71) had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

Conclusions

7.2019 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (EC-71) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL soybeans (EC-71) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval

[1500] It is worth recalling, more generally, that the approval procedures which were completed before there was a moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1501] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

procedure concerning LL soybeans (EC-71), the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning LL soybeans (EC-71) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement.*

(xii) LL oilseed rape (EC-72)

7.2020 One Complaining Party, the United States, claims that the completion of the approval procedure concerning LL oilseed rape has been unduly delayed.

7.2021 The **United States** argues that the total time taken at the member State level for the initial review of this application was over four years, as this product still had not been forwarded to the Commission at the time of establishment of the Panel. The United States contrasts this with the 90 days referred to in Directives 90/220 and 2001/18. Although the United States initially indicated that the applicant had provided answers to all of the questions from the lead CA, in response to a question from the Panel the United States recognized that the applicant failed to provide some of the data requested.[1502] Nonetheless, the United States contends that the delays by the lead CA in completing the approval procedure concerning LL oilseed rape are undue.

7.2022 The United States also points out that the application concerning LL oilseed rape is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL oilseed rape is excessive and unjustified and, hence, undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2023 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Following receipt of the application, the lead CA requested further information from the applicant. The lead CA also requested a preliminary review by its scientific committee, the Advisory Committee on Releases to the Environment (hereafter "ACRE"). The ACRE found that the dossier contained inconsistent data on molecular characterization and was presented in a manner which made assessment difficult. In December 1999, the lead CA requested the applicant to provide a substantial revision and clarification.

7.2024 According to the European Communities, the applicant did not get back to the lead CA on this dossier for almost two years. In January 2003, the applicant provided some up-dated documents in accordance with Directive 2001/18, but the European Communities argues that the full dossier was not submitted. During the first half of 2003, there were various exchanges between the lead CA and the applicant, and the applicant provided additional updates and information. Following a request in

[1502] US answer to Panel question No. 168.

June 2003 for the re-submission of a complete dossier, in March 2004 the applicant withdrew the pending notification and submitted a new notification. The European Communities maintains that it cannot be responsible for delays arising at the instigation of the applicant.

7.2025 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2026 We note that in the approval procedure concerning LL oilseed rape the applicant submitted an application to the lead CA (the United Kingdom) on 28 January 1999. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. An updated application was submitted following the entry into force of Directive 2001/18, although the record is not clear as to when a complete dossier was actually submitted. At the time of establishment of the Panel, this application was still under consideration by the lead CA.

7.2027 The United States contends that the lead CA took too long to complete its assessment. It is correct that the lead CA took much more time for its assessment of the application than the 90 days envisaged in Directives 90/220 and 2001/18. However, we have observed that that deadline was not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Moreover, the European Communities contends that much of the time taken by the lead CA until August 2003 is attributable to failures by the applicant promptly to provide requested information. The European Communities submits that without this information, it was not possible for the lead CA to complete its assessment and submit a report to the Commission. We therefore need to examine whether the lead CA was justified in not completing its assessment by August 2003.

7.2028 As we noted in our previous consideration of this application, the record before us is not complete. Following receipt of the application, the lead CA promptly requested additional information from the applicant in February and March 1999. This information was provided in June 1999, and the lead CA acknowledged on 30 June 1999 that the clock had been "restarted". One month later, the lead CA requested further information, but this information was not provided by the applicant before the date of repeal of Directive 90/220. The letter from the lead CA dated 20 July 1999 requests that the applicant provide further information and clarification on points raised in an annex to the letter, but the annex was not provided to us.[1503]

7.2029 In November 1999, the lead CA apparently requested the ACRE to provide guidance to the lead CA as to where the application needed improvement and noted that the ACRE would be asked for formal advice only at a later stage. The preliminary advice by ACRE was that there were a number of inconsistencies in the molecular data provided, some deficiencies in the molecular studies and too much important material was in annexes rather than being in the core dossier. It was noted that the appropriate experimental data may have been supplied somewhere in the application dossier but it was not immediately obvious where it might be.[1504] As advised by ACRE, the lead CA in December 1999 requested that the applicant undertake substantial revision and clarification of the dossier. The lead CA suggested a meeting with the applicant later in the same month to provide the applicant with some guidance. There is no evidence in the information before the Panel that such a meeting took place, and that the applicant provided what was requested in December 1999. Indeed, the record shows no further communication from the applicant until January 2003, when the applicant updated its application under Directive 2001/18.

[1503] Exhibit EC-72/At. 11.
[1504] Exhibit EC-72/At. 12.

7.2030 On 16 January 2003, the applicant submitted an updated application under Directive 2001/18 to the lead CA.[1505] In acknowledging receipt of the updated application, the lead CA indicated, on 27 January 2003, that the dossier was still incomplete and information requested in July and December 1999 was still missing.[1506] Further requests for clarifications or modification of the application were made by the lead CA in the first half of 2003, with responses apparently provided by the applicant in May 2003.[1507] On 13 June 2003, the lead CA requested further clarifications and suggested that a complete version of the application be re-submitted.[1508] On 26 March 2004, the applicant withdrew the application, saying that certain elements of that application were incomplete or out-of-date, and submitted a new one (C/GB/04/M5/4).[1509]

7.2031 In reviewing the lead CA's conduct in this approval procedure, we note that the exchanges between the lead CA and the applicant generally took place in a timely fashion, with the lead CA reacting promptly to information provided by the applicant. It is clear from the foregoing, however, that the consideration of the application concerning LL oilseed rape was delayed for almost two years between 2 December 1999 and the repeal of Directive 90/220 in October 2002, following a letter from the lead CA advising the applicant that the dossier required substantial revision and clarification. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the additional information and clarification requested by the lead CA in July and December 1999. However, the precise reasons for the failure of the applicant to respond to the information solicited by the lead CA in July and December 1999 are unclear.

7.2032 We note that the United States has not specifically challenged the justifiability of any of the requests for additional data or clarifications made by the lead CA. We nonetheless asked the experts advising us whether the information requested by the lead CA up to and in December 1999 was necessary to ensure that conclusions of the safety assessment were valid.[1510] Dr. Nutti, the only expert who responded to this question, concurred that the deficiencies in the application as identified by the ACRE were such that the requested information was necessary for the safety assessment.[1511] Taking account of these elements, we have no grounds for considering that the lead CA's requests of July and December 1999 which led to the gap between December 1999 and January 2003 were not justified.

7.2033 Regarding the assessment of the application concerning LL oilseed rape under Directive 2001/18, we note that the United States has offered no specific arguments relating to the consideration of this application under Directive 2001/18. At any rate, the facts as summarized by us above do not suggest that the time taken by the lead CA up to August 2003 for assessing the application under Directive 2001/18 was unjustifiably long. We note in particular the repeated requests by the lead CA for completion of the updated application, and the fact that the applicant itself withdrew the application in March 2004 saying that certain elements of its application were incomplete.

7.2034 Based on the above considerations, the Panel is not persuaded that the time taken by the lead CA for its assessment of the application concerning LL oilseed rape was unjustifiably long.

[1505] Exhibit EC-72/At. 15.
[1506] Exhibit EC-72/At. 16.
[1507] Exhibit EC-72/Ats. 18 and 19.
[1508] Exhibit EC-72/At. 28.
[1509] Exhibit EC-72/At. 29.
[1510] Annex H, Panel Question 29.
[1511] Annex H, para. 600.

Total amount of time taken since submission of application

7.2035 The United States also puts forward the argument that the total amount of time during which the application concerning LL oilseed rape was pending is excessive and unjustified. The application concerning LL oilseed rape was first submitted for approval under Directive 90/220 in January 1999. This means that as of August 2003, the approval procedure had been pending for four years and seven months.

7.2036 The Panel agrees with the United States that, in absolute terms, this is a long period of time for the assessment by the lead CA. However, as we have explained earlier, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2037 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL oilseed rape was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning LL oilseed rape.[1512]

7.2038 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for over four and a half years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL oilseed rape had already been pending for almost six months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1513] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL oilseed rape was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2039 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning LL oilseed rape had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

[1512] It is worth recalling, more generally, that the approval procedures which were completed before there was a *de facto* moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1513] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

Conclusions

7.2040 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its assessment of the application concerning LL oilseed rape was unjustifiably long, or that the total period of time during which the application concerning LL oilseed rape had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning LL oilseed rape, the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xiii) BXN cotton (EC-73)

7.2041 One Complaining Party, the United States, claims that the completion of the approval procedure concerning BXN cotton has been unduly delayed.

7.2042 The **United States** argues that the total time taken at the member State level for the initial review of this application was over four years, as this product still had not been forwarded to the Commission at the time of establishment of the Panel. The United States contrasts this with the 90 days referred to in Directives 90/220 and 2001/18. The United States contends that although the applicant had provided answers to all of the questions from the lead CA, the lead CA still failed to complete its assessment. The United States contends that the delays by the lead CA in completing the approval procedure concerning BXN cotton are undue.

7.2043 The United States also points out that the application concerning BXN cotton is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning BXN cotton is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2044 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Following receipt of the application, the lead CA requested further information from the applicant to address deficiencies in the application. Spain's scientific committee, the National Biosafety Committee, found that a considerable amount of information was missing on issues such as compositional analysis, environmental impact, toxicity and nutritional analysis. In addition, a number of points required clarification, such as the scope of the application and the labelling proposal. The lead CA requested this information from the applicant in July 1999.

7.2045 The European Communities contends that the applicant did not respond to the lead CA's request for three years, until January 2003. At that time, the lead CA was informed of a change in the company submitting the application, and the new applicant company submitted an up-dated notification in accordance with Directive 2001/18. However, according to the European Communities, the new dossier was also incomplete with regard to the molecular characterization of the product. The European Communities points out that further information was requested of the applicant in October 2003.

7.2046 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2047 We note that in the approval procedure concerning BXN cotton, the applicant submitted an application to the lead CA (Spain) on 3 May 1999. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. On 16 January 2003, an updated application was submitted following the entry into force of Directive 2001/18. At the time of establishment of the Panel, this application was still under consideration by the lead CA.

7.2048 The United States contends that the lead CA took too long to complete its assessment. It is correct that the lead CA took much more time for its assessment of the application than the 90 days envisaged in Directives 90/220 and 2001/18. However, we have observed that that deadline was not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Moreover, the European Communities contends that much of the time taken by the lead CA until August 2003 is attributable to failures by the applicant to promptly provide requested information. The European Communities submits that without this information, it was not possible for the lead CA to complete its assessment and submit a report to the Commission. We therefore need to examine whether the lead CA was justified in not completing its assessment by August 2003.

7.2049 As we noted in our previous consideration of this application, the record before us is very incomplete. This said, it is clear that within two months of receipt of the application, the Spanish National Biosecurity Committee identified a number of concerns with the application, and these were communicated to the applicant in July 1999. Two months later, the applicant provided the information requested. The applicant clarified, *inter alia*, that the application was both for the import and processing of seeds of BXN cotton as well as for the cultivation of BXN cotton. Following the further examination of the application in January 2000 by the Spanish National Biosafety Committee, the lead CA requested further clarifications on some of the same issues in a communication dated 2 February 2000.[1514] The applicant did not respond to this request before an updated application was submitted in January 2003 under Directive 2001/18.[1515]

7.2050 On 15 January 2003, the lead CA was informed of a change in the company pursuing the application, and on 16 January 2003 an updated application was submitted under Directive 2001/18 and completed in March 2003. It appears that the updated application concerns only the importation of seed for processing, but not for cultivation. In August 2003, when this Panel was established, the application appears to have been under review by the National Biosafety Committee.[1516]

[1514] Exhibit EC-73/At. 6.
[1515] This is confirmed by Exhibit EC-73/At. 12.
[1516] There is no information about when the application was submitted to the National Biosafety Committee.

7.2051 It is clear from the foregoing that in this procedure a delay of more than two and a half years occurred between February 2000, when the lead CA requested clarifications, and October 2002, when Directive 90/220 was repealed. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the requested clarifications. However, the precise reasons for the failure of the applicant to respond to the lead CA's February 2000 request are unclear.

7.2052 The United States has not specifically challenged the justifiability of any of the requests for additional data or clarifications made by the lead CA. In the light of the three-year delay in response from the applicant following the request in February 2000 for additional information, we asked the experts advising us whether the information requested by the lead CA up to and in February 2000 was necessary to ensure that conclusions of the safety assessment were valid.[1517] The experts noted that only the table of contents of the actual submission by the applicant had been provided, and the response from the applicant. On the basis of this limited information, Dr. Nutti was of the view that the responses provided by the applicant in September 1999 appeared to be satisfactory as far as food safety was concerned. These responses provided clarification or explanations of information that presumably was contained in the original application.[1518] Dr. Andow noted that the information previously requested by the lead CA was normally necessary to assess environmental risks, particularly those related to the cultivation of the plant. However, without the application itself, he could not determine to what extent relevant information may have already been provided by the applicant, or how much additional information might be necessary. Dr. Andow further observed that, according to the table of contents, only two pages of the text of the application were devoted to issues relating to environmental impact studies, herbicide or residue toxicity or ecotoxicity tests or proposals to manage, monitor and handle the crop to reduce the risk of herbicide resistance in weeds.[1519]

7.2053 Like the experts advising us, we consider that the incomplete information before us does not permit us to form a definitive view on whether the clarifications requested by the lead CA in February 2000 were justified to ensure that conclusions of the safety assessment were valid and hence on whether the resulting three-year delay in the consideration of the application was justified by the need to check and ensure that relevant requirements of Directive 90/220 were fulfilled.

7.2054 Turning to Spain's assessment of the application concerning BXN cotton under Directive 2001/18, we note that the updated notification was submitted to Spain on 16 January 2003. It was not until 14 February 2003, *i.e.*, almost one month later, that the lead CA requested the applicant to submit a summary of the application as required by Directive 2001/18. The applicant provided such a summary on 19 March 2003, and thus the updated application appears to have been complete as of that date. The application was apparently forwarded to the National Biosafety Committee for an assessment, but as of August 2003 that assessment had not yet been completed. The record shows that the assessment was completed in September 2003.[1520]

7.2055 The European Communities offers no justification for the time taken by the lead CA to follow up with the applicant to request a summary of the application. We are not persuaded that almost a full month was required to determine the completeness of the updated application and forward an appropriate request to the applicant.

[1517] Annex H, Panel Questions 30 and 31.
[1518] Annex H, para. 601.
[1519] Annex H, paras. 604-612.
[1520] Exhibit EC-73/At. 12.

7.2056 Furthermore, with regard to the time taken by the lead CA to assess the application once it had been completed by the applicant in March 2003, we recall that in accordance with Article 14(2) of Directive 2001/18, the lead CA should have prepared an assessment report within 90 days. The 90 days do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant. In the present case, the record shows that the lead CA requested additional information only in October 2003.[1521] Thus, the lead CA should have completed its assessment at the latest 90 days after 19 March 2003, which is the date on which the applicant completed its updated application. However, as of August 2003, the lead CA had still not completed its assessment. Thus, as of 29 August 2003, the lead CA had already taken more than five months to assess the application, and first request for additional information was forwarded more than a month later.

7.2057 As we have said, the question of whether or not the lead CA complied with the 90-day deadline stipulated in Directive 2001/18 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. However, as we have also noted earlier, the deadline set forth in Directive 2001/18 nonetheless provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under that Directive. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2058 The European Communities provides no justification for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the updated application was incomplete with regard to the molecular characterization of the product. It is correct that the lead CA in October 2003 requested additional information, including on molecular characterization of the product. However, we are not convinced that more than five months were needed to identify this and other substantive shortcomings in the updated application.

7.2059 From the record of the consideration of this application by the National Biosafety Committee, it is clear that the Committee had also been reviewing the applications concerning Bt-531 cotton and RR-1445 cotton, for which Spain was also the lead CA. However, we recall that pursuant to Directive 2001/18, the lead CA was to prepare an assessment report within 90 days after receipt of an application. It should also be noted in this connection that the National Biosafety Committee's assessment concerning BXN cotton is quite short, *i.e.*, there is no indication that the preparation of the Committee's assessment required much time. Additionally, we note that the lead CA in this case was not examining the application concerning BXN cotton for the first time. While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, it seems equally clear that the prior assessments rendered the lead CA's task less complex than it would have been if the lead CA had had to undertake an assessment of the application for the first time.

7.2060 Taking account of the foregoing elements, we consider that the lead CA could and should have acted more promptly than it did when it received an updated, but incomplete, application in January 2003 and subsequently, when the applicant submitted the missing summary in March 2003. Accordingly, we conclude that the time taken by the lead CA up to August 2003 for its assessment of the application concerning BXN cotton under Directive 2001/18 was unjustifiably long.

7.2061 In addition, we recall that the United States claims that the approval procedure concerning BXN cotton was unduly delayed because, due to the moratorium, the European Communities failed to

[1521] Exhibit EC-73/At. 13.

consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by Spain to assess the application concerning BXN cotton under Directive 90/220 and subsequently under Directive 2001/18 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct after the entry into force of Directive 2001/18 was a consequence of the general moratorium on approvals.

7.2062 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2063 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning BXN cotton under Directive 2001/18 was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning BXN cotton for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning BXN cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xiv) Bt-1507 maize (EC-74)

7.2064 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (EC-74) has been unduly delayed.

7.2065 The **United States** argues that the application concerning Bt-1507 maize (EC-74) was delayed at the member State level. The United States submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed its consideration of the product. The United States explicitly contests the justifiability of one of the information requests by the lead CA, as well as of a number of the objections raised by other member States following the circulation of the application by the Commission.

7.2066 The United States also points out that the application concerning Bt-1507 maize (EC-74) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (EC-74) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2067 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Exchanges between the lead CA and the applicant regarding data relating to molecular characterization, allergenicity, toxicity of CRY1F and labelling went on until late 2002. In two instances, the applicant requested an extension of the time granted by the lead CA to submit further data or information. The applicant updated the notification just after the entry into force of Directive 2001/18. After a further exchange on compositional data, a monitoring plan, and confidentiality of the detection method, the lead CA submitted the full application and its assessment report to the Commission in August 2003. The European Communities observes that once the application reached the Community level, a considerable number of objections were raised by member States, including on environmental effects, the monitoring plan, molecular characterisation, sampling and detection methods, allergenicity and toxicity.

7.2068 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2069 We recall that in the approval procedure concerning Bt-1507 maize (EC-74), the applicant submitted an application to the lead CA (the Netherlands) on 23 November 2000. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The dossier was forwarded to the Commission with a favourable assessment report on 15 August 2003, after the applicant had provided an updated application in accordance with Directive 2001/18.

7.2070 The United States contends that the lead CA took too long to complete its assessment. On the other hand, the European Communities contends that all of the time taken by the lead CA until August 2003 when the lead CA forwarded its assessment report to the Commission was necessary to resolve scientific and technical issues. It therefore needs to be examined whether the lead CA was justified in forwarding an assessment report to the Commission only in August 2003.

7.2071 As we noted previously, there was frequent communication between the lead CA and the applicant on this product from the initial application on 23 November 2000 until the lead CA sent its assessment report to the Commission on 15 August 2003. The United States explicitly challenges the justifiability of only one of the requests for additional data made by the lead CA, namely, the lead CA's follow-up request of 13 December 2001. We recall that in response to a March 2001 request from the lead CA the applicant on 16 October 2001 provided field trials from Chile, France and Italy, which it considered representative for the cultivation areas exporting maize to the European Communities.[1522] Yet on 13 December 2001 the lead CA indicated that it was not convinced by the response and maintained its request. Specifically, the lead CA indicated that it was not convinced that these locations would be representative of locations exporting maize to the European Communities. It therefore requested that the applicant conduct additional field trials and provide compositional data for two consecutive growing seasons.[1523]

7.2072 The applicant addressed this further request for additional field trials in its responses of 21 November 2002. It provided arguments as to why the results of the field trials for 1998/1999 from Chile, France and Italy should be considered to be sufficient, and also submitted the results of field trials for 1999/2000 from Bulgaria, France and Italy.[1524] On 10 February 2003, the lead CA indicated that it accepted this response, but requested that the data provided from the field trials in Chile be

[1522] Exhibit EC-74/At. 33.
[1523] Exhibit EC-74/At. 52.
[1524] Exhibit EC-74/At. 65, response to Panel Question 3.

presented in the same detail and manner as for France and Italy, and suggested a format.[1525] This was apparently done by the applicant on 24 March 2003.[1526]

7.2073 The United States argues that when the lead CA on 13 December 2001 rejected the applicant's compositional data from field trials that had been conducted in France, Italy and Chile, on the grounds that these locations were insufficiently representative of locations exporting maize to the European Communities, the lead CA provided no explanation for its conclusion that the locations were "insufficiently representative." The United States argues that the data provided by the applicant in October 2001 would generally be considered "representative" and relevant for evaluating maize that might be imported into the European Communities. The United States maintains that, in the absence of some further explanation, such as an anomaly in the submitted data, the only explanation for the lead CA's request for additional field trials of 13 December 2001 appeared to be the resulting two-year delay caused by the time it would take for the applicant to generate the data.

7.2074 Even assuming that the additional field trials were not necessary, we note that the applicant's response of 21 November 2002 was provided together with responses to a request of March 2002 for other additional information which has not been questioned by the United States. It is therefore not clear that the delay in the consideration of the application until 21 November 2002 is attributable to the request for additional field trials.

7.2075 At any rate, we note that on 21 November 2002 the applicant also updated its application in the light of the new requirements of Directive 2001/18. This resulted in the lead CA requesting further information from the applicant on 10 February 2003 with respect to a surveillance plan and the confidentiality of the proposed detection method. Furthermore, as noted, in February 2003 the lead CA dropped its request for the additional field trials, but requested that the data be presented in a uniform manner. The responses to these requests were provided by the applicant on 24 March 2003, and on 28 May 2003 the applicant withdrew the request for confidentiality with respect to the detection method.

7.2076 In the light of the foregoing, we consider that by the end of March 2003 the lead CA had all the elements to complete its safety assessment. The outstanding clarification of the confidentiality issue should not have delayed the completion of the safety assessment itself. In any event, as we have noted, the confidentiality issue was resolved in May 2003. Notwithstanding this, the lead CA did not send its completed assessment report to the Commission until 15 August 2003.

7.2077 We recall that in accordance with the requirements of Directive 2001/18 the lead CA was to have transmitted its completed assessment report at the latest 90 days after receipt of the updated application. As we have already pointed out, following the receipt of the application in November 2002, the lead CA reviewed the application for more than two and a half months before forwarding its request for additional information. After receiving the applicant's response in March 2003, the lead CA took an additional period of time of more than four and a half months to complete its assessment report and transmit it to the Commission. Thus, by the time the lead CA sent its assessment report to the Commission it had taken more than seven months to evaluate the updated application instead of the 90 days envisaged in Directive 2001/18.

7.2078 We have observed earlier in respect of the 90-day deadline stipulated in Directive 2001/18 that that deadline provides a useful indicator for determining how much time might be needed to complete an assessment. As we have said, in the case of the application concerning Bt-1507 maize

[1525] Exhibit EC-74/At. 84.
[1526] Exhibit EC-74/Ats. 87-88.

(EC-74), by the end of March 2003 the lead CA had all the elements to complete its safety assessment. If the lead CA at that point in time had taken a full 90-day period to complete its assessment, it would have completed its assessment before the end of June 2003.

7.2079 The European Communities has offered no justification for the time taken by the lead CA between March and August 2003. It is pertinent to note in this respect that the lead CA in 2003 was not examining the application concerning Bt-1507 maize (EC-74) for the first time. While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, the lead CA had already spent two and a half months assessing the application in question. Moreover, it seems clear that the lead CA's prior assessment of the same application under Directive 90/220 rendered the lead CA's task considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Yet notwithstanding this, even when the lead CA had all the necessary information, it failed to complete and transmit its assessment report within 90 days.

7.2080 Thus, even if we were to accept that it was legitimate for the lead CA to insist on the confidentiality issue being resolved before it transmitted its assessment report to the Commission, in the light of the generally applicable 90-day period stipulated in Directive 2001/18, and in the absence of any justification offered by the European Communities, we are not convinced that the lead CA could not have completed and transmitted its assessment report considerably earlier than mid-August 2003. Hence, taking account of the aforementioned elements, we consider that the lead CA should have transmitted its assessment report to the Commission more promptly than it did.

7.2081 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-74) – notably the time taken by the lead CA after May 2003, when the applicant withdrew the request for confidentiality with respect to the detection method – was unjustifiably long.

7.2082 In relation to DS291, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (EC-74) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of the Netherlands to complete its assessment of the application concerning Bt-1507 maize (EC-74) earlier than in August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2083 In view of our conclusion with regard to the time taken by the Netherlands for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2084 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-74) was

> unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (EC-74) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (EC-74), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xv) Bt-1507 maize (EC-75)

7.2085 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (EC-75) has been unduly delayed. To recall, this application concerns the same product as above, however it was submitted to Spain and concerns the cultivation of the product. The previous application was for processing, food and feed use, but not for cultivation.

7.2086 The **United States** argues that the application concerning Bt-1507 maize (EC-75) was delayed at the member State level.. The United States submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed consideration of the product. The United States also contests the justifiability of some of the information requested by the lead CA, and particularly of a number of the objections raised by other member States following its circulation by the Commission.

7.2087 The United States also points out that the application concerning Bt-1507 maize (EC-75) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (EC-75) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2088 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. The European Communities argues that following a preliminary assessment of this application by the Spanish National Biosafety Committee, the lead CA requested further data relating to molecular characterization, allergenicity and toxicity of CRY1F, environmental impact and a monitoring plan. These requests were dealt with by the applicant during the following 12 months, until 17 July 2002.[1527] After the entry into force of Directive 2001/18, the applicant updated the application in line with the requirements of the new legislation. Exchanges between the applicant and the lead CA continued until the 28 May 2003. The lead CA submitted the full application and its assessment report to the Commission on 5 August 2003.

7.2089 The European Communities further observes that once the application reached the Community level, a considerable number of objections were raised by member States, including on the monitoring plan, molecular characterization, effects on non-target organisms, toxicity, allergenicity, and detection methods.

[1527] Exhibit EC-75/Ats. 1-3.

7.2090 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2091 We recall that following the receipt of the application concerning Bt-1507 maize (EC-75), the lead CA (Spain) consulted with its National Biosafety Committee, which took more than two and a half months to review the application. The lead CA then waited over a month, until 30 October 2001, before requesting additional information from the applicant based on the advice received from the Committee. This request was apparently repeated in a communication of 28 November 2001. A response was provided by the applicant on 14 February 2002. Once again, the lead CA consulted with the National Biosafety Committee. The Committee took three months to review the additional information submitted in February 2002. As it had done previously, the lead CA waited over a month, until 17 June 2002, before submitting another request for additional information to the applicant. The applicant responded to these requests on 17 December 2002. This was after the date of repeal of Directive 90/220.

7.2092 Even assuming that the October/November 2001 and June 2002 requests were necessary to ensure that the conclusions of the safety assessment were valid, we recall that in accordance with the requirements of Directive 90/220 the lead CA was to have completed its assessment at the latest 90 days after receipt of the application concerning Bt-1507 maize (EC-75). As we have already pointed out, following the receipt of the application in July 2001, the lead CA exceeded the 90-day period even before it submitted its initial request for additional information to the applicant. Of particular concern in this connection is the circumstance that the lead CA waited for more than one month before forwarding the questions suggested by the National Biosafety Committee in September 2001.

7.2093 The European Communities has offered no justification for the time taken by the lead CA to transmit the October/November 2001 request for additional information. We note that the time taken by the lead CA in this instance contrasts with other approval procedures where Spain was also the lead CA and where the Spanish CA forwarded requests for information from the National Biosafety Committee more promptly.[1528] Furthermore, we note that the lead CA did not modify the questions suggested by the National Biosafety Committee, but simply forwarded them.

7.2094 We recognize that the application in this case was submitted and acknowledged just fifteen months before the date of repeal of Directive 90/220. However, we do not consider that in September 2001, when the lead CA received the suggested questions from the National Biosafety Committee, the lead CA could have legitimately concluded that it was impossible to complete the required steps and have the application approved or rejected while Directive 90/220 was still in force.

7.2095 Taking account of the aforementioned elements, we consider that the lead CA could, and should, have forwarded the questions suggested by the National Biosafety Committee in September 2001 more promptly than it did.

7.2096 We recall that in May 2002 the lead CA received a further suggested request for additional information from the National Biosafety Committee. The lead CA again waited for over a month before forwarding the request in June 2002, even though it did not modify the Committee's request.

7.2097 We recognize that May 2002 was relatively close to the date of repeal of Directive 90/220. However, even if we were to accept, *arguendo*, that the application could not go through the required steps before the repeal of Directive 90/220, in our view, this would not have justified the lead CA in

[1528] *See, e.g.*, the approval procedure concerning BXN cotton. Exhibit EC-73/Ats. 2-3 and 5 and 6.

delaying the transmission of the new request for information. We note in this regard that Directive 2001/18 entered into force in October 2002. If the application submitted under Directive 90/220 remained incomplete or required further clarification, knowledge of this would have assisted the applicant in correcting any deficiencies and submitting an updated, more complete application soon after the entry into force of Directive 2001/18.[1529]

7.2098 Therefore, as with the previously discussed delayed transmission of a request for additional information, we consider that the lead CA could, and should, have forwarded the Committee's request more promptly than it did.

7.2099 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-75) – notably the time taken by the lead CA to forward questions from the National Biosafety Committee – was unjustifiably long.

7.2100 In relation to DS291, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (EC-75) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of the application concerning Bt-1507 maize (EC-75) earlier than in August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2101 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2102 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-75) was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (EC-75) for final approval, and that this resulted in "undue delay" in the completion of the

[1529] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the time taken by Spain to forward the questions suggested by the National Biosafety Committee. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (EC-75), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xvi) NK603 maize (EC-76)

7.2103 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning NK603 maize has been unduly delayed.

7.2104 The **United States** argues that the application was delayed at the first stage of the approval process under 90/220 because the lead CA declined to forward the application to the Commission. Although the applicant provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed this product under Directive 90/220. The application remained at member State level for a period of 25 months. This product was resubmitted under Directive 2001/18, and received favourable initial assessments from the Spanish CA.

7.2105 The United States also points out that the application concerning NK603 maize is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning NK603 maize is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2106 **Argentina** notes that a risk assessment of NK603 maize was initiated under Directive 90/220 and re-initiated under Directive 2001/18. This was concluded with a favourable opinion from the scientific panel. Argentina notes that, as of April 2004, the approval procedure concerning NK603 maize, which was initiated on 4 August 2000, had lasted 3 years and 8 months and no final decision had been reached on the application for approval.

7.2107 The **European Communities** claims that the only delays in the application for NK603 maize arose due to questions on additional information; otherwise the application process has proceeded smoothly. In addition, the European Communities asserts that the application submitted in August 2000 was incomplete and therefore not considered as received until January 2001. The European Communities further claims that 44 days after the application was submitted, the clock was stopped because the scientific committee of the lead CA requested additional information on issues such as molecular characterization, nutritional composition, and environmental impact.[1530]

7.2108 The **United States** notes that using the January 2001 date of receipt suggested by the European Communities, and taking account of the "clock stop" when requested information was awaited from the applicant, out of the total 25 months for which the application was at the CA level, the European Communities had delayed action on the application for NK603 maize under Directive 90/220 for 12 months.

7.2109 The **European Communities** responds that, given that the applicant had taken 13 months to gather additional information, it was not unreasonable that the lead CA required 12 months to digest and process that information.

[1530] Exhibit EC-76/At. 1.

7.2110 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at the member State level

7.2111 We recall that the applicant sent the first application to the Spanish CA on 4 August 2000. Four months later, on 20 December 2000, the applicant resubmitted the application in Spanish and apparently with additional studies added to the application.[1531] We note that there is no record of these additional studies. The Spanish CA acknowledged receipt of the information in a letter of 2 January 2001.

7.2112 The record shows that the lead CA requested additional information in February 2001, October 2001 and May 2002.[1532] The progress of the application was adversely affected notably by the February and October 2001 requests, in that the applicant took more than six months to respond to the February 2001 request and more than five months to respond to the October 2001 request.

7.2113 We recall that we asked the experts advising us whether the information requested by the lead CA in February 2001 was necessary to ensure that conclusions of the product's safety assessment were valid. Dr. Nutti concluded that the further studies requested were not necessary for the assessment of the safety of NK603 as a food. Furthermore, given that the application was for import and use in the European Communities and not for cultivation, Dr. Andow concluded that requests for additional detailed environmental studies were not justified, although some information relating to potential adverse effects of spillage could be considered reasonable. The European Communities submits that the expert replies with respect to the food safety studies were based on the mistaken premise that certain studies had already been provided, which the European Communities argues was not the case. We note that on the basis of the information provided to us, we cannot determine whether or not such information had been previously provided.

7.2114 Turning to the October 2001 request for additional information, we note that this request concerned additional information which the Spanish CA emphasized was "essential for product traceability". Further details were also requested on the potential environmental impact of accidental dissemination or germination. When the applicant provided the additional information requested more than five months later, in March 2002, the applicant stressed that the conclusion provided in relation to safety was not altered by the new studies that had been requested. In response to a question from the Panel regarding this second request for information, Dr. Andow noted that information on the potential environmental impact of accidental release could be useful to the lead CA, but also observed that the lead CA could have been more specific regarding its particular concerns.[1533]

7.2115 Even if we were to accept that all of the information requested by the lead CA in February and October 2001 and in May 2002 was necessary to ensure the validity of the safety assessment, it is apparent from the record that the lead CA in this approval procedure exceeded the maximum period of 90 days envisaged in Directive 90/220 for a lead CA assessment. Between January 2001 and August 2002, when the applicant of its own motion updated its application in accordance with the requirements of Directive 2001/18[1534], the lead CA spent six and a half months evaluating the application without finishing its assessment report. This is more than twice the length of time established in Directive 90/220.

[1531] Exhibit EC-76/At. 3.
[1532] Exhibit EC-76/Ats. 6, 10 and 14, respectively.
[1533] Annex H, Dr. Andow's response to Panel Question 38.
[1534] Exhibit EC-76/Ats. 15 and 18.

7.2116 Specifically, the lead CA initially took one and a half months to assess the application before it forwarded the February 2001 request for additional information.[1535] Subsequently, the lead CA reviewed the application for over one month before it transmitted its October 2001 request for additional information.[1536] Then, the lead CA spent just under two months prior to sending its last request for additional information in May 2002.[1537] The applicant responded to this last request in June 2002. However, the lead CA did not complete its assessment in the following two months, *i.e.*, prior to the end of August of 2002, when the applicant updated its application based on the new requirements of Directive 2001/18. This is despite the fact that at its meeting of 11 July 2002, the Spanish scientific body assessing the application, the National Biosafety Committee, recommended for adoption a favourable report on the application.[1538]

7.2117 As we have said before, we recognize that the question of whether or not the lead CA complied with the 90-day deadline stipulated in Directive 90/220 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. However, we have also said that the deadline set forth in Directive 90/220 provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under that Directive. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2118 The European Communities provides no justification for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the time taken by the lead CA was not unreasonable in view of the need to digest and process the information provided by the applicant. While we agree that the lead CA needs to be able to "digest and process" information provided at its request, it is clear from Directive 90/220 that the EC legislator considered that 90 days was a reasonable period of time within which to do so. Also, the European Communities does not argue that in the case at hand the replies and documents provided by the applicant at the lead CA's request were particularly voluminous or complex, such that more than double the amount of time was required than the maximum amount of time Directive 90/220 allows lead CAs for the assessment of applications. From a review of the relevant documents, it is not apparent to us that they are any more voluminous or complex than others on the record which concern different applications.

7.2119 We have previously pointed out that Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Spanish CA's conduct reflects a precautionary approach. Notably, we are not convinced that the Spanish CA could not have identified its needs for additional information and forwarded appropriate requests for information to the applicant sooner than it did, even while following a precautionary approach.

7.2120 Moreover, we do not think that there was insufficient time to complete the approval procedure while Directive 90/220 was still in force. We note that as of July 2002, the lead CA had all necessary information, including positive scientific advice from the National Biosafety Committee, to complete its assessment. We recognize that as of July 2002 there was not much time left to complete the approval procedure under Directive 90/220. However, if Spain had proceeded more rapidly at earlier stages in the procedure, there would certainly have been enough time for the other member States to

[1535] Exhibit EC-76/Ats. 4 and 5.
[1536] Exhibit EC-76/Ats. 7 and 10.
[1537] Exhibit EC-76/Ats. 11 and 14.
[1538] Exhibit EC-76/At. 17.

review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of NK603 maize.[1539] As indicated above, we consider that Spain could have identified its needs for additional information and forwarded appropriate requests for information sooner than it did, particularly prior to forwarding its request for information of May 2002.

7.2121 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning NK603 maize – notably the time taken by the lead CA up to August 2002, when the applicant updated its application in accordance with the requirements of Directive 2001/18 – was unjustifiably long.

7.2122 In relation to DS291, we recall that the United States claims that the approval procedure concerning NK603 maize was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of NK603 maize earlier than in January 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2123 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2124 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning NK603 maize was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning NK603 maize for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning NK603 maize, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1539] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified Spain's failure to forward an assessment report to the Commission prior to the date of repeal of Directive 90/220. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning NK603 maize was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning NK603 maize without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xvii) GA21 maize (EC-78)

7.2125 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning GA 21 maize (EC-78) has been unduly delayed.

7.2126 The **United States** argues that even though GA21 maize (EC-78) was forwarded by the lead CA to the Commission with a favourable opinion, received a positive opinion from the SCP in September 2000, the consultations with relevant member States were completed, and the scope of the application was reduced to exclude cultivation, the Commission failed to submit a draft measure to the Regulatory Committee. The United States argues that there was no action or communication by the Commission on this application. The United States adds that the only activity that occurred after the SCP's positive opinion was efforts by the applicant to re-start the process, including the applicant's voluntary offer in September 2001 to update the application (in the form of undertakings) to the requirements of the impending Directive 2001/18. Furthermore, the United States argues that although the applicant submitted all necessary supplementary information according to Directive 2001/18 to the lead CA on 15 January 2003, no action was taken in the following eight months, either by the lead CA or the Commission, to move the product towards consideration by the Regulatory Committee.

7.2127 The United States submits, finally, that the application concerning GA21 maize (EC-78) is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning GA21 maize (EC-78) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2128 **Argentina** argues that once the SCP issued its favourable opinion on 22 September 2000, the procedure on this application was suspended. Two years and two months had elapsed between the submission of the application and its suspension. Upon the replacement of Directive 90/220 by Directive 2001/18, the application had to be re-submitted. However, the approval process has not made any progress since that time. One year and eight months elapsed from the re-submission until September 2003, when the application was withdrawn. In total, counting the time that elapsed under Directives 90/220 and 2001/18, the procedure dragged on for 5 years and 2 months without a definitive response concerning approval.

7.2129 The **European Communities** argues that after assessment at both member State and Community level, the application was withdrawn by the applicant on 15 September 2003. The European Communities notes that the applicant, in its withdrawal letter, gave three reasons for the

withdrawal: *first*, the progress in the notification procedure of another Roundup Ready maize to a more advanced stage than the GA21 maize (EC-78) notification; *second*, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and *third*, the change of the company's commercial priorities.

7.2130 **Argentina** responds that although the applicant's letter of withdrawal does not have a specific reference to "undue delay", this does not imply that no "undue delay" occurred. Argentina considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather that it was due to the applicant's concern with maintaining good relations with the approving authorities.

7.2131 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2132 We recall that the SCP issued a favourable opinion on 22 September 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee until Directive 90/220 was repealed in October 2002. The United States and Argentina argue that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002. The European Communities argues that the application was being assessed according to the procedures.

7.2133 We recall that according to the procedures set out in Directive 90/220, after the issuance of the SCP opinion, it was for the Commission to submit a draft measure to the Regulatory Committee for a vote. The Commission did not do so, however. Indeed, it seems that unlike in other procedures[1540], the Commission in this procedure never launched inter-service consultations on a draft measure. We are therefore not persuaded by the European Communities' assertion that the application concerning GA21 maize (EC-78) was being assessed according to the procedures.

7.2134 At any rate, we observe that the preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than two years. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1541] It may be inferred from this that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.2135 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. We note in this respect that the SCP's favourable opinion stated that "[t]he applicant should however establish a monitoring plan to identify unexpected and unusual events and analyse grower experiences, in order to develop and implement any necessary changes in crop management practices in response to the results of monitoring."[1542] However, as with the approval procedures we have considered earlier, there is no evidence that the Commission or the lead CA ever requested the applicant to propose a monitoring plan in accordance with the SCP's opinion. In January 2003, the applicant submitted an updated application, including a monitoring plan. But this information was submitted at the applicant's initiative, in anticipation of the

[1540] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[1541] Exhibit EC-65/Ats. 48 and 51.
[1542] Exhibit EC-78+85/At. 90.

entry into force of the new requirements contained in Directive 2001/18, and not because the applicant was requested to address the SCP opinion.[1543] Therefore, there is no reason to believe that the Commission was waiting for the applicant to put forward a monitoring plan, or, indeed, to provide any of the other additional information submitted by the applicant in January 2003. Consequently, we do not consider that the SCP's recommendation justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002

7.2136 We further note that four months after the SCP issued its opinion, in January 2001, the applicant sent a letter to the lead CA requesting that the scope of its application be limited to import only and no longer include cultivation.[1544] In March 2001, the lead CA informed the Commission that it had no objection to the applicant's request.[1545] There is no indication that the Commission opposed the applicant's request. While the scope of the application was relevant to the draft measure to be submitted by the Commission to the Regulatory Committee, the requested change of scope did not, in our view, present an obstacle to the Commission launching, or continuing, inter-service consultations on a draft measure.

7.2137 Nor do we see a possible obstacle in the fact that Directive 90/220 was repealed in October 2002. Indeed, the SCP opinion in this procedure dates from September 2000. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[1546] In our assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning GA21 maize could not be completed while Directive 90/220 was still in force.

7.2138 In its earlier findings on the application concerning GA21 maize, the Panel noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it was doubtful that there would be enough time in view of anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have legitimately invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

7.2139 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure

[1543] Exhibit EC-78+85/At. 94.
[1544] Exhibit EC-78+85/At. 91.
[1545] Exhibit EC-78+85/At. 92.
[1546] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

to the Regulatory Committee – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long.

7.2140 Regarding DS291, we recall that the United States claims that the approval procedure concerning GA21 maize (EC-78) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.2141 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2142 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning GA21 maize (EC-78) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning GA21 maize (EC-78), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning GA21 maize (EC-78) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xviii) MON810 x GA21 maize (EC-82)

7.2143 One Complaining Party, the United States, claims that the completion of the approval procedure concerning MON810 x GA21 maize has been unduly delayed.

7.2144 The **United States** argues that this application never reached the Community level stage of review due to the moratorium. On 30 November 1999, the lead CA requested that the applicant provide several additional studies to support the application for this product.[1547] The applicant responded in August 2001 to all requests, except for a scientifically unjustified study on the nutritional composition of milk from dairy cows fed this product.[1548] Given the demonstrated safety of maize in feed generally, as well as the substantial data submitted to support the feed safety of both transgenic parents, there is no scientific basis to suggest a concern. One of the parental lines (MON810 maize) was approved by the European Communities several years prior to this application, and the feed safety was established as part of that process.[1549] In addition, as part of its original submission, the applicant had relied on substantial compositional analyses of the other parent (GA21 maize), as well as feeding studies.[1550] None of these studies identified anything that would provide any basis for the concern raised by the member State.

7.2145 The United States notes that the lead CA also requested additional studies of the hybrid in order to verify the stability of both events jointly. In the view of the United States, there was no logical basis for this request, which implies some interaction between the MON810 and GA21 events. The United States submits that the applicant had already shown the stability of these transformation events in each parental line. The insertions, having been shown to be stable in the parental lines, would be no more likely to be affected by crossing than any other gene already present in either parent.

7.2146 The United States notes that the applicant provided translations in January 2002 of various studies it had previously submitted. Following that, the only activity by the lead CA was a meeting held in April 2002.[1551] No further action was taken on this application for over 18 months, until the applicant volunteered to update the application under Directive 2001/18 on 16 January 2003.[1552] The applicant, however, subsequently withdrew the application on 15 September 2003, at the same time it withdrew the application for GA21 maize (EC-78), as the delays caused by the moratorium had rendered the applications for GA21 maize (EC-78) and MON810 x GA21 maize commercially obsolescent.[1553]

7.2147 The United States also points out that the application concerning MON810 x GA21 maize is one of nine applications identified by the United States which have been pending at the member State

[1547] Exhibit EC-82/At. 8.

[1548] Exhibit EC-82/ Ats. 9, 10 and 11. According to the United States, conducting the dairy cattle feeding study would have involved considerable cost and delay to the applicant. Such a test would require the applicant to obtain approval for further experimental plantings to generate sufficient maize for the feeding study; employ external consultants to undertake the required study; grow maize for the feeding study in the 2000 season; harvest, transport and ensile the maize under rigorous experimental conditions; undertake the cow-feeding phase; analyse the milk samples; and produce all reports to the Standards of Good Laboratory Practice.

[1549] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[1550] Exhibit EC-82/Ats. 2 and 5.

[1551] Exhibit EC-82/At. 18.

[1552] Exhibit EC-82/At. 20.

[1553] Exhibit EC-82/At. 21.

level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MON810 x GA21 maize is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2148 The **European Communities** argues that the delays identified by the United States can be explained by the fact that the safety of one of the parental lines of this hybrid product, GA 21 maize, had not yet been assessed. The lead CA was awaiting that assessment. The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open. Furthermore, according to the European Communities, the United States acknowledges that the delays were caused by the applicant when it stated in response to a question from the Panel that "the applicant was unable to devote resources to respond to the questions posed by the [lead CA] in a timely fashion".[1554]

7.2149 The European Communities further observes that after discussions between the lead CA and the applicant, the application was withdrawn with a letter of 15 September 2003. The applicant gave three reasons for the withdrawal: first, the progress in the procedure of NK603 maize to a more advanced stage than the GA21 maize (EC-78) application; second, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and third, the change of the company's commercial priorities.

7.2150 The **United States** denies acknowledging that the delays were caused by the applicant. The summary table of the US response to question 47 from the Panel was not intended to indicate that delay was the fault of the applicant. Rather, the applicant recognized that the application for MON810 x GA21 maize would not move forward as long as consideration of the application for the single trait parent GA21 maize (EC-78) remained suspended under the moratorium. The United States contends that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize when the approval of GA21 maize (EC-78) had been stalled for years under the moratorium. Thus, the delay in the application for MON810 x GA21 maize was a direct consequence of the delay in the application for GA21 maize (EC-78) under the moratorium.

7.2151 The United States points out that because of the delay in the approval procedure concerning GA21 maize (EC-78), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). The United States maintains that the applicant may not have cited undue delays in its withdrawal letter because it had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays.

7.2152 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2153 We recall that the lead CA (Spain) in November 1999 requested additional information from the applicant. The applicant did not provide the information requested until August 2001. A translation into Spanish of the documents submitted in the August 2001 response was provided to the Spanish CA in January 2002. The United States has pointed out that the applicant did not comply

[1554] The European Communities refers to the United States' response to question 47 of the Panel, table in Annex I.

with the Spanish CA's request that it provide a study on the nutritional composition of milk from dairy cows which had been fed the product in question.

7.2154 It was only in April 2002 that the Spanish National Biosafety Committee completed its review of the January 2002 Spanish translation of the applicant's documents. The National Biosafety Commission concluded that it still needed the results of feeding studies on cows, and other information.[1555] However, there is no indication in the record that a further request for information was ever sent to the applicant prior to the repeal of Directive 90/220 in October 2002.

7.2155 According to the European Communities, the failure of the lead CA to forward the application concerning MON810 x GA21 maize to the Commission prior to the date of repeal of Directive 90/220 is justified by the fact that the lead CA was waiting for the result of the Community level assessment of one of the parental lines of this hybrid product, GA21 maize (EC-78). The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open.

7.2156 We recall that the Spanish CA in May 1999 had given a favourable assessment to the application concerning GA21 maize (EC-78) and forwarded that application to the Commission. When the application concerning MON810 x GA21 maize was submitted, the application concerning GA21 maize (EC-78) was under assessment at Community level. Furthermore, in September 2000 the SCP also issued a favourable opinion on the application concerning GA21 maize (EC-78).[1556] It is therefore not clear to us why the Spanish CA would not be in a position to reach a conclusion also with regard to the application concerning the hybrid product, *i.e.*, MON810 x GA21 maize. Indeed, the record does not indicate that the Spanish CA ever indicated to the applicant that it was unable to proceed due to the failure of the European Communities to approve the GA21 maize (EC-78) parent.

7.2157 As a general matter, it may be correct to say, as the European Communities does, that "the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open". However, it would seem that the assessment of the parental lines could also be made in the context of the assessment of the hybrid. At any rate, the Spanish CA could not "conclude" the assessment of the application concerning MON810 x GA21 maize completely on its own. If other member States had concerns with Spain's assessment of GA21 maize (EC-78), even though that assessment appears to have been confirmed by the SCP, they could have raised an objection on that basis to Spain's assessment of MON810 x GA21 maize and the assessment of that application would then also have been "concluded" at Community level.

7.2158 For these reasons, it is not apparent to us that the Spanish CA needed to keep the application at the member State level in order to avoid the possibility of conflicting assessments of GA21 maize, and we therefore do not consider that the fact that one of the parental lines was still pending justified Spain in not completing its assessment of the application concerning MON810 x GA21 maize.

7.2159 We note that after receiving a translation of the additional information requested from the applicant, it was incumbent on the Spanish CA either to seek further clarifications or to complete its assessment within the 90-day period provided for in Directive 90/220. As indicated, the National Biosafety Commission did not complete its review of the information until two and a half months later. Moreover, there is no evidence that the Spanish CA requested additional or missing information once the National Biosafety Commission had completed its review of the applicant's documents. Nor

[1555] Exhibit EC-82/At. 18.
[1556] Exhibit EC-78+85/At. 90.

did the Spanish CA complete its assessment after receiving further advice from the National Biosafety Commission in April 2002.

7.2160 We recognize that, by April 2002, the date of repeal of Directive 90/220 was approaching. However, we note that in another approval procedure, the Spanish CA forwarded questions from the National Biosafety Commission as late as mid-June 2002.[1557] Moreover, even if the lead CA had taken another two or three months to complete its assessment[1558], we think that there was still enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of MON810 x GA21 maize.[1559]

7.2161 Taking account of the aforementioned elements, we see no justification for the lead CA's failure, after receiving further advice from the National Biosafety Commission in April 2002, to follow up with the applicant to seek more information or additional clarifications, or for the lead CA's failure to complete its assessment in April 2002 or soon thereafter. We therefore are not convinced that the lead CA could not have proceeded more promptly than it did.

7.2162 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize – notably the time taken by the lead CA between January and October 2002 – was unjustifiably long.

7.2163 In addition, we recall that the United States claims that the approval procedure concerning MON810 x GA21 maize was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of the application concerning MON810 x GA21 maize prior to the repeal of Directive 90/220 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2164 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1557] Exhibit EC-75/At. 13.

[1558] We note, however, that by April 2002 the 90-day period envisaged in Directive 90/220 for a lead CA assessment had already been exceeded.

[1559] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified Spain's failure to complete its assessment prior to the date of repeal of Directive 90/220. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

Conclusion

7.2165 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MON810 x GA21 maize for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MON810 x GA21 maize, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xix) RR sugar beet (EC-88)

7.2166 One Complaining Party, the United States, claims that the completion of the approval procedure concerning RR sugar beet has been unduly delayed.

7.2167 The **United States** claims that the application for RR sugar beet was delayed at the first stage of the approval process under 90/220 because the lead CA (Belgium) declined to forward the application to the Commission. The United States argues that although the applicant provided answers to all of the questions raised by the lead CA, the lead CA failed to complete its review.

7.2168 The United States also points out that the application concerning RR sugar beet is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR sugar beet is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2169 The **European Communities** notes that after discussions between the lead CA and the applicant, the application was withdrawn by the companies producing the product on 16 April 2004. As the reason for the withdrawal, the applicant pointed to a decision to stop any further development of the RR sugar beet derived from event T9100152.

7.2170 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2171 We recall that the application was considered at a meeting of the Belgian Biosafety Advisory Council held on 26 April 1999. The questions which were generated by this meeting were transmitted to the applicant in June 1999 and included questions on agricultural practices, molecular

characterization, toxicology, allergenicity, and food/feed equivalence.[1560] The applicant provided responses to some of these questions in July 1999.[1561] Other questions were answered in December 1999.[1562]

7.2172 In October 1999 the lead CA requested additional information on gene transfer in digestive tracts.[1563] The applicant provided such information in January 2000.[1564] We asked the experts advising us whether the information regarding allergenicity, molecular characterization and gene transfer in digestive tracts requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti stated that the information provided by the applicant prior to October 1999 on these three topics was adequate to ensure that the conclusions of the assessment were valid.[1565]

7.2173 In February 2000, the lead CA requested missing bibliographical references. The applicant provided the relevant references in February and March 2000.[1566] According to the chronology provided to us, in April 2000 the applicant met with the CA to discuss issues relating to identity preservation, Good Agricultural Practices, post-market monitoring, traceability, public information, line-specific detection methods and primers. The record of this meeting was not provided to us, however. In July 2000, the applicant at its own initiative provided additional information on the characterization of a protein and detection protocols. The applicant noted that this data did not change the conclusions of the safety assessment.[1567]

7.2174 In November 2000, the lead CA requested further clarifications regarding molecular characterization and allergenicity of "event '77'".[1568] We asked the experts if the information regarding molecular characterization and allergenicity of "event '77'" requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti emphasized that the information "for allergenicity was not necessary to ensure that the conclusions of the safety assessment were valid", as the initial application had satisfactorily established the safety of this product in this respect.[1569] The applicant apparently did not provide the requested information.

7.2175 In January 2001 the lead CA "invited" the applicant to provide a proposal for labelling and traceability as well as a proposal for a monitoring plan and Good Agricultural Practices in accordance with the principles of the Common Position of the Council on the amendment of Directive 90/220. The lead CA indicated that in the absence of voluntary compliance with these principles, it seemed that the Commission and the other member States would oppose the approval of the application even if the lead CA forwarded it with a positive assessment.[1570] The applicant apparently did not reply to the lead CA's invitation. In June 2001, the lead CA sent the applicant some comments on its application, asking the applicant to make corresponding corrections.[1571] After the June 2001 communication from the lead CA there appear to have been no further exchanges between the lead CA and the applicant until the repeal of Directive 90/220 in October 2002.

[1560] Exhibit EC-88/Ats. 8 and 9.
[1561] Exhibit EC-88/At. 10.
[1562] Exhibit EC-88/At. 13.
[1563] Exhibit EC-88/At. 12.
[1564] Exhibit EC-88/At. 15.
[1565] Annex H, Dr. Nutti's response to Panel Question 42.
[1566] Exhibit EC-88/Ats. 17-21.
[1567] Exhibit EC-88/At. 22.
[1568] Exhibit EC-88/At. 27.
[1569] Annex H, Dr. Nutti's response to Panel Question 43.
[1570] Exhibit EC-88/At. 29.
[1571] Exhibit EC-88/At. 30.

7.2176 We begin our examination of the lead CA's assessment of the application under Directive 90/220 by recalling that the applicant did not respond to the lead CA's November 2000 request for additional information.[1572] It would therefore appear that after November 2000 the lack of progress of the application under Directive 90/220 is attributable to the applicant. The focus of our examination is therefore on the lead CA's conduct prior to the November 2000 request.

7.2177 We note in this respect that by the end of March 2000 the applicant had provided all additional information requested by the lead CA. Moreover, there is no indication that the Biosafety Advisory Council had been asked for further scientific input either before or after March 2000. Notwithstanding this, the lead CA did not complete its assessment in the next several weeks. Instead, more than seven months later, in November 2000, the lead CA requested further clarification on molecular characterization and allergenicity issues previously addressed by the applicant. As indicated previously, notably in the case of the clarifications sought concerning allergenicity, Dr. Nutti questioned the need for the information that was requested. Even ignoring this, we note that the European Communities did not provide an explanation for why the Belgian CA could not have sought these clarifications much earlier, given that the applicant had provided additional information on these issues before the end of 1999.

7.2178 Furthermore, even assuming *arguendo* that the lead CA could not have finished its assessment between March 2000, when the applicant provided all additional information requested by the lead CA, and the end of July 2000, when the applicant voluntarily submitted additional information, and accepting, again *arguendo*, that the lead CA required some time to review the July 2000 information, we recall that the November 2000 request came more than seven months after the applicant had provided all information requested by the lead CA. We are not persuaded that the completion of the review of the March and July 2000 information required more than twice the maximum 90-day period envisaged in Directive 90/220 for the entire assessment by a lead CA. We note in this connection that by November 2000, Belgium had already far exceeded the 90-day period provided for in Directive 90/220.

7.2179 Moreover, the seven-month delay after March 2000 could not, in our view, be excused on the basis that there was insufficient time to complete the approval procedure concerning RR sugar beet while Directive 90/220 was still in force. Directive 90/220 was not repealed until October 2002. There was thus enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of RR sugar beet.[1573]

7.2180 Taking account of the aforementioned elements, we consider that, even assuming that the lead CA's November 2000 request for additional information was justified, the lead CA could have sought that information earlier than it did. We also consider that the lead CA should have done so, as we think that by November 2000 the lead CA should have been able to resolve all other outstanding scientific or technical issues.

[1572] The lead CA in January 2001 reminded the applicant of its November 2000 request for information. Exhibit EC-88/At. 29.

[1573] We note that Belgium could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the seven-month delay after March 2000. Belgium might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. However, as pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

7.2181 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning RR sugar beet – notably the time taken by the lead CA between March and November 2000 – was unjustifiably long.

7.2182 In addition, we recall that the United States claims that the approval procedure concerning RR sugar beet was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by Belgium to complete its assessment is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Belgium's conduct was a consequence of the general moratorium on approvals.

7.2183 In view of our conclusion with regard to the time taken by Belgium for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2184 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR sugar beet was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR sugar beet for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR sugar beet, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement.

(xx) MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape (EC-90)

7.2185 One Complaining Party, Canada, claims that the completion of the separate approval procedures for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have been unduly delayed. While we are mindful of the fact that Canada is making separate product-specific claims in respect of the two approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, in view of the very similar facts of these procedures, we examine the two claims together.

7.2186 **Canada** argues that the delays in completing the approval procedures for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape are both excessive and unjustified, and hence undue. The EC decisions authorizing the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape in July 1997 stated that "consent shall be given by the competent authority of France to

the placing on the market" of the products in question[1574], yet in 2003, when the Panel was established, the lead CA had still failed to give its consent for either product.

7.2187 Canada notes that although the Commission took the procedural step of sending a "reasoned opinion" to France in relation to the withholding of consent for these products on 7 July 1999, the Commission has not pursued legal proceedings against France for infringement of European law before the European Court of Justice.[1575] No explanation has been provided by France for its refusal to comply with the Commission decisions and Directive 90/220, nor by the Commission for not pursuing legal action against France. This is despite the November 2000 judgment of the French Conseil d'Etat that, without new information concerning the risks associated with MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, the French Ministry could not call into question the decision taken by the Commission.[1576]

7.2188 Canada contends that the length of time it has taken, so far, for these applications to move through the approval system – more than eight years – is, by any reasonable standard, "undue" and therefore a violation of Annex C(1)(a), keeping in mind that the final approval for these products still has not been given. However, the amount of time these applications have languished in the approval procedure is not the sole reason for Canada's claim that the delays have been undue. First and foremost, the European Communities has had in place, since October 1998, an unjustified moratorium on approvals. Furthermore, the refusal to approve the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape are not based on risk assessments, particularly since both products were formally approved by the Commission in 1997.

7.2189 The **European Communities** argues that these products obtained a market authorization by virtue of Commission decisions of 6 June 1997. The European Communities submits that from the point of view of EC law, the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market. The doctrine of "direct effect" in Community law means that the applicant could assert the rights granted them through the provisions of EC law.[1577]

7.2190 The European Communities confirms that the Commission initiated infringement proceedings against France in 1998, however it decided not to take the case to the Court. This was because the very legislation on the basis of which the approval had been granted had been identified to be insufficient and was being revised. Furthermore, France had raised the same environmental risk concerns regarding these two products as it had for the products for which it subsequently adopted safeguard measures (*i.e.* the identical product MS1/RF1 oilseed rape which had been approved for breeding activities in 1996).

7.2191 The approvals of MS1/RF1 and MS1/RF2 oilseed rape for import, processing and cultivation in 1996 and 1997 did not provide for any reporting or monitoring of marketing in the European

[1574] Article 1(1) of each Decision respectively. Exhibits CDA-48 and -49.

[1575] European Commission, GMOs: Commission moves against Luxembourg and France, Commission Press Release, IP/99/438, Brussels, 7 July 1999 (Exhibit CDA-52). *See also* European, Commission, Seventeenth Annual Report on Monitoring the Application of Community Law (1999), COM (2000) 92 final, Brussels, 23 June 2000 (Sector on Chemicals and Biotechnology), p. 80 (Exhibit CDA-53)

[1576] European Commission, Eighteenth Annual Report on Monitoring the Application of Community Law (2000), COM (2001) 309 final, Brussels, 16 July 2001 (Sector on Chemicals and Biotechnology), p. 67 (Exhibit CDA-50); *see also*, European Court of Justice, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche*, C-6/99 [2000] ECR I-01651 (Exhibit CDA-51).

[1577] The European Communities refers to European Court of Justice, *Leberpfennig*, Case 9/70 [1970] ECR 825.

Communities. Accordingly, the European Communities claims it is unable to say whether these products have been sold in the European Communities. According to the European Communities, no oilseed rape varieties derived from MS1/RF1 or MS1/RF2 oilseed rape have been registered in member States' national catalogues or in the Common Catalogue of varieties of agricultural plant species – which is a prerequisite for allowing their commercial cultivation – because there has been no application from companies to do so.

7.2192 **Canada** rejects the EC argument that the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market. Canada submits that this would require the applicant to pursue legal proceedings within the European Communities in order to bring to an end the approval procedures. According to Canada, under these circumstances it is obvious that the European Communities has failed to complete the relevant approval procedures under Directive 90/220. The applicant has been unable to market its products in the European Communities as a result of the failure of France to issue the letters of consent and the consequent uncertainty regarding the legal status of the products. Therefore, the European Communities has failed to "complete" the relevant approval procedures without "undue delay" in patent violation of Annex C(1)(a) of the *SPS Agreement*. Moreover, Canada argues that by failing to complete the approval procedures, the European Communities has instituted and maintained effective product-specific marketing bans for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape.

7.2193 The **Panel** begins its analysis by addressing the delay allegedly caused by France as the lead CA.

Member State failure to give consent to placing on the market

7.2194 The Panel notes that although the two applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were formally approved by the Commission for placing on the market in June 1997, the lead CA subsequently failed to take the final step of the approval procedure provided for in Article 13(4) of Directive 90/220, which is to grant written consent to the placing on the market of a product. The relevant Commission decisions, which are addressed to the member States, also provide in their Article 1(1) that "consent shall be given by the competent authority of France to the placing on the market" of the oilseed rape products in question.[1578]

7.2195 Neither Article 13(4) of Directive 90/220 nor the relevant Commission decisions lay down specific time periods within which the lead CA had to give consent. However, it is clear to us that this does not mean that the lead CA could take any amount of time to complete the step required of it. If it were otherwise, the deadlines stipulated in Directive 90/220 for the completion of other steps of the approval procedure, such as the 90-day member State assessment period set out in Article 12, the 60-day objection period set out in Article 13 and the three-month action period set out in Article 21, could easily be nullified and rendered meaningless. We recall that in the case of the two applications at issue, the approval for both applications was given by the Commission on 6 June 1997. As of October 2002, when Directive 90/220 was repealed, France had not granted its consent to the placing on the market of the products at issue. Thus, under Directive 90/220, France did not grant its consent for more than five years.[1579]

[1578] Exhibits CDA-48 and -49.

[1579] We note, by way of example, that in the approval procedure concerning the Red-hearted chicory, which was also conducted under Directive 90/220, the lead CA gave its written consent two-and-a-half months after the Commission approved the application for breeding activities. Exhibit EC-77/At. 42.

7.2196 There is some uncertainty as to the status of the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape after the repeal of Directive 90/220. Article 35 of Directive 2001/18 provides that applications submitted under Directive 90/220 in respect of which the approval procedures under Directive 90/220 have not been completed by 17 October 2002 are subject to Directive 2001/18. It further provides that by 17 January 2003 applicants had to complement their applications in accordance with Directive 2001/18. There is no indication that the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were complemented in accordance with Directive 2001/18.

7.2197 The European Communities appears to argue, however, that the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were completed under Directive 90/220. The European Communities contends that in accordance with the jurisprudence of the European Court of Justice the absence of the final consent from the lead CA does not mean that the applicant is not legally entitled to place MS1/RF1 oilseed rape (EC-89) and/or MS1/RF2 oilseed rape on the market. According to the European Communities, the applicant could invoke before French courts the obligation imposed by the above-noted Commission decisions on France to give its consent to the placing on the market of the products in question. Canada did not contest that the applicant would have this right under EC law. In these circumstances, and in the absence of evidence to the contrary, we see no grounds for rejecting the European Communities' contention regarding the position under its own law.

7.2198 Accepting the European Communities' contention means that as of the date of establishment of this Panel, the above-noted Commission decisions were still legally binding, and that as of that date the applicant could still invoke the above-noted Commission decisions against France, since France had not given its written consent by then. This does not mean, however, that either before or after the repeal of Directive 90/220 France itself was no longer required to comply with the Commission decisions and was not obliged to grant its written consent.

7.2199 We must not, and hence do not, express a view on whether the approval procedures conducted under Directive 90/220 concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were "completed" as a matter of EC law.[1580] However, we may express a view on whether these approval procedures were "completed" within the meaning of Annex C(1)(a), first clause. We have observed earlier that the verb "complete" as it appears in Annex C(1)(a), first clause, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded, and that the phrase "undertake and complete", which also appears in Annex C(1)(a), first clause, covers all stages of approval procedures and should be taken as meaning that approval procedures are to be started and carried out from beginning to end.[1581]

7.2200 We do not consider that the European Communities finished, or concluded, the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, or that the European Communities carried out these procedures from beginning to end. Indeed, Directive 90/220 provides for the granting of the lead CA's written consent to the placing on the market as an integral and last step of the approval procedure.[1582] In our view, the fact that the applicant could invoke before French courts the obligation imposed by the above-noted Commission decisions on France to give its consent to the placing on the market of the products in question does not demonstrate that the relevant approval procedures have already been "completed" within the meaning of Annex C(1)(a), first

[1580] We note that Article 35 of Directive 2001/18 uses the phrase "not [...] completed" in connection with procedures commenced under Directive 90/220.

[1581] *See supra*, para. 7.1494.

[1582] Article 13(4) of Directive 90/220.

clause. Rather, it indicates that, notwithstanding France's failure to finish the procedures, the Commission decisions may be enforceable *vis-à-vis* France.

7.2201 Having determined that the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have not been completed, we now turn to address whether the time taken by France to grant its written consent is unjustifiably long. The European Communities asserts in this respect that France's inaction after June 1997 was due to concerns about environmental risks, and that these same risks led France in November 1998 to adopt a safeguard measure on MS1/RF1 oilseed rape (EC-161).[1583] In considering the EC assertion, we note that we have been provided very little information on the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. In particular, we have seen no evidence which points to the alleged environmental concerns by France. To the contrary, the Commission decisions approving the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape make clear that France forwarded the application to the Commission with a favourable opinion.

7.2202 Furthermore, there is no indication that France after June 1997 sought additional information from the applicant, or proposed to the applicant voluntarily to accept stricter conditions to meet France's alleged environmental concerns. Moreover, the Commission decisions approving the two products specify that Directive 90/220 provides for additional safeguards if new information on risks of the products in question became available. In the light of this, even if France considered that by June 1997 there were justifiable reasons for it to consider that the products in question constituted a risk to the environment, it could have taken a safeguard measure, as it did for MS1/RF1 oilseed rape (EC-161), *after* giving its written consent to the placing on the market of the two products in question.[1584] The concerns underlying France's safeguard measure would then have been examined by the SCP, and a decision on the validity of France's concerns would then have had to be taken at Community level.

7.2203 For these reasons, we are not persuaded that there were outstanding environmental issues which were specific to the products in question, and which France was trying to have the applicant address prior to giving its written consent to the placing on the market of these products.

7.2204 The European Communities offered no other explanation for France's prolonged inaction. We recall in this regard that in June 1999 France was one of the Group of Five countries which declared that they would take steps to suspend further approvals under Directive 90/220 pending the adoption of new EC rules on labelling and traceability. We found earlier that at least as from June 1999 France's conduct is consistent with the June 1999 declaration by the Group of Five countries. Indeed, despite a clear legal obligation to give written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, France withheld its consent and thus prevented these products from being approved. As we have explained earlier[1585], however, we consider that the perceived need for new EC rules on labelling and traceability does not provide a sufficient justification for not completing the approval procedures for the products in question and for preventing their final approval.

[1583] The application concerning MS1/RF1 oilseed rape (EC-161) had been submitted to the United Kingdom and was approved for breeding activities in 1996.

[1584] There is nothing in Directive 90/220 which says that a lead CA forwarding an application with a positive opinion and giving written consent to the placing on the market of a product may not subsequently take a safeguard measure in respect of that product.

[1585] *See supra*, paras. 7.1511-7.1518.

7.2205 Based on the above considerations, the Panel concludes that the time taken by France up to August 2003, including the time taken after June 1999, for the purpose of giving its written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape following the approval of both applications by the Commission in June 1997 is unjustifiably long.

7.2206 In view of this conclusion, we do not go on to examine other arguments put forward by Canada in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2207 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada) – MS1/RF1 oilseed rape (EC-89)

With reference to DS292, the Panel recalls its findings that the time taken by France to give its written consent for the placing on the market of MS1/RF1 oilseed rape (EC-89) following its approval by the Commission in June 1997 – no consent was given between June 1997 and August 2003 – was unjustifiably long. Based on these findings, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay" the application concerning MS1/RF1 oilseed rape (EC-89), and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS1/RF1 oilseed rape (EC-89), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada) – MS1/RF2 oilseed rape (EC-90)

With reference to DS292, the Panel recalls its findings that the time taken by France to give final consent for the placing on the market of MS1/RF2 oilseed rape following its approval by the Commission in June 1997 – no consent was given between June 1997 and August 2003 – was unjustifiably long. Based on these findings, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay" the application concerning MS1/RF2 oilseed rape, and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS1/RF2 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(c) Novel Foods – Applications submitted under Regulation 258/97

7.2208 We now turn to examine the approval procedures which were conducted under Regulation 258/97 for the applications identified by the Complaining Parties. Before embarking on an examination of individual approval procedures, however, we should briefly address certain issues presented by the application of Annex C(1)(a), first clause, to approval procedures conducted under Regulation 258/97.

(i) Application of Annex C(1)(a), first clause, to approval procedures conducted under Regulation 258/97

7.2209 We have found earlier that the approval procedure set out in Regulation 258/97, to the extent it is applied to check and ensure the fulfilment of the requirement that novel foods not present a danger for the consumer, constitutes an "approval procedure" within the meaning of Annex A(1) of the *SPS Agreement*. On the other hand, we found that to the extent the same approval procedure is applied to check and ensure the fulfilment of the requirements that novel foods not mislead the consumer and that they not be nutritionally disadvantageous for the consumer, that procedure is not an "approval procedure" within the meaning of Annex A(1) of the *SPS Agreement*.

7.2210 Under Regulation 258/97, once an application for the approval of a novel food product is submitted, the fulfilment of the aforementioned three requirements is to be checked through one single approval procedure. Regulation 258/97 also envisages that if an application does not meet one of three requirements, the relevant food product may not be placed on the market. We recall that the Complaining Parties did not challenge Regulation 258/97 as such, and thus did not question the European Communities' decision to conduct one single approval procedure to check all three requirements and to grant approvals only in cases where applications comply with all three requirements.

7.2211 It follows from the design of Regulation 258/97 that in the event there is a delay in the processing of an application due to the need to check the fulfilment of the requirement that novel foods not mislead the consumer, or that they not be nutritionally disadvantageous for the consumer, that delay would also affect the SPS approval procedure conducted for the same application, *i.e.*, the procedure applied to check and ensure the fulfilment of the requirement that novel foods not present a danger for the consumer. In other words, the SPS approval procedure would be delayed if, and to the extent that, there was a delay in the non-SPS approval procedure.

7.2212 We have previously stated that, in our view, Annex C(1)(a), first clause, requires that SPS approval procedures be undertaken and completed with no unjustifiable loss of time. In the context of Regulation 258/97, the issue thus arises whether a delay caused by the need to check the fulfilment of, *e.g.*, the non-SPS requirement that novel foods not be nutritionally disadvantageous for the consumer should be considered to constitute, *ipso facto*, unjustifiable loss of time.

7.2213 In addressing this issue, we recall that the Complaining Parties did not challenge or question the fact that Regulation 258/97 provides that for each application a single procedure is to be conducted, leading to a single approval. We consider that, in these circumstances, a delay in the SPS approval procedure should not be viewed as "undue" merely because it arose from the need to check the fulfilment of one of the two non-SPS requirements contained in Regulation 258/97, *e.g.*, the requirement that novel foods not be nutritionally disadvantageous for the consumer. Indeed, if it were otherwise, a situation might arise where the European Communities would have to complete the procedure with a substantive decision on the application concerned even if it had not yet been able adequately to determine whether the application meets the requirement that the novel food product not be nutritionally disadvantageous for the consumer. The European Communities might thus have to approve a novel food product the consumption of which is nutritionally disadvantageous for the consumer, and this even though the Complaining Parties never questioned the fact that in accordance with Regulation 258/97 the requirement that a product not be nutritionally disadvantageous must be fulfilled before a product is approved.

7.2214 While we thus do not consider that, in the specific circumstances of this case, a delay in the SPS approval procedure should be treated as "undue" merely because it arose from the need to check

the fulfilment of one of the two non-SPS requirements contained in Regulation 258/97, it is our view that for instance if the time taken to check the fulfilment of one of those non-SPS requirements exceeded the time that is required to do so, the resulting delay in the SPS approval procedure would be at least partly "undue".

7.2215 In view of the above considerations, we think that for the purposes of our examination of the relevant approval procedures in the light of Annex C(1)(a), first clause, we need not, and hence do not, make specific findings on whether any delays in a relevant approval procedure arose from the need to check the fulfilment of the SPS requirement that novel foods not present a danger for the consumer or whether they arose from the need to check the fulfilment of the non-SPS requirements that novel foods not mislead the consumer and that they not be nutritionally disadvantageous for the consumer. In the circumstances of this case, either type of delays would be relevant to an inquiry under Annex C(1)(a), first clause.

7.2216 As an additional, but separate, matter, we should recall that the Regulation 258/97 applications covering foods or food ingredients which contain or consist of GMOs are subject to Article 9 of Regulation 258/97 which provides that the Commission decision approving the placing on the market under Regulation 258/97 must "respect the environmental safety requirements laid down by [Directive 90/220] to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]". As we have said earlier, it would seem to follow from Article 9 that if the applicant did not submit an environmental risk assessment, a Regulation 258/97 application could not be approved by the Commission unless a Directive 90/220 application concerning the same biotech product had previously been approved. We observe in this context that it would in our view be contrary to the requirements of Annex C(1)(a), first clause, for the European Communities to proceed with a Regulation 258/97 procedure at a delayed pace merely because of delays which have occurred, or are anticipated to occur, in a parallel Directive 90/220 (or Directive 2001/18) procedure concerning the same biotech product, provided that further progress in the Regulation 258/97 procedure is still possible. In other words, we consider that the European Communities must proceed as far as possible with a Regulation 258/97 procedure as promptly as possible, unless the applicant requests that the Regulation 258/97 procedure proceed more slowly, or that it not proceed faster or further, than a parallel Directive 90/220 (or Directive 2001/18) procedure. In the case of the Regulation 258/97 applications at issue in this dispute, we are not aware of the existence of such a request by an applicant or of a situation where no further progress in the relevant Regulation 258/97 procedure was possible.

7.2217 Finally, we recall that in Section VII.D we have addressed whether the reason for the general EC moratorium on final approvals could have provided a justification for delays which might have occurred as a result of that moratorium. These earlier observations are relevant and applicable also to our examination of the Regulation 258/97 approval procedures identified by the Complaining Parties.

7.2218 With these general observations in mind, we now proceed with the examination of the individual product-specific measures complained against.

(ii) GA21 maize (food) (EC-91)

7.2219 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning GA21 maize (food) has been unduly delayed.

7.2220 The **United States** argues that the application concerning GA21 maize (food) under Regulation 257/98 was delayed first at the member State level in that the lead CA (the Netherlands)

took at least 10 months more than required to complete its initial assessment. Subsequently, the SCF failed to consider the application for 11 months, and later delayed issuing its assessment for 11 months without explanation. Finally, following the positive assessment of the SCF, the Commission failed to submit a draft decision to the Regulatory Committee for approval of this product prior to the establishment of the Panel. The United States considers these delays to be unwarranted and thus undue.

7.2221 The United States observes that this product was under consideration by the lead CA between the submission of the application in July 1998 and the lead CA's opinion in January 2000. In February 1999, the lead CA requested the applicant to perform a further study on compositional analysis, and the applicant provided its response in October 1999. Therefore, of the total 18 months during which this product was considered at the member State level, only 8 were used by the applicant to answer questions.

7.2222 The United States points out that the application was forwarded to the Commission on 21 January 2000. The official member State consultation period was over by April 2000. The United States notes that the Commission asked the SCF for an opinion on 18 May 2000. However, it was eleven months later that the SCF contacted the applicant for the first time, asking for additional information.[1586] Within less than one month, the applicant provided answers to all questions.[1587] It took a further 11 months for the SCF to issue an opinion on 27 February 2002.[1588] Hence the application was delayed for 17 months at the Community level before the SCF rendered its positive opinion on 27 February 2002. In its opinion, the SCF concluded that the data submitted, including the two whole food studies, were "sufficient for evaluation"[1589] and cited these studies in support of its ultimate conclusion that "from the point of view of consumer health, maize grain from maize line GA21 and derived products […] are as safe as grain and derived products from conventional maize lines."[1590]

7.2223 According to the United States, almost two months passed after the positive SCF opinion with no activity on this application. On 23 April 2002, the applicant offered to reduce the scope of the application to include only processed grain and derived ingredients, but not unprocessed grains, in order to enable the authorization procedure under Regulation 258/97 to proceed immediately.[1591] The applicant explained that the reason for this proposal was because the food use of unprocessed grains is also subject to Directive 90/220 and that "progress under this Directive has been suspended for some time, with the result that GA21 maize grain has not yet been considered for consent."[1592]

7.2224 The United States argues that despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee after the positive SCF opinion. Instead, as reflected in the minutes of a meeting on 5 June 2002 between the Commission and the applicant, the Commission noted that although the next step was to take a Community Decision, "[i]t is desirable that such a Decision would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and

[1586] Exhibit EC-91/At. 39.
[1587] Exhibit EC-91/At. 40.
[1588] The current revised regulatory framework recognizes that a period of six months is an achievable timeframe for the EC's Scientific Authority (EFSA GMO Panel) to come to an opinion. Regulation (EC) No. 1829/2003, Article 6.1.
[1589] Exhibit EC-91/At. 43, pp. 11-12.
[1590] Exhibit EC-91/At. 43.
[1591] Exhibit EC-91/At. 44.
[1592] Exhibit EC-91/At. 44.

feed as well as the labelling of GM products".[1593] The United States maintains that the European Communities simply halted the processing of this application in anticipation of possible upcoming changes to its regulations, an action entirely consistent with the moratorium which the European Communities and member State officials had announced. Although both the new food and feed and traceability and labelling legislations would not enter into force until 2004, and although the applicant stated its preference to apply the labelling requirements currently in effect under Regulation 258/97, the Commission noted that "it is clear that it would be more difficult to obtain a favourable opinion by a majority of Member States in the Comitology procedure" if the applicant were not required to anticipate the new labelling requirements before the new legislation was adopted.[1594] In other words, the applicant was required to wait until the requirements for labelling under pending legislation were finalized. Thus the Commission failed to forward a draft measure to the Regulatory Committee as is required to complete the approval process, resulting in further delay that lasted until the new Food and Feed regulation was passed in September 2003.

7.2225 The United States submits, in addition, that the application concerning GA21 maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning GA21 maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2226 **Argentina** argues that consideration of the application for GA-21 maize (food) under Regulation 258/97 dragged on for a total of 5 years and 2 months without a definitive response. Argentina further contends that the chronologies provided by the European Communities verify the numerous opportunities in which information additional to what is necessary for appropriate control, inspection and approval procedures was required from the applicant. Argentina contends that since 27 February 2002, the date on which the SCF expressed its favourable opinion, there has been no further progress in the approval process. Argentina indicates that the application was withdrawn in September 2003 because no progress had been made since 27 February 2002.

7.2227 The **European Communities** argues that the 18 months spent at member State level were due to the incompleteness of the dossier initially submitted and to the need for additional scientific data.[1595] The dossier was circulated at the Community level in January 2000, as required by the regulation. Many member States requested additional information and raised questions, several raised objections mainly on grounds of insufficient data on molecular characterisation and on compositional analysis (substantial equivalence). In May 2000, the Commission requested the opinion of the SCF. The SCF found that the dossier did not contain sufficient information concerning substantial equivalence and toxicity testing, and had to request the relevant information from the applicant.[1596] The SCF finally issued its opinion February 2002.

7.2228 The European Communities notes the difference between risk assessment and risk management and argues that the former is the task of the scientific committees, while the latter is the function of the Regulatory Committee. Since the Regulatory Committee fulfils risk management functions, it has to take into account all relevant factors, including risk assessment *stricto sensu*. The

[1593] Exhibit EC-91/At. 45, p. 1.
[1594] Exhibit EC-91/At. 45**,** p. 2.
[1595] Exhibit EC-91/At. 1-6.
[1596] *See* Request of 24 April 2001 (Exhibit EC-91/At. 17).

European Communities argues that the draft measures forwarded by the Commission to the Regulatory Committee are therefore supported by scientific assessments, but also address other legitimate issues, including risk management issues, which are not addressed by a scientific committee.

7.2229 In relation to Regulation 258/97, the European Communities contends that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In relation to the application concerning GA21 maize (food), the European Communities submits that the SCF's opinion did not address sufficiently all relevant elements. The elements which determined the insufficiency of the SCF's opinion related to the issues of validation of detection methods, which were requirements to be included in the new legislation on "Food and Feed" and on whose importance the applicant agreed. More particularly, the European Communities notes that in view of the pending legislative proposal for "Food and Feed", in June 2002 the applicant committed on a voluntary basis to providing detection and validation methods for its product in collaboration with the Joint Research Centre of the Commission (hereafter the "JRC").

7.2230 The European Communities notes that agreement on the amount of data and material and the circumstances of their submission to the JRC took a considerable amount of time. All the necessary data were received in proper condition in mid-September 2003. The pre-validation study was initiated in October and was concluded after the applicant delivered the full data set at the end of November 2003. Some additional testing on the method and materials was carried out in early 2004. The collaborative study of method validation was launched in April 2004 and was expected to be finished by the end of June 2004.

7.2231 The **Panel** begins its analysis by addressing the Commission's failure up to August 2003 to submit a draft measure to the Regulatory Committee.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2232 We recall that the SCF issued a positive evaluation of this application in February 2002. Following the issuance of the SCF opinion, the Commission did not submit a draft measure to the Regulatory Committee at any point up to August 2003. The United States and Argentina argue that the Commission should have prepared and submitted a draft measure to the Regulatory Committee shortly after the issuance of the SCF opinion.

7.2233 The record shows that some two months after the issuance in February 2002 of the favourable opinion by the SCF Instead, on 23 April 2002, the applicant informed the Commission that it was no longer seeking to obtain approval to place on the market unprocessed GA21 maize grain for food use. The applicant explained that this food use would be subject to Directive 90/220[1597], and noted that the progress of the application concerning GA21 maize (EC-78) under Directive 90/220 had been suspended for some time. The applicant was hoping that this move would enable the application under Regulation 258/97 to proceed immediately.[1598]

[1597] Pursuant to Article 9 of Regulation 258/97, in the case of foods or food ingredients containing or consisting of GMOs, the approval decision to be taken must "respect the environmental safety requirements laid down by Directive 90/220 to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]".

[1598] Exhibit EC-91/At. 44.

7.2234 The record further shows that more than a month later, on 5 June 2002, the Commission services met with the applicant. According to a Commission report about the meeting, the Commission indicated at the meeting that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1599] Specifically, the Commission sought voluntary commitments with regard to the labelling of foods and food ingredients derived from GA21 maize as well as with regard to detection methods and reference materials.

7.2235 At the June 2002 meeting, the applicant agreed to provide additional information and materials, including a detection method, so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. The Commission's report of the meeting notes in this regard that the Commission might present a draft measure to the Regulatory Committee in November 2002, provided that a validated detection method was available by then. At the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.2236 The record of the approval procedure concerning GA21 maize (food) does not contain any evidence to show that the Commission in this procedure launched inter-service consultations on a draft measure after the issuance in February 2002 of the favourable opinion by the SCF. This contrasts with the record of other approval procedures which contains such evidence.[1600] Therefore, we cannot assume that inter-service consultations were launched on a draft measure on GA21 maize (food).

7.2237 Indeed, it appears that the Commission preferred first to explore whether the applicant would be willing to provide certain additional information, or to make certain additional commitments, on the basis of proposals for new EC legislation. While we accept that the applicant's response could have had an impact on the kind of draft measure on which the Commission would launch inter-service consultations, this circumstance would not explain why the Commission waited for more than three months after the issuance of the SCF opinion before approaching the applicant.

7.2238 Since the Commission was seeking voluntary commitments, it was possible that the applicant would reject the Commission's request in its entirety. Had the applicant done so, the Commission would have delayed the procedure by more than three months, as the Commission would have launched inter-service consultations only at that point.

7.2239 The record contains no information which suggests that June 2002 was the earliest date on which the Commission could have sought the relevant voluntary commitments. Indeed, the European Communities itself stated in relation to Regulation 258/97 that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In the light of this, we fail to see why it would not have been possible for the Commission to explore the possibility of voluntary commitments with the applicant already in March 2002 rather than only in June 2002. Indeed, the Commission had circulated proposals for appropriate EC legislation as early as July 2001. Had the applicant said no to the Commission's request, this would have disposed of the issue.

7.2240 In fact, it is clear from the record that the applicant showed little interest in undertaking additional commitments with regard to labelling. However, the applicant did accept the

[1599] Exhibit EC-91/At. 45.
[1600] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 60.

Commission's request to provide reference material and a detection method which was to be validated by the Joint Research Centre of the Commission. It appears to us from the record that the applicant accepted this request on the basis of the Commission proposals for new legislation, since the European Parliament was apparently scheduled to debate the proposals only in July 2002. This supports our view that the Commission could have sought this particular commitment prior to June 2002.

7.2241 The Commission's report of the June 2002 meeting indicates that the Commission expected "no particular problem with respect to the validation. However, the availability of reference material has not been discussed."[1601] It is clear from this statement that the Commission was aware that relevant material might or might not have been available, and that it was therefore possible that the applicant would require time to put together relevant data and material. Moreover, as this approval procedure shows, a material transfer agreement needed to be reached before any materials would be transferred. Finally, the Commission in its report of the June 2002 meeting made clear that it would not forward a draft measure to the Regulatory Committee until a detection method had been validated. Therefore, had the applicant been made aware of the Commission's request earlier, the detection method could have been validated sooner, and a draft measure would also have been submitted to the Regulatory Committee sooner.

7.2242 Taking account of the foregoing elements, we consider that for the purposes of exploring the possibility of the applicant undertaking voluntary commitments, the Commission could, and should, have approached the applicant soon after the issuance of the SCF opinion (or before) rather than more than three months later.

7.2243 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – and in particular the time taken by the Commission to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long.

7.2244 Regarding DS291, we recall that the United States claims that the approval procedure concerning GA21 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee meeting concerning GA21 maize (food) prior to August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's conduct was a consequence of the general moratorium on approvals.

7.2245 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1601] Exhibit EC-91/At. 45.

Conclusions

7.2246 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning GA21 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning GA21 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning GA21 maize (food) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iii) Bt-11 sweet maize (food) (EC-92)

7.2247 One Complaining Party, the United States, claims that the completion of the approval procedure concerning the Bt-11 sweet maize (food) has been unduly delayed.

7.2248 The **United States** submits that the processing of this application had been delayed at the Commission stage of the process, as the Commission had refused to forward a draft measure to the Regulatory Committee as is required to complete the approval process, and the request remained blocked as of then.

7.2249 The United States also points out that the application concerning Bt-11 sweet maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-11 sweet maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2250 The **European Communities** notes that, after the lead CA sent its initial assessment report to the Commission in May 2000, four member States raised objections and several more requested additional information, relating mainly to the antibiotic resistance marker used (PAT protein) and to the toxicity studies done in relation to this protein as well as to molecular characterization.

7.2251 The Commission requested the opinion of the SCF in December 2000. The SCF requested further data which the applicant only supplied in February 2002. The SCF issued its opinion in April 2002, stating that on the basis of the information supplied in the application and further material supplied by the applicant in response to queries raised by member States and in the light of the published literature, it was to be concluded that Bt-11 sweet maize (food) was as safe for human food use as its conventional counterparts.

7.2252 According to the European Communities, in view of the pending legislative proposal on "Food and Feed", the applicant, on a voluntary basis, agreed to provide detection and validation methods for its product in collaboration with the JRC. The amount of data and material and the circumstances of their submission to the JRC were agreed upon in a planning meeting in October 2002. The first set of material sent at the beginning of 2003 was inadequate in terms of necessary amounts and the method provided by the applicant performed very poorly in a pre-validation study. The applicant delivered a proper method and all the necessary materials only by July 2003. The JRC finalized the validation method in October 2003.

7.2253 In November 2003, the Commission submitted a draft measure to the Regulatory Committee. At member States' request, however, the Commission did not ask for a formal vote, given that several member States considered that the scientific questions they had formulated earlier on the basis of their conflicting national scientific evaluations were still open, and others were still awaiting further scientific risk assessments of their national scientific committees. Between October and early December 2003, three new risk assessments were issued by the member States, all of which conflicted with the SCF opinion.

7.2254 Finally, the Commission asked for the formal vote on its draft measure. However, the draft measure did not obtain a qualified majority in the Regulatory Committee, nor subsequently in the Council. The draft measure was adopted by the Commission on 19 May 2004.

7.2255 With regard to the period of time taken by the Commission before requesting the SCF for an opinion, the **United States** maintains that when the application was first evaluated at the Community level in 2000, member States objected on the basis not of scientific grounds, but the general moratorium. The United States cites, as an example, that Denmark's Agriculture and Fisheries Council recalled "[i]n August 2000, Denmark submitted an objection to the approval of Bt-11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licenses (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products derived from them, the moratorium countries would block any new licenses for the cultivation and marketing of GMOs."[1602] Also in August 2000, France cited the yet to be implemented food and feed regulations as a reason for withholding support for Bt-11 sweet maize (food), choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.[1603]

[1602] Exhibit EC-92/At. 80.
[1603] Exhibit EC-92/At. 23, p.2.

7.2256 According to the United States, there is no scientific basis for the requests from Austria, France and Greece for additional long-term animal feeding studies given the results of the compositional analyses, and the fact that feeding studies conducted on Bt-11 field maize had been provided along with simulated digestibility studies, and acute toxicity tests.[1604] Greece had acknowledged that these latter studies "showed not a single adverse effect in the dosage tested."[1605] Furthermore, Greece did not identify, with any specificity, any deficiencies in the data provided, nor any reason to believe that these proteins would behave any differently than any other protein would spontaneously develop new or different toxic properties or would otherwise interact with other components of the food. Instead, Greece merely noted that "the *in vitro* methodology to study degradability of Btk and PAT proteins can be improved", but failed to specify how.

7.2257 The key difference between sweet and field maize being that sweet maize has a higher amount of natural sugars, the United States maintains that there is no reason to believe that this fact alone would render the results of the safety assessments conducted on the field maize inapplicable to this product. Nonetheless, Austria, Greece and the United Kingdom also argued that additional compositional and safety data were necessary to establish the equivalence between Bt-11 sweet maize (food) and Bt-11 field maize. Austria summarily rejected the applicant's reliance on the risk assessments conducted by the lead CA and the SCP on Bt-11 field maize, on the grounds that this evidence "cannot be considered adequate since sweet maize and field maize have different component spectrums."[1606] Greece required "analyses for all the parameters" (especially for amino acids, fatty acids, anti-nutrients and secondary plant substances) for both the Bt-11 sweet maize (food) and Bt-11 field maize, without identifying any unique property that would make the Bt-11 sweet maize (food) behave differently than all of the data indicated was likely.[1607] Even though the United Kingdom acknowledged that "it is accepted that the protein [in sweet maize] is the same as in the field maize", it nevertheless objected on the grounds that studies relating to the expression of the introduced genes in sweet maize were necessary.[1608] No further explanation was provided for rejecting the results of the safety data conducted on the parent field maize.

7.2258 The United States observes that these concerns were discounted by the SCF. Indeed, the SCF noted that "the distinction between the results for the sweet maize and field maize is not relevant to the assessment as long as the appropriate corresponding non-modified maize is used as control".[1609]

7.2259 With regard to the period after the positive assessment of the SCF in April 2002, the United States notes that the European Communities attempts to justify delays in the processing of the Bt-11 application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risks assessment were issued by the Member States, all of which conflicted with the SCF opinion".[1610] These risk assessments were supposedly provided by Austria, Belgium and France. The United States maintains that the EC contention is unsupported by the record. No risk assessments were submitted during that time period, according to the European Communities' own chronology. None of the documents submitted during that time period contain any purported risk assessments conducted by France, Austria, or Belgium. At the 10 November 2003 meeting of the

[1604] The applicant had referenced the whole food feeding studies it had performed on Bt-11 field maize in its submission of 28 November 1998. The European Communities did not provide the original submission of 6 April 1998 for processed products of sweet maize.

[1605] Exhibit EC-92/At. 28.

[1606] Exhibit EC-92/At. 25.

[1607] Exhibit EC-92/At. 28.

[1608] Exhibit EC-92/At. 22.

[1609] Exhibit EC-92/At. 53, section 3.10.

[1610] Responses by the European Communities to the questions posed by the Panel on 3 June 2004, Response to Question 1.

Regulatory Committee,[1611] only a comment was provided by France, not a risk assessment.[1612] At the Regulatory Committee meeting on 8 December 2003, Austria[1613], Belgium[1614] and France[1615] submitted written declarations to their votes. But none of these was a risk assessment. Rather, when the Regulatory Committee failed to obtain a qualified majority, it was because certain member States objected due to the proposed new traceability and labelling regulations (which did not become effective until April 2004).[1616]

7.2260 The **Panel** begins its analysis by addressing the Commission's failure up to August 2003 to submit a draft measure to the Regulatory Committee.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2261 We recall that the SCF issued a positive evaluation of this application in April 2002. Following the issuance of the SCF opinion, the Commission did not submit a draft measure to the Regulatory Committee at any point up to August 2003, although subsequently it did submit a draft measure to the Regulatory Committee which was on the Committee's agenda in November 2003. The United States argues that the Commission should have prepared and submitted a draft measure to the Regulatory Committee shortly after the issuance of the SCF opinion in April 2002.

7.2262 More than a month and a half later, on 5 June 2002, the Commission services met with the applicant. The Commission in its report of the meeting states that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1617]

7.2263 More specifically, the report of the meeting addresses the issue of "[d]etection methods, traceability, reference materials [and] identification". According to the report, the applicant "agree[d] to provide" the necessary information and materials to the JRC in a timely manner.[1618] There is nothing in the record which indicates that this "agreement" from the applicant was not voluntary. The report notes that a draft measure might be presented to the Regulatory Committee in November 2002, provided that a validated detection method was available by then. At the time of establishment of the

[1611] Exhibit EC-92/At. 67.

[1612] The French comment does not "evaluate the potential for adverse effects on human or animal health" posed by the sweet corn's different sugar metabolism from field corn. The comment is concerned with unintended effects, theoretical risks not identified by any of the existing protein toxicity or animal studies conducted. As the Commission stated in its Proposal for a Council Decision of 28 January 2004, "[t]he concerns raised in the opinion of the 'Agence française de sécurité sanitaire des aliments' (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt-11 carried out by the competent authorities of the Netherlands". In fact, these concerns were also expressed in two AFSSA opinions of 21 July 2000 and 20 March 2001 and were duly considered by the SCF in its opinion of 17 April 2002, which confirmed the findings of the initial assessment that Bt-11 sweet maize is as safe for human food use as conventional maize. Exhibit EC-92/At. 77.

[1613] Exhibit EC-92/At. 71.

[1614] Exhibit EC-92/At. 73.

[1615] Exhibit EC-92/At. 72.

[1616] Exhibit EC-92/Ats. 67 ("Finally, several Member States questioned the opportunity to proceed with the authorization of this product in anticipation of the coming into application of Regulation (EC) 1829/2003 and 1830/2003."),71,74,75 and76.

[1617] Exhibit EC-92/At. 54.

[1618] *Ibid*.

Panel, the question of the validation of the detection method had not yet been resolved, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.2264 The record of the approval procedure concerning Bt-11 sweet maize (food) does not contain any evidence to show that the Commission in this procedure launched inter-service consultations on a draft measure after the issuance in April 2002 of the favourable opinion by the SCF. This contrasts with the record of other approval procedures which contains such evidence.[1619] Therefore, we cannot assume that inter-service consultations were launched on a draft measure on Bt-11 sweet maize (food).

7.2265 Indeed, it appears that the Commission preferred first to explore whether the applicant would be willing to provide certain additional information, or to make certain additional commitments, on the basis of proposals for new EC legislation. While we accept that the applicant's response could have had an impact on the kind of draft measure on which the Commission would launch inter-service consultations, this circumstance would not explain why the Commission waited for more than a month and a half after the issuance of the SCF opinion before approaching the applicant.

7.2266 Since the Commission was seeking voluntary commitments, it was possible that the applicant would reject the Commission's request in its entirety. Had the applicant done so, the Commission would have delayed the procedure by more than a month and a half, as the Commission would have launched inter-service consultations only at that point.

7.2267 The record contains no information which suggests that June 2002 was the earliest date on which the Commission could have sought the relevant voluntary commitments. Indeed, the European Communities itself stated in relation to Regulation 258/97 that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In the light of this, we fail to see why it would not have been possible for the Commission to explore the possibility of voluntary commitments with the applicant earlier than only in June 2002. Indeed, the Commission had circulated proposals for appropriate EC legislation as early as July 2001. Had the applicant said no to the Commission's request, this would have disposed of the issue.

7.2268 In fact, the applicant did accept the Commission's request to provide reference material and a detection method which was to be validated by the Joint Research Centre of the Commission. It appears to us from the record that the applicant accepted this request on the basis of the Commission proposals for new legislation, since the European Parliament was apparently scheduled to debate the proposals only in July 2002. This supports our view that the Commission could have sought this particular commitment prior to June 2002.

7.2269 As we have noted earlier in the context of the approval procedure concerning GA21 maize (food), we have reason to believe that in seeking the provision by the applicant of a detection method, the Commission was aware that relevant reference material might or might not have been available, and that it was therefore possible that the applicant would require time to put together relevant data and material. Moreover, as the European Communities itself points out, the amount of data and material and the circumstances of their submission to the JRC needed to be agreed upon. Finally, the Commission in its report of the June 2002 meeting made clear that it would not forward a draft measure to the Regulatory Committee until a detection method had been validated. Therefore, had the applicant been made aware of the Commission's request earlier, the detection method could have been

[1619] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 60.

validated sooner, and a draft measure would also have been submitted to the Regulatory Committee sooner.

7.2270 In our view, since the Commission sought the provision of a detection method on a voluntary basis, the Commission could even have approached the applicant prior to the issuance of the SCF opinion in April 2002. The applicant would then have had the opportunity to make sure that reference material and other documents and materials relevant to the validation of a detection method were available if and when the Commission sought their transmission. Indeed, we note that in the approval procedure concerning NK603 maize (food), work on method validation was undertaken even before the Commission had sought a scientific opinion of the EFSA.[1620]

7.2271 Taking account of the foregoing elements, we consider that for the purposes of exploring the possibility of the applicant undertaking voluntary commitments, the Commission could, and should, have approached the applicant either before or soon after the issuance of the SCF opinion rather than more than a month and a half later.

7.2272 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – and in particular the time taken by the Commission to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long.

7.2273 In addition, we recall that the United States claims that the approval procedure concerning Bt-11 sweet maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee meeting concerning Bt-11 sweet maize (food) prior to August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's conduct was a consequence of the general moratorium on approvals.

7.2274 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2275 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's conduct was a consequence of the general moratorium on approvals. Based on these

[1620] Exhibit EC-96/At. 34, as well as entries concerning 20 February 2003 and 31 March 2003.

findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-11 sweet maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-11 sweet maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iv) LL soybeans (food) (EC-93)

7.2276 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning LL soybeans (food) has been unduly delayed.

7.2277 The **United States** submits that the lead CA (Belgium) refused to forward the application for LL soybeans (food) for consideration at the Community level.

7.2278 The United States also points out that the application concerning LL soybeans (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL soybeans (food) is excessive and unjustified and, hence, undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2279 **Argentina** claims that as of the date of Argentina's first written submission the application was delayed at the member State level for 5 years and 8 months without a final decision on its approval. Argentina asserts that the European Communities neither processed the application nor conducted the required risk assessment. Argentina argues that there is no scientific justification for the delay, as the "initial reports" were not prepared.

7.2280 The **European Communities** notes that the application for LL soybean (food) was with the Belgian CA only as of February 1999. The Commission gave notice of the Belgian application to all other member States in March 1999. In April 1999, the Belgium Biosafety Council requested additional information from the applicant in order to proceed with the initial assessment. The request touched upon the issues of substantial equivalence and presence of transgenic PAT DNA and PAT protein.[1621] The applicant did not fully respond to this request for additional information. Greece (June 1999) and Italy (July 1999) also asked for additional information on various points such as nutritional and biochemical characterization and toxicity of the transgenic plant, but did not receive any answer.[1622] In April 2004, the lead CA reminded the applicant to respond to the requests for additional information so that it would be able to finalize the pending assessment report.

7.2281 The European Communities submits that the United States and Argentina choose to ignore the fact that the applicant failed to provide the additional information that was requested by the lead CA in April 1999, and by Greece and Italy in June and July 1999. According to the European Communities, all three requests for additional information remained mostly unanswered. The European Communities also notes that on 6 July 2004, the applicant withdrew its application.

[1621] Exhibit EC-93/At. 11.
[1622] Exhibit EC-93/Ats. 16 and 17.

7.2282 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2283 We note that contrary to what the European Communities asserts, the application concerning LL soybeans (food) was with the Belgian CA as of early December 1998, and not only as of February 1999.[1623] On 8 December 1998, the Belgian General Food Inspectorate requested the Belgian Biosafety Council to prepare a first evaluation report within 90 days of referral of the file.

7.2284 The record indicates that the Biosafety Council met on the application on 17 December 1998. At that meeting, concerns were raised that while the application focused on animal nutrition, a number of tests concerning possible human consumption impacts were absent. The applicant apparently gave a written undertaking to address these concerns relating to substantial equivalence following instructions from a Belgian expert.[1624]

7.2285 Towards the end of April 1999, the Belgian Biosafety Council responded to a query from the Belgian General Food Inspectorate. The letter notes that the applicant had still not addressed the Biosafety Council's concerns relating to substantial equivalence. The letter further states that the applicant needed to provide additional information regarding the implementation of labelling and, more specifically, the presence of PAT DNA and PAT protein in derived soya products.[1625] The letter of the Biosafety Council concludes by saying that due to the absence of data and information on substantial equivalence and the presence of transgenic PAT DNA and PAT protein it was not possible for the Biosafety Council to issue a final evaluation report with regard to the application concerning LL soybeans (food). We asked the experts advising us whether information regarding substantial equivalence and the presence of transgenic PAT DNA and PAT protein was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that these requests were valid.[1626]

7.2286 In May 1999, the lead CA sent a reminder to the applicant informing it that it had yet to reply to the two requests for additional information referred to in the letter of April 1999.[1627] The lead CA also informed the Commission that the deadline for evaluation of this application would not be met due to the lack of response from the applicant to the aforementioned two requests for additional information.[1628] The record indicates that as of August 2003, the applicant had still not fully replied to the first request relating to substantial equivalence.[1629] It appears that the applicant responded to the first request concerning the presence of PAT DNA and PAT protein in derived soya products, but it is not clear when.[1630]

7.2287 Greece (June 1999) and Italy (July 1999) also requested additional information regarding nutritional and biochemical characterization and toxicity of the transgenic plants. We again asked the experts advising us whether the additional information requested by Greece and Italy was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that the application did not provide all the information which would be expected in order to comply with the recommended Codex evaluation procedure, and therefore the requests for some of this information

[1623] Exhibit EC-93/Ats. 1 and 3.
[1624] Exhibit EC-93/At. 11.
[1625] *Ibid*.
[1626] Annex H, Dr. Nutti's response to Panel Question 48.
[1627] Exhibit EC-93/At. 14.
[1628] Exhibit EC-93/At. 13.
[1629] Exhibit EC-93/At. 25.
[1630] *Ibid*.

were justified.[1631] In December 2000 and again in July 2001, the applicant apparently provided additional information to the lead CA regarding insert characterization, however this information was not provided to us. In the same correspondence, the applicant indicated that information on compositional analyses would be forthcoming at a later date.[1632] Seven months later, in correspondence dated July 2001, the applicant apparently provided information to satisfy these requests, although this information was not included in the evidence provided to us.[1633]

7.2288 In August 2001, the lead CA requested clarification regarding nutritional composition, stating that the data provided by the applicant in July 2001 had not adequately addressed the lead CA's request of April 1999. We again asked the experts whether this clarification was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti noted that the information requested would normally be necessary to judge the safety of the product, however given the incompleteness of the record, it was impossible for her to determine whether or not this information had previously been provided to the lead CA.[1634] The lead CA also inquired about a broiler chicken growth performance study which the applicant had said was already included in the dossier, but which the lead CA could not find. Finally, the lead CA indicated that in accordance with new recommendations by the Biosafety Council on molecular characterization, the lead CA would be requesting some additional information on molecular characterization.

7.2289 The record suggests that the applicant never replied to the August 2001 request for clarification. Indeed, in June 2003, in internal e-mail correspondence concerning a request from the Commission for an update on this dossier, the lead CA highlighted the fact that the applicant had not provided the requested broiler chicken growth study. The lead CA also indicated that it had requested, but not received, additional information on molecular characterization. However, the record does not indicate that such a request was forwarded to the applicant.[1635]

7.2290 It is unfortunate that the evidence provided on this application is incomplete. While the experts indicated that much of the information requested by the lead CA and by other member States was necessary to ensure a valid safety assessment, it was not possible to determine to what extent such information may already have been provided by the applicant. It is also very difficult to determine from the information before us whether particular requests for information were met by the applicant.

7.2291 This said, as noted earlier, it appears that the applicant never fully replied to the lead CA's April 1999 request for additional information. As also noted, the part of the request which remained unresolved, notwithstanding the applicant's undertaking to provide the relevant information, was made known to the applicant already after the December 1998 meeting. It also appears that the responses which were given by the applicant in response to the April 1999 request were not provided in a timely manner. Furthermore, the record suggests that the applicant never responded to the August 2001 request for clarification. In fact, there does not appear to have been any further communication from the applicant until it withdrew its application in July 2004.

7.2292 In the light of the foregoing elements, and in particular the fact that the applicant did not provide information it apparently undertook to provide and otherwise failed to respond to requests for information which were not explicitly challenged, we are not persuaded by the United States' and

[1631] Annex H, Dr. Nutti's response to Panel Question 49.
[1632] Exhibit EC-93/At. 21.
[1633] Exhibit EC-93/At. 22.
[1634] Annex H, Dr Nutti's responses to Panel Question 50.
[1635] Exhibit EC-93/At. 25.

Argentina's assertion that the time taken by Belgium up to August 2003 to assess the application concerning LL soybeans was unjustifiably long.

7.2293 In view of our conclusion with regard to the time taken by Belgium for its assessment, we go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Total amount of time taken since submission of application

7.2294 The United States and Argentina also put forward the argument that the total amount of time during which the application concerning LL soybeans (food) was pending is excessive and unjustified. The application concerning LL soybeans (food) was first submitted for approval at the end of November 1998. This means that as of August 2003, the approval procedure had been pending for four years and nine months.

7.2295 We agree with the United States and Argentina that, in absolute terms, this is a long period of time for an initial assessment. However, as we have explained earlier, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2296 The United States argues that that before there was an EC moratorium, approval procedures used to be completed in less than three years. Even if the United States were correct, however, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL soybeans (food) was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process that particular application.

7.2297 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for well over four years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL soybeans (food) had already been pending for almost seven months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1636] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL soybeans (food) was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2298 Accordingly, the Panel is unable to accept the United States' and Argentina's assertion that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

[1636] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

Conclusions

7.2299 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its initial assessment of the application concerning LL soybeans (food) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL soybeans (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning LL soybeans (food), the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its initial assessment of the application concerning LL soybeans (food) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. In the light of these findings, the Panel concludes that in respect of the approval procedure concerning LL soybeans (food), Argentina has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(v) MON810 x GA21 maize (food) (EC-94)

7.2300 One Complaining Party, the United States, claims that the completion of the approval procedure concerning MON810 x GA21 maize (food) has been unduly delayed.

7.2301 The **United States** argues that approval for MON810 x GA21 maize (food), which is produced by conventionally hybridizing two "parental" biotech products, MON810 maize and GA21 maize, has been delayed by the failure of the lead CA to complete its initial assessment. More specifically, the United States argues that at the time of establishment of the Panel, the application had already been under consideration by the lead CA for three and a half years. The United States contends that this lag had two distinct causes.

7.2302 According to the United States, one cause for the lag was the undue delay in the EC approval of GA21 maize under Regulation 258/97. The application for approval of MON810 x GA21 maize (food) submitted under Regulation 258/97 referenced the detailed risk assessments undertaken on the parental biotech products, complemented with confirmatory safety and characterization data on the MON810 x GA21 hybrid. One parent, MON810 maize, was approved under Directive 90/220 in

1998[1637] and was notified in 1998 on the basis of an opinion of substantial equivalence as required under Regulation 258/97 in 1998.[1638] However, the application for the single trait parent GA21 maize (food) under Regulation 258/97 stalled at the Commission level after the Commission requested an opinion from the SCF in May 2000 and then again after the final SCF opinion in February 2002. Therefore, progress on GA21 maize (food) was a limiting step on the progress of the application concerning MON810 x GA21 maize (food) in the regulatory process. In fact, in its comments on the application for MON810 x GA21 maize (food), Italy stated that "examination of the documentation relating to authorization [of MON810 x GA21 maize] should only be carried out after the marketing of GA21 has been authorized [under Regulation 258/97]."[1639] At the time of establishment of the Panel, the approval of GA21 maize (food) under Regulation 258/97 had not yet been granted.

7.2303 The United States contends that the other cause of the lag reflected, in part, the need for the applicant to respond to requests for information that were scientifically unjustified. The United States points out that the lead CA insisted on molecular characterization of the MON810 x GA21 line without regard to the previous data that had been submitted on the parental lines. In particular, the lead CA requested an additional whole food study in mice.[1640] The rationale offered for this request was the need to address hypothetical concerns that unknown pieces of DNA could be scattered over the genome. The impact of any such insertions can be determined by evaluating the compositional analyses of the plant as well as its agronomic performance. If both analyses indicate no unexpected changes, the United States argues, there is no basis on which to hypothesize a food safety concern for food from the plant. In this case, such assessments had been performed on each of the parental lines and no unexpected changes were observed. At no time did the lead CA provide any explanation of the reason it believed that the compositional analyses or feeding studies previously submitted on both the parent lines, as well as the compositional analyses submitted on the hybrid, did not adequately address this issue.

7.2304 The United States notes that, nonetheless, the applicant analysed the composition of the MON810 x GA21 maize, which was found to be comparable to that of the parental lines and other commercial maize varieties.[1641] The applicant also had previously submitted several whole food feeding studies, including a 90-day feeding study in rats using MON810 maize or GA21 maize, and a broiler chicken feeding study using grain from MON810 x GA21 maize. None of these studies revealed any adverse effects.

7.2305 Furthermore, the United States notes, the lead CA requested further information on the levels of EPSPS protein expressed in the hybrid lines, although such information is not relevant to assessing the risks given the known safety information about the EPSPS protein.[1642] The lead CA also requested unnecessary comparisons of compositional data between the new hybrid and non-transgenic control lines. The data submitted in the application analysed the new hybrid in comparison to the

[1637] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[1638] Exhibit US-132.

[1639] Exhibit EC-94/At. 11.

[1640] Exhibit EC-94/At. 12.

[1641] Exhibit EC-82/At. 9.

[1642] The United States refers to LA Harrison, MR Bailey, MR Naylor, JE Ream, BG Hammond, DL Nida, BL Burnette, TE Nickson, TA Mitsky, ML Taylor, RL Fuchs, and SR Padgette, "The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolypyruvylshikimate-3-Phosphate Synthase from Agrobacterium sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavaged Mice", *Journal of Nutrition* 126:728-740 (1996) (Exhibit US-143).

transgenic parental lines.[1643] The transgenic parental lines had already been shown to be substantially equivalent to non-genetically modified maize except for the introduced traits. Given all of the data that had been submitted on both parental lines, the United States argues that the requests for yet further studies lacked any scientific basis.

7.2306 According to the United States, the United Kingdom also insisted that the applicant provide extensive characterization of the new hybrid, rather than rely on the analyses previously carried out on the transgenic parental lines.[1644] As part of this request, the United Kingdom requested molecular characterization to "confirm[] the absence of antibiotic resistance markers and have details regarding the homology between the two constructs introduced as a result of the crosses."[1645] Given that neither parent contained an antibiotic marker gene, there is absolutely no scientific basis, in the United States' view, for theorizing that cross-breeding between the two products would somehow introduce such a gene.

7.2307 Under these circumstances, the United States argues that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize (food) as long as consideration of the applications for the single trait parent GA21 maize remained suspended under the moratorium. The United States contends that the delay in the application for MON810 x GA21 maize (food) and GA21 maize (food) is thus a direct consequence of the delays in the application for GA21 maize under the moratorium. The United States further points out that because of the delay in the approval procedure concerning GA21 maize (food), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). Nonetheless, the applicant has continued to pursue the necessary regulatory clearance for MON810 x GA21 maize (food).

7.2308 The United States submits, in addition, that the application concerning MON810 x GA21 maize (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MON810 x GA21 maize (food) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2309 The **European Communities** argues that the lead CA requested additional information from the applicant in July 2000, and that that request was only partly answered in February 2002. Contrary to the United States, the European Communities maintains that the lead CA request for a whole food study in mice was necessary to assess unintended effects caused by possible additional DNA fragments. The request was made on valid grounds. Therefore, the delay caused by it cannot be considered "undue." The European Communities adds that issues such as molecular characterization of inserted DNA from transgenic parent lines, the determination of flanking DNA or compositional analysis, still remain unaddressed. Furthermore, the European Communities considers that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open.

7.2310 The **Panel** commences its analysis with the alleged delay at member State level.

[1643] Exhibit EC-94/At. 2.
[1644] Exhibit EC-94/At. 10.
[1645] *Ibid*.

Delay at member State level

7.2311 We recall that although the application was submitted on 29 February 2000, the record shows that the first contact by the lead CA to request additional information from the applicant occurred only on 17 July 2000[1646], *i.e.*, more than four and a half months after receipt of the application. The response to the July 2000 request for information was provided by the applicant only on 15 February 2002. Subsequently, there was a further, five-month delay before the lead CA followed up with the applicant to request additional information on 2 July 2002. Finally, we note that no information has been provided regarding any action on this application between July 2002 and August 2003. It appears that during that period the applicant did not respond to the lead CA's July 2002 request for information.

7.2312 The United States contends that the lengthy delay caused by the applicant due to the time it took to respond to the July 2000 request for information occurred, in part, because there was no justification for requesting the relevant data. In our earlier findings, we observed that the experts expressed the view that whereas some of the information requested by the lead CA was not necessary to ensure the validity of the safety assessment, other requested information was indeed needed. We also previously noted the disagreement of the European Communities with the views expressed by the experts regarding the need for the data requested.

7.2313 Even accepting that contrary to the views of the experts the information requested by the lead CA in July 2000 was necessary to ensure the validity of the safety assessment, this could not provide a justification for the time taken by the lead CA for its assessment of the application both before and after the July 2000 request for information.

7.2314 In examining the issue of the time taken by the lead CA before and after the July 2000 request, we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2315 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of July 2000. We note that when the Commission circulated notice of this application to all member States, it indicated that the initial assessment was to be completed by the lead CA by 16 June 2000 at the latest.[1647] However, by 16 June 2000, the lead CA not only had not completed its initial assessment, but it apparently had not even identified any need for further information. It was not until one full month after the deadline circulated by the Commission that the lead CA forwarded an initial request for information.

7.2316 The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to July 2000. Even if it were accepted that in this procedure the lead CA could not have

[1646] Exhibit EC-94/At. 12.
[1647] Exhibit EC-94/At. 5.

met the mid-June deadline circulated by the Commission, this would not imply that the lead CA could not have requested missing information much sooner, rather than a full month after the date on which it should have completed its entire initial assessment.

7.2317 We note that three member States submitted substantive comments or requests for further data prior to July 2000.[1648] However, Regulation 258/97 does not require the lead CA to await comments from other member States, let alone possible responses thereto from the applicant, prior to undertaking its initial assessment.

7.2318 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forward an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2319 We now turn to the time taken by the lead CA after it had received the applicant's response to its initial request for information of July 2000. As we indicated above, four and a half months lapsed between the receipt of the information requested in July 2000 and the next request, in July 2002, for additional information. Thus, the lead CA took more time to assess the additional information than it should have used, in accordance with Regulation 258/97, to complete its entire initial assessment.

7.2320 As with the time taken by the lead CA up to the first request for information, the European Communities asserts that the time taken by the lead CA up to the second request for information was necessary to resolve scientific and technical issues. However, the European Communities provides no specific justification for why the lead CA required more than four and a half months to complete its consideration of the responses provided and to identify short-comings. It is pertinent to note in this respect that the information provided by the applicant in response to the July 2000 request was 34 pages long. Given this, and in the absence of a specific justification offered by the European Communities, we are not convinced that the lead CA could not have evaluated much sooner than it did whether additional information was still needed. We also consider that the Dutch CA could have forwarded its July 2002 request for additional information to the applicant at a much earlier date even while following a precautionary approach.

7.2321 In relation to the time taken by the lead CA both before and after the July 2000 request for information, we note, as an additional matter, the European Communities argument that the assessment of a hybrid product such as MON810 x GA21 maize cannot be concluded as long as the assessment of one of its parental lines is still open. Thus, the European Communities appears to argue that the time taken by the lead CA to assess the application concerning MON810 x GA21 maize (food) is justified by the fact that the lead CA was waiting for the result of the Community level assessment of one of the parental lines of this hybrid product, GA21 maize (food).

7.2322 It is correct that between February 2000 and July 2002, the application concerning GA21 maize (food) was still being evaluated at Community level. However, the record does not indicate that the Dutch CA ever stated that it was unable to proceed due to the failure of the European Communities to approve the GA21 maize (food) parent. Moreover, we recall that it was the same Dutch CA which assessed the application concerning GA21 maize (food) and which in late January 2000 forwarded it to the Commission with a favourable assessment. Therefore, we see no reason why

[1648] Exhibit EC-94/Ats. 9-11.

the Dutch CA would not be in a position to reach a conclusion also with regard to the application concerning the hybrid product, *i.e.*, MON810 x GA21 maize.

7.2323 As a general matter, it may be correct to say, as the European Communities does, that "the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open". However, it would seem that the assessment of the parental lines could also be made in the context of the assessment of the hybrid. At any rate, the Dutch CA could not have "concluded" the assessment of the application concerning MON810 x GA21 maize (food) completely on its own. If other member States had concerns with the Dutch assessment of the application concerning GA21 maize (food) (even though that assessment was confirmed by the SCP in early 2002), they could have raised an objection on that basis to the Dutch assessment of the application concerning MON810 x GA21 maize (food) and the assessment of that application would then have been "concluded" at Community level.

7.2324 For these reasons, it is not apparent to us that the Dutch CA needed to keep, or would have been justified in keeping, the application at the member State level in order to avoid the possibility of conflicting assessments of MON810 x GA21 maize (food), and we therefore do not consider that the fact that one of the parental lines was still pending justified the Netherlands in not completing its assessment of the application concerning MON810 x GA21 maize (food).

7.2325 Taking account of all of the aforementioned elements, we consider that upon receipt of the original application and subsequently upon on receipt of the information requested by it in July 2000, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded appropriate requests to the applicant more promptly.

7.2326 Based on the above considerations, we therefore conclude that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize (food) was unjustifiably long.

7.2327 In addition, we recall that the United States claims that the approval procedure concerning MON810 x GA21 maize (food) was unduly delayed because, due to the moratorium, the Netherlands failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands for its initial assessment of MON810 x GA21 maize (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2328 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2329 In the light of the above, we reach the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize was

> unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MON810 x GA21 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MON810 x GA21 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vi) Bt-1507 maize (food) (EC-95)

7.2330 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (food) has been unduly delayed.

7.2331 The **United States** argues that the lead CA (Netherlands) refused to forward this application to the Commission, thereby unduly delaying its consideration for approval.

7.2332 The United States also points out that the application concerning Bt-1507 maize (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2333 The **European Communities** observes that after receiving the application in February 2001, the lead CA asked for additional information in June 2001. This information was finally provided in February 2003. Between February 2003 and July 2003, there was ongoing correspondence between the applicant and the lead CA on additional information to be submitted by the applicant, in particular on labelling, monitoring, molecular characterization, and event-specific detection methods. The lead CA finalized the initial assessment report in November 2003 and concluded that the consumption of Bt-1507 maize as well as foods and food ingredients derived from it were as safe for humans as the consumption of the non-genetically modified counterparts.

7.2334 The European Communities further notes that the Commission forwarded the initial assessment report to member States for comments in December 2003, and received comments and reasoned objections against the initial assessment. On 26 March 2004, the complete dossier (including responses to the objections and comments raised by member States) was forwarded to EFSA for consideration under Regulation 1829/2003. In parallel, the applicant undertook the steps to ensure the production of certified reference material and for the validation of a detection method by the JRC.

7.2335 The **Panel** notes that the United States' claim is based on an alleged delay at member State level.

Delay at member State level

7.2336 We recall that the application concerning Bt-1507 maize (food) was submitted on 15 February 2001. However, the first request for additional information from the lead CA was made only on 28 June 2001, *i.e.*, almost four and a half months following receipt of the application. Although the applicant apparently provided a partial response in November 2001, it appears that it did not provide all of the information requested until 12 February 2003. Following the twenty-month period taken by the applicant to provide all the information requested, in March 2003, the lead CA requested further clarifications, which were provided in May 2003. In June 2003, the lead CA posed questions in relation to the applicant's May 2003 reply. The applicant provided answers by 9 July 2003. The information as provided by 9 July 2003 was apparently deemed sufficient by the lead CA to conclude its assessment. As noted, a positive assessment was reported on 4 November 2003.

7.2337 It is clear from the foregoing that the major delay in the assessment of this application is attributable to the time taken by the applicant to provide the information requested in June 2001. We asked the experts advising us for their views on the necessity of the information requested by the lead CA in June 2001 to ensure that the conclusions of the safety assessment were valid. We recall that the experts considered that some of the information requested by the lead CA in June 2001 was not necessary to ensure the validity of the safety assessment for Bt-1507 maize (food). This included some of the information which was not provided by the applicant until February 2003.

7.2338 Even if we were to accept that all of the information requested by the lead CA in June 2001 was necessary to ensure the validity of the safety assessment, this could not provide a justification for the time taken by the lead CA for its assessment of the application before the June 2001 request for information. We recall that the application concerning Bt-1507 maize (food) had been under review in the Netherlands for more than four and a half months before the Dutch CA forwarded its June 2001 request for information.

7.2339 In examining the issue of the time taken by the lead CA before the June 2001 request, we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2340 We note that by the time the lead CA forwarded its first request for information at the end of June 2001, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by a month and a half, yet it was far from completing its initial assessment. The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to the end of June 2001. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much more promptly than it did whether additional information was still needed.

7.2341 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2342 Taking account of all of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2343 Based on the above considerations, we thus conclude that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information – was unjustifiably long.

7.2344 In addition, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (food) was unduly delayed because, due to the moratorium, the Netherlands failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of the Netherlands to complete the initial assessment of the application concerning Bt-1507 maize (food) by August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands failure to complete its initial assessment by August 2003 was a consequence of the general moratorium on approvals.

7.2345 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2346 In the light of the above, we reach the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (food) – particularly the time taken prior to the lead CA's initial request for additional information – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vii) NK603 maize (food) (EC-96)

7.2347 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning NK603 maize (food) has been unduly delayed.

7.2348 The **United States** argues that although the application concerning NK603 maize (food) eventually received a positive assessment from the lead CA (Netherlands), this product was at the member State level for almost 19 months, instead of the 90 days foreseen by Regulation 258/97. Of this period of time, only three and a half months were used by the applicant to provide additional information; the lead CA used the remaining fourteen and a half months.

7.2349 The United States questions certain requests for additional information from the lead CA, arguing they were scientifically unnecessary. For example, the lead CA requested an additional whole food feeding study in mice or rats, to address concerns about the presence of unintended DNA fragments that the applicant had identified as part of their molecular characterization data.[1649] The lead CA stated that "the presence of additional unintended modifications cannot be excluded with sufficient certainty". The United States argues that the mere fact that an additional insert is present does not necessarily mean that the product presents an additional risk. Rather, the determination turns on the results of all of the other data and information provided by the applicant, which the lead CA failed to take into consideration in making this request. If the results of those tests raise questions, then further examination would be warranted. But in this case, the applicant had conducted compositional analysis and a broiler chicken whole food study with the product containing the additional insert, and in these circumstances would have detected any resulting changes relevant to food safety. The United States observes that the applicant nevertheless conducted the requested test, which identified no adverse effects.

7.2350 The United States further argues that once the application had reached the Community level Austria filed an objection in respect of the application for NK603 maize (food) on the grounds that not only acute but also sub-chronic, mutagenic, reproductive and ecotoxic effects of the protein (EPSPS) should be studied. However, Austria failed to discuss the results of the acute studies, or to provide an explanation of why the proteins in this product would behave differently than all available data indicate is likely. The United States submits that given that EPSPS proteins are commonly found in a wide variety of food sources which have a long history of safe use, the available information regarding the enzyme function of the protein, lack of homology to toxic proteins based on bioinformatics searches, and lack of acute oral toxicity when administered to mice at high doses, the additional toxicological testing for the EPSPS protein that Austria demanded is unfounded and unreasonable. Such testing exceeds Codex Alimentarius guidelines,[1650] as well as the European Communities' own Scientific Committee Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (March 2003).

7.2351 The United States submits, in addition, that the application concerning NK603 maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning NK603 maize (food) is undue. The

[1649] Exhibit EC-96/At. 7.

[1650] The United States refers to Codex Alimentarius, "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants", CAC/GL 45-2003, paras. 37, 38.

United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2352 **Argentina** argues that NK603 maize (food) was stalled at various stages of the approval process under Regulation 258/97. Argentina notes that the assessments performed by the lead CA and subsequently the EFSA concluded that there was no evidence of risk to human health or life. Therefore, it is clear that the delays by the lead CA to complete its initial assessment and forward this application to the Commission were not justified.

7.2353 The **European Communities** notes that the application for food use of the NK603 maize was submitted to the Netherlands in 2001. After the applicant submitted additional information requested by the lead CA, the lead CA completed its evaluation in November 2002 and sent its initial assessment report to the Commission. The eighteen months spent at member State level were due to the incompleteness of the dossier initially submitted by the applicant and the need for further data on molecular characterization and compositional analysis.

7.2354 The European Community further notes that the Commission circulated the dossier to all member States in January 2003. Three member States raised objections and several others requested additional information. The European Communities points out in this connection that Regulation 258/97, in general terms, provided an adequate framework for a risk assessment for GM food products. However, in terms of risk management, it became clear in 1999 that there would have to be new legislation addressing some issues such as labelling and traceability, and also the development and validation of detection methods. The application concerning NK603 maize (food) was partially affected by this situation as it had reached the Community level and the stage of risk management considerations. Thus, it was considered necessary to require the validation of a detection method as a pre-condition for marketing approval. This was done on the basis of a voluntary agreement with the applicant. These detection methods were validated for NK603 maize (food) and the decision-making process was launched immediately after.

7.2355 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2356 We recall that the applicant first submitted the application to the lead CA in April 2001. Two months later the lead CA requested copies of cited literature and data in order to facilitate the lead CA's work. The applicant provided these documents in July 2001. However, the first request for additional information from the lead CA was made only in December 2001, more than four and a half months later. In August 2002, five months after the applicant supplied the information requested by the lead CA, the lead CA's advisory body, the Dutch Health Council's Committee on the Safety Assessment of Novel Foods, finished its assessment report. It was not until November 2002, however, that the lead CA forwarded its assessment report to the Commission.

7.2357 It is clear from the foregoing that the December 2001 request for information led to delay in the consideration of this application inasmuch as the applicant took more than three months and a half to respond to the request. We asked the experts advising us for their views on the necessity of the information requested by the lead CA in December 2001 to ensure that the conclusions of the safety assessment were valid. We recall the view expressed by one of the experts that the request in question was not necessary to ensure the validity of the safety assessment.

7.2358 However, even accepting that the information requested by the lead CA in December 2001 was appropriate to ensure the validity of the safety assessment, this could not provide a justification

for the time taken by the lead CA to assess the application. Notably, the application concerning NK603 maize (food) had been under review in the Netherlands for more than seven months before the Dutch CA forwarded its December 2001 request for information.[1651] Moreover, once the applicant had provided information in response to the Dutch CA's December 2001 request for information, the Health Council's Committee on the Safety Assessment of Novel Foods still took more than four months to complete its initial assessment report. While this report needed to be adopted by the Dutch CA, the report was not forwarded to the Commission for another two and a half months.

7.2359 In examining the issue of the time taken by the lead CA for its assessment of the application concerning NK603 maize (food), we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2360 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of December 2001. We note that by the time the lead CA forwarded its first request for information, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by more than four months, yet it was far from completing its initial assessment.[1652] The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to December 2001. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much more promptly than it did whether additional information was still needed.

7.2361 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2362 Taking account of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

[1651] The application had been under review for more than four months after receipt of copies of the cited literature and data. These copies were not requested by the lead CA until two months after receipt of the application.

[1652] Even if it were considered that a complete application was only available as of the end of July 2001, the lead CA would still have exceeded the three-month period by more than four and a half months.

7.2363 We now turn to consider the time taken by the lead CA to complete and forward its assessment report. To recall, five months after the applicant supplied the information requested by the lead CA in December 2001, the lead CA's scientific advisory body in August 2002 finished its assessment report. However, the lead CA did not forward its assessment report to the Commission until November 2002, *i.e.*, for more than two and a half months.

7.2364 While accepting that the advisory body's assessment report needed to be adopted by the Dutch CA, we recall that in accordance with Regulation 258/96 the Dutch CA was required to complete its entire initial assessment within no more than three months. Given this, and lacking a specific justification by the European Communities, we are not convinced that the Dutch CA could not have adopted the report in question much sooner than it did in the case of the application concerning NK603 maize (food).

7.2365 Thus, based on the above considerations, we conclude that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long.

7.2366 In addition, we recall that the United States claims that the approval procedure concerning NK603 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its initial assessment of the application concerning NK603 maize (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2367 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2368 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning NK603 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning NK603 maize (food), the European

Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning NK603 maize (food) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(viii) RR sugar beet (food) (EC-102)

7.2369 One Complaining Party, the United States, claims that the completion of the approval procedure concerning RR sugar beet (food) has been unduly delayed.

7.2370 The **United States** argues that the lead CA (Netherlands) refused to forward the application to the Commission and that this resulted in undue delay.

7.2371 The United States also points out that the application concerning RR sugar beet (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR sugar beet (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2372 The **European Communities** argues that after discussions between the Dutch CA and the applicant, the request was withdrawn on 16 April 2004. As the reason for its withdrawal the applicant pointed to a decision to stop any further development of the RR sugar beet.

7.2373 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2374 We recall that the applicant submitted the application concerning RR sugar beet (food) to the lead CA on 3 November 1999. However, the first request for additional information from the lead CA was made only on 24 March 2000, almost five months later. The applicant responded one month later. In May 2000, the lead CA requested further information. That information was provided on 7 December 2000. On 16 May 2001, after reviewing the additional information provided by the applicant in December 2000, the lead CA requested further information. The lead CA indicated that it was not yet fully satisfied with the information provided by the applicant concerning the likelihood of specific protein formation. In addition, mentioning recent studies which had shown that "unintended effects on GMOs" were possibly caused by transformation of plant cells, the lead CA also requested a semi-chronic oral toxicity study on rats in order to "to rule out possible undesirable effects [...] with

sufficient certainty".[1653] No specific study was cited in this regard. There is no indication in the evidence before us that the applicant responded to the requests from the lead CA for further information prior to August 2003.

7.2375 We sought the advice of the experts assisting us regarding whether the additional information requested by the lead CA in May 2001 was necessary to ensure that the conclusions of the safety assessment were valid. Dr. Nutti expressed the view that "the information requested by the lead CA regarding the derived proteins and the request for a semi-chronic oral toxicity test on mice or rats with edible parts of sugar beet was not necessary to ensure that the conclusions of the safety assessment were valid". She emphasized that the applicant had already completed an acute toxicity test on rats and conducted studies which confirmed that RR sugar beet "was equivalent in composition and nutrition to the conventional counterpart".[1654]

7.2376 Even accepting that contrary to the views of Dr. Nutti the information requested in May 2001 was necessary to ensure the validity of the safety assessment, this would not provide a justification for the time taken by the lead CA before initially requesting additional information in March 2000 (almost five months), and the time taken to review the information received in December 2000 (five months).

7.2377 In examining the issue of the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food), we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2378 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of March 2000. We note that by the time the lead CA forwarded its first request for information, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by almost two months, yet it was far from completing its initial assessment. The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to March 2000. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have determined much more promptly than it did whether additional information was still needed.

7.2379 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not

[1653] Exhibit EC-102/At. 32.
[1654] Annex H, paras. 775 and 778.

convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2380 Taking account of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2381 We now turn to consider the time taken by the lead CA taken to review the information received in December 2000. To recall, more than five months after the applicant supplied the information requested by the lead CA in May 2000, the lead CA requested further information on protein analysis and a semi-chronic oral toxicity study on rats in order to "to rule out possible undesirable effects". Regarding protein analysis, the lead CA indicated that it was not yet fully satisfied with the information previously provided by the applicant. Regarding the requested toxicity study, the lead CA mentioned recent studies which had shown that "unintended effects on GMOs" were possibly caused by transformation of plant cells. However, as noted, no specific study was cited in this regard.

7.2382 Since it is not clear from the record what recent studies the lead CA was referring to, we have no basis on which to determine whether the lead CA could, and should, have put forward its request for a toxicity study earlier than it did.

7.2383 With regard to protein analysis, we note that the European Communities provides no specific justification for why the lead CA required more than five months to identify a need for yet more information. In the absence of a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much sooner than it did whether additional information on protein analysis was still needed. We are also of the view that the Dutch CA could have requested supplementary information on protein analysis at a much earlier date even while following a precautionary approach.

7.2384 Taking account of the aforementioned elements, we consider that the lead CA could, and should, have determined more promptly that additional information was needed on protein analysis and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2385 Thus, based on the above considerations, we conclude that the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to review the information received in December 2000 and to put forward a new request for information – was unjustifiably long.

7.2386 In addition, we recall that the United States claims that the approval procedure concerning NK603 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its initial assessment of the application concerning RR sugar beet (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2387 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

7.2388 Taking account of the aforementioned elements, we consider that the time taken by the lead CA before initially requesting additional information in March 2000, and the time taken to review the information received in December 2000, is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time.

Conclusion

7.2389 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to review the information received in December 2000 and to put forward a new request for information – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR sugar beet (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR sugar beet (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(d) Summary of the Panel's conclusions

7.2390 In view of the large number of approval procedures reviewed, it is useful to summarize in table form the Panel's conclusions on the Complaining Parties' claim that the European Communities has failed to complete the relevant approval procedures without undue delay and hence has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

7.2391 We should recall that most of the conclusions identified in the table are relevant to only one or two of the three complaints we are examining. Our preceding analysis identifies which of these conclusions are applicable to which complaint(s).

	Approval procedures examined by the Panel	Panel's conclusions on asserted "undue delay" (X: unduly delayed, ✓: not unduly delayed)
1	Falcon oilseed rape	X
2	MS8/RF3 oilseed rape	X
3	RR fodder beet	X
4	Bt-531 cotton	X
5	RR-1445 cotton	X
6	Transgenic potato	✓
7	Liberator oilseed rape	X
8	Bt-11 maize (EC-69)	X
9	RR oilseed rape (EC-70)	X
10	LL soybeans (EC-71)	X
11	LL oilseed rape	✓
12	BXN cotton	X
13	Bt-1507 maize (EC-74)	X
14	Bt-1507 maize (EC-75)	X
15	NK603 maize	X
16	GA21 maize (EC-78)	X
17	MON810 x GA21 maize	X
18	RR sugar beet	X
19	MS1/RF1 oilseed rape (EC-89)	X
20	MS1/RF2 oilseed rape	X
21	GA21 maize (food)	X
22	Bt-11 sweet maize (food)	X
23	LL soybeans (food)	✓
24	MON810 x GA21 maize (food)	X
25	Bt-1507 maize (food)	X
26	NK603 maize (food)	X
27	RR sugar beet (food)	X
Total:		X: 24 ✓:3

10. Consistency of the product-specific measures with Article 8 and Annex C(1)(a), second clause, of the *SPS Agreement*

7.2392 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(a), second clause, of the *SPS Agreement*.

7.2393 Article 8 of the *SPS Agreement* provides:

> "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."

7.2394 Annex C(1)(a), second clause, of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (a) such procedures are undertaken and completed [...] in no less favourable manner for imported products than for like domestic products[.]"

7.2395 **Argentina** argues that Annex C(1)(a), second clause, establishes an obligation to avoid discriminatory treatment. Members must not differentiate the treatment granted to an imported product and to a like domestic product. Argentina submits that in the present case a comparison should be made between the manner in which the EC approval system has been applied in the case of biotech products and the manner in which it has been applied in the case of novel non-biotech products. Specifically, Argentina points to Regulation 258/97 which it says defines a procedure that does not differ in terms of implementation between the two products. According to Argentina, undue delays have, however, occurred only in the treatment of biotech products. Furthermore, Argentina identifies another instance of less favourable treatment of biotech products. In the view of Argentina, prior to 1998, the European Communities granted approvals for the marketing of biotech products, whereas it has not done so since, as a consequence of the general *de facto* moratorium on approvals.

7.2396 The **European Communities** argues that the differences in treatment alleged by Argentina between biotech products and novel non-biotech products, and between biotech products before and after the "moratorium", have nothing to do with the national treatment obligation set forth in Annex C(1)(a), second clause. According to the European Communities, a national treatment issue would arise if the European Communities in the application of its approval system treated imported biotech products differently from domestic biotech products. The European Communities submits that this is not the case as all products are being treated equally, irrespective of their origin. The European Communities considers, therefore, that Argentina has failed to establish an inconsistency with Annex C(1)(a), second clause.

7.2397 The **Panel** notes that Argentina relies on the alleged inconsistency of the product-specific measures with Annex C(1)(a), second clause, to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(a), second clause, before turning to Article 8.

(a) Annex C(1)(a), second clause

7.2398 We note that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(a) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(a). Therefore, the European Communities was and is required under the provisions of Annex C(1)(a) to "undertake and complete" the approval procedures set out in Directives 90/220 and 2001/18 as well as

Regulation 258/97 (to the extent it is an SPS measure) "in no less favourable manner for imported products than for like domestic products".

7.2399 Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications. In our view, the type of measure challenged by Argentina could conceivably constitute, or lead to, a breach of the European Communities' obligations under Annex C(1)(a), second clause, and it can therefore be examined in the light of the provisions of Annex C(1)(a), second clause. Since Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), second clause, this conclusion applies also to Article 8.

7.2400 In order to establish an inconsistency with Annex C(1)(a), second clause, Argentina must establish (i) that imported products have been treated in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures, and (ii) that the imported products which are alleged to have been treated less favourably are "like" the domestic products which are alleged to have been treated more favourably. If either one of these two elements is not met, that is, if imported products have not been treated "less favourably" than the domestic products to which they are being compared, or if these domestic products are not "like" the relevant imported products, Argentina's claim of inconsistency must fail. In the circumstances of this case, we find it appropriate to begin our analysis with the first element. Thus, we will examine first whether Argentina has demonstrated that imported products have been treated in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures.

7.2401 We note the phrase "in no less favourable manner". It is clear from this phrase that Annex C(1)(a), second clause, lays down a national treatment obligation. National treatment obligations are found in numerous WTO agreements. Moreover, the relevant provisions often use similar language. The Appellate Body has confirmed that, in such circumstances, the jurisprudence on a national treatment provision in one WTO agreement may be useful in interpreting a national treatment provision in another WTO agreement.[1655] In the present case, we find it useful to look to the jurisprudence on Articles III:1 and III:4 of the GATT 1994 for appropriate interpretative guidance.

7.2402 Article III:1 provides:[1656]

> "The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production."

7.2403 Article III:4 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

[1655] Appellate Body Report, *US – Section 211 Appropriations Act*, para. 242.
[1656] *Ad* Note omitted.

7.2404 In *EC – Asbestos*, the Appellate Body had this to say on the term "less favourable treatment" as it appears in Article III:4:

> "[...] there is a second element [in addition to the 'likeness' of the products being 'compared] that must be established before a measure can be held to be inconsistent with Article III:4. [...] A complaining Member must [...] establish that the measure accords to the group of 'like' *imported* products 'less favourable treatment' than it accords to the group of 'like' *domestic* products. The term 'less favourable treatment' expresses the general principle, in Article III:1, that internal regulations 'should not be applied … so as to afford protection to domestic production'. If there is 'less favourable treatment' of the group of 'like' imported products, there is, conversely, 'protection' of the group of 'like' domestic products. However, a Member may draw distinctions between products which have been found to be 'like', without, for this reason alone, according to the group of 'like' *imported* products 'less favourable treatment' than that accorded to the group of 'like' *domestic* products. In this case, we do not examine further the interpretation of the term 'treatment no less favourable' in Article III:4, as the Panel's findings on this issue have not been appealed or, indeed, argued before us."[1657]

7.2405 Subsequently, in *Dominican Republic – Import and Sale of Cigarettes*, the Appellate Body again addressed the meaning of the phrase "less favourable treatment", stating that:

> "[T]he existence of a detrimental [competitive] effect on a given imported product resulting from a measure does not necessarily imply that this measure accords less favourable treatment to imports if the detrimental effect is explained by factors or circumstances unrelated to the foreign origin of the product, such as the market share of the importer in this case."[1658]

7.2406 We recognize that Annex C(1)(a), second clause, does not use the phrase "treatment no less favourable", but the phrase "in no less favourable manner". In our view, there is, however, a close conceptual similarity between these two phrases, and the textual difference between them does not, therefore, render inapposite appropriate reliance on the Appellate Body's interpretation of the phrase "treatment no less favourable" as it appears in Article III:4.

7.2407 We also recognize that Annex C(1) to the *SPS Agreement* does not contain a provision analogous to Article III:1 of the GATT 1994. But the fact that Article III:4 expresses a general principle which is explicitly spelt out in Article III:1 does not necessarily mean that a similar general principle cannot be implicit in Annex C(1)(a), second clause. Indeed, we consider that a central purpose of the provisions of Annex C(1)(a), second clause, is precisely to prevent Members from applying their approval procedures in a manner which would afford protection to domestic production. This view is consistent with Article 2.3 of the *SPS Agreement*, which is part of the context of Annex C(1)(a). The second sentence of Article 2.3, which would appear to be applicable to approval procedures, provides that SPS measures "shall not be applied in a manner which would constitute a disguised restriction on international trade". Thus, we do not think that the absence in Annex C(1) of an analogue to Article III:1 should prevent us from being guided by the Appellate Body's interpretation of the phrase "treatment no less favourable".

[1657] Appellate Body Report, *EC – Asbestos*, para. 100 (emphasis in original).
[1658] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 96.

7.2408 Reading Annex C(1)(a), second clause, in the light of the jurisprudence on Article III:4, we consider that in undertaking and completing its approval procedures, a Member may, in principle, differentiate between products that have been found to be like because this would not, by itself, mean that the relevant approval procedures have been undertaken or completed in less favourable manner for the group of like imported products than for the group of like domestic products. In particular, a mere showing that a Member has undertaken or completed a particular approval procedure in a manner which is unfavourable for a given imported product would not be sufficient to establish a "less favourable manner" of undertaking or completing approval procedures if the relevant Member's conduct is explained by factors or circumstances unrelated to the foreign origin of the product.

7.2409 With these considerations in mind, we now turn to analyse Argentina's arguments. Argentina's first argument is that the European Communities has undertaken approval procedures under Regulation 258/97 in less favourable manner for the biotech products which are the subject of the product-specific measures challenged by Argentina than for like novel non-biotech products. Argentina asserts that undue delays have occurred only in the processing of applications concerning biotech products.

7.2410 We note that it is not entirely clear from Argentina's submissions which approval procedures are at issue. We understand Argentina to refer to the procedures set out in Articles 4, 6, 7 and 8 of Regulation 258/97. These procedures apply in the same way to biotech products as they do to novel non-biotech products. These procedures also apply equally to imported and domestic products. Finally, we note that we have previously determined that these procedures constitute an approval procedure within the meaning of Annex C. Therefore, in undertaking and completing these procedures, the European Communities must comply with Annex C(1)(a), second clause.

7.2411 Turning to the merits of Argentina's argument, we observe, initially, that Argentina has not provided factual information about the processing of applications concerning those novel non-biotech products which Argentina considers to be like the biotech products at issue. At any rate, even if it were the case, as Argentina seems to assert, that the processing of applications concerning the relevant imported biotech products (*e.g.*, imported biotech maize) has been unduly delayed, while the processing of applications concerning the corresponding domestic non-biotech varieties (*e.g.*, domestic novel non-biotech maize) has not been unduly delayed, this would not be sufficient, in and of itself, to raise a presumption that the procedures envisaged in Regulation 258/97 have been applied in less favourable manner for the group of like imported products than for the group of like domestic products. Argentina does not assert that the processing of applications concerning relevant domestic biotech products (*e.g.*, domestic biotech maize) has not been unduly delayed, or that the processing of applications concerning corresponding imported non-biotech varieties (*e.g.*, imported novel non-biotech maize) has been unduly delayed. In other words, Argentina is not alleging that the manner of processing applications under Regulation 258/97 has differed depending on the origin of the products. In these circumstances, it is not self-evident that the alleged less favourable manner of processing applications concerning the relevant imported biotech products (*e.g.*, imported biotech maize) is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and novel non-biotech products in terms of the required care in their safety assessment, risk for the consumer, etc. Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2412 In the light of the above, we find that Argentina has not established that the approval procedures set out in Regulation 258/97 have been undertaken or completed in a less favourable manner for imported products than for domestic products.

7.2413 Argentina's second argument is that after 1998 the European Communities has applied its approval procedures in a less favourable manner for the biotech products which are the subject of the product-specific measures challenged by Argentina than for like biotech products before 1998. More particularly, Argentina submits that after 1998 undue delays have occurred in the processing of applications under the relevant approval procedures. The year 1998 is the year in which, in Argentina's view, the European Communities began applying its general *de facto* moratorium on approvals.

7.2414 We understand Argentina's second argument to relate to the approval procedures contained in Directives 90/220 and 2001/18 as well as Regulation 258/97. Directives 90/220 and 2001/18 as well as Regulation 258/97 apply equally to imported and domestic biotech products. We have previously determined that these pieces of legislation contain approval procedures within the meaning of Annex C. Therefore, in undertaking and completing these approval procedures, the European Communities was and is required to comply with Annex C(1)(a), second clause. We note that Directive 2001/18 is formally and, to some extent, substantively different from Directive 90/220. Argentina appears to assume that the obligation laid down in Annex C(1)(a), second clause, applies not only in situations where imported and domestic products are dealt with under one and the same approval procedure, but also in situations where like products are dealt with under formally or substantively different approval procedures. For the purposes of our analysis of Argentina's argument, we are prepared to proceed on the basis of this assumption, but we do not make a finding in this regard.

7.2415 It seems to us that Argentina wishes to argue, in effect, that approval procedures were applied in less favourable manner for relevant imported biotech products after 1998 than for like domestic biotech products before 1998. Even if this were correct as a factual matter, however, this would not be sufficient, in and of itself, to raise a presumption that the approval procedures at issue have been applied in less favourable manner for the group of like imported products than for the group of like domestic products. Argentina asserts that after 1998 applications concerning the relevant biotech products were processed in less favourable manner, irrespective of whether they were of foreign or domestic origin, and that before 1998 applications concerning biotech products were processed in more favourable manner, irrespective of whether they were of foreign or domestic origin. Thus, it is not Argentina's contention that there has been a difference, before and after 1998, in the manner in which the European Communities has processed applications concerning imported biotech products and the manner in which it has processed applications concerning domestic biotech products. It is therefore not obvious that the alleged less favourable manner of conducting approval procedures for the relevant imported biotech products after 1998 is explained by the foreign origin of these products rather than by other factors or circumstances, such as a different perception of risks associated with biotech products, etc. Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2416 Additionally, we note that one of the consequences of accepting Argentina's second argument would be that Members could not consistently with Annex C(1)(a), second clause, elect to conduct their approval procedures in a less favourable manner for all subject products regardless of their origin, *e.g.*, in response to new scientific evidence suggesting that the risks associated with the products subject to the approval requirement had previously been underestimated. In our view, it would be unreasonable to interpret Annex C(1)(a), second sentence, so as to produce such an outcome.

7.2417 In the light of the above, we are not persuaded by Argentina's argument that the European Communities has undertaken and completed its approval procedures in a less favourable manner for

imported products than for domestic products by processing applications concerning biotech products in a less favourable manner after 1998 than before 1998.

7.2418 Since we have found that Argentina has not demonstrated to our satisfaction that imported products have been processed in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures, there is no need to go on to examine whether the imported products which Argentina alleges have been treated less favourably are "like" the domestic products which Argentina alleges have been treated more favourably.

7.2419 Based on all of the above considerations, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(a), second clause.

(b) Article 8

7.2420 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), second clause. We have determined that Argentina has failed to establish its claims under Annex C(1)(a), second clause. Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

(c) Overall conclusion

7.2421 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(a), second clause, of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

11. Consistency of the product-specific measures with Article 8 and Annex C(1)(b) of the *SPS Agreement*

7.2422 The United States and Argentina claim that the product-specific measures identified by them are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(b) of the *SPS Agreement*.

7.2423 Article 8 of the *SPS Agreement* provides:

> "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."

7.2424 Annex C(1)(b) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained[.]"

7.2425 As we have noted earlier, Annex C(1)(b) essentially sets out five separate, but related, obligations to be observed by Members in the operation of approval procedures. These obligations relate to:

(i) the publication or communication to applicants of the processing period of each procedure;

(ii) the examination of the completeness of the documentation and the communication to applicants of deficiencies;

(iii) the transmission of the results of the procedure;

(iv) the processing of applications which have deficiencies; and

(v) the provision of information about the stage of a procedure and the provision of an explanation of any delay.

7.2426 The **United States** argues that under the relevant product-specific measures – the product-specific moratoria – the European Communities does not allow its approval procedures to proceed to conclusion. As such, the product-specific moratoria are inconsistent with each of the related procedural obligations in Annex C(1)(b) and, consequently, with Article 8 as well.

7.2427 Regarding the *first obligation* (publication or communication of processing period), the United States submits that although the applicable EC approval legislation contains processing periods, under the product-specific moratoria those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the product-specific moratoria, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

7.2428 Regarding the *second obligation* (completeness of documentation), the United States argues that under the product-specific moratoria the European Communities does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the applicable EC legislation are stalled, without explanation. More specifically, the United States

submits that in the Bt-531 cotton, RR-1445 cotton, MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape applications, the applicant was not informed in a precise and complete manner of all deficiencies. To the contrary, when the Regulatory Committee fails to approve an application by qualified majority vote, or when the Commission enters into inter-service consultations rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the lead member State fails to take the final step of placing the product on the market.

7.2429 Regarding the *third obligation* (transmission of results), the United States argues that under the product-specific moratoria results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation. More specifically, the United States submits that in the Bt-531 cotton, RR-1445 cotton, MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape applications, the applicant was not informed in a precise and complete manner of all deficiencies. To the contrary, when the Regulatory Committee fails to approve an application by qualified majority vote, or when the Commission enters into inter-service consultations rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the lead member State fails to take the final step of placing the product on the market.

7.2430 Regarding the *fourth obligation* (processing of deficient applications), the United States argues that under the product-specific moratoria the European Communities does not proceed as far as practicable in the approval process. Instead, applications are stalled in the approval process.

7.2431 Regarding the *fifth obligation* (explanation of delay), the United States argues that under the product-specific moratoria delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the general moratorium.

7.2432 **Argentina** argues that Annex C(1)(b) stipulates obligations of publication and notification of the applicant and requires the competent bodies of Members to perform their obligations "promptly" and to explain "any delay". Argentina considers that the undue delay which has been caused by the European Communities in the specific approval procedures identified by it is inconsistent with Article 8 and Annex C(1)(b). Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not promptly determine whether the documentation was complete (second obligation), and in other cases did not inform the applicant of the results of the procedure (third obligation) or of the current stage of the procedure (fifth obligation). Argentina argues in this regard that it has demonstrated that, for instance, in the approval procedure concerning GA21 maize (EC-78) the applicant was still waiting for a definitive answer with respect to its application after more than five years. Finally, Argentina submits that a violation of the provisions of Annex C simultaneously represents a violation of Article 8.

7.2433 The **European Communities** submits that the United States and Argentina have offered a mere assertion that the European Communities has not done what it is required to do under the different obligations contained in Annex C(1)(b). Argentina has offered no evidence in support of its allegations. The United States also considers it sufficient simply to allege that applications were stalled in the approval process and gives no explanations. However, it is a complaining party's burden to establish a prima facie case. In any event, the detailed chronologies of individual approval procedures and other documents submitted by the European Communities demonstrate that the allegations of the United States are unfounded.

7.2434 Regarding the United States' claim that no standard processing periods have been published for the "product-specific moratoria", the European Communities argues that these "moratoria" are individual applications subject to their own particular facts. In the European Communities' view, it is difficult to see how a "standard" processing period other than the one laid down in the legislation could be set out for these applications collectively.

7.2435 The **Panel** notes that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(b) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(b). Therefore, in respect of the approval procedures set out in the aforementioned Directives and Regulation, the European Communities was and is required to comply with the provisions of Annex C(1)(a).

7.2436 We recall that the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval. We have observed in this regard that this is essentially a challenge to the application by the European Communities of a particular way of operating the relevant EC approval procedures. We also recall that Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications.

7.2437 In our view, the type of measure challenged by the United States and Argentina could conceivably constitute, or lead to, a breach of EC obligations under Annex C(1)(b), and it can therefore be examined in the light of the provisions of Annex C(1)(b). Since the United States and Argentina seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(b), this conclusion applies also to Article 8.

7.2438 In view of the fact that the United States' and Argentina's claim under Article 8 is in the nature of a consequential claim, we will begin our analysis with the claims under Annex C(1)(b).

(a) First obligation in Annex C(1)(b) (publication or communication of processing period)

7.2439 Only the United States has presented arguments in relation to the first obligation contained in Annex C(1)(b). Specifically, the United States puts forward two main arguments. The first argument is that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not follow the standard processing periods which are published in the applicable EC approval legislation. The United States appears to infer from this that the effective standard processing period was not published.

7.2440 We agree with the European Communities that the first obligation in Annex C(1)(b) does not, and logically cannot, require the European Communities to publish a "standard" processing period for every individual approval procedure undertaken by it. The processing period to be published is the period which is intended to be the norm for all approval procedures of a particular type, *e.g.*, the approval procedures envisaged in Directive 2001/18 for the placing on the market of biotech products. This follows from the word "standard", which in the specific context of the first obligation should be understood as meaning "normal".[1659] However, we do not understand the United States to argue that

[1659] The dictionary defines "standard" as "[o]f a prescribed or normal size, amount, quality, etc.". *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3028. The French

the European Communities should have published a standard processing period for each individual approval procedure conducted by it.

7.2441 We understand the United States to argue that the failure by the European Communities to consider a particular application for final approval meant that it was not following the published standard processing period for the relevant type of procedure and that the effective standard processing period for the relevant type of procedure was no longer published. Even if we were to accept that what has to be published in accordance with the first obligation in Annex C(1)(b) is the "effective" standard processing period, the mere fact that the European Communities in one particular approval procedure might not have followed the published standard processing period would not, by itself, justify the conclusion that there was a new and unpublished effective "standard" processing period. A single departure from the published standard processing period in our view does not demonstrate the existence of a new "standard" processing period.[1660] In any event, even if there was a new standard processing period, the fact that it was unpublished would not be a consequence of the failure by the European Communities to consider the relevant application for final approval. In other words, it would not be a consequence of the product-specific measure at issue. Rather, it would be a consequence of a separate and independent failure by the European Communities to publish the new standard processing period.

7.2442 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the first obligation contained in Annex C(1)(b), insofar as these claims are based on the requirement to publish the standard processing period of each procedure.

7.2443 The United States' second argument in support of its claim under Annex C(1)(b) is that since the European Communities does not acknowledge its failure to consider the relevant applications for approval, the anticipated processing period is not communicated to the applicants. We note that pursuant to Annex C(1)(b) the anticipated processing period is to be communicated to the applicant "upon request". The United States has provided no evidence to show (i) that an applicant requested that the anticipated processing period be communicated to it, (ii) that the request was denied by a relevant EC entity, and (iii) that this was because of a deliberate failure to consider the relevant applications for approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not communicating to applicants the anticipated processing periods upon request. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to communicate to the applicant the anticipated processing period upon request, as required by Annex C(1)(b).

7.2444 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the first obligation contained in Annex C(1)(b), insofar as these claims are based on the requirement to communicate to applicants the anticipated processing period.

(b) Second obligation in Annex C(1)(b) (completeness of documentation)

7.2445 Concerning the second obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

("la durée normale") and Spanish ("el período normal de tramitación") versions of the *SPS Agreement* support this interpretation.

[1660] We recall that the measures at issue are individual product-specific measures, and not the product-specific measures collectively or the general moratorium on approvals.

7.2446 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not promptly examine the completeness of documentation and inform applicants of any deficiencies. The United States has identified individual approval procedures which it believes support its claim under the second obligation.

7.2447 Among the applications referred to by the United States are those concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape. We have determined above that there are twenty-five product-specific measures on which the United States is seeking findings. However, the applications concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape are not part of these twenty-five measures. We are therefore not entitled to make product-specific findings on these two applications concerning oilseed rape.

7.2448 The United States also refers to the applications concerning Bt-531 cotton and RR-1445 cotton. They are among the applications which are the subject of product-specific claims put forward by the United States. In relation to these applications, the United States argues that when the Regulatory Committee failed to approve them by a qualified majority vote, or when the Commission entered into inter-service consultations after the Regulatory Committee vote, the applicant was given no explanation, and thus no opportunity to correct any deficiencies. As an initial matter, we note that the second obligation in Annex C(1)(b) applies when a "competent body" "receives" an application. In our view, the competent body receiving the applications concerning Bt-531 and RR-1445 cotton was the lead member State to which these applications were submitted for initial assessment, not the Regulatory Committee or the Commission at the post-Regulatory Committee stage.

7.2449 In any event, the United States has not demonstrated that either the Regulatory Committee or the Commission identified deficiencies in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner. We recall that in the case of the application concerning Bt-531 cotton, three member States made written statements in support of their votes in the Regulatory Committee in February 1999, and that the applicant provided additional information more than two years after the Regulatory Committee meeting and the launching by the Commission of inter-service consultations. The United States has not shown that any of the member State statements identified deficiencies in the documentation submitted by the applicant. We have found earlier that none of the member State statements specifically called for the provision of the additional information and that there is no indication that the applicant submitted the additional information in response to the written statements. We also recall our earlier finding that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant and for that reason did not submit a draft measure to the Council. We therefore do not consider that the additional information provided by the applicant addressed "deficiencies" which had been identified by the Regulatory Committee or the Commission.

7.2450 Regarding the application concerning RR-1445 cotton, we note that as in the case of the application concerning Bt-531 cotton, a number of member States made written statements in support of their votes in the Regulatory Committee in February 1999. The United States has not shown that any of these statements identified deficiencies in the documentation submitted by the applicant. Moreover, we have found earlier that the record of the consultation of the Regulatory Committee does not contain any indication of a request to the applicant for further information. In fact, no further information was provided subsequent to the Regulatory Committee vote. Finally, the United States itself points out in a different context that nothing in the record indicates that the Commission communicated any scientific concerns to the applicant or identified any shortcomings in the application following the Regulatory Committee vote. We therefore consider that the United States has not demonstrated that either the Regulatory Committee or the Commission identified deficiencies

in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner.

7.2451 By way of an additional consideration, we note that the failure by the European Communities to consider particular applications for final approval did not necessarily result in the European Communities not examining promptly the completeness of documentation and not informing applicants of any deficiencies. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to examine the completeness of the documentation or inform the applicant of deficiencies in the documentation submitted, as required by Annex C(1)(b).[1661]

7.2452 In the light of the above considerations, we conclude that the United States has failed to establish its product-specific claims under the second obligation contained in Annex C(1)(b).

7.2453 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not promptly determine whether the documentation was complete. Argentina has failed specifically to identify these "cases" and has not demonstrated that in these cases the competent body found deficiencies in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner.

7.2454 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the second obligation contained in Annex C(1)(b).

(c) Third obligation in Annex C(1)(b) (transmission of results)

7.2455 With regard to the third obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

7.2456 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not promptly communicate the results of procedures to applicants so that corrective action could be taken if necessary. The United States has identified individual approval procedures which it believes support its claim under the third obligation. Among the applications referred to by the United States are those concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape. We have already determined that we are not entitled to make product-specific findings on the two applications concerning oilseed rape.

7.2457 The United States also refers to the applications concerning Bt-531 cotton and RR-1445 cotton. They are among the product-specific measures challenged by the United States. In relation to these approval procedures, the United States argues that when the Regulatory Committee failed to approve them by a qualified majority vote, or when the Commission entered into inter-service consultations after the Regulatory Committee vote, the applicant was given no explanation, and thus no opportunity to correct any deficiencies.

7.2458 We note at the outset that when the applications concerning Bt-531 and RR-1445 cotton reached the Regulatory Committee stage, they were subject to Directive 90/220. It is clear from Article 21 of Directive 90/220 that the role of the Regulatory Committee is to assist the Commission in its decision-making by delivering opinions on draft measures proposed by the Commission. The

[1661] We note in this regard that certain progress in the approval process is not inconsistent with a deliberate failure by the European Communities to move a particular application to final decision.

Regulatory Committee cannot by itself take decisions on applications. Moreover, Directive 90/220 does not provide for the applicant to be given an explanation of the vote.[1662] Indeed, we have noted earlier that there is no publicly available record of Regulatory Committee votes. The European Communities has pointed out in this regard that Regulatory Committee votes have no external legal effect and cannot, therefore, be challenged under EC law.[1663] Thus, there is no "corrective action" which can be taken by the applicant in response to an unfavourable Regulatory Committee vote. For all these reasons, we are not persuaded that a vote in the Regulatory Committee can be considered a "result of the procedure" within the meaning of the third obligation contained in Annex C(1)(b). In our view, the Regulatory Committee vote is rather a "stage of the procedure" of which the applicant must be informed upon request in accordance with the fifth obligation in Annex C(1)(b).

7.2459 We believe that the same is true for inter-service consultations held by the Commission prior to the submission of a draft measure to the Council. Such consultations are a "stage of the procedure", not a "result of the procedure". At any rate, the outcome of such consultations is a draft measure to be transmitted to the Council for action, not a decision on an application.

7.2460 Based on the preceding considerations, we find that the Regulatory Committee votes and the opening of inter-service consultations by the Commission in the approval procedures concerning Bt-531 and RR-1445 cotton were not "results" which the European Communities was required to transmit to the applicant.

7.2461 More generally, we note that the failure by the European Communities to consider particular applications for final approval meant that no final results were achieved. Thus, there were no final results which could have been communicated to applicants as required by the third obligation in Annex C(1)(b).[1664]

7.2462 In the light of the above, we conclude that the United States has failed to establish its product-specific claims under the third obligation contained in Annex C(1)(b).

7.2463 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not inform the applicant of the results of the procedure. Argentina has failed specifically to identify these "cases" and has not demonstrated that in these cases there were "results" which needed to be transmitted to the applicants. We note that Argentina has referred to the fact that in the approval procedure concerning GA21 maize (EC-78), the applicant was still waiting for a definitive answer regarding its application after more than five years. We recall in this regard that the third obligation in Annex C(1)(b) requires the competent body to "transmit" as soon as possible "the results of the procedure" in a precise and complete manner to the applicant so that corrective action may be taken if necessary. Thus, the third obligation applies in situations where results have been reached.[1665] Argentina's example is one where no final results have been reached yet. Since no results have been reached, none could be transmitted

[1662] It is important to recall in this context that the United States is not alleging that Directive 90/220 is, as such, WTO-inconsistent.

[1663] In support of its statement, the European Communities refers to the jurisprudence of the European Court of First Instance, case T-326/99, *Nancy Fern Olivieri v. Commission and EMEA*, decision of 18 December 2003, paras. 51 *et seq*.

[1664] As is clear from the discussion of the approval procedures concerning Bt-531 and RR-1445 cotton, the United States has failed to establish that "results" other than the final results of the relevant procedures had to be transmitted to the relevant applicants and that those results were not transmitted to them.

[1665] We note that the requirement in Annex C(1)(a), first clause, that approval procedures be "completed" without undue delay serves to ensure that "results" are reached.

to the applicant. In our view, the example of the approval procedure concerning GA21 maize (EC-78) does not, therefore, assist Argentina in establishing an inconsistency with the third obligation.

7.2464 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the third obligation contained in Annex C(1)(b).

(d) Fourth obligation in Annex C(1)(b) (processing of deficient applications)

7.2465 Only the United States has presented arguments in relation to the fourth obligation contained in Annex C(1)(b). The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not proceed as far as practicable in the approval process.

7.2466 We note that pursuant to Annex C(1)(b) the competent body is to proceed as far as practicable with the procedure "if the applicant so requests". The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying that request because of a decision by the European Communities not to consider the relevant application for final approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not proceeding as far as practicable with procedures if applicants so requested. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to proceed as far as practicable with that procedure upon request, as required by Annex C(1)(b).[1666]

7.2467 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the fourth obligation contained in Annex C(1)(b).

(e) Fifth obligation in Annex C(1)(b) (explanation of delay)

7.2468 Regarding the fifth obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

7.2469 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, delays were not explained. The fifth obligation states that "upon request", the applicant is to be informed of the stage of the procedure, with any delay being explained. The United States has provided no evidence of an applicant making such a request, or of a relevant EC entity denying an explanation of any delay because of a deliberate failure by the European Communities to consider the relevant application for approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not informing applicants of the stage of procedures and not explaining any delays, if applicants so requested. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to inform applicants of the stage of procedures and explain any delays, as required by Annex C(1)(b).

7.2470 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the fifth obligation contained in Annex C(1)(b).

[1666] We note in this regard that certain progress in the approval process is not inconsistent with a deliberate failure by the European Communities to move a particular application to final decision.

7.2471 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not inform the applicant of the current stage of the procedure. Argentina has failed specifically to identify these "cases" and has not demonstrated that the relevant applicants requested information about the stage of the procedure and were denied such information.

7.2472 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the fifth obligation contained in Annex C(1)(b).

(f) Article 8

7.2473 Turning now to the United States' and Argentina's claims under Article 8, we recall that the United States and Argentina seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(b). We have determined that the United States and Argentina have failed to establish their claims under Annex C(1)(b). Under the approach followed by the United States and Argentina, this means that their claims under Article 8 have not been established either.

(g) Overall conclusions

7.2474 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

12. Consistency of the product-specific measures with Article 8 and Annex C(1)(c) of the *SPS Agreement*

7.2475 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(c) of the *SPS Agreement*.

7.2476 Article 8 of the *SPS Agreement* provides:

> "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."

7.2477 Annex C(1)(c) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs[.]"

7.2478 **Argentina** submits that the European Communities acted inconsistently with the provisions of Annex C(1)(c) by delaying the examination of the relevant applications and by requiring excessive submissions under the terms of subsequent legislation. Regarding the submission of information under the terms of subsequent legislation, Argentina points out that the European Communities has invoked requirements contained in subsequent legislation as grounds for not processing applications. According to Argentina, this is clear from the fact that applications submitted under Directive 90/220 had to be resubmitted under Directive 2001/18 even in cases where the procedures had already been in progress under the old Directive for three years. Argentina also points out that there were numerous requests for additional information in the approval procedures which are the subject of its product-specific claims under Annex C(1)(c). Finally, Argentina argues that a violation of the provisions of Annex C simultaneously represents a violation of Article 8.

7.2479 The **European Communities** argues that delays do not fall within the scope of application of Annex C(1)(c). Regarding information requirements, the European Communities submits that the question of which information requirements are necessary is a question of standards set forth in the *SPS Agreement* itself. The European Communities also argues that Argentina should have attacked Directive 2001/18 if it considered the requirement to resubmit an updated dossier upon entry into force of Directive 2001/18 to be inconsistent with the *SPS Agreement*.

7.2480 The **Panel** notes that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(c) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(c). Therefore, in respect of the approval procedures set out in the aforementioned Directives and Regulation, the European Communities was and is required to comply with the provisions of Annex C(1)(c).

7.2481 We note that Argentina relies on the alleged inconsistency of the relevant product-specific measures with Annex C(1)(c) to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(c).

(a) Annex C(1)(c)

7.2482 We recall that the product-specific measures which Argentina says give rise to an inconsistency with Annex C(1)(c) are undue delays caused by the European Communities in the consideration of particular applications. Argentina asserts that the European Communities has breached its obligations under Annex C(1)(c) by delaying the completion of the relevant approval procedures. We are not persuaded by this assertion. In our view, the failure by the European Communities to complete particular approval procedures without undue delay did not itself impose, or lead to the imposition of, information requirements which were not necessary. We therefore fail to see how the measures challenged by Argentina could be considered to give rise to an inconsistency with Annex C(1)(c). At any rate, Argentina has not identified specific information requirements which were imposed on applicants in the relevant approval procedures, nor has it explained why any such requirements were not necessary for appropriate approval procedures.

7.2483 Argentina also asserts that the European Communities has breached its obligations under Annex C(1)(c) by requiring excessive submissions under the terms of subsequent legislation. Here again, we must recall that the product-specific measures which Argentina is challenging are undue delays caused by the European Communities in the consideration of particular applications. The failure by the European Communities to complete particular approval procedures without undue delay did not impose a requirement on applicants to provide information based on legislation not yet in force, nor did it cause such a requirement to be imposed. Likewise, the European Communities' failure to complete particular approval procedures without undue delay did not require applicants to update their applications in accordance with the provisions of Directive 2001/18 once that Directive had entered into force. Nor did that failure cause such a requirement to be imposed.[1667] We are therefore unable to agree with Argentina that the European Communities has breached its obligations under Annex C(1)(c) by requiring excessive submissions under the terms of subsequent legislation. In any event, Argentina has not explained why the submissions it referred to were "excessive" and thus not necessary.

7.2484 We note Argentina's argument that there were numerous requests for additional information in the approval procedures which are the subject of its claims under Annex C(1)(c). It is sufficient to note in this regard that if Argentina was of the view that some or all of these requests for additional information constitute information requirements and that these requirements were not limited to what was necessary, it should have challenged these requests.

7.2485 In the light of the above, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(c).

(b) Article 8

7.2486 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(c). We have determined that Argentina has failed to establish its claims under Annex C(1)(c). Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

[1667] As pointed out by the European Communities, the requirement to update applications in accordance with the provisions of Directive 2001/18 flows from Article 35 of that Directive. Argentina does not challenge Article 35 as such.

(c) Overall conclusion

7.2487 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(c) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

13. Consistency of the product-specific measures with Article 8 and Annex C(1)(e) of the *SPS Agreement*

7.2488 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(e) of the *SPS Agreement*.

7.2489 Article 8 of the *SPS Agreement* provides:

> "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."

7.2490 Annex C(1)(e) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary[.]"

7.2491 **Argentina** argues that the detailed requirements of Directive 2001/18 and of its predecessor, Directive 90/220, as well as of Regulation 258/97 do not seem to meet the criteria of "reasonableness and necessity". Moreover, the European Communities has failed to exercise the authority granted to it by the aforementioned legislation, and that failure to act cannot be deemed reasonable or necessary. Furthermore, when Directive 2001/18 came into force, no consideration was given to the newly submitted applications, nor were those applications approved which had already been submitted under the predecessor Directive. Argentina further submits that the application of the European Communities' approval procedures is not limited to what is reasonable and necessary for the approval of biotech products.

7.2492 The **European Communities** argues that to the extent that Argentina's argument relates to the EC approval legislation itself, there is no reason to respond as the legislation is not a measure at issue. Furthermore, Argentina offers no support for its assertion that the application of the European Communities' approval procedures is not limited to what is reasonable and necessary for the approval

of biotech products. The European Communities submits, therefore, that Argentina has not established a prima facie case.

7.2493 The **Panel** notes that Argentina relies on the alleged inconsistency of the relevant product-specific measures with Annex C(1)(e) to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(e).

(a) Annex C(1)(e)

7.2494 We note that Annex C(1)(e) imposes limitations on any requirements for approval of "*individual specimens* of a product" (emphasis added). The product-specific measures challenged by Argentina do not concern "individual specimens" of biotech products. They concern specific biotech products for which marketing approval has been sought. We also recall that the product-specific measures which Argentina says give rise to an inconsistency with Annex C(1)(e) are undue delays caused by the European Communities in the consideration of particular applications. It is not apparent to us that the European Communities' failure to complete approval procedures concerning particular biotech products without undue delay imposed, or led to the imposition of, any requirements for the approval of individual specimens of the relevant biotech products. We therefore fail to see how the measures challenged by Argentina could be considered to give rise to an inconsistency with Annex C(1)(e).

7.2495 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(e).

7.2496 To the extent Argentina is seeking to challenge requirements contained in the EC approval legislation, we agree with the European Communities that the relevant legislation is not a measure within our terms of reference.

(b) Article 8

7.2497 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(e). We have determined that Argentina has failed to establish its claims under Annex C(1)(e). Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

(c) Overall conclusion

7.2498 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(e) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

14. Consistency of the product-specific measures with Article III:4 of the GATT 1994

7.2499 Canada and Argentina claim that the European Communities has acted inconsistently with its obligations under Article III:4 of the GATT 1994 in respect of the product-specific measures they are challenging. We recall that the United States did not present claims under the GATT 1994.

7.2500 Article III:4 of the GATT 1994 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

7.2501 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada falls within the scope of the GATT 1994 and is inconsistent with the European Communities' obligations under Article III:4. According to Canada, the measures at issue are "laws, regulations or requirements laws, regulations or requirements affecting the internal sale, offering for sale, purchase, and distribution" of the biotech products concerned; the biotech products subject to the product-specific measures are "like" domestically-grown non-biotech counterparts in the light of the criteria put forth by the Appellate Body; and the imported biotech products concerned are accorded treatment less favourable than that accorded like non-biotech products of national origin. Canada submits that, for these reasons, the measures at issue constitute a violation of the European Communities' national treatment obligations under Article III:4.

7.2502 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina is inconsistent with Article III:4 of the GATT 1994, because it gives less favourable treatment to biotech products than to non-biotech products. Argentina argues that the inconsistencies result from the fact that (i) biotech and non-biotech products are "like products", (ii) the suspension of consideration of, or the failure to consider, the particular applications are "requirements affecting the sale, offering sale, purchase, transport, distribution and use of products on the domestic market", and (iii) the suspension of consideration of, or the failure to consider, the particular applications has modified the conditions of competition in the relevant market to the detriment of imported products.

7.2503 The **European Communities** argues that there is no violation of Article III:4 of the GATT 1994 with regard to the product-specific measures challenged by Canada and Argentina. This is because: (i) the measures challenged by Canada and Argentina are alleged delays in dealing with specific requests for approval within a specified timeframe, and these measures are not in themselves "laws, regulations or requirements" as provided for by Article III:4 of the GATT 1994; (ii) imported products are not accorded less favourable treatment than like domestic products, as there is no discrimination between relevant imported biotech products and same biotech products cultivated or processed domestically, which are the only "like products" to the imported biotech products concerned.

7.2504 The **Panel** will analyse Canada's and Argentina's claim separately.

(a) DS292 (Canada)

7.2505 In relation to DS292, we recall that we have already reached the conclusion that the failure by the European Communities to consider or approve, without undue delay, the four particular applications identified by Canada has given rise to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant measures are also inconsistent with Article III:4. Accordingly, we exercise judicial economy with regard to Canada's claim under Article III:4.

(b) DS293 (Argentina)

7.2506 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.2507 Argentina challenges under Article III:4 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1668] under Regulation 258/97.

7.2508 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article III:4 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.2509 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.2510 Argentina claims that the alleged suspension of consideration of, or the failure to consider, the relevant eight applications is inconsistent with Article III:4 of the GATT 1994 because it resulted in less favourable treatment being accorded to the biotech products which are the subject of the eight applications than to like non-biotech products.

7.2511 Argentina submits that the alleged suspension of consideration of, or the failure to consider, an application for the approval of a biotech product constitutes a "requirement" affecting the sale, offering for sale, etc. within the meaning of Article III:4. For the purposes of our analysis, we are willing to proceed on the assumption that the alleged suspension of consideration of, or the failure to consider, an application constitutes a "requirement" within the meaning of Article III:4. Moreover, we initially focus our analysis on the "no less favourable treatment" obligation contained in Article III:4, rather than on the "like products" element. We recall in this connection that the

[1668] Argentina's first written submission, paras. 201-202.

Appellate Body in *EC – Asbestos* and *Dominican Republic – Import and Sale of Cigarettes* made statements in relation to the meaning of the phrase "no less favourable treatment" in Article III:4.[1669] We find these statements to be relevant to the type of measures challenged by Argentina under Article III:4.

7.2512 Argentina contends that, as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications, the European Communities has accorded "less favourable treatment" to the biotech products which are the subject of the eight applications than to like non-biotech products. More particularly, Argentina considers that the measures at issue have modified the conditions of competition in the EC market to the detriment of imported biotech products. Argentina notes in this regard that as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications the biotech products which are the subject of these applications were not approved.

7.2513 In considering Argentina's contention, the first thing to be observed is that Argentina has not provided specific factual information about the treatment accorded by the European Communities to the non-biotech products which Argentina considers to be like the biotech products at issue. It appears to be Argentina's contention, however, that these non-biotech products may be marketed in the European Communities, whereas the relevant biotech products may not be marketed.

7.2514 At any rate, even if it were the case that, as a result of the measures challenged by Argentina, the relevant imported biotech products cannot be marketed, while corresponding domestic non-biotech products can be marketed, in accordance with the aforementioned statements by the Appellate Body this would not be sufficient, in and of itself, to raise a presumption that the European Communities accorded less favourable treatment to the group of like *imported* products than to the group of like *domestic* products. We note that Argentina does not assert that domestic biotech products have not been less favourably treated in the same way as imported biotech products, or that the like domestic non-biotech varieties have been more favourably treated than the like imported non-biotech varieties. In other words, Argentina is not alleging that the treatment of products has differed depending on their origin. In these circumstances, it is not self-evident that the alleged less favourable treatment of imported biotech products is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and non-biotech products in terms of their safety, etc. In our view, Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2515 In the light of the above, we find that Argentina has not established that, as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications, the European Communities has accorded "less favourable treatment" to imported products than to domestic products.

7.2516 Since we have found that Argentina has not demonstrated to our satisfaction that imported products have been treated "less favourably" than domestic products, there is no need to go on to determine whether the challenged measures in fact constitute "requirements" within the meaning of Article III:4, and whether the imported products which Argentina alleges have been treated less favourably are "like" the domestic products which Argentina alleges have been treated more favourably. Our finding on the "no less favourable treatment" obligation necessarily implies that Argentina has failed to establish its claim under Article III:4 with regard to the eight product-specific measures in question.

[1669] We have reproduced the relevant statements at paras. 7.2404 and 7.2405 above.

(c) Conclusions

7.2517 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the product-specific measures which are being challenged by Canada are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Article III:4 of the GATT 1994.

15. Consistency of the product-specific measures with the *TBT Agreement*

7.2518 The Panel now turns to address Canada's and Argentina's claims of inconsistency under the *TBT Agreement*. We recall that the United States did not present claims under the *TBT Agreement*.

7.2519 **Canada** considers that the product-specific measures it is challenging are SPS measures and that, as such, they are not subject to the requirements of the *TBT Agreement*. Canada argues, however, that if the Panel decides that the product-specific measures at issue are not SPS measures, then Canada submits, in the alternative, that these measures are subject to the requirements of the *TBT Agreement*. More particularly, Canada's alternative claim is that the relevant measures are inconsistent with Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement.*

7.2520 Furthermore, Canada states that to the extent that the Panel determines that parts of the measures at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's TBT claims are to be considered cumulative rather than alternative, *vis-à-vis* its SPS claims.

7.2521 **Argentina** considers that the Panel should examine the product-specific measures Argentina is challenging under the *SPS Agreement*. However, if the Panel concludes that it should not analize Argentina's claim under the *SPS Agreement*, Argentina submits, in the alternative, that the product-specific measures at issue are subject to the requirements of the *TBT Agreement*. More particularly, in Argentina's view the relevant measures are inconsistent with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*.

7.2522 The **European Communities** considers that, given the reasons on which the relevant product-specific measures are based, they fall in part within the scope of the *SPS Agreement* and in part outside the scope of the *SPS Agreement*. However, the European Communities rejects the alternative claims by Canada and Argentina that the relevant product-specific measures they are challenging are inconsistent with the *TBT Agreement*.

7.2523 The **Panel** will analyse Canada's and Argentina's claims separately.