7.419 **Canada** argues that the approval procedures contained in Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97 are clearly "approval procedures" for the purposes of Annex C of the *SPS Agreement*. It is clear that the approval legislation applicable to biotech products is a "law, regulation or requirement". Moreover, the approval procedures are imposed to "check and ensure" the fulfilment of the requirements of the European Communities' approval legislation, namely that food and food ingredients do not "present a danger for the consumer"[546] or that the release into the environment of biotech products "will be safe for human health and the environment".[547] The approval procedures check and ensure that all of the relevant information has been submitted and that the risks associated with placing biotech products on the market have been identified and assessed. Finally, the European Communities' approval legislation for biotech products is a "sanitary or phytosanitary" measure as defined in Annex A(1) of the *SPS Agreement*.

7.420 **Argentina** argues that the EC legislation which establishes the procedure for the prior approval of GMOs (Directive 90/220 and subsequently Directive 2001/18, and Regulation 258/97) defines the procedures for the approval of biotech agricultural products of both domestic and foreign origin. Argentina submits that this legislation contains provisions related to the system of control, inspection and approval.

7.421 The **European Communities** states that to the extent that its approval system set up under the relevant GMO legislation addresses risks coming under Annex A(1) of the *SPS Agreement*, it accepts that that system is a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". The procedures sets forth in the relevant legislation are designed to ensure that adverse effects on human health and the environment are avoided. To the extent this is done by verifying and assessing the risks coming under the *SPS Agreement*, those procedures can be said to be applied in order "to check and ensure the fulfilment of sanitary or phytosanitary measures".

7.422 The **Panel** commences its analysis with the form element of the definition of the term "SPS measures". The second paragraph of Annex A(1) indicates that SPS measures "include" all "laws, decrees [and] regulations". In our view, the reference to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form. Rather, we consider that SPS measures may in principle take many different legal forms.

7.423 We note that Directives 90/220 and 2001/18, as well as Regulation 258/97, are legislative acts adopted by the European Council and the European Parliament.[548] As such, they are governmental measures attributable to the European Communities. We also note that they are legally binding. Directives 90/220 and 2001/18 are addressed to EC member States and are to be transposed by them through legislative or administrative action.[549] Regulation 258/97 states, *in fine*, that it is binding in its entirety and directly applicable in all EC member States. In the light of these elements, we consider that, for the purposes of Annex A(1), Directives 90/220 and 2001/18, as well as Regulation 258/97, may be assimilated to measures adopted in the form of "laws" and, therefore, meet the form element of the definition of the term "SPS measures".

7.424 Regarding the nature of SPS measures, we recall that the second paragraph of Annex A(1) refers to a variety of "requirements and procedures" which are quite different in nature. Among the "procedures" specified in Annex A(1) are "testing, inspecting, certification and approval procedures".

[546] Article 3 of Regulation 258/97.
[547] Preambular paragraph 47 of Directive 2001/18.
[548] Directive 90/220 was adopted by the Council only.
[549] Articles 23 and 24 of Directive 90/220; Articles 34 and 38 of Directive 2001/18.

In the present case, the Parties have consistently referred to Directives 90/220 and 2001/18, as well as Regulation 258/97, as setting out "EC approval procedures" for biotech products. Annex A(1) does not define the term "approval procedures". However, Annex C to the *SPS Agreement*, which is entitled "Control, Inspection and Approval Procedures", contains a footnote which clarifies that "[c]ontrol, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification".[550] Furthermore, the lead-in to Annex C(1) makes clear that Annex C(1) establishes disciplines "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". On the basis of these elements, the term "approval procedures" can be understood as encompassing procedures applied to check and ensure the fulfilment of one or more substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market.

7.425 As is apparent from our earlier description of the procedures set out in Directives 90/220 and 2001/18, GMOs may not be released into the environment unless the consent of the competent authority has been obtained.[551] Similarly, in the case of Regulation 258/97, foods containing or consisting of GMOs may not be placed on the market unless an authorization decision has been obtained.[552] Thus, it is clear that Directives 90/220 and 2001/18 as well as Regulation 258/97 each impose a pre-marketing approval requirement.

7.426 In the case of Directives 90/220 and 2001/18 the granting of marketing approval is conditional on a demonstration to the satisfaction of the competent authorities that the GMO to be released into the environment does not pose a risk to human health or the environment.[553] We have already determined that Directives 90/220 and 2001/18, as measures which are applied to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs, meet the purpose element of the definition of the term "SPS measure". Therefore, we consider that the requirement established by Directives 90/220 and 2001/18 that GMOs released into the environment not pose a risk to human health or the environment is a substantive requirement imposed for the purposes mentioned in Annex A(1).

7.427 Regarding Regulation 258/97, we note that the granting of marketing approval is conditional, *inter alia*, on a satisfactory demonstration that the novel food for which approval is sought not present a danger for the consumer.[554] We have determined above that to the extent the Regulation is applied for this purpose, it meets the purpose element of the definition of the term "SPS measure". Consistent with this, we consider that the requirement established by Regulation 258/97 that novel foods not present a danger is a requirement imposed for a purpose mentioned in Annex A(1).

7.428 If, as we suggest, Directives 90/220 and 2001/18, as well as Regulation 258/97, contain substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market, the next question to be considered is whether Directives 90/220 and 2001/18, as well as Regulation 258/97, contain procedures to check and ensure the fulfilment of these requirements. The answer is in the affirmative.[555] We have described in detail the procedures set out

[550] Footnote 7 of the *SPS Agreement*.

[551] Articles 6, 10, 11 and 13 and preambular paragraphs 17, 18 and 20 of Directive 90/220; Articles 4, 6, 13, 15 and 19, and preambular paragraphs 28 and 47 of Directive 2001/18.

[552] Articles 3, 4, 6 and 7 and preambular paragraph 2 of Regulation 258/97. We note that the exception of the simplified procedure provided for in Article 5 of Regulation 258/97.

[553] Articles 4, 11 and 13, as well as preambular paragraph 21 of Directive 90/220; Articles 4, 13 and 15, as well as preambular paragraph 47 of Directive 2001/18.

[554] Article 3(1) of Regulation 258/97.

[555] *See* Articles 11-13 and 21 of Directive 90/220; Articles 13-22 and 30 of Directive 2001/18; Articles 3, 4-7 and 11-13 of Regulation 258/97.

in Directives 90/220 and 2001/18, as well as Regulation 258/97. These procedures serve the purpose of checking and ensuring the fulfilment of the relevant substantive SPS requirements.

7.429 The foregoing considerations lead us to the view that the procedures set out in Directives 90/220 and 2001/18, as well as Regulation 258/97, are procedures applied to check and ensure the fulfilment of one or more substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market. We have said earlier that such procedures can be considered as "approval procedures" within the meaning of Annex A(1) and C(1).

7.430 Since we have found that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), constitute "approval procedures" within the meaning of Annex A(1), it follows that they meet the nature element of the definition of the term "SPS measure".

7.431 In the light of the above, we conclude that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), qualify as SPS measures within the meaning of Annex A(1) as far as their form and nature are concerned.

(i) Conclusion on whether the EC approval procedures are "SPS measures"

7.432 We have now considered Directives 90/220 and 2001/18, as well as Regulation 258/97, in terms of their purpose, their form and their nature. In relation to each of these issues, we have found that they satisfy the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), constitute "SPS measures" within the meaning of Annex A(1).

7.433 At this juncture, we could go on and address whether any of the three EC approval procedures at issue in this dispute embodies more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the EC approval procedures falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. Indeed, in their submissions to the Panel, the Parties treated Directives 90/220 and 2001/18 as well as Regulation 258/97 as constituting one SPS measure each. Also, in this case, our disposition of the Complaining Parties' claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) is not affected by whether we treat any of the EC approval procedures as constituting a single SPS measure or as embodying more than one SPS measure. Taking account of these elements, like the Parties, we will treat each of the EC approval procedures as constituting one single SPS measure.

(d) Whether the EC approval procedures may affect international trade

7.434 Article 1.1 of the *SPS Agreement* provides, *inter alia*, that the *SPS Agreement* "applies to all [SPS] measures which may, directly or indirectly, affect international trade". Thus, for an SPS measure to be subject to the disciplines of the *SPS Agreement*, it must be capable of affecting international trade. Accordingly, we now turn to consider, as an additional and separate matter, whether Directives 90/220 and 2001/18 as well as Regulation 258/97 may affect international trade.

7.435 In our view, it is not necessary to demonstrate that an SPS measure has an actual effect on trade. Article 1.1 merely requires that an SPS measure "may, directly or indirectly, affect international trade". Bearing this in mind, we first recall our earlier determination that

Directives 90/220 and 2001/18 as well as Regulation 258/97 set out procedures which are applied to check and ensure the fulfilment of a substantive SPS requirement the satisfaction of which is necessary to obtain approval to place a product on the market. It is uncontested that Directives 90/220 and 2001/18 as well as Regulation 258/97 apply to GMOs and foods containing or consisting of GMOs which are produced outside the European Communities and hence would be imported into the European Communities upon approval. Finally, we note that the procedures in question may themselves have a direct or indirect effect on international trade, *e.g.*, because their completion takes time, or because they impose information and documentation requirements on applicants.

7.436 For these reasons, we conclude that Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer) are SPS measures which may, directly or indirectly, affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, are subject to the provisions of the *SPS Agreement*.

7.437 With this conclusion in mind, we now proceed to examine the first measure challenged by the Complaining Parties, the alleged general EC moratorium on approvals.

D. GENERAL EC MORATORIUM

1. Measure at issue

7.438 The Panel begins its examination of the first measure at issue in this dispute – the alleged general EC moratorium – by setting out the Complaining Parties' descriptions of that measure as well as the European Communities' response thereto.

7.439 The **United States** asserts in its panel request that since October 1998, the European Communities has applied a moratorium on the approval of biotech products. Pursuant to the moratorium, the European Communities has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the European Communities has blocked in the approval process under the relevant EC legislation all applications for placing biotech products on the market, and has not considered any application for final approval. Thus, as described, the measure at issue is the suspension by the European Communities of consideration of applications for, or granting of, approval of biotech products.[556]

7.440 The United States subsequently added in its submissions that it is not claiming that each and every application stopped all progress beginning in 1998.[557] To the contrary, the moratorium was a decision by the European Communities not to move products to a *final* decision in the approval process. Thus, certain progress in the process, short of final decision, is not inconsistent with a moratorium on final approvals.

7.441 **Canada** asserts in its panel request that since October 1998, the European Communities has maintained a moratorium on the approval of biotech products. The European Communities effectively has suspended the consideration of applications for approval of biotech products, and the granting of approvals for those products, under the relevant EC approvals processes. Accordingly, as described, the measure at issue is the general suspension by the European Communities of its own

[556] *See* the US request for the establishment of a panel. WT/DS291/23, paras. 1 and 3.
[557] US first written submission, para. 2.

processes for the consideration of applications for, and of the granting of, approval of biotech products.[558]

7.442 Canada subsequently added in its submissions that the moratorium maintained by the European Communities did not involve the complete shutdown of the approval process, at every stage.[559] While the processing of certain applications was completely suspended, some progress was made in relation to other applications. Moreover, throughout the existence of the moratorium, the Commission continued to refer applications to the various scientific committees for their opinion. However, it is at the critical decision-making junctures, or key stages, of the approval procedure that applications were blocked.

7.443 **Argentina** asserts in its panel request that the European Communities has applied a *de facto* moratorium on the approval of agricultural biotechnology products since October 1998. This *de facto* moratorium has led to the suspension of consideration of, and failure to consider, various applications for approval of biotech products as well as to undue delays in finalizing the processing of applications for the approval of such products under the relevant EC legislation. Thus, the measure at issue is the suspension by the European Communities of consideration of, and failure to consider, various applications for approval of biotech products.[560]

7.444 Argentina subsequently added in its submissions that it is not arguing that there was a total lack of movement through the successive stages of the approval process.[561] Rather, Argentina argues that since 1998, any such movement has failed to lead to approval due to deliberate blockage or stalling at key stages of the approval process.

7.445 The **European Communities** suggests that the Complaining Parties' allegation that it suspended consideration of applications only at key stages in the approval process is at odds with the concept and definition of a moratorium.[562] The European Communities further suggests that the Complaining Parties are not challenging a measure, but an alleged practice – an alleged repeated pattern of suspending consideration of individual applications.

7.446 The European Communities argues that an examination of the applications identified by the Complaining Parties shows that there has never been a "general suspension" of approvals, and that the individual applications have not been stalled at any moment. The evaluation process has continued through the past years, with the EC and member States authorities taking into account the changing legislative and regulatory framework as well as the evolving scientific debate in the treating of the pending applications. The European Communities notes that many applications had to be re-submitted under Directive 2001/18 by January 2003, and that many applications have been withdrawn, usually for purely commercial reasons.

7.447 The European Communities observes that all pending applications have been subject to requests for additional information, often related to insufficient data having been provided in the dossier to allow for a proper risk assessment. Some requests, however, especially with regard to monitoring and traceability issues, were made in anticipation of the new legislation to be adopted, and were based on voluntary commitments from the applicants. The European Communities maintains

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[558] *See* Canada's request for the establishment of a panel. WT/DS292/17, paras. 1 and 5.
[559] Canada's first written submission, para. 2.
[560] *See* Argentina's request for the establishment of a panel. WT/DS293/17, paras. 2 and 5.
[561] Argentina's first written submission, paras. 198 *et seq.*
[562] EC second written submission, para. 296.

that since the entry into force of Directive 2001/18 individual applications haves been moving smoothly through the different steps of the relevant EC approval procedures.

7.448 The **Panel** notes that the Complaining Parties use slightly different language to describe the measure at issue. Yet none of the Complaining Parties ever suggested that they were challenging different measures. Indeed, the Complaining Parties' submissions all refer to the measure in question as the "moratorium". The Panel therefore proceeds on the basis that the Complaining Parties are contesting one and the same measure – the alleged moratorium on the approval of biotech products.

7.449 According to the Complaining Parties, the alleged moratorium was in effect between October 1998 and 29 August 2003, which is the date this Panel and its terms of reference were established. It is important to point out in this respect that the Complaining Parties are not of the opinion that the alleged moratorium was lifted after August 2003. To the contrary, in the Complaining Parties' view, the alleged moratorium was still in effect in February 2005, when the Panel's second and last substantive meeting with the Parties was held.

7.450 The Complaining Parties sometimes refer to the measure at issue in this Section as the "general moratorium" or the "across-the-board moratorium". This reflects the fact that this particular measure is alleged to have been applied to all applications for approval of biotech products which were pending during the relevant time period (October 1998 to August 2003).[563] It is well to recall in this context that the Complaining Parties are also challenging certain product-specific measures, *i.e.*, measures which are alleged to apply only to individual biotech products.

7.451 The Complaining Parties did not identify a formal EC legislative or administrative act giving effect to the moratorium allegedly imposed by the European Communities. However, it is not the Complaining Parties' argument that the European Communities adopted a formal, *de jure* moratorium on approvals during the relevant time period. According to the Complaining Parties, the moratorium on approvals adopted and applied by the European Communities during the relevant time period was an effective, *de facto*, moratorium.[564]

7.452 In describing the measure at issue in their panel requests, all three Complaining Parties refer, *inter alia*, to a "suspension by the European Communities of the consideration of applications for approval of biotech products". This could be understood as meaning that the European Communities suspended the processing of all applications, and that all approval procedures were brought to a complete standstill. In their submissions to the Panel, the Complaining Parties point out, however, that they are not alleging that the European Communities suspended all consideration of applications, at all stages of the approval process. What they are alleging is that the European Communities effectively suspended consideration of applications at certain critical stages with a view to preventing the final approval of these applications. This allegation is not inconsistent with the reference in the panel requests to a "suspension by the European Communities of the consideration of applications for approval of biotech products". In the Panel's view, the Complaining Parties' submissions do not allege the existence of a measure which is different from that described in the panel requests. They rather provide further clarification of the descriptions contained in the panel requests.

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[563] US first written submission, para. 34; US second written submission, paras. 34-35 and 52; Canada's first oral statement, para. 38; Canada's second written submission, para. 1; Canada's third written submission, para. 203; Argentina's first written submission, para. 19; Argentina's second written submission, para. 137; Argentina's third written submission, paras. 53 and 59.

[564] US first written submission, para 3; Canada's first oral statement, para. 37; Argentina's first written submission, para. 52.

7.453 The European Communities suggests that the Complaining Parties' allegation that it suspended consideration of applications only at key stages in the approval process is at odds with the concept and definition of a moratorium.[565] The Panel is not convinced by this argument. In their panel requests, the Complaining Parties do not allege the existence of a moratorium on the processing of applications for approval. They allege the existence of a moratorium on the approval of applications. A moratorium on approvals does not necessarily imply a suspension of approval procedures at every stage in the approval process. As noted by the Complaining Parties, it is consistent with the notion of an approvals moratorium that individual applications are allowed to make some progress in the approval process, provided that no application is allowed to obtain final approval.

7.454 The European Communities further suggests that the Complaining Parties are not challenging a measure, but an alleged practice – an alleged repeated pattern of suspending consideration of individual applications. The United States responds that this is not the case. It points out that it is challenging the alleged moratorium, and not the pattern of non-decisions that resulted from the moratorium. The United States notes that it does not contend that the moratorium itself constitutes a mere practice. Rather, the United States argues that the moratorium is a measure. According to the United States, the absence of approvals is the result of a definitive, albeit unpublished, act – a conscious, political-level decision by the European Communities not to allow any application to reach the stage of final approval.[566]

7.455 The Panel does not understand Canada and Argentina to conceive of the alleged moratorium differently from the United States. Indeed, Canada contends that the European Communities decided to stop authorizing new biotech products, regardless of the actual risks involved for individual products.[567] In Canada's view, there was an effective "political" decision on the part of the European Communities not to approve applications. Canada considers that it is this effective "decision not to decide", or in other words, the effective decision not to complete any approval procedures, that is the source of the alleged moratorium.[568] Argentina also submits that the *de facto* moratorium is the result of a decision.[569] Argentina asserts that since 1998 there have been no approvals of biotech products because the European Communities decided that there should be no new approvals.[570] It is true that Argentina stated that the alleged moratorium has been applied and maintained as a practice in the European Communities.[571] However, Argentina also stated that the *de facto* moratorium is a measure. Moreover, Argentina used the word "practice" after noting that the alleged moratorium had been imposed *de facto* and was not set forth in any piece of legislation.[572] As the Panel understands it, Argentina's reference to a practice was intended to distinguish between, on the one hand, measures the existence of which is self-evident because they take the form of laws or regulations and, on the other hand, measures the existence of which is revealed by an observable pattern of conduct, *e.g.*, by repeated and systematic actions and omissions.

7.456 In conclusion, the Panel considers that the measure which is being challenged by the Complaining Parties is the alleged EC moratorium on the approval of biotech products. The essential

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[565] EC second written submission, para. 296.

[566] US first oral statement, para. 42; US second written submission, para. 45; US third written submission, paras. 5 and 17.

[567] Canada's third written submission, para. 124.

[568] *Ibid*., paras. 202, 203 and 214; Canada's replies to Panel question Nos. 172 and 179.

[569] Argentina's third written submission, para. 50; Argentina's second oral statement, p. 5.

[570] *Ibid*., paras. 17, 50 and 153; Argentina's second written submission, paras. 49 and 129.

[571] Argentina's first written submission, para. 34.

[572] *Ibid*.

elements characterizing the alleged EC moratorium, which the Complaining Parties say was in effect between October 1998 and the date of establishment of this Panel (*i.e.*, 29 August 2003), are the following:

(a) It was not adopted through a formal EC rule- or decision-making process, but it nonetheless constitutes a measure attributable to the European Communities.

(b) It was applicable to all applications for approval of biotech products which were pending or newly submitted during the relevant time period.

(c) It involved the effective suspension by the European Communities of final approval decisions with regard to the applications mentioned in the preceding sub-paragraph.

2. Existence of a general moratorium on approvals

7.457 The **European Communities** argues that there is no moratorium and no suspension that the Panel could rule on because there has been neither a moratorium nor a suspension of the approval process since October 1998. The European Communities acknowledges that no applications were approved between October 1998 and August 2003[573], and that some applications suffered important delays. But the European Communities submits that the absence of approvals and the delays were the result of prudent and responsible actions and not of a "decision not to decide".

7.458 The European Communities asserts that it has never adopted any formal or informal act of any kind to impose a moratorium on approvals. It also notes that the Complaining Parties were unable to identify a single decision attributable to the European Communities which imposed such a moratorium. It is therefore the contention of the European Communities that the measure described by the Complaining Parties did not and does not exist.

7.459 The **Panel** notes that the European Communities contests, not just certain aspects of the alleged general moratorium, but its very existence. It is therefore necessary to examine in detail whether the evidence supports the Complaining Parties' assertion that between October 1998 and August 2003 the European Communities applied a general *de facto* moratorium on the approval of biotech products.

7.460 The Panel will begin its examination by considering how, in the Complaining Parties' view, the European Communities allegedly suspended approvals and whether the European Communities could suspend approvals in this manner. Next, the Panel will determine whether there are any grounds for believing that the European Communities or one of its entities (the member States, the Commission, the Council, etc.) intended to suspend approvals. Then, the Panel will analyse whether the European Communities actually suspended approvals during the relevant time period. As part of this analysis, the Panel will in a first step determine whether any biotech products were approved during the relevant period. In a subsequent step, the Panel will review a substantial number of EC documents and statements by EC and member State officials which were submitted by the Complaining Parties and which they say acknowledge and confirm the existence of a general moratorium during the relevant time period. Finally, the Panel will review the facts and history of individual applications for the approval of biotech products. The Complaining Parties argue that these application histories support and confirm their other allegations, while the European Communities submits that the histories rebut the Complaining Parties' allegations.

[573] The European Communities notes, however, that a number of biotech food products were placed on the market during the period in question. *See infra*, para. 7.497.

(a) Alleged manner of suspending approvals

7.461 As noted above, the Complaining Parties allege that the European Communities suspended consideration of applications at certain critical stages of the EC approval process with a view to preventing the final approval of applications. This leaves open the question of which are relevant stages in the approval process and of which EC entities (member States, Commission, Regulatory Committee, Council, etc.) contributed to the suspension of approvals and how. Therefore, the Panel will now describe how, according to the Complaining Parties, the European Communities allegedly suspended approvals and examines whether it was possible for the European Communities to suspend approvals in this manner.

7.462 The **United States'** main contention in this respect is that at a certain point certain EC member States decided that they were not going to vote for new approvals of biotech products in the relevant Regulatory Committee or in the Council. The United States recalls that under the European Communities' rules of qualified majority voting in the Regulatory Committee or the Council, a minority of member States can block EC action. Blocking minorities in the Regulatory Committee or the Council may be overridden by a simple majority vote in the Commission. But, according to the United States, the record shows that the Commission decided not to do so. The Commission did not submit draft measures to the appropriate Regulatory Committee or to the Council. The United States further argues that if one of the member States that is unwilling to grant marketing approvals was the original recipient of an application, then that single member State could block an application all by itself. The same single member State could also block a product approval by refusing to complete the process, that is to say, by not allowing the product to be placed on the market once it has been approved at Community level by Commission decision.

7.463 **Canada** asserts that the European Communities has suspended the approval of applications through one or more of the following acts and omissions. *First*, at EC member State level, the competent authorities of certain EC member States have failed to ensure that the approval procedures are completed without undue delay. *Secondly*, at Community level, certain member States have routinely objected to favourable assessments by the competent authority of another member State. *Thirdly*, where an application is supported by favourable risk assessments, the Commission has in some cases failed to submit a draft measure to the relevant Regulatory Committee. *Fourthly*, certain member States have blocked the adoption of draft measures by the Regulatory Committee, regardless of the scientific merits of the application in question. *Fifthly*, where there has been an impasse at the Regulatory Committee, the Commission has failed to break the impasse by referring the matter to the Council. *Lastly*, when a product has been approved by Commission decision, the competent authority of the responsible member State has failed to allow that product to be marketed.

7.464 **Argentina** submits that the European Communities has prevented the approval of biotech products since 1998 through various actions and omissions. *First*, failure by the lead CA to complete the relevant approval procedures without undue delay. *Secondly*, failure by the Commission to present draft measures to the Regulatory Committee for approval of products that have received a favourable opinion from the scientific committees. *Thirdly*, systematic opposition by EC member States to approval when a draft is submitted, with no scientific grounds for opposing the Commission's draft measure. *Fourthly*, failure by the Commission to refer a proposal to the Council when the Regulatory Committee issues no opinion.

7.465 The **European Communities** notes that the kinds of "acts and omissions" referred to by the Complaining Parties are part of an internal EC decision-making process and do not have external legal effect. Only the definitive outcome of the decision-making procedure has legal effect. The European

Communities deduces from this that the "acts and omissions" referred to by the Complaining Parties are not reviewable as measures in their own right.

7.466 The **Panel** notes that, according to the Complaining Parties, there were two EC entities with responsibilities in the EC approval process which through their actions and/or omissions prevented the final approval of applications during the time period in question (October 1998 to August 2003). The two entities are EC member States and the Commission. The issue the Panel must consider, therefore, is whether it was possible for these two entities to prevent or delay approvals of biotech products in the manner alleged by the Complaining Parties.

7.467 The Panel first turns to consider the member States' ability to prevent or delay approvals through their actions and/or omissions. Based on its understanding of the relevant EC approval procedures, the Panel agrees with the Complaining Parties that during the relevant time period EC member States could prevent or delay approvals of biotech products in the following ways:[574]

(a) The member State acting as the lead CA could delay the completion and circulation of its initial assessment.

(b) Other member States could object to the placing on the market of a biotech product following a favourable assessment by the lead CA.

(c) A group of member States that constituted a blocking minority could prevent the relevant Regulatory Committee and the Council from reaching the qualified majority necessary to adopt draft measures proposing the approval of applications.

(d) The member State acting as the lead CA in the context of an approval procedure conducted under Directives 90/220 or 2001/18 could refuse to give its consent to the placement on the market of a biotech product after the Commission had approved an application.[575]

7.468 The Panel now turns to consider the Commission's ability to prevent or delay approvals. In this case as well, the Panel agrees with the Complaining Parties that during the relevant time period the Commission could prevent or delay approvals of biotech products in the following ways:[576]

(a) The Commission could delay the submission of a draft measure to the appropriate Regulatory Committee, or it could fail to convene the Regulatory Committee for a vote on a draft measure which has been submitted.

(b) The Commission could delay the submission of a draft measure to the Council where the Regulatory Committee was unable to reach the qualified majority necessary to deliver an opinion.

7.469 It is clear that in two of the above-mentioned scenarios involving member State action, such action would not be sufficient, in itself, to prevent the *final* approval of an application. One scenario

[574] We stress that we are focusing here on whether the member States had the ability to prevent or delay approvals of biotech products, and not whether it would have been legal under EC law for them to do so.

[575] As explained above, under Regulation 258/97 applications for which a decision has to be taken at Community level are approved by the Commission with direct and immediate effect. No subsequent consent at member State level is required.

[576] Here as well, we stress that we are focusing on whether the Commission had the ability to prevent or delay approvals of biotech products, and not whether it would have been legal under EC law for it to do so.

is that of one or more member States objecting to the placing on the market of a biotech product following a favourable assessment by the lead CA. Such member State objections alone could not prevent the final approval of an application because when such objections are raised, it is incumbent on the Commission to submit a draft measure to the Regulatory Committee for its opinion. The other scenario is that of a group of member States preventing the Regulatory Committee and/or the Council from adopting a draft measure proposing the approval of an application. The vote in the Regulatory Committee and/or the Council could not prevent the application from moving towards final approval because in such cases, it would be incumbent on the Commission to submit a draft measure to the Council and, if the Council were to fail to reach a qualified majority in favour or against the draft measure, to adopt the draft measure submitted to the Council. However, in both of these scenarios, the Commission could prevent the final approval of an application by not submitting draft measures to the Regulatory Committee or the Council.

7.470 The European Communities alleges that also in the scenario where the lead CA, in the context of an approval procedure conducted under Directives 90/220 or 2001/18, refuses to give its consent to the placement on the market of a biotech product, member State action would not be sufficient, in itself, to prevent the final approval of an application. The European Communities submits that in cases where a biotech product has been approved by Commission decision, the applicant would be entitled under EC law to place the product on the market even if the lead CA has not yet taken the necessary steps to allow that product to be marketed. According to the European Communities, the applicant could invoke before national courts the obligation imposed on the lead CA by the aforementioned Commission decision. This is an issue to which the Panel will revert later, when it discusses the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. At this point, it is sufficient to note that even if the applicant could ultimately prevail before a national court, the lead CA could effectively prevent the product from being marketed until there was an enforceable court ruling.

7.471 Regarding the European Communities' argument that actions and/or omissions by member States or the Commission in the context of EC approval procedures are not reviewable measures in their own right, the Panel need only note its understanding that the Complaining Parties are not challenging these actions and/or omissions *per se*. The Complaining Parties are challenging the alleged moratorium on approvals. The actions or omissions of member States and the Commission are, however, directly relevant to the Complaining Parties' challenge as they are claimed to constitute the manner in which the European Communities gave effect to the alleged moratorium.

(b) Intention to suspend approvals

7.472 In the above analysis, it has been considered whether individual EC member States, a group of EC member States, and/or the Commission could prevent the final approval of applications during the time period in question (October 1998 to August 2003). The Panel was able to agree with the Complaining Parties' main contention in this regard.

7.473 The issue to which the Panel now turns is whether there are any grounds for believing that any member State and/or the Commission intended to prevent the final approval of applications during the time period in question.

(i) EC member States

7.474 With regard to the member States, the Complaining Parties provided to the Panel a formal declaration made by five member States (Denmark, Greece, France, Italy and Luxembourg) in June 1999. The declaration was made in the context of the meeting of the Council of 24/25 June 1999 at

which a political agreement – a common position – was reached on the proposal to amend Directive 90/220. The declaration reads as follows:[577]

> Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations
>
> The Governments of the following Member States (Denmark, Greece, France, Italy and Luxembourg), in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs),
>
> given the need to put in place a tighter, more transparent framework, in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling,
>
> given the need to restore public and market confidence,
>
> point to the importance of the Commission submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended.

7.475 According to the **Complaining Parties**, the key element of the above-quoted declaration is the statement that:

> "[I]n exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms […] they [the five member States in question] will take steps to have any new authorizations for growing and placing on the market suspended."

7.476 In the Complaining Parties' view, this passage demonstrates that the five member States at issue decided that they would block the approval process. The Complaining Parties argue that the "steps" the five member States said they would take include using their votes in the relevant Regulatory Committee or the Council so as to block the adoption of draft measures approving applications. It has been pointed out in this regard that, taken as a group, the five member States in question have enough votes in the Regulatory Committee and the Council to form a blocking minority.

7.477 In response to a question from the Panel, the **European Communities** stated that declarations to Council minutes, such as the above-quoted June 1999 declaration by five member States, have no legal significance or effect in the European Communities, as confirmed by the jurisprudence of the European Court of Justice.[578] The European Communities submits that its member States are fully aware of this position, but have recourse to such declarations for political purposes – to send a message to other institutions, to the public or to satisfy a political need.

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[577] Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations, 2194th Council Meeting - Environment-, Luxembourg, 24/25 June 1999. Exhibits US-76 and 77; Exhibit CDA-3; Exhibit ARG-12.

[578] The European Communities refers to case C-375/98, *Ministério Público and Fazenda Pública v Epson Europe BV*, [2000] ECR I-4243, para. 26.

7.478 The **Panel** considers that the June 1999 declaration by Denmark, Greece, France, Italy and Luxembourg (hereafter the "Group of Five") clearly reveals an intention on the part of the Governments of the Group of Five countries to do what is within their power to prevent the approval of further applications, pending the adoption of EC rules ensuring "labelling and traceability of GMOs and GMO-derived products". The phrase "state that […] they will take steps" necessarily implies such an intention.

7.479 It is important to note, however, that the June 1999 declaration amounts to more than a statement of intent. It does more than tentatively pronounce how the Group of Five countries intend to exercise their powers. The declaration definitively announces how the Group of Five countries will exercise their powers. Indeed, the Group of Five countries in their declaration do not "state that [...] they [intend] to take steps" to prevent the approval of further applications. Rather, they "state that [...] they *will* take steps" (emphasis added) to do so. In the Panel's view, it may be inferred from this language that each of the Group of Five countries made a decision on how it would exercise its powers.

7.480 The European Communities pointed out that declarations like the June 1999 declaration have no legal effect under EC law. The text of the June 1999 declaration does not suggest otherwise. There is no indication that the declaration was intended to impose obligations on the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. The European Communities appears to infer from the circumstance that the 1999 declaration itself is not legally binding that it might not reflect the real intentions of the Governments of the Group of Five countries and that it may have been made merely for the sake of expediency, "to satisfy a political need". However, a panel must not lightly cast doubt on the good faith underlying governmental declarations and on the veracity of these declarations. In the instant case, the precise, legal-style drafting of the 1999 declaration demonstrates that it is not a casual statement, but a carefully considered one. What is more, the 1999 declaration is a formal, on-the-record declaration made on behalf of the Governments of the Group of Five countries and reflecting their official position. In these circumstances, and in the absence of evidence to the contrary, it may be presumed that the 1999 declaration by the Governments of the Group of Five countries accurately expresses their true intentions.[579]

[579] With respect to DS292 we note that Canada has introduced evidence which suggests that the Group of Five declaration was reiterated over time. *First*, evidence submitted by Canada suggests that the declaration was reiterated at the formal adoption of the Common Position on 9 December 1999. Exhibit CDA-32, p. 5. *Secondly*, Canada refers to a statement by the Group of Five countries plus Austria of 15 February 2001 which also reaffirmed the intention expressed in the June 1999 declaration. The statement accompanied the adoption by the Council of the definitive legislative act embodying the revised Directive 90/220, following the European Parliament's second reading under the co-decision procedure. The Council decided to make the statement public. It reads in full:

> "Statement by the Danish, Greek, French, Italian, Austrian and Luxembourg Delegations
>
> Having regard to the principle of prevention and precaution, the delegations of the following Member States: Denmark, Greece, France, Italy, Austria and Luxembourg
>
> - reaffirm the need to introduce a more rigorous, transparent and comprehensive framework concerning risk assessment and risk management (taking account of the specific characteristics of European eco-systems), monitoring, traceability and labelling of GMOs and to generally restore the confidence of the public and of operators;

7.481 Another element which needs to be noted in respect of the 1999 declaration is the fact that it is a joint declaration. More particularly, what is of interest is the composition of the Group of Five countries. During the time period in question (October 1998 to August 2003), the member States making up the Group of Five countries had enough votes in the appropriate Regulatory Committee or the Council to prevent these bodies from achieving the qualified majority that is necessary to adopt a draft measure proposing the approval of an application.[580] In other words, the Group of Five countries

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- note that the amended provisions of Directive 90/220/EEC significantly but only partially improve the existing arrangements and emphasise the essential improvements made concerning transparency, public access to information, regional biological monitoring of the countryside, gradual elimination of antibiotic resistance markers, legal certainty and ratification of the Carthagena Protocol;
- ask the Commission to follow up its commitment concerning the early submission of comprehensive legislative proposals on GMO traceability and labelling, environmental liability and ratification of the Carthagena Protocal.

Accordingly, the above delegations

- *reaffirm their intention, when exercising the powers conferred upon them, of ensuring that the new authorizations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products*;
- call on the Commission to make rapid progress towards the establishment of a system of environmental liability to supplement the regulatory framework necessary for development in the field of biotechnologies, as in other environmental fields." (Exhibit CDA-114; emphasis added).

We note that Argentina also refers to Exhibit CDA-114. Finally, evidence submitted by Canada suggests that the Group of Five countries plus Austria reaffirmed their previous declarations at the final adoption of the revised Directive 90/220 on 12 March 2001. Exhibit CDA-31, p. 1. Argentina also refers to Exhibit CDA-31, p.1.

[580] Article 21 of Directive 90/220 provides that Regulatory Committee opinions "shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission". It further provides that in those cases where a measure cannot be adopted after the Regulatory Committee stage and the matter goes before the Council, "[t]he Council shall act by a qualified majority". Article 148(2) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties* provides in relevant part (emphasis added):

"Where the Council is required to act by a qualified majority, the votes of its members shall be weighted as follows:

Belgium	5
Denmark	*3*
Germany	10
Greece	*5*
Spain	8
France	*10*
Ireland	3
Italy	*10*
Luxembourg	*2*
Netherlands	5
Austria	4
Portugal	5
Finland	3
Sweden	4
United Kingdom	10

constituted a "blocking minority" at the level of decisions by the Regulatory Committee and the Council. It should be recalled in this context that the 1999 declaration states that the Governments of the Group of Five countries "will take steps to have any new authorizations for growing and placing on the market suspended". One of the steps open to the Governments of the Group of Five countries was to act as a "blocking minority" in the relevant Regulatory Committee or Council. Thus, to the extent that the 1999 joint declaration by the Group of Five countries was perceived as announcing or confirming the formation of a credible "blocking minority", it sent an important signal to other member States and the Commission. It would have signalled that if the Group of Five countries were to act in accordance with their declaration, applications could henceforth be approved only at Community level[581] and only if the Commission was willing (i) to submit draft measures to the Regulatory Committee and the Council and (ii) to override a "blocking minority" by adopting the proposed measures.

7.482 Before proceeding further, we also need to address the substance of the declaration by the Group of Five countries. To begin with, we recall that in their declaration, the Group of Five countries pointed to the importance of the Commission "submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products" and stated that "pending the adoption of such rules, they would take steps to have any new authorizations for growing and placing on the market suspended". This suggests that upon adoption of such rules, the Group of Five countries might no longer use the powers conferred upon them so as to prevent the approval of applications.[582] It is therefore important to be clear about the rules the Group of Five countries wanted to see adopted, all the more so as subsequent to the June 1999 declaration the European Communities adopted two legislative acts which specified labelling and traceability requirements.

7.483 In March 2001, the European Communities adopted the amended Directive 90/220 as Directive 2001/18. Directive 2001/18 laid down labelling requirements in Article 21 and certain traceability and monitoring requirements in Article 4(6) (and Annex IV) and in Article 20 (and Annex VII). In September 2003, *i.e.*, shortly after this Panel was established, the European Communities adopted Regulation 1830/2003 "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC". For the reasons set out below, the Panel is of the view that the rules which the Group of Five countries wanted to see adopted are the rules adopted in September 2003 as Regulation 1830/2003, and not those adopted in March 2001 as Directive 2001/18.[583]

For their adoption, acts of the Council shall require at least:

62 votes in favour where this Treaty requires them to be adopted on a proposal from the commission."

Since the total number of votes is 86, the 30 votes of the Group of Five countries (Denmark, Greece, France, Italy and Luxembourg) are sufficient to prevent the required qualified majority of 62 votes from being achieved.

[581] It could be expected that in any case where a lead CA that was not part of the Group of Five countries made a favourable assessment at member State level, one or more of the Governments of the Group of Five countries would take the "step" of objecting to the product being placed on the market in order to force a decision at Community level where the Group of Five countries could take the further "step" of acting as a "blocking minority".

[582] It should be noted that in the context of the EC legislative process, the adoption of rules by the European Parliament and the Council is a stage that is different from the proposal for such rules by the Commission and the entry into force of such rules.

[583] As we explain further below, we think it is plausible that the new EC rules which the Group of Five countries wanted to see adopted also include the rules adopted in September 2003 as Regulation 1829/2003.

7.484 *First*, the June 1999 declaration by the Group of Five countries calls on the Commission to submit a proposal for rules ensuring labelling and traceability. By June 1999, the Commission had already submitted a proposal for an amendment of Directive 90/220.[584] In contrast, the Commission did not submit a proposal for what was to become Regulation 1830/2003 until 2001.[585] *Secondly*, the June 1999 declaration calls for rules "ensuring labelling and traceability of GMOs and *GMO-derived products*" (emphasis added). Neither Directive 90/220 nor Directive 2001/18 applied to GMO-derived products.[586] In contrast, Regulation 1830/2003 applies to such products.[587] *Lastly*, mention should be made of a June 1999 formal declaration by seven member States (Austria[588], Belgium[589], Finland, Germany, Netherlands, Spain and Sweden). Like the Group of Five declaration, the declaration in question was made in the context of the meeting of the Council of 24/25 June 1999 at which a political agreement was reached on the proposal to amend Directive 90/220. The declaration by the seven member States (hereafter the "Group of Seven") is reproduced in relevant part below:[590]

> "Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations
>
> Being aware of the increasing public concern about the potential risks to health and environment linked to the release and the placing on the market of GMOs, the above-mentioned delegations
>
> – stress the need to implement a more transparent and strict framework concerning critical issues such as risk assessment taking into account the specificity of European ecosystems, monitoring and labelling as well as the need to restore the trust of public opinion and of the market;
>
> – reaffirm their intention to work for a rapid finalisation of the legislative process concerning the proposal for an amendment of Directive 90/220/EEC and invite the European Parliament to join the Council and the Commission in their intention so that the legislative process can be rapidly finalised.
>
> Against this background the Governments of these Member States, having regard to the precautionary principle set out in Article 174(2) of the Treaty, intend:

That Regulation lays down additional labelling requirements for genetically modified food and feed. *See infra*, para. 7.1039.

[584] The proposal was published on 4 May 1998. Preamble to Directive 2001/18; Exhibit US-71.

[585] The proposal was published on 30 October 2001. Preamble to Regulation 1830/2003.

[586] Article 2(4) of Directive 90/220; Article 2(7) of Directive 2001/18.

[587] Article 2 in conjunction with Article 3(2) of Regulation 1830/2003.

[588] We recall that Canada submitted evidence which shows that Austria in February 2001 formally expressed its support for the June 1999 declaration by the Group of Five countries. Exhibit CDA-114. Argentina also refers to Exhibit CDA-114.

[589] We note that the United States submitted a document which suggests that Belgium as of December 2001 also supported the June 1999 declaration by the Group of Five countries. The document, which appears to be based on a press release, says that Belgium decided that new EC rules on traceability and labelling would need to be formally approved before other measures could be taken. The document also states that Belgium decided to discuss this issue again in October 2002. Exhibit US-79. Canada and Argentina also refer to Exhibit US-79.

[590] Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations, 2194th Council Meeting - Environment, Luxembourg, 24/25 June 1999. Exhibits US-76 and -77; CDA-3; ARG-12.

> – to take a thoroughly precautionary approach in dealing with applications and authorizations for the placing on the market of GMOs,
>
> – not to authorize the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health, and
>
> – to the extent legally possible to apply immediately the principles, especially regarding traceability and labelling, laid down in the political agreement for a revision of Directive 90/220/EEC reached by the Council on 24/25 June 1999.
>
> Therefore, these delegations invite the Commission as a matter of urgency to make a proposal for effective implementation of the provisions regarding labelling and traceability of GMOs through the comitology procedure foreseen in Directive 90/220/EEC."

7.485 The declaration by the Group of Seven countries is of interest because it talks about "the principles […] regarding labelling and traceability of GMOs *laid down in the [June 1999] political agreement for a revision of Directive 90/220/EEC*" (emphasis added). The parallel declaration by the Group of Five countries, when referring to rules ensuring labelling and traceability, nowhere references the June 1999 political agreement. Had the Group of Five countries wanted to see the adoption of the provisions regarding labelling and traceability laid down in the June 1999 political agreement, one would have expected a reference to that agreement along the lines of the reference contained in the declaration by the Group of Seven countries.

7.486 We further find noteworthy that the declaration by the Group of Seven countries calls for a *de facto* implementation of the provisions regarding labelling and traceability of GMOs laid down in the June 1999 political agreement prior to the entry into force of the agreed amendment of Directive 90/220. Apparently, this was considered insufficient by the Group of Five countries. Reading the declaration by the Group of Five countries together with the declaration by the Group of Seven countries, it seems to us that the Group of Five countries considered it insufficient to adopt the provisions laid down in the June 1999 political agreement, even if those provisions were implemented before their adoption, as the Group of Seven countries requested. It appears that the Group of Five countries wanted to go further and adopt new rules which the Commission was invited to propose without delay.

7.487 Another issue which concerns the substance of the declaration by the Group of Five countries is whether the declaration also covers applications for the approval of biotech food products, *i.e.*, applications which fall within the scope of Regulation 258/97. At this point, it is sufficient to note that, in our view, the declaration can be interpreted to apply also to such applications. We will address this issue further at paragraphs 7.1038-7.1041 below.

(ii) Commission

7.488 Unlike in the case of the Group of Five countries, the Complaining Parties did not refer the Panel to a declaration by the Commission in which it stated an intention to delay or prevent the final approval of applications. Nor did the Complaining Parties argue that they had provided other direct evidence of such an intention on the part of the Commission. It is nevertheless clear that it is the contention of the Complaining Parties that the Commission intentionally delayed or prevented the final approval of applications during the relevant time period (October 1998 to August 2003). This

intention can be inferred, in the Complaining Parties' view, from the absence of approvals during the relevant time period and the Commission's conduct in the context of individual approval procedures. The Panel will address these two elements later in its analysis.

7.489 In the absence of evidence which directly establishes that the Commission intentionally delayed or prevented final approvals, it is pertinent to ask why in the Complaining Parties' view the Commission would have wanted to delay or prevent such approvals. As the Panel understands it, the Complaining Parties' answer is that the decision to do so was based on political considerations.[591] More particularly, the argument essentially appears to be that following the announcement by the Group of Five countries that they would act as a "blocking minority" in the Regulatory Committee and the Council, the Commission considered that it lacked the necessary political support for completing approval procedures by adopting its own draft measures.

7.490 It should be mentioned in this respect that the United States and Canada in their submissions both refer to, and quote from, the summary of a January 2001 meeting between the lead CA in the approval procedure concerning RR fodder beet and the applicant.[592] According to the summary, which was prepared by the applicant and sent to the lead CA (Denmark) by way of confirmation, the applicant was given to understand by the lead CA that – in the applicant's words – "[t]he re-start of the regulatory process will depend on the willingness of the Commission to do it. It is commonly analysed that the Commission will not promote an Art 21 [Regulatory Committee] vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively."[593] If the applicant's summary correctly reflects Denmark's statement, this statement suggests that the Commission at the time viewed the political support of member States as a necessary precondition for it convening Regulatory Committee meetings for votes on applications. It should be borne in mind, however, that Denmark is one of the Group of Five countries. Hence, even if Denmark made the statement in question, it might have overstated the importance of Group of Five countries' support.

7.491 Canada also submitted a Commission document entitled "GMOs Issues Paper – Strategy on Possible Ways Forward".[594] The document was prepared by the "services" for the "Commission orientation debate on GMOs" of 12 July 2000. Thus, it was written after the June 1999 declaration by the Group of Five countries, but before the adoption of Directive 2001/18. Against this background, the document states in a passage quoted by Canada that "[o]ur objective is to have, by the end of the conciliation process and the adoption of the revised Directive [90/220], the elements necessary to complete the authorization process and to convene a meeting of the regulatory committee under Directive 90/220/EC. *If the Member States are still not prepared to vote positively in the Committee, the Commission should be ready to make full use of the procedures set out in the Directive to complete the authorization process.*"[595] The last sentence implies that, at the time in question, the Commission could have considered member State opposition a reason for not making full use of the procedures envisaged in Directive 90/220 to complete the approval process. Otherwise there would have been no point in recommending that the Commission should be ready to complete the approval process. It must also be noted, however, that it cannot be assumed that the views expressed in a strategy paper prepared by the Commission services necessarily reflect those of the Commission.

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[591] US reply to Panel question No. 74; US second oral statement, paras. 36-38; Exhibit US-148; US third written submission, para. 21; Canada's second written submission, paras. 23 and 26; Canada's third written submission, paras. 202-203; Argentina's second written submission, para. 52.

[592] US third written submission, para. 92; Canada's second written submission, para. 34.

[593] Exhibit EC-64/At. 120.

[594] Exhibit CDA-113. The document was first submitted by Argentina as Exhibit ARG-50.

[595] Exhibit CDA-113, p. 3 (emphasis added).

7.492 In the Panel's view, it is clear even without the above-mentioned statements attributed to Denmark and the Commission services that member State support might in some circumstances be an issue for the Commission. To see why, it is useful to recall a fundamental aspect of the structure and design of the EC approval procedures. Canada described this aspect in the following terms:

> "Directives 90/220 and 2001/18 foresee an approval based on the lead member State's review as the primary route to a decision. Only in relatively limited cases should the Regulatory Committee need to become involved. And only as an exception to this exception is the Council required to act. And finally, only as an exception to the exception to the exception does the Commission have the final say."[596]

7.493 Canada may or may not be correct with regard to what should be the "primary route to a decision" and what should happen "only in relatively limited cases". But there can be little doubt that the Commission's "final say" was intended by the EC legislator as a last resort, to avoid deadlocks that might otherwise occur in the event that the member States in the Regulatory Committee and the Council fail to achieve the required qualified majority.[597] Notwithstanding this, exceptional circumstances might arise where the Commission routinely would have the final say and the "exception to the exception to the exception", as Canada put it, would become the rule, contrary to the design of the EC approval procedures. This could be the case, for instance, in circumstances where member State opposition to Commission proposals is not merely sporadic but systematic, and where the relevant member States at the same time have enough votes to act as a "blocking minority" in the Regulatory Committee and the Council.

7.494 As noted by the Panel in its preceding remarks, the Group of Five countries in June 1999 signalled precisely such systematic opposition to final approvals. In addition, the combined votes of the Group of Five countries enabled them to act as a "blocking minority". The Commission thus had reason to believe that it could no longer approve applications with the (qualified majority) support of the member States. In such highly exceptional circumstances, and considering the sensitivity of approvals of biotech products, it is plausible that the systematic lack of political support, and indeed opposition, by the Group of Five countries was an issue and concern for the Commission. This situation could, in our view, have dissuaded the Commission from making full use of the relevant procedures to complete the approval process, despite the applicable legal obligations[598].

(c) Absence of approvals during the relevant time period

7.495 The Complaining Parties assert not only that certain member States (notably the Group of Five countries) and the Commission had the ability and intention to prevent the final approval of applications during the time period in question. They also assert that these member States and the Commission actually prevented the final approval of applications during that time period. That there was an actual suspension on final approvals is evidenced, in the view of the Complaining Parties, by the following two elements: (i) the number of final approvals in the relevant time period, and (ii) official and internal EC documents as well as statements by EC and member State officials. In the

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[596] Canada's third written submission, para. 196. A statement along very similar lines could be made in respect of Regulation 258/97.

[597] It is useful to note in this context that the regulatory committee procedure, whereby the Commission is assisted by a regulatory committee, involves a delegation of implementing powers from the Council to the Commission. *See, e.g.*, Council Decision 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission. The Decision is referred to in Article 30(2) of Directive 2001/18.

[598] Article 21 of Directive 90/220; Article 13(3) and (4) of Regulation 258/97.

present Subsection, the Panel addresses the first element – the issue whether there were any approvals in the relevant time period (October 1998 to August 2003).

7.496 The **Complaining Parties** argue that between October 1998 and August 2003, when the Panel's terms of reference were established, the European Communities failed to approve a single biotech product under either Directives 90/220 and 2001/18 or under Regulation 258/97. This is despite the fact that many applications were pending during that period and that many of these applications had been favourably assessed by the European Communities' own scientific committees. In contrast, up to October 1998 – the date of the last approval of a biotech product – the European Communities had approved at least ten biotech products.[599]

7.497 The **European Communities** responds that it does not contest that other than the biotech food products approved under the simplified procedure of Regulation 258/97[600], there have not been any approvals for a given period of time due to the fact that the EC regulatory regime was incomplete. Regarding the simplified procedure of Regulation 258/97, the European Communities states that between October 1998 and 2004 seven biotech food products were approved.

7.498 The **United States** submits that the simplified procedure set out in Regulation 258/95 does not require action by the Council or Regulatory Committee. The United States further states that the simplified procedure does not appear to be affected by the EC moratorium.

7.499 **Canada** notes that the simplified procedure is only available in limited circumstances and does not require the Commission to take a decision at Community level. Canada submits that each of the applications referred to by the European Communities were assessed by food assessment bodies from one member State. Other member States did not have an opportunity to block or stall this process. That the relevant member State food assessment bodies acted on the basis of sound science and in accordance with EC law does not, in Canada's view, disprove the existence of the moratorium.

7.500 **Argentina** argues that the simplified procedure of Regulation 258/97 only requires that one member State issue an opinion that the product is "substantially equivalent" to existing foods or food ingredients. Once that opinion is issued, the marketing of the product in question cannot be prevented by other member States or the Commission. Argentina submits on that basis that the simplified procedure is not an approval procedure, but a application procedure.

7.501 The **Panel** notes that it is not in dispute that during the relevant time period (October 1998 to August 2003) numerous applications for placing on the market were awaiting approval under either Directives 90/220 and 2001/18 or Regulation 258/97.[601]

7.502 Also uncontested are the following facts:

(a) Under Directive 90/220, no application was approved or rejected between October 1998 and October 2002, when Directive 90/220 was repealed.[602]

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[599] Canada contends that twelve biotech products were approved. Canada's first written submission, para. 65.

[600] For an explanation of the simplified procedure, *see* section VII.C.3(c): Novel foods and novel food ingredients: Regulation 258/97.

[601] *See* Subsection (e) below entitled "Facts and histories of individual approval procedures".

[602] It should be noted that, according to the European Communities, one application was withdrawn after it had received a negative assessment. EC reply to Panel question No. 14. As the European Communities

(b) Under Directive 2001/18, no application was approved or rejected between October 2002, when Directive 2001/18 entered into force, and August 2003.

(c) Under the ordinary procedure of Regulation 258/97[603], no application was approved or rejected between October 1998 and August 2003.

(d) Under the simplified procedure of Regulation 258/97[604], a number of biotech food products were placed on the market between October 1998 and August 2003.[605]

7.503 Accordingly, with the exception of biotech products subject to the simplified procedure of Regulation 258/97 to which the Panel will revert below, the European Communities did not approve or reject any biotech product between October 1998 and August 2003.[606]

7.504 It should also be noted, however, that both before October 1998 and after August 2003, the European Communities did approve applications for the placing on the market of biotech products. Up to and including October 1998, the European Communities approved the following ten agricultural biotech products:[607]

- BXN tobacco (in June 1994);
- MS1/RF1 oilseed rape (EC-161) (in February 1996; for breeding activities); MS1/RF1 oilseed rape (EC-89) (in June 1997; for import and processing)[608];
- MON soybeans (in April 1996);
- Transgenic red-hearted chicory (in May 1996);
- Bt-176 maize (in January 1997);
- MS1/RF2 oilseed rape (in June 1997)[609];
- Topas oilseed rape (in April 1998);
- T25 maize (in April 1998);

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provided no details, it is unclear whether this application had been submitted under Directives 90/220 or 2001/18 or under Regulation 258/97.

[603] The ordinary procedure is laid down in Articles 4, 6 and 7 of Regulation 258/97.

[604] The simplified procedure is laid down in Article 5 of Regulation 258/97.

[605] The European Communities asserts that between October 2003 and 2004 seven products were placed on the market. But the European Communities provides no documentary support which would allow the Panel to confirm this number. EC reply to Panel question No. 14. Evidence submitted by the United States (Exhibit US-107, Annex 5), Canada (Exhibit CDA-25) and Argentina (Exhibit ARG-6, Annex 4) supports the conclusion that between October 1998 and August 2003 a total of six biotech food products were placed on the market.

[606] The European Communities has pointed out that one application concerning a genetically modified potato was withdrawn after it had received a negative assessment, but no details were provided to the Panel.

[607] Exhibits US-97 and 107 (Annex 1); CDA-34 (Annex 1); ARG-6 (Annex 1). It is clear from these exhibits that in addition to the agricultural biotech products already mentioned, several more biotech products were approved (certain vaccines, a test kit to detect antibiotic residues in milk and certain carnation lines). Two of these additional products were approved in October 1998.

[608] MS1/RF1 oilseed rape (EC-161) and MS1/RF1 oilseed rape (EC-89) are the same products; but the scope of the underlying applications was different. Regarding MS1/RF1 oilseed rape (EC-89), the Complaining Parties assert that, despite the fact that the Commission took a favourable decision on the application concerning MS1/RF1 oilseed rape, the lead CA never granted written consent to the placing on the market of this product. The Panel will revert to this issue below at paras. 7.1018-7.1028.

[609] The Complaining Parties assert that, despite the fact that the Commission took a favourable decision on the application concerning MS1/RF2 oilseed rape, the lead CA never granted written consent to the placing on the market of this product. The Panel will revert to this issue below at paras. 7.1018-7.1028.

– Bt-11 maize (EC-163) (in April 1998); and
– MON810 maize (in April 1998).

7.505 After 29 August 2003, that is to say, after the Panel was established, and before the Panel's second substantive meeting with the Parties, a further three applications concerning two different biotech products were approved by the Commission:

– Bt-11 maize (food) was approved under Regulation 258/97 on 19 May 2004[610];
– NK603 maize was approved under Directive 2001/18 on 19 July 2004[611]; and
– NK603 maize (food) was approved under Regulation 258/97 on 26 October 2004[612].

7.506 Like the pre-October 1998 approvals, the aforementioned post-August 2003 approvals are relevant facts which the Panel may take into account in the context of its determination of whether the European Communities applied a general moratorium on approvals between October 1998 and August 2003. In respect of the post-August 2003 approvals, it is important to bear in mind, however, that they were all granted while the present panel proceedings were already under way.[613] The European Communities contends that these approvals are nevertheless evidence that there was no general moratorium during the relevant time period. Referring to the example of Bt-11 maize (food), which it describes as representative of other applications, the European Communities points out that the relevant application was submitted in 2000 and then steadily proceeded to the final approval in 2004.[614] Argentina considers that the approval of Bt-11 maize (food) may well be directly attributable to the present panel proceedings and should therefore not be regarded as representative of other applications.[615] The United States, for its part, asserts that the existence and timing of the approval of Bt-11 maize (food) is no coincidence and should be seen against the background of the panel proceedings and the entry into force of the new EC rules on labelling and traceability in April 2004.[616]

7.507 Significantly, all Complaining Parties also maintain that prior to being approved in 2004, the applications concerning Bt-11 maize (food), NK603 maize and NK603 maize (food) were affected by the alleged general moratorium. Thus, the fact that three applications were approved after August 2003 is not necessarily inconsistent with the Complaining Parties' assertion that between October 1998 and August 2003 certain member States and the Commission intentionally prevented the final approval of all applications.

7.508 It should be noted that after the Panel's second substantive meeting with the Parties, the European Communities sent two letters to the Panel and the other Parties, for information, stating that

[610] Exhibit EC-92/At. 81; Exhibits CDA-109 and 138; EC comments on Complaining Parties' replies to Panel questions, para. 63.

[611] Exhibit CDA-137; EC comments on Complaining Parties' replies to Panel questions, para. 62. This application was approved by the Commission pursuant to the provisions of Directive 2001/18. The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[612] US third written submission, para. 101; EC comments on Complaining Parties' replies to Panel questions, para. 63. NK603 maize and NK603 maize (food) are the same products; but the scope of the underlying applications was different.

[613] The first of these approvals came a few weeks after the Complaining Parties filed their first written submissions. Prior to that, the Complaining Parties had already outlined their cases in their requests for the establishment of a panel. These requests are dated 7 August 2003.

[614] EC first oral statement, paras. 29-32.

[615] Argentina's second written submission, para. 23.

[616] US third written submission, para. 15; US second written submission, paras. 47-49.

the Commission approved two additional applications concerning two different biotech products. Specifically, the European Communities stated that:

- MON863 maize was approved under Directive 2001/18 on 8 August 2005[617];
- RR oilseed rape (EC-70) was approved under Directive 2001/18 on 31 August 2005[618].

7.509 As the European Communities sent its letters for information, no supporting evidence was provided and no arguments were exchanged in relation to the two Commission approvals. However, the Complaining Parties did not question the European Communities' contention that the two applications were in fact approved by the Commission under Directive 2001/18. The Panel further notes that, curiously, the approval procedure concerning MON863 maize was never examined by the Complaining Parties or the European Communities in their written or oral submissions.[619] As the Panel has been given no detailed information on this application and the Parties have offered no examination of this application, the Panel will not, and indeed cannot, address it for the purposes of its analysis of whether or not the European Communities applied a general *de facto* moratorium on the approval of biotech products between October 1998 and August 2003.

7.510 As indicated above, it is necessary to consider in more detail the simplified procedure of Regulation 258/97 under which a number of biotech food products were placed on the market during the relevant time period. At the request of the Panel, the European Communities provided an explanation of the simplified procedure, which is reproduced below in relevant part:[620]

> "Under the simplified procedure products cannot be placed on the market without having been notified. Application in turn is only possible if it has been demonstrated that the product in question is substantially equivalent to existing foods or food ingredients [...]
>
> Substantial equivalence, according to Article 3(4), in principle can be demonstrated in two ways: (1) by relying on scientific evidence available and generally recognized and (2) by relying on an opinion delivered by one of the competent food assessment

[617] The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[618] The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[619] In its first written submission, the European Communities stated that "in order to complete the picture", it would provide a brief overview of those applications which were not mentioned in the Complaining Parties' requests for the establishment of a panel. EC first written submission, paras. 196 and 334. While the European Communities listed a number of applications which had been submitted under Directive 2001/18 and were still pending, no mention was made of MON863 maize, even though that application was not mentioned in the Complaining Parties' panel requests. Subsequently, in its reply to Panel question No. 91, the European Communities made a passing reference to MON863 maize, stating nothing more than that the application would be discussed in the Regulatory Committee in the autumn of 2004. In relation to DS292, we note that Canada submitted two opinions by the GMO Scientific Panel of the European Food Safety Authority of April 2004 which concern MON863 maize. One was issued in respect of an application under Directive 2001/18 and the other was issued in respect of an application under Regulation 258/97. These opinions, which post-date the date of establishment of the Panel, were submitted, together with numerous other opinions, as attachments to a list provided in support of Canada's general assertion that there were applications pending under Directive 2001/18 and Regulation 258/97 which had received a favourable scientific opinion by an EC scientific committee. Canada's first written submission, paras. 50 and 54.

[620] EC reply to Panel question No. 15.

> bodies of the EU Member States (see Article 4(3)). Only the latter option, however, is *de facto* applicable to GM products as there exists no generally recognised scientific evidence on the substantial equivalence of these products. Accordingly, no applicant for GM products under the simplified procedure has ever even tried to demonstrate substantial equivalence under this first option.
>
> In order to obtain an opinion from a competent food assessment body in an EU Member State, an applicant has to submit a dossier on, and the competent body proceeds to a full assessment of, the product in question.
>
> Once the competent body has reached a positive opinion, the applicant may proceed to notifying the product on the basis of that opinion. The application is made to the Commission. Neither the Commission nor another Member State, at this stage, can prevent the application on the basis that it would not agree with the opinion. [...]"

7.511 In the European Communities' view, because biotech food products subject to the simplified procedure effectively require prior recognition of "substantial equivalence" through a member State food assessment body, they effectively require prior approval.[621] The issue therefore arises whether the simplified procedure is an approval procedure. If it is, the fact that a number of biotech food products were placed on the market during the relevant time period would present the further issue of whether the Complaining Parties are correct in claiming that no "applications" for the placing on the market of biotech products were "approved" in the relevant time-frame.[622]

7.512 Article 5 of Regulation 258/97, which lays down the simplified procedure, states that the applicant shall "notify the Commission of the placing on the market when he does so" and that "[s]uch applications shall be accompanied by the relevant details provided for in Article 3(4)". As pointed out by the European Communities, the relevant details commonly include an opinion delivered by a member State food assessment body confirming the "substantial equivalence" of the biotech food product in question. Thus, the text of Article 5 makes clear that the applicant may proceed to place the relevant product on the market without seeking prior approval or authorization. The applicant must merely "notify" the Commission when the product is placed on the market; the Commission is neither required nor authorized to take an authorization decision on the product.[623] Similarly, the relevant member State food assessment body is tasked with delivering a scientific "opinion" on "substantial equivalence"; it is not empowered to decide whether and on what conditions the relevant product may be placed on the market. As noted by the European Communities, once a member State food assessment body has delivered an opinion confirming "substantial equivalence", neither the relevant member State nor another member State can prevent the product from being placed on the market.[624]

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[621] *Ibid*.

[622] *See* the Complaining Parties' requests for the establishment of a panel as contained in documents WT/DS291/23, WT/DS292/17 and WT/DS293/17.

[623] In contrast, under the ordinary procedure of Regulation 258/97, the applicant may place the product on the market only if one of the following two conditions are met: (i) the lead CA has "decided", after an initial assessment, that no additional assessment is required and has informed the applicant that it "may" place the product on the market (*see* Articles 6(3) and 4(2) of Regulation 258/97), or (ii) the Commission has taken a favourable "authorization decision" in accordance with the regulatory committee procedure (*see* Article 7 of Regulation 258/97).

[624] In contrast, the record demonstrates that under the approval procedures set out in Directives 90/220 and 2001/18 as well as in Articles 4, 6 and 7 of Regulation 258/97, applicants did not and could not proceed to place their products on the market even though specialized bodies at member State or Community level had

7.513 In the light of the foregoing, the Panel considers that it would not be correct to say, in relation to the biotech food products which were placed on the market between October 1998 and August 2003, that the placing on the market of these products was "approved", or authorized, by the specialized member State food assessment bodies which confirmed their "substantial equivalence", and even less that there were "applications" for the placing on the market of these products which were "approved" by these specialized bodies. Accordingly, the Panel finds that the fact that a number of biotech food products were placed on the market during the relevant time period does not disprove the Complaining Parties' claim that no "applications" for the placing on the market of biotech products were "approved" by the European Communities in the relevant time-frame.

(d) Documents and statements referring to a "moratorium"

7.514 As previously noted, in support of their assertion that certain EC member States and the Commission actually prevented the final approval of applications during the relevant time period (October 1998 to August 2003), the Complaining Parties point to two elements of proof: (i) the absence of final approvals in the relevant time period, and (ii) official and internal EC documents as well as statements by EC and member State officials.[625] In this Subsection, the Panel addresses the second element.

7.515 The Complaining Parties have submitted numerous documents and statements which are identified further below[626] and which can be divided into five categories:

(i) Commission documents and statements by individual Commissioners;

(ii) Council documents;

(iii) European Parliament documents;

(iv) statements by member State officials; and

(v) EC statements at the WTO.

7.516 The **Complaining Parties** contend that these documents and statements acknowledge and demonstrate the existence of a general moratorium on approvals during the relevant time period.

7.517 The **European Communities** argues that none of the documents or statements referred to by the Complaining Parties represents the official position of the European Communities. The official position of the European Communities is that there was no moratorium between 1998 and 2003 and that there has been no moratorium since. Rather, every application is decided on its own merits, against the background of proposed and actual new legislation and changes in scientific knowledge and understanding.

7.518 The European Communities further argues that none of the documents and statements referred to by the Complaining Parties provide evidence of the existence of a *de facto* moratorium.

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delivered favourable scientific opinions on these products. This is because notwithstanding these favourable opinions, during the relevant time period no authorization decisions were taken in respect of these products.

[625] The Complaining Parties have all stated that they rely on the relevant documents and statements as evidence of the existence of the alleged general moratorium on approvals. US first oral statement, para. 25; Canada's first oral statement, para. 36; Argentina's first oral statement, paras. 18-19.

[626] *See infra*, para. 7.524 *et seq*.

They neither prove nor confirm the existence of a suspension of the approval process. Regarding the statements by EC officials or member State officials, the European Communities observes that they are expressions of opinion associated with specific persons or reflect views of individual member States. They simply describe a situation and do not assert the existence of a practice of suspending the approval process. The European Communities submits that the fact that there have been no authorizations for some time may be perceived from the outside as a situation of "standstill". But the absence of a decision is not the same thing as a decision not to decide. The European Communities states that the perceived "standstill" in reality is a reflection of the fact that in the relevant approval procedures there have been requests for additional information on complex risk assessment and risk management issues. Furthermore, in the great majority, the references in some of the documents and statements submitted to a "moratorium" or "*de facto* moratorium" were made in the context of legislative changes in the European Communities. While during that transition period approval procedures may in some cases have suffered important delays, that period has ended, and so the documents and statements referred to by the Complaining Parties do not establish a "moratorium" that is currently in existence.

7.519 The **United States** responds that the Complaining Parties are not relying on casual statements. The statements cited by the Complaining Parties are statements made by the European Communities' highest officials, by its official bodies and by its member States. In the United States' view, the numerous statements from every EC entity – member States, Commission, Council, and Parliament – are strong evidence of the existence of a general moratorium. The United States further argues that the relevant documents and statements do not refer simply to the fact that no biotech products reached final decision; they uniformly refer to the existence of a "moratorium". The United States submits that the term "moratorium" was used because it precisely fit the situation: namely, that the European Communities had decided not to allow any biotech application to move to final approval.

7.520 **Canada** argues that the relevant documents and statements are strong, consistent further confirmation by the most senior officials in the European Communities that it has maintained a moratorium. These statements are not casual, nor are they perceptions "from the outside".

7.521 **Argentina** considers that the statements in question demonstrate both the existence of the *de facto* moratorium and the period during which it has been applied. The statements show that the existence of the moratorium has been acknowledged by senior EC officials with direct competence on the matter considered in this dispute. Moreover, one document – a background note from the Council's press service of April 2004 – confirms that the moratorium was still in existence at that time.

7.522 The **Panel** begins by noting that there appears to be no disagreement among the parties that EC documents or statements by EC or member State officials may constitute evidence of the existence of a measure. The European Communities referred in this respect to the GATT panel report on *Japan – Semi-conductors*.[627] In that case, the panel considered a position paper of the responding party which described the measure at issue as well as the responding party's statements before the panel and found that they provided "further confirmation" of a certain fact.[628] In the Panel's view, it cannot be inferred from this that such documents or statements may be relied on to confirm facts that have already been found to exist based on other evidence, but that they may not be relied on, together with other evidence, to establish facts. At a minimum, such an inference would appear unwarranted in a case such as this one where the existence of a *de facto* measure is alleged. In such cases, it is often

[627] Panel Report, *Japan – Trade in Semi-Conductors*, BISD 35S/116.
[628] *Ibid*., para. 116; EC first written submission, para. 556.

inevitable that Complaining Parties base their complaints largely on circumstantial evidence. This said, it is clear that statements by individual government officials and similar evidence must be given proper weight, which weight can only be determined in the specific circumstances of each case.

7.523 The Panel now turns to review one by one the various documents and statements referred to by the Complaining Parties. The documents and statements have been divided into the above-mentioned five categories and are listed in chronological order. It should be noted that in no case did the European Communities question the authenticity of a document or statement or suggest that statements were incorrectly reported or wrongly attributed.

(i) Commission documents and statements by individual Commissioners

7.524 Following is a list of Commission documents referred to by one or more Complaining Parties:

(a) *November 2000 working document of the Commission services*. A working document of the Commission services states that "[a]gainst this background [of intense public and political debate about the impact of genetically modified organisms on the environment and food safety], it has become increasingly difficult to approve the placing on the market of new GMOs under Directive 90/220/EEC and a parallel situation has arisen for authorizations for products containing and derived from GMOs under product based legislation. As a result the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill. [...] The Commission [in July 2000] proposed a strategy to re-launch the authorization procedure".[629]

This document refers to a "standstill" in the "current authorization procedure". It does not support the EC argument that there was a standstill because of "requests [by member States or the Commission] for additional information on complex issues of risk assessment and management"[630]. Rather, it suggests that the standstill was the result of public concerns and political debate, which, according to the document, made it difficult to approve applications. The document also notes that the Commission proposed a strategy to "re-launch" the authorization procedure. It is not clear why the Commission would do so if the approval procedures were held up because the member States or the Commission were waiting for individual applicants to provide additional information. Thus, this document implies that there was a deliberate failure by relevant authorities to approve applications.

(b) *July 2001 Commission press release.* A Commission press release states that the adoption by the Commission of new legislative proposals for Regulations concerning traceability and labelling as well as genetically modified food and feed, together with the March 2001 adoption of Directive 2001/18, "will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs".[631]

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[629] Advance Copy of Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived from GMOs, ENV/620/2000, November 2000, p. 1 (footnote omitted) (Exhibits US-93; CDA-32).

[630] EC first written submission, para. 561.

[631] "Commission improves rules on labelling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety", Commission Press Release IP/01/1095, 25 July 2001, p. 2 (Exhibit CDA-39; also referred to by the United States).

The quoted statement suggests that in July 2001 a moratorium was in effect. Also, the statement does not appear to "describe a factual situation"[632], but a measure that could be "lifted". The point that the legislative proposal for new EC rules concerning traceability and labelling would "contribute" to the lifting of the moratorium is consistent with the June 1999 declaration by the Group of Five countries. That declaration said that the Group of Five countries would use their powers to suspend approvals pending the adoption of such rules.

(c) *October 2001 working paper of the Commission services*. A working paper of the Commission services states that "[t]his reluctance to go forward with authorizations of GMOs has resulted in a *de facto* moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation".[633]

The quoted statement suggests that in October 2001 a moratorium was in effect. A review of the document shows that the "reluctance" referred to is the reluctance by the Group of Five countries as first expressed in the June 1999 declaration by the Group of Five countries. Thus, this document supports the view that the absence of final approvals was not the result of "requests for additional information" but of the declared intention of certain member States to prevent approvals.

(d) *July 2003 Commission fact sheet*. A Commission fact sheet on GMO regulation states that "[t]he revised Directive [90/220] and the two proposals for Regulations [concerning traceability and labelling and on genetically modified food and feed] are expected to pave the way for a resumption of GM authorizations in the European Union".[634]

The statement that Directive 2001/18 and the July 2001 Commission proposals for new Regulations are "expected to pave the way for a resumption of GM authorizations in the European Union" echoes the July 2001 Commission press release. It also suggests that after the entry into force of Directive 2001/18 there was no resumption of authorizations. This is consistent with the June 1999 declaration by the Group of Five countries.

(e) *January 2004 Communication to the Commission from the President*. A Communication to the Commission from the President of the Commission in association with a number of other Commissioners with responsibility for biotech products states in relevant part:[635]

> "[D]espite the 'interim approach' [agreed on by the Commission in July 2000 and entailing the anticipation of the key provisions (labelling, traceability, monitoring, etc.) of Directive 2001/18]:

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[632] *Ibid*., para. 561; EC second written submission, para. 295.

[633] Working Paper of DG Environment and DG Health and Consumer Protection: Resumption of the Authorization Procedure for GMOs, October 2001, p. 1 (Exhibits US-27; CDA-31).

[634] "Question and Answers on the regulation of GMOs in the EU", p. 12 (Exhibits US-107 and CDA-26).

[635] Communication to the Commission (from the President in association with Mrs Wallström, Mr Byrne, Mr Fischler, Mr Lamy, Mr Liikanen and Mr Busquin): For an orientation debate on Genetically Modified Organisms and related issues, January 2004, p. 3 (emphasis omitted) (Exhibit CDA-33; also referred to by the United States).

> – no authorizations have been granted since October 1998[636].
>
> […]
>
> To date,
>
> – authorization procedures under the Novel Foods Regulation are being finalised in line with the interim approach agreed on 12 July 2000 by anticipating the key forthcoming provisions agreed by the Council (i.e. labelling, traceability, monitoring, etc.) into individual authorizations of GMOs. […]
>
> - Applications under Directive 2001/18/EC are currently being processed in accordance with the authorization procedure. […]"
>
> The European Communities correctly notes that this communication does not confirm the existence of a suspension of the approval process. However, it is the Complaining Parties' assertion that there was a suspension of final approvals, and not that there was a suspension of the processing of applications. The Communication itself states that despite the fact that the so-called "interim approach" had allegedly been followed in respect of applications submitted under Directive 90/220 since July 2000[637], no such product had been approved before the entry into force of Directive 2001/18. Furthermore, the statement in the Commission Communication that "authorization procedures under the Novel Foods Regulation are being finalised" and that "[a]pplications under Directive 2001/18/EC are [...] being processed" does not necessarily imply that the relevant applications will be approved. Nonetheless, based on the quoted passage of the Communication alone, it cannot be determined whether a moratorium on approvals was in effect between October 1998 and August 2003 or whether the absence of approvals was the result of a series of delays due to "requests for additional information".

7.525 The following statements by the Commissioner for the Environment were referred to by all Complaining Parties:

(a) *July 2000 news report*. A news report notes that on 13 July 2000 the Commission at a news conference revealed its plan to propose the above-mentioned "interim approach" to member States. The report quotes then Commissioner Margot

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[636] (*original footnote*) With the exception of applications under the simplified procedure of the Novel Foods Regulation (derogation from the full authorization procedure).

[637] In response to a question from the Panel, the European Communities described the "interim approach" as a practice by the Commission which "consisted in anticipating certain stricter requirements which were to be put in Directive 2001/18 as identified in the Council Common Position of June 1999 [...] in line with the precautionary principle. [...] [I]t was clear that the existing legislation, *i.e.*, Directive 90/220, did not provide a legal basis to impose these requirements on pending applications. The notifiers, therefore, were approached to see whether they would be willing to implement such requirements on a voluntary basis. [...] With the entry into force of Directive 2001/18 the 'interim approach' ended as applications could not be assessed under the new legal basis." EC reply to Panel question No. 13.

Wallström as stating in this context that "[w]e have already waited too long to act. The moratorium is illegal and not justified."[638]

The statement attributed to the Environment Commissioner explicitly refers to the existence of a moratorium in July 2000. Together with the Commissioner for Health and Consumer Protection, the Environment Commissioner is responsible within the Commission for the approval of applications for the placing on the market of biotech products. Clearly, therefore, the statement does not reflect a "perception from the outside"[639].

(b) *October 2001 news report*. A report on a news conference states that following a meeting of the Environment Council, Commissioner Wallström "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand."[640] She is quoted as saying that "[t]here is no other EU legislation in the same situation where we just simply decline to take a decision" and that "[w]e have 11 GMO seed applications approved. [...] But then there was an arbitrary line drawn before I came into office [in 2000] to stop all approval for the 13 other pending applications. But many of these 13 are simply varieties of the first 11 approved. They are essentially the same products. There is no science that says these are more or less dangerous than others".[641]

The statement attributed to the Environment Commissioner suggests that in October 2001 a moratorium was still in effect. It also suggests that the absence of approvals was the result of a "decision not to decide"[642] and not, as the European Communities contends, of delays due to requests for additional information.

7.526 The following statements by the Commissioner for Health and Consumer Protection and his spokesperson were referred to by one or more Complaining Parties:

(a) *June 2000 speech*. A speech by then Commissioner David Byrne at the European Business Summit in Brussels states that "[t]he horizontal directive 90/220 [...] was adopted in 1990, at a time when concern about GMOs was less obvious. The authorization procedure became obsolete as consumer concerns grew and consequently, Member States have become more and more reluctant to approve the placing on the market of new GMOs under Directive 90/220. This has resulted in a complete standstill in the current authorizations and a de facto moratorium on the commercial release of GMOs".[643]

It should first of all be recalled that the Commissioner for Health and Consumer Protection and the Environment Commissioner are responsible within the

[638] "EU Moves to Break Gene Crop Deadlock", Reuters, 13 July 2000 (Exhibits US-33, CDA-42 and ARG-29).

[639] EC first written submission, para. 561.

[640] "EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place," BNA Daily Report for Executives, Regulation, Law & Economics, 30 October 2001, p. A-8 (Exhibits US-2, CDA-43, ARG-14).

[641] *Ibid*.

[642] *See* EC second written submission, para. 294.

[643] "Biotechnology: Building Consumer Acceptance," Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, Brussels, 10 June 2000, p. 3 (Exhibits US-1 and CDA-44).

Commission for the approval of applications for the placing on the market of biotech products. Hence, the remarks of the Commissioner for Health and Consumer Protection on the functioning of the EC approval process cannot be considered "perceptions from the outside"[644]. The speech suggests that in June 2000 a moratorium was in effect. It should also be pointed out that the quoted portion of this speech is closely similar in content to the above-noted November 2000 and October 2001 working documents of the Commission services.

(b) *November 2000 speech.* A speech by Commissioner Byrne at the conference on "Genetics and the future of Europe" in Brussels states that "[i]n the EU public concerns about the application of biotechnology in the agri-food sector have resulted in a de-facto moratorium on authorizations of new GMOs. In fact no GMOs have been approved over the last two years".[645]

This speech echoes the June 2000 speech.

(c) *July 2001 public statement.* A statement by Commissioner Byrne, made on the day the Environment Commissioner and himself presented to the Commission two proposals for new Regulations concerning traceability and labelling as well as genetically modified food and feed, reads in relevant part: "The adoption of today's proposals together with the recent adoption of the revised legislation on the deliberate release of GMOs into the environment will build up public confidence by responding to questions and concerns raised by the general public and providing a high level of protection for human health and the environment. This will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs and the standstill on the authorizations of GMOs and GM-products in Europe".[646]

This statement is closely similar in content to the above-noted July 2001 Commission press release. It suggests that in July 2001 a moratorium was in effect.

(d) *September 2001 speech.* A speech by Commissioner Byrne at an informal Agriculture Council on new technologies in agriculture in Alden Biesen states that "[i]n the EU, the Scientific Committees have already assessed a number of GMOs and concluded that they do not pose a danger to the environment or to human health. However, these GMOs are still pending final approval and some of them have now been awaiting approval for quite some time."[647]

The quoted passage of this speech does not explicitly state that the absence of final approvals was the result of a moratorium or of reluctance by member States to approve applications in the face of public concerns. The passage could, however, be interpreted to imply such a statement. Such an interpretation does not seem

[644] EC first written submission, para. 561.

[645] Speech by David Byrne, European Commissioner for Health and Consumer Protection, Conference on "Genetics and the future of Europe", Brussels, 7 November 2000, p. 3 (Exhibit ARG-17).

[646] "The Right to Know about GM Food", Statement by David Byrne, European Commissioner for Health and Consumer Protection, 25 July 2001, p. 3 (Exhibits US-34, CDA-45 and ARG-18).

[647] "New Technologies in Agriculture – Biotechnology", Speech by David Byrne, European Commissioner for Health and Consumer Protection, Informal Agriculture Council, Alden Biesen, 18 September 2001, p. 7 (Exhibit ARG-8). The same statement is made in "Proposal for a regulation on GMO Food and Feed", Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Parliament, Brussels, 11 September 2001, p. 4 (Exhibit ARG-20).

unreasonable in the light of, *e.g.*, Commissioner Byrne's November 2000 speech, his July 2001 statement and his subsequent October 2001 speech.

(e) *October 2001 speech*. A speech by Commissioner Byrne to the National Press Club in Washington, D.C., states that "[t]he final point I wish to make on biotechnology relates to the effective moratorium on new approvals in the EU. This is an unfortunate situation and has helped nobody in my view. It is my firm hope and intention that we can get the approvals process working again. I have mandated my officials to start a dialogue with the Member States of the European Union with a view to re-starting approvals".[648]

The quoted passage suggests that there was a moratorium on new approvals in October 2001. This is consistent with the above-mentioned October 2001 news report quoting a similar statement by the then Environment Commissioner.

(f) *October 2001 news report*. A news report quotes the spokeswoman of Commissioner Byrne as saying that "[t]he moratorium has no legal basis".[649]

The statement attributed to the spokesperson of Commissioner Byrne suggests that there was a moratorium on new approvals in October 2001. Again, this is consistent with the October 2001 news report quoting a similar statement by the then Environment Commissioner.

(g) *November 2001 speech*. A speech by Commissioner Byrne at the European Voice Conference "Farm to Fork" in Brussels states that "[d]espite our scientific advisors having given the green light for growing and marketing GMO plants and foods, our Member States have blocked new authorizations since 1998. This is, I believe, an untenable situation".[650] Three paragraphs later, the text continues: "The effective moratorium on new approvals in the EU is an unfortunate situation and its continuation, in my personal view, helps nobody."[651] And another three paragraphs later, the text says: "As a result [of the June 1999 declaration by the Group of Five countries], the authorization of both pending and new products has come to a grinding halt".[652]

The quoted passages of this speech suggest that in November 2001 a moratorium on new approvals was in effect. The speech further suggests that the absence of approvals was the result of the June 1999 declaration by the Group of Five countries, and not of a series of delays due to requests for additional information.

(h) *February 2003 news report*. A news report quotes Commissioner Byrne as stating at a press conference that "[w]e have taken account of the opinions of the scientists and

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[648] "A European approach to food safety and GMOs", Speech by David Byrne, European Commissioner for Health and Consumer Protection, National Press Club, Washington D.C., 9 October 2001, p. 3 (Exhibit ARG-9).

[649] "EU States Seek Stricter GM Labelling", Reuters, 16 October 2001 (Exhibits US-35 and CDA-46).

[650] "Risk versus benefit", Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Voice Conference "Farm to Fork", 22 November 2001, p. 2 (Exhibit ARG-10; also referred to by Canada).

[651] *Ibid*.

[652] *Ibid*.

put legislation in place ... now let's turn over the page! The conclusion of all this is that we must lift the moratorium".[653]

The statement attributed to Commissioner Byrne suggests that in February 2003 a moratorium was in effect. It also suggests that the term "moratorium" is used to describe a measure that should be "lifted" rather than a mere "factual situation"[654] characterised by the absence of any approvals.

7.527 The following statement by the Commissioner for Trade was referred to by two Complaining Parties:

(a) *January 2002 speech*. A speech by then Commissioner Pascal Lamy at the Woodrow Wilson International Center for Scholars in Washington, D.C., states that "the current moratorium is not plucked out of thin air by the Member States for protectionist reasons: it reflects the fact that food safety is a highly sensitive and political issue for European citizens".[655]

The quoted passage of this speech suggests that in January 2002 a moratorium was in effect. The Trade Commissioner is not responsible within the Commission for approvals of biotech products. However, as is evidenced by the present panel proceedings, the absence of approvals is also a trade issue. As a result, and in view of the similar statements made by the Commissioners with direct responsibility for approvals, the view expressed by the Trade Commissioner cannot be dismissed as a "perception from the outside".

(ii) Council documents

7.528 Following is a list of Council documents referred to by one or more Complaining Parties:

(a) *July 2003 note by the General Secretariat of the Council*. A note issued by the General Secretariat of the Council to the Committee of Permanent Representatives on the outcome of the European Parliament's second reading of the proposed new EC rules on traceability and labelling of biotech products attributes to the rapporteur of the relevant committee of the European Parliament the statement that the proposed rules would "possibly lead to the lifting of the current *moratorium*."[656]

The statement attributed to the rapporteur of one of the committees of the European Parliament dealing with biotech products suggests that in July 2003 a moratorium was in effect. While the rapporteur was not involved in the day-to-day operation of the EC approval process, it is nevertheless reasonable to assume that he and his committee were aware of the possible implications of the adoption of the new rules in question, including the possible implications on the operation of the approval process. The view apparently expressed by the rapporteur – that new EC rules on labelling and

[653] "Sine die postponement of inter-ministerial meeting planned on GMOs in Washington", Agence Europe, 6 February 2003, p. 2 (Exhibit US-37).
[654] *Ibid*.; EC second written submission, para. 295.
[655] "Steeling the EU-US Relationship for the challenges ahead", Speech by Pascal Lamy, European Commissioner for Trade, Washington, D.C., 25 January 2002, p. 4 (Exhibits US-89 and ARG-15).
[656] Note from the General Secretariat, 3 July 2003, p. 1 (Exhibits US-38 and CDA-41).

traceability might lead to the lifting of the moratorium – is consistent with the June 1999 declaration by the Group of Five countries.

(b) *April 2004 background note by the General Secretariat of the Council.* A background note from the press office of the Council's General Secretariat concerning the Agriculture and Fisheries Council of April 2004 at which the Council was to decide on the application concerning Bt-11 maize (food) states that "[t]he adoption of a decision to authorize Bt11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe".[657]

This background note, which expresses the view of the General Secretariat of the Council, suggests that in April 2004 a general moratorium was in effect. The note was issued shortly before the Council voted on the application concerning Bt-11 maize (food). It can therefore be assumed that the Council's own General Secretariat was in a position to assess correctly the significance of the Council vote and the context within which it took place.

(iii) European Parliament documents

7.529 Following is a list of European Parliament ("EP") documents referred to by one or more Complaining Parties:

(a) *February 2001 motion for an EP resolution.* A European Parliament resolution proposed for adoption by the Committee on Industry, External Trade, Research and Energy "[o]bserves that the existing de facto moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU", and in the following paragraph "[w]elcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labelling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the de facto moratorium on the release of GMOs".[658] The accompanying explanatory statement notes that "no authorizations have been approved under this directive [90/220] since October 1998. This demonstrates a lack of mutual recognition between Member States and a de facto moratorium on all development".[659]

This motion for a resolution suggests that in February 2001 a general moratorium was in effect.[660] The motion was sponsored by the Committee on Industry, External Trade, Research and Energy. It is reasonable to assume that the members of that Committee were familiar with the situation and concerns of researchers and the

[657] General Secretariat of the Council, Press Office, Background for Agriculture and Fisheries Council of 26 (and possibly 27) April 2004, 23 April 2004, p. 2 (Exhibits US-109; CDA-108; also referred to by Argentina).

[658] European Parliament, Committee on Industry, External Trade, Research and Energy, Report on the Future of the Biotechnology Industry, Motion for a European Parliament resolution, FINAL A5-0080/2001, 28 February 2001, p. 12 (Exhibit US-119).

[659] *Ibid*., p. 20.

[660] The record does not indicate whether the resolution was ever adopted by the European Parliament.

industry in the biotechnology sector and otherwise sufficiently well informed to express a view on whether or not a general moratorium was in effect at the time.

(b) *June 2002 EP committee report*. The European Parliament Committee on the Environment, Public Health and Consumer Policy, in its report on the proposal for new Regulations concerning traceability and labelling as well as food and feed, states that the fragmentation of then-existing EC legislation concerning biotech products "led to reservations and a moratorium over the last three years on the marketing authorization procedures at EU level, pending the adoption of an integrated traceability and labelling system".[661]

The quoted passage from the report by the Committee on the Environment, Public Health and Consumer Policy suggests that in June 2002 a moratorium was in effect, and that it might remain in place until the new Regulation concerning traceability and labelling of biotech products was adopted. The latter suggestion is consistent with the June 1999 declaration by the Group of Five countries. The Committee on the Environment, Public Health and Consumer Policy was not directly involved in the operation of the EC approval procedures. However, it seems clear that in order to report to the European Parliament on the merits of the legislative proposals, the Committee needed to have an understanding of the political context within which the proposals for the two new Regulations were made. The moratorium referred to in the report forms part of that context.

(c) *November 2002 EU bulletin*. The EU Bulletin, in a summary of the content of a resolution by the European Parliament on the Communication from the Commission on "Life Sciences and Biotechnology – A Strategy for Europe"[662], contains the following sentence: "With regard to food supply, the Parliament fully shares the opinion that an end must be called to the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998, which should be lifted in 2003, to provide greater choice and increased benefits to the consumer as well as to promote innovation".[663]

The statement attributed to the European Parliament suggests that a moratorium on biotech food products was in effect in November 2002. The reference to the year 2003 is probably a reference to the presumed date of adoption of the two proposed Regulations on labelling and traceability as well as food and feed. As is confirmed by the above-mentioned June 2002 committee report, the European Parliament was considering these proposals at the time. While the European Parliament does not have a role in the day-to-day operation of the EC approval procedures, it is reasonable to assume that it would not call for the lifting of a moratorium in a resolution if there was uncertainty as to whether such a moratorium on approvals of biotech food products existed.

[661] European Parliament, Committee on the Environment, Public Health and Consumer Policy, Report on the proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, FINAL A5-0229/2002, 12 June 2002, p. 27 (Exhibits US-36 and CDA-40).

[662] The Communication was not submitted to the Panel.

[663] "Resolution of the European Parliament on the Communication of the Commission on 'Life Sciences and biotechnology – A strategy for Europe", EU Bulletin, November 2002, section 1.3.64 (translated from Spanish) (Exhibit ARG-7).

(d) *March 2003 motion for an EP resolution*. A motion by two Members of the European Parliament for an EP resolution states in a preambular paragraph that "in view of the risks which GMOs represent, there are no grounds for lifting the *de facto* moratorium on GMO authorization, especially since no labelling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming" and "[u]rges the Council and the Commission to continue the moratorium and to launch a broad public debate on the impact of GMOs on organic/conventional farming".[664]

This motion for a resolution suggests that in March 2003 a moratorium was in effect, and that it was within the power of the Council and the Commission to continue or end it. The motion represents the view of two Members of the European Parliament[665], but the statement that a moratorium existed in March 2003 is consistent with the above-mentioned February 2003 news report quoting Commissioner Byrne and the July 2003 Commission fact sheet.

(e) *June 2003 statement by an EP committee rapporteur*. The rapporteur of the European Parliament Committee on the Environment, Public Health, and Consumer Policy in an explanatory statement on the recommendation for the second reading of the Parliament on the common position of the Council with a view to adopting a new Regulation concerning traceability and labelling of biotech products states that he is of the view that the prompt adoption of the new Regulation, as well as of the new Regulation concerning genetically modified food and feed, "will lead to the removal of the 'de facto' moratorium on the approval of new GMOs [...]".[666]

This statement suggests that in June 2003 a general moratorium was in effect. The statement appears to be the same as that which is referred to in the previously addressed July 2003 note from the General Secretariat of the Council.

(iv) Statements by member State officials

7.530 Following is a list of statements by high-ranking member State officials which were referred to by one or more Complaining Parties:

(a) *July 2003 news report*. A press article reporting on the meeting of 22 July 2003 of the Agriculture and Fisheries Council attributes to the then French Agriculture Minister the statement that "public information campaigns would be necessary in advance of lifting the moratorium" and to Italy's Agriculture Minister the statement that "no decision on lifting the moratorium on the authorization of GMO crops could

[664] European Parliament, Motion for a European Parliament resolution on the impact of genetically modified organisms (GMOs) on organic/conventional farming by Ilda Figueiredo and Jonas Sjöstedt, B5-0190/2003, 18 March 2003, p. 2 (Exhibit US-120).

[665] The record does not indicate whether the resolution was ever adopted by the European Parliament.

[666] European Parliament, Committee on the Environment, Public Health and Consumer Policy, Recommendation for the second reading on the common position of the Council with a view to adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, FINAL A5-0204/2003, 4 June 2003, p. 22 (Exhibit ARG-11).

be made until there is agreement on the European Commission proposals on guidelines for the coexistence of GMO crops and non-GMO crops".[667]

The statements attributed to the then French and Italian Agriculture Ministers suggest that in July 2003 a moratorium was in effect. As noted above, it was the Council of Agriculture and Fisheries Ministers that voted on the Bt-11 maize (food) application. Thus, the Agriculture Ministers have direct responsibility, perhaps jointly with other Ministers, for approvals of biotech products. Moreover, both France and Italy are part of the Group of Five countries which had declared in June 1999 that they would exercise their powers so as to suspend approvals. Finally, it should be noted that the reported statements clearly use the term "moratorium" to refer to a measure that could be lifted and not to describe a "factual situation"[668] where no approvals had been granted.

(b) *June 2004 parliamentary response*. A response provided by the French Minister for Research to a question from a Member of the French Parliament states that "[i]n 1999, in order to take account of the legitimate concerns of public opinion, France and four other member States of the European Union – Denmark, Italy, Greece, and Luxembourg – obtained a moratorium from the European Commission suspending any new authorizations for growing and placing on the market of genetically modified plants pending both effective rules concerning the traceability and informative labelling of all GMO-derived products, and the necessary clarifications concerning different aspects of the law relating to the use of these new technologies. [...] This moratorium period made it possible [...] to progressively reconcile the positions of the member States and harmonize the assessment and authorization periods. Thus [...] Directive 2001/18/EC was adopted [...]. The new Directive, coupled with the two community regulations, 1829/2003 and 1830/2003, provides a tight, general and very complete framework in which the Government has expressed its full confidence when it comes to proceeding, at the European level, with new GMO commercial authorizations, which will be granted on a case by case basis".[669]

The response by the French Minister for Research suggests that a moratorium had been in effect since 1999 when the Group of Five countries made their declaration at the June 1999 Environment Council. The response also suggests that in June 2004 France no longer saw a need to use its powers to suspend approvals, although it is unclear when the French Government made that decision, i.e., whether the decision was made after the adoption in September 2003 of the new Regulations concerning labelling and traceability as well as food and feed (as France had indicated in the June 1999 declaration by the Group of Five countries), or after their entry into force in April 2004.

[667] "EU Ag Ministers Approve GMO Traceability Plan Opposed by White House, U.S. Farmers" International Trade Reporter, 24 July 2003, p. 1 (Exhibits US-39 and CDA-47) .

[668] *Ibid*., para. 561; EC second written submission, para. 295.

[669] Reply to question No. 27131 of Mr Martin Philippe-Armand (Union for a Popular Movement (UMP) – Marne), 12th legislature, 1 June 2004 (translation from French) (Exhibit ARG-48).

(v) EC statements at the WTO

7.531 The following WTO document was referred to by one Complaining Party:

(a) *November 2001 minutes of meeting*. The minutes of a meeting of the WTO Committee on Sanitary and Phytosanitary Measures state under the heading "US concerns on EC agricultural biotechnology approval processes" that "[t]he representative of the European Communities reaffirmed the European Commission's interest and positive actions aimed at allowing the authorization procedures to continue. The recent meeting of the European Environment Council had started a very important discussion on proposals presented by the Commission to restart the authorization procedure".[670]

This statement, which was made on behalf of the European Communities, suggests that in November 2001 a moratorium was in effect, as it refers to the need to "restart the authorization procedure". The statement is consistent with the above-mentioned July 2001 statement by Commissioner Byrne and uses language similar to that used in the November 2000 Commission working document.

(vi) General assessment

7.532 The Panel considers that all of the above-listed documents and statements are relevant to the issue of whether certain member States and the Commission intentionally prevented the final approval of applications. With few exceptions, the statements referred to were made by the highest-ranking officials of the Commission or member States, or by or on behalf of key parliamentary committees. Also, each of the Complaining Parties submitted documents or statements not just from a single source, but from multiple EC institutions or representatives thereof. Many of the documents provided were prepared directly by the competent administrative services or parliamentary committees, and the statements by Commissioners and Ministers were made by Commissioners and Ministers with responsibility for biotech products. Accordingly, the documents and statements cannot be said to represent outsiders' perspectives. For the most part, the statements referred to consist of prepared statements, such as speeches. Such statements cannot properly be considered casual statements. While a small number of the statements submitted were made in the context of news conferences, the content of these statements is very similar to that of the other statements or documents submitted. Finally, it is important to note that notwithstanding the fact that the documents and statements stem from different EC institutions or representatives thereof, they all consistently, albeit not identically, refer to the existence of a "moratorium" or of a "standstill", or to a possible "resumption" of approvals. For all these reasons, the Panel is unable to agree with the European Communities that the documents and statements referred to by each Complaining Party provide no evidence of the existence of a *de facto* moratorium.[671]

7.533 The documents and statements relied on by each Complaining Party add an important element to the evidence discussed in the previous Subsection: they point to a reason for the absence of approvals during the relevant time period. The relevant documents and statements suggest that there were no approvals because a moratorium on approvals was in effect. Of the twenty-six documents or

[670] Document G/SPS/R/25, para. 105.
[671] EC first written submission, para. 553.

statements listed above, twenty-one explicitly use the term "moratorium". The other five documents are all consistent with the view that there were no approvals because a moratorium was in effect.[672]

7.534 Conceptually, a moratorium on approvals implies a temporary absence of approvals. But in addition the concept of a moratorium on approvals implies that the absence of approvals must be the consequence of a deliberate temporary suspension of approvals. This is confirmed by the dictionary definition of the term "moratorium". As noted by the European Communities, the dictionary defines the term "moratorium" as "a postponement or deliberate temporary suspension of some activity".[673] In the light of this, the Panel considers that the references in the various documents and statements to an EC "moratorium" on approvals support what the Complaining Parties are asserting: that action was taken by relevant authorities, or deliberately not taken, so as to prevent approvals for a certain period of time. The Panel is not convinced that the relevant documents and statements use the term "moratorium" merely to describe a "factual situation"[674] – a temporary absence of approvals. The documents and statements do not support such a conclusion. For example, the November 2000 speech by Commissioner Byrne states that "public concerns […] have resulted in a de-facto moratorium on authorizations of new GMOs. In fact no GMOs have been approved over the last two years".[675] If the term "moratorium" in the first part of this statement were understood as merely referring to a temporary absence of approvals, it would be unclear why the term "*de facto*" was used. It makes little sense to say that there was a *de facto* absence of approvals. Conversely, it makes sense to say that there was a *de facto* suspension of approvals.

7.535 The European Communities appears to argue in the alternative that the references to a "moratorium" were made, for the most part, during what it refers to as the "transition period" from 1998 to 2001.[676] During that period, Directive 90/220 was being revised and the new Directive 2001/18 – the Directive amending Directive 90/220 – entered into force. The European Communities submits that the documents and statements which were made during that period and which refer to a "moratorium" all imply that the "moratorium" would end when the transition period ends. It is correct that a number of documents and statements indicate that the adoption of Directive 2001/18 would contribute to the lifting of the "moratorium". However, there is no document or statement which suggests that this would be a sufficient condition for the lifting of the "moratorium". Rather, the documents or statements mention the new Regulation concerning labelling and traceability as an additional condition, which is consistent with the June 1999 declaration by the

[672] It should nonetheless be recalled that the January 2004 Communication to the Commission and the September 2001 speech by Commissioner Byrne, when considered in isolation from the other documents and statements, could also be interpreted so as to be consistent with the European Communities' view that the absence of approvals was due to "requests for additional information".

[673] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 1828.

[674] EC first written submission, para. 561.

[675] Similar language was used in Commissioner Byrne's June 2000 speech and in the October 2001 Commission working paper.

[676] The European Communities' submissions are less than clear regarding when the so-called "transition period" ended. The Panel is assuming that the European Communities meant to argue that the period ended in 2001, when Directive 2001/18 was adopted. EC first written submission, para. 4; EC second written submission, paras. 292. Other EC statements appear to suggest, however, that the period ended in 2003. EC second written submission, para. 293. But the relevance of 2003 is nowhere explained. Directive 2001/18, which is referred to in the aforementioned paragraphs of the EC written submissions, came into force in 2002. In contrast, in none of the aforementioned paragraphs of the EC submissions is there a reference to the adoption in 2003 of the new EC regulations on labelling and traceability as well as food and feed. In any event, the Panel's analysis of the EC argument about the transition period is unaffected by the issue of whether that period ended in 2001 or 2003.

Group of Five countries.[677] Moreover, all three Complaining Parties have referred to documents or statements which suggest that a moratorium was still in effect after the adoption of Directive 2001/18 in March 2001, and even after the entry into force of that Directive in October 2002.[678] In fact, the April 2004 background note by the Council's General Secretariat, which was relied on by all Complaining Parties, suggests that a moratorium continued to be in effect even after the adoption in September 2003 of the new Regulation concerning labelling and traceability. The note also implies that a moratorium was in effect in August 2003, the date of establishment of this Panel.[679]

7.536 It should be mentioned as well that all Complaining Parties have submitted a document or statement which refers to the fact that no applications have been approved under Directive 90/220 since October 1998.[680] However, the fact that no applications have been approved since October 1998 does not necessarily mean that a moratorium was in effect as from October 1998. None of the documents or statements submitted by the United States and Canada suggests that a moratorium was in effect as of October 1998. The June 2002 EP committee report refers to "a moratorium over the last three years", implying that a moratorium was in effect since June 1999, which is when the Group of Five countries issued their joint declaration. Argentina submitted one document, the November 2002 EU Bulletin, which refers to an EP resolution according to which "the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998 […] should be lifted in 2003". This suggests that a *de facto* moratorium was in effect since 1998. It is possible, though, that the year 1998 was referred to simply because after 1998 no applications were approved until 2004. In any event, other statements and documents submitted by Argentina – the November 2001 speech by Commissioner Byrne[681] and the June 2004 parliamentary response by the French Minister for Research[682] – support the view that a moratorium was in effect only as from June 1999.[683] In the light

[677] *See*, *e.g.*, the July 2001 Commission press release; the July 2003 Commission fact sheet; the July 2001 statement by Commissioner Byrne; and the June 2004 parliamentary response by the French Minister for Research.

[678] *See*, *e.g.*, the July 2003 Commission fact sheet; the February 2003 news report quoting Commissioner Byrne; the July 2003 note by the Council's General Secretariat; the April 2004 background note by the Council's General Secretariat; the March 2003 motion for an EP resolution; the June 2003 statement by an EP committee rapporteur; and the July 2003 news report quoting Ministers of France and Italy.

[679] The July 2003 Commission fact sheet, the July 2003 note by the Council's General Secretariat, the June 2003 statement by an EP committee rapporteur and the July 2003 news report quoting Ministers of France and Italy all indicate that a moratorium was in effect in June and July of 2003.

[680] *See* the January 2004 Communication to the Commission; the November 2000 speech by Commissioner Byrne; and the February 2001 motion for an EP resolution.

[681] Commissioner Byrne's speech suggests that it was as a result of the positions expressed by the Group of Five countries in 1999, specifically their positions expressed in the June 1999 joint declaration, that "the authorization of both pending and new products has come to a grinding halt". The speech in question also contains the statement that "[d]espite our scientific advisors having given the green light for growing and marketing GMO plants and foods, our Member States have blocked new authorizations since 1998". The Panel understands this statement to refer to the fact that in four successive votes held in the Regulatory Committee from October 1998 onwards, the Regulatory Committee failed to achieve a qualified majority, even though the relevant applications had all received favourable opinions from an EC scientific committee. After these four votes, no further votes were held in the Regulatory Committee prior to the date of establishment of this Panel. EC reply to Panel question No. 96(c). As is explained in more detail below, in the Panel's view, the votes in question do not support the view that a moratorium was in effect as from October 1998. *See, infra*, para. 7.1248.

[682] The Minister's response, in what seems to be a reference to the fact that the Group of Five countries issued a joint declaration in June 1999, states that it was in 1999 that the Group of Five countries gained the Commission's support for a moratorium.

of this, the Panel does not consider that the documents and statements submitted by each Complaining Party permit the inference that a general *de facto* moratorium was in effect before June 1999.

7.537 The documents and statements are important also because they lend support to the Complaining Parties' assertion that the European Communities applied an across-the-board moratorium, *i.e.*, a moratorium applicable to all pending and new applications for the approval of biotech products. Many of the documents and statements relied on by each Complaining Party explicitly refer to a generally applicable moratorium.[684] Others refer more broadly to a "moratorium".[685] However, given the absence of a textual qualifier, and reading the statements and documents concerned together with others, there is no reason to assume that the broad references to a "moratorium" should be understood as meaning that the "moratorium" in question was selective, that is to say, that it applied to only some applications. Separately, it should be pointed out that the documents and statements relied on by each Complaining Party suggest that an across-the-board moratorium was in effect between June 1999 and August 2003.[686]

7.538 It has been observed above that almost all of the relevant documents and statements refer to a "moratorium" on approvals and that this implies that actions were taken by relevant authorities, or deliberately not taken, so as to prevent approvals for a certain period of time. The Complaining Parties assert that the relevant authorities are certain member States – notably the Group of Five countries – and the Commission, and that they intentionally prevented applications from reaching the stage of final approval. The documents and statements provide some, albeit limited, confirmation of this assertion. To begin with, according to the October 2001 news report, Commissioner Wallström characterized the "moratorium" as a "situation where we just simply decline to take a decision". While this statement does not make clear who is meant by "we", it tends to confirm that there was a "decision not to make final decisions" and not to allow final approvals. Furthermore, all Complaining Parties have relied on documents or statements which suggest that the "moratorium" is the result of

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[683] *See also* para. 7.1254 *et seq*. for our discussion of Argentina's argument that the Commission's conduct prior to the June 1999 declaration by the Group of Five countries confirms the existence of a general moratorium on approvals as from October 1998.

[684] *See, e.g.*, the October 2001 Commission working paper ("a *de facto* moratorium on the marketing of new GMOs"); the July 2001 statement by Commissioner Byrne ("the *de facto* moratorium on the commercial release of GMOs and GM-products"); the April 2004 background note by the Council's General Secretariat ("the current *moratorium* on genetically modified food and feed"); the February 2001 motion for an EP resolution ("the de facto moratorium on the release of GMOs"); the June 2002 EP committee report ("a moratorium […] on the marketing authorization procedures at EU level"); the November 2002 EU Bulletin summarizing an EP resolution ("the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998"); the June 2003 statement by an EP committee rapporteur ("the 'de facto' moratorium on the approval of new GMOs"); the July 2003 news report quoting the Agriculture Minister of Italy ("the moratorium on the authorization of GMO crops"); and the June 2004 parliamentary response by the French Minister for Research ("a moratorium [...] suspending any new authorizations for growing and placing on the market of genetically modified plants ").

[685] *See, e.g.*, the July 2000 news report quoting Commissioner Wallström; the October 2001 news report quoting Commissioner Wallström; the October 2001 news report quoting the spokeswoman for Commissioner Byrne; the January 2002 speech by Commissioner Lamy; and the July 2003 note by the General Secretariat of the Council.

[686] *See, e.g.*, the November 2000 Commission working document; the November 2000 speech by Commissioner Byrne; the June 2002 EP committee report; the November 2002 EU Bulletin summarizing an EP resolution; the July 2003 Commission fact sheet; the June 2003 statement by an EP committee rapporteur; the July 2003 news report quoting the Agriculture Minister of Italy; the April 2004 background note by the Council's General Secretariat; and the June 2004 parliamentary response by the French Minister for Research.

member State opposition to approvals.[687] In addition, the March 2003 motion for a European Parliament resolution, which was referred to only by the United States, implies that the "continuation" of the "moratorium" depends not only on the member States but also the Commission.[688] Similarly, the June 2004 parliamentary response by the French Minister for Research, which was referred to only by Argentina, implies that a "moratorium" could not have been imposed without Commission involvement.[689]

(vii) Official EC position

7.539 The final point to be addressed is the EC argument that whatever the documents or statements submitted by the Complaining Parties may say, none of them represents the official position of the European Communities. For its official position, the European Communities refers the Panel to the following two documents:[690]

(a) *Commission press release of May 2003*. This press release was issued on the day the United States announced its intention to file a WTO complaint. It quotes then Trade Commissioner Pascal Lamy as saying that "[t]he US claim that there is a so-called 'moratorium', but the fact is that the EU has authorized GM varieties in the past and is currently processing applications".[691]

(b) *EC opening statement during the consultations of June 2003*. This statement was delivered by the European Communities during the consultations preceding the present panel proceedings. It states that "[u]nder the old regime, 18 GMOs were approved. With the new rules [contained in Directive 2001/18], pending applications have been revised and they are being examined with a view to making decisions on the authorization of new products. Currently 20 applications are being examined under Directive 2001/18. That is a fact: not an allegation, not an opinion, not a press statement."[692]

7.540 The Panel notes that neither of these statements contradicts the Complaining Parties' basic assertions. As already discussed in the previous Subsection, the Complaining Parties do not dispute the fact that biotech products were approved prior to October 1998. Nor do they contest that applications were being processed, or examined, between October 1998 and August 2003. The Complaining Parties' assertion is that the European Communities imposed a *de facto* moratorium on final approvals. According to the Complaining Parties, under this type of moratorium, applications were in most cases allowed to complete some stages of the EC approval process, but in no case were they allowed to proceed to the stage of final approval. The documents and statements submitted by

[687] *See*, *e.g.*, the October 2001 Commission working paper; the June 2000 speech by Commissioner Byrne; the November 2001 speech by the same Commissioner (referring specifically to the Group of Five countries); and the January 2002 speech by Commissioner Lamy.

[688] The motion urges "the Council and the Commission to continue the moratorium".

[689] The response states that the Group of Five countries "obtained a moratorium from the European Commission suspending any new authorizations".

[690] EC first written submission, para. 557.

[691] "European Commission regrets US decision to file WTO case on GMOs as misguided and unnecessary", Commission Press Release IP/03/681, 13 May 2003, p. 1 (Exhibit EC-113).

[692] Exhibit EC-112, p. 2.

each Complaining Party support the assertion that the "moratorium" affected the final approval of applications, but not necessarily their processing at every step in the process.[693]

(e) Facts and histories of individual approval procedures

7.541 In their submissions to the Panel, the Complaining Parties have also addressed individual applications for the placing on the market of biotech products. According to the **Complaining Parties**, the approval procedures for these applications confirm that certain member States and/or the Commission did in fact prevent the final approval of applications in the manner asserted by the Complaining Parties. In other words, in the Complaining Parties' view, the relevant approval procedures confirm that member States and/or the Commission suspended the approval of applications through one or more of the acts and/or omissions identified in Subsection (a) above.

7.542 In discussing individual approval procedures, the Complaining Parties in their first written submissions relied largely on publicly available information.[694] Subsequently, they mainly used the information submitted by the European Communities at its own initiative or at the request of the Panel. It should be noted in this respect that most of the information relating to individual applications is in the sole possession of member States, the Commission and the applicants. However, some information – *e.g.*, the minutes of Regulatory Committee meetings or communications between member States and the Commission – is in the exclusive possession of the European Communities. Also, while some of the applicants are US companies, others are European companies. There do not appear to be any applicants which are Canadian or Argentinean companies.[695] The Panel notes nonetheless that all of the Complaining Parties produce for export products subject to this complaint.

7.543 The **European Communities** argues that the claims relating to the general moratorium collapse when the specific facts and history of each approval procedure are considered. The European Communities submits that an analysis of the facts shows that during the relevant time period (October 1998 to August 2003) there were no acts and omissions that stalled applications at key decision-making stages in the approval process. The processing of individual applications continued without interruption, and applications were not systematically stalled.

7.544 According to the European Communities, in assessing applications, the competent authorities tried to take account of the changing EC legislative and regulatory framework as well as the evolving scientific debate. In some cases, this necessitated long discussions between the lead CA and the applicant on a number of scientific or regulatory issues that were not appropriately addressed in the original application, which delayed the forwarding of applications to the Community level. In other cases, discussions took place at Community level, before and/or after the opinion of the EC scientific

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[693] *See*, *e.g.*, the July 2001 Commission press release; the October 2001 Commission working paper; the July 2003 Commission fact sheet; the October 2001 news report quoting Commissioner Wallström; the June 2000 speech by Commissioner Byrne; the November 2000 speech by Commissioner Byrne; the July 2001 statement by Commissioner Byrne; the October 2001 speech by Commissioner Byrne; the November 2001 speech by Commissioner Byrne; the March 2003 motion for an EP resolution; the June 2003 statement by an EP committee rapporteur; the July 2003 news report quoting the Italian Agriculture Minister; and the June 2004 parliamentary response of the French Minister for Research.

[694] *See*, *e.g.*, Exhibits US-30 and -31; CDA-26 and -34; ARG-6.

[695] The European Communities argues that the relevant information should have been known to the Complaining Parties before the initiation of these proceedings, through their contacts with applicants. EC second written submission, para. 254. Canada indicated that it consulted with applicants in preparing its case, but nevertheless suggests that it did not have full access to the information in question, despite a request to the European Communities for disclosure during the consultations. Canada's third written submission, para. 8.

committees, among various member States. Furthermore, an important number of applications were withdrawn by the applicants because of various commercial reasons and changes in strategies. There is, however, no consistent pattern in respect of the applications pending during the relevant time period. Each application was dealt with on its own merits. In the light of this, the Panel cannot determine whether there was a general "moratorium" without looking at the decisions and actions taken in relation to each individual application. The Panel must consider each of the relevant approval procedures for the applications.

7.545 Finally, the European Communities submits that even if the delays that affected certain approval procedures before, and because of, the adoption of new legislation were to be seen as the result of a measure (the alleged "moratorium"), that measure would have ended with the entry into force of that legislation, namely with the entry into force in January 2003 of Directive 2001/18.

7.546 The **Panel** notes the contention of all Parties that the facts and history of individual approval procedures confirm their respective positions. The European Communities in particular insists on the importance of individual application histories, arguing that no conclusion can be drawn with regard to whether a general moratorium on approvals was in effect between October 1998 and August 2003 until and unless each application has been considered individually. Further below, the Panel undertakes a separate analysis of each relevant application.

7.547 The applications covered by the Panel's analysis are those mentioned by the Complaining Parties in their requests for the establishment of a panel, with one exception.[696]. We are mindful of the fact that the Complaining Parties' panel requests mention specific applications in connection with their product-specific claims, and not in connection with their general moratorium claim. However, we are referring to the panel requests here merely to identify the applications covered by our analysis. Since the Complaining Parties' claim in respect of the alleged general moratorium is that the moratorium was applicable to any and all applications pending between October 1998 and August 2003, it is clear that, for the purposes of establishing the general moratorium claim, each of the Complaining Parties may put forward evidence and arguments in respect of any and all pending applications.

7.548 The applications mentioned by the Complaining Parties in their panel requests include those which were withdrawn between October 1998 and August 2003. We think that they are pertinent to the Panel's assessment of whether the alleged general *de facto* moratorium on final approvals existed. Up until the date of their withdrawal, these applications, and the relevant approval procedures, constitute factual evidence which the Panel is not only entitled to take into account, but is required to take into account in view of its obligation to make an objective assessment of the facts of the case. We also note that the findings we make with regard to the relevant approval procedures relate to the Complaining Parties' claim that the European Communities applied a general moratorium on final approvals. They do not relate to the issue of the WTO-consistency of actions or omissions by relevant EC entities in the context of the approval procedures in question.

7.549 The Panel's analysis also covers one additional application referred to by the European Communities.[697] It does not cover eight other applications which were mentioned by the European

[696] The application concerning T14 maize was mentioned by Argentina. However, according to information provided by the European Communities, that application, which was submitted to France in June 1996, was withdrawn by the applicant on 15 July 1998. Exhibit EC-156/At. 57. In other words, the approval procedure concerning T14 maize was terminated prior to the alleged moratorium period (October 1998 to August 2003).

[697] Application concerning Transgenic green-hearted chicory.

Communities "in order to complete the picture".[698] Regarding the eight applications mentioned by the European Communities for completeness' sake, we note that seven of these were submitted under Directive 2001/18. Of those seven, three were submitted after the date of establishment of this Panel (29 August 2003)[699]. They are not relevant to a determination of whether a general moratorium was in effect until 29 August 2003. One application was submitted in July 2003[700], which means it had been assessed by the relevant member State for only one month when this Panel was established.[701] For the remaining three applications, unlike for all applications referred to by the Complaining Parties, the European Communities submitted no detailed chronologies with supporting documents. Instead, it provided status reports which indicate the state of play of the applications in the spring of 2004.

7.550 In the European Communities' view, these status reports demonstrate that the relevant approval procedures are "proceeding smoothly".[702] However, one of the three applications in question appears to have been delayed at the member State level as a result of a request by the competent member State authorities for additional information.[703] Another application, an application submitted to the United Kingdom, was apparently also delayed at the member State level at the time this Panel was established.[704] The report provided by the European Communities does not indicate any reason for this delay. The last of the three applications was submitted to Germany. This application was apparently assessed quickly, and favourably, by the competent German authorities. However, when the application moved to Community level, despite the favourable assessment by Germany, other member States appear to have raised objections to the placing on the market of this product.[705] The report provided by the European Communities does not contain any information about the basis for these objections.[706] In the light of the foregoing, the Panel does not consider that the information supplied by the European Communities in respect of the three above-mentioned applications is sufficient to support the inference that no general moratorium on final approvals was in effect before or in August 2003.

7.551 The eighth application which was mentioned only by the European Communities was submitted to Germany under Regulation 258/97 and apparently concerns the same product that was submitted to Germany under Directive 2001/18. In respect of this application, the European Communities provided neither a chronology with attachments nor a status report indicating the state of play. The European Communities merely indicates that the application was submitted in 2003 and

[698] EC first written submission, para. 334. It should be recalled that the application concerning MON863 maize is not part of the eight applications mentioned by the European Communities. As explained previously, due to the fact that the Panel has no information on this application other than an EC letter stating that in September 2005 the application was approved by the Commission under Directive 2001/18, the Panel is not in a position to determine whether or not the history of the approval procedure concerning MON863 maize is consistent with the Complaining Parties' contention that a general moratorium on approvals was in effect between October 1998 and August 2003.

[699] Exhibits EC-103 (maize), -108 (rice) and -109 (cotton).

[700] Exhibit EC-107 (maize).

[701] Pursuant to Article 14(2) of Directive 2001/18, a member State has 90 days from the date of receipt of an application to prepare an assessment report on the application.

[702] EC first written submission, para. 336.

[703] Exhibit EC-104 (sugar beet).

[704] Exhibit EC-105 (maize). The United Kingdom took more than 13 months to prepare and forward its assessment report instead of the 90 days laid down in Article 14(2) of Directive 2001/18.

[705] Exhibit EC-106 (maize).

[706] The report suggests that the member States were unable to reach an agreement and that the application was therefore referred to an EC scientific committee for an opinion. However, this was after the present Panel had been established.

quickly moved up to the Community level, where it appears to have run into objections from other member States.[707] In respect of this application as well, the Panel does not consider that the information supplied by the European Communities is sufficient to support the inference that no general moratorium on final approvals was in effect until August 2003.

7.552 In the remainder of this Subsection, the Panel will examine the facts and histories of all other relevant applications with a view to determining whether they are consistent with the Complaining Parties' contention that during the relevant time period (October 1998 to August 2003) the European Communities applied a general moratorium on final approvals, or whether they are inconsistent with the Complaining Parties' contention and hence lead to the "collapse" of the Complaining Parties' claims in relation to the general moratorium, as the European Communities asserts. The structure of this examination reflects the arguments of the Complaining Parties. More specifically, the Panel's examination is structured according to the acts and omissions through which, in the Complaining Parties' view, the European Communities gave effect to the alleged general moratorium on approvals. The Panel will first address applications submitted under Directives 90/220 and/or 2001/18. Thereafter, the Panel will address applications submitted under Regulation 258/97.

7.553 Once the Panel has completed its analysis of individual approval procedures, it will focus on the conduct of Group of Five countries generally, notably their voting behaviour and their objections to favourable assessments by lead CAs. In addition, the Panel will address certain conduct by the Commission prior to the June 1999 declaration by the Group of Five countries.

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

7.554 The Panel first turns to address those of the relevant applications which were submitted and dealt with under the provisions of Directive 90/220 and, subsequently, Directive 2001/18 concerning the deliberate release of GMOs into the environment. It is useful to recall in this regard that in accordance with Article 36 of Directive 2001/18, Directive 90/220 was repealed on 17 October 2002. Furthermore, Article 35 of Directive 2001/18 provides that applications which were received pursuant to Directive 90/220 and in respect of which the procedures under Directive 90/220 were not completed by 17 October 2002, were subject to Directive 2001/18 as of that date. Pursuant to Article 35, such pending applications had to be complemented by the applicants in accordance with Directive 2001/18. The date by which applicants had to do so was 17 January 2003.

7.555 We further recall that this means that irrespective of the procedural stage reached by an application under Directive 90/220, an application which was updated in accordance with the requirements of Directive 2001/18 had to go through all procedural stages provided for in Directive 2001/18, beginning with the initial assessment by the lead CA.[708] However, according to the European Communities, any results and conclusions reached under the procedures of Directive 90/220 on the basis of the then-existing data and information were in principle still relevant under the procedures of Directive 2001/18 and hence did not need to be re-examined.

7.556 In reviewing the approval procedures conducted for the relevant applications, we will first focus on the Commission's conduct. Subsequently, we will also consider the conduct of individual member States acting as lead CAs.

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[707] EC first written submission, para. 337.

[708] It is useful to recall that the Complaining Parties did not challenge the obligation contained in Article 35 of Directive 2001/18.

7.557 Before commencing our examination of individual approval procedures, we should note that the European Communities acknowledges that delays occurred in some approval procedures which were pending under Directive 90/220. According to the European Communities, these delays occurred because of the adoption of Directive 2001/18. The European Communities argues, however, that after the entry into force of Directive 2001/18 all approval procedures have been proceeding normally. We will revert to this argument after reviewing all relevant applications.

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

7.558 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Council a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[i]f the measures envisaged [by the Commission] are not in accordance with the opinion of the [Regulatory] committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken".

Bt-531 Cotton (EC-65)

7.559 The application concerning Bt-531 cotton was first submitted to Spain (lead CA) in December 1996, and was provided to the Commission for circulation to all member States in December 1997. Following a positive opinion by the SCP on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee at its meeting of 22 February 1999 voted on the draft measure submitted by the Commission, but failed to reach the qualified majority necessary to deliver an opinion. Accordingly, 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.

7.560 The **United States** argues that the Commission was required under EC law to submit a draft measure to the Council "without delay". The United States submits that despite that legal obligation, the Commission failed to do so, with the result that the application languished for over three years without any activity other than purported inter-service consultations, until the application was updated in early 2003 to meet the requirements of Directive 2001/18. According to the United States, the "inter-service consultations" which the Commission launched in May 1999 and the Commission's failure to adhere to its legal obligation to act "without delay" confirm the existence of a moratorium.

7.561 **Canada** also argues that despite the positive opinion by the lead CA, the positive opinion by the SCP and the failure of the Regulatory Committee to deliver an opinion and despite an express legal obligation to do so, the Commission failed to submit to the Council a draft measure in order to break the deadlock at the Regulatory Committee in accordance with the legal obligation under Directive 90/220. According to Canada, the inter-service consultations following the Regulatory Committee vote and which were going on for close to four years resulted in a suspension of the approval procedure. In Canada's view, the only reasonable explanation for the time taken by the Commission to conduct inter-service consultations is the existence of a moratorium.

7.562 **Argentina** argues that instead of submitting a draft measure to the Council, the Commission intentionally stalled the approval procedure concerning Bt-531 cotton until the application had to be resubmitted under Directive 2001/18. Argentina maintains that the Commission did so by starting inter-service consultations, a phase not foreseen in the relevant EC legislation. In Argentina's view,

the Commission's inter-service consultations are evidence of the existence of a moratorium inasmuch as they reveal the European Communities' intention not to allow the final approval of applications.

7.563 The **European Communities** argues that the Regulatory Committee failed to reach a qualified majority because a number of member States raised legitimate 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 required 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 required additional information.

7.564 The **United States** responds that nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State statements made at the Regulatory Committee meeting. According to the United States, the applicant was not responding to any request, but, on its own initiative, provided additional information to the lead CA as the state of scientific knowledge had advanced since the first submission of the application more than four years before. The United States submits that this information was submitted as part of the applicant's commitment to stewardship and initiatives to provide additional relevant new information as it becomes available.[709]

7.565 **Argentina** also considers that the additional information was provided by the applicant on its own initiative, as the record does not indicate that the applicant was specifically requested by the European Communities to provide that information.

7.566 The **European Communities** disagrees with the United States and Argentina, maintaining that the applicant was formally requested to submit the information in question.

7.567 The **Panel** begins its analysis by noting that on 25 July 2001, more than two years after the Commission launched inter-service consultations on a draft measure to be submitted to the Council, the applicant sent a letter to the lead CA providing an updated and extended molecular characterization of Bt-531 cotton and a safety assessment of Bt-531 cotton (analysis of flanking regions). The letter by the applicant does not state that the information it contains was provided in response to a specific request from the lead CA or another agency (another CA, the Commission, the SCP, etc.).[710] Nor does it indicate that the lead CA or the Commission had any knowledge that the applicant would be providing the additional information in question.

7.568 The European Communities has noted that at the Regulatory Committee meeting of February 1999, Austria, Sweden and the United Kingdom made written statements in support of their votes.[711] As also noted by the European Communities, these statements related to concerns about the presence of an antibiotic resistance marker gene, possible non-target effects on beneficial insects and the sufficiency of the monitoring plan to analyse indirect effects of Bt-531 cotton. None of these statements specifically call for an updated molecular characterization of Bt-531 cotton or a safety

[709] The United States submitted a statement from the applicant in which it confirms to the United States that it provided the information in question without a previous specific request from relevant authorities and that it did so to provide supplementary information that comes to light as a result of ongoing research and to help advance the approval process. Exhibit US-137.

[710] Exhibit EC-65/At. 61.

[711] Austria and the United Kingdom voted against, Sweden in favour of the proposed draft measure. Exhibit EC-65/At. 59.

assessment (analysis of flanking regions). There is therefore no indication that the applicant submitted the July 2001 information in response to the written statements made at the February 1999 meeting of the Regulatory Committee.[712]

7.569 Regarding the possibility that the information submitted by the applicant in July 2001 was in response to requests for information or concerns put forward prior to the February 1999 meeting of the Regulatory Committee[713], it should be observed that the lack of that information did not prevent the Commission from submitting a draft measure to a vote by the Regulatory Committee, and it did not prevent the Regulatory Committee from holding a vote on that measure. We therefore fail to see how the lack of the same information could provide a justification for the Commission's failure to submit a draft measure to the Council.

7.570 At any rate, based on the date of the applicant's letter (July 2001) and the type of information provided (an updated molecular characterization) we are not convinced that the applicant's July 2001 letter was intended as a direct response to a specific request for information from before February 1999.[714] The date of the letter and type of information provided rather suggest that the applicant sought to update its application in accordance with some of the requirements of Directive 2001/18, which had been adopted in March 2001. The European Communities itself advances this circumstance as constituting one of the reasons for the July 2001 letter, stating that by July 2001 "Directive 2001/18 had been adopted [...] and, as mentioned several times, applicants were updating their dossiers to match the new requirements".[715] In our view, the applicant in this approval procedure might well have done so in the hope that the updated information would make it possible for its application to be approved while Directive 90/220 was still in force.

7.571 It follows from the above remarks that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant and that this was why the Commission did not submit a draft measure to the Council. Indeed, 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.

7.572 It appears that the European Communities also seeks to explain the Commission's failure to act by the fact that the draft measure which the Commission had submitted to a vote in the Regulatory Committee in February 1999 failed to achieve a qualified majority and that at that same meeting Austria, Sweden and the United Kingdom made statements in support of their votes. According to the

[712] It is also not clear that the content of the statements in question was ever brought to the attention of the applicant. According to the Complaining Parties, the minutes of Regulatory Committee meetings are confidential. The European Communities states that any request for information, comment or objection by a member State is automatically forwarded, through the lead CA, to the applicant (EC reply to Panel question No. 200). But the European Communities did not say that this also applies to comments or written statements made in the context of a Regulatory Committee meeting.

[713] The European Communities appears to make this point in its reply to Panel question No. 200.

[714] In its reply to Panel question No. 200, the European Communities suggests that the July 2001 information was provided in response to concerns raised by CAs other than the lead CA (*see* the references, e.g., to EC-65/At. 16-25). However, the Panel has seen no evidence, nor has it been informed, that the lead CA ever transmitted the July 2001 information to the Commission and other CAs. If, as it seems, this did not happen, then it would be difficult to accept the European Communities' suggestion that the information was provided in response to requests for information or concerns put forward by other CAs.

[715] EC reply to Panel question No. 200.

European Communities, these statements expressed legitimate scientific concerns that had not been previously addressed by the applicant.[716]

7.573 As no qualified majority was reached at the Regulatory Committee meeting, it seems reasonable to assume that the Commission used 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.[717] The statements by Austria and the United Kingdom could have been relevant to that task.[718]

7.574 In the present case, however, the Commission apparently never completed this task, even though the Commission launched its inter-service consultations more than three years before the date of repeal of Directive 90/220. It should be noted in this regard 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 some member States voted against the Commission's draft measure and that some made written statements.[719] Moreover, the European Communities does not assert that Austria and the United Kingdom raised new or particularly complex scientific concerns. We are therefore not convinced that either the absence of a qualified majority vote in the Regulatory Committee or the statements made by the aforementioned member States explain the Commission's failure, over a three-year period, to submit a draft measure to the Council.

7.575 The Complaining Parties consider that the Commission's failure to act rather reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission launched its inter-service consultations with regard to Bt-531 cotton shortly before the June 1999 declaration by the Group of Five countries. At the time it conducted its inter-service consultations, the Commission thus had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[720] It is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition of the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure

[716] As pointed out by the United States, however, the concerns referred to in the statements by Austria, Sweden and the United Kingdom were addressed in the SCP opinion. Exhibit EC-65/At. 47, paras. 6.2.1 and 6.3.3-6.3.4.

[717] The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals. We address this further *infra*, paras. 7.1254-7.1261.

[718] We note that Sweden voted in favour of the Commission's draft measure and that Sweden's statement suggests that its concerns were met.

[719] 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 maize (Exhibit EC-92) 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.

[720] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

concerning Bt-531 cotton to the Council is consistent with the contention that the Commission made and followed such a decision.

7.576 In the light of the above considerations, we conclude that the Commission's failure after the February 1999 Regulatory Committee meeting to submit a draft measure concerning Bt-531 cotton to the Council is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR-1445 cotton (EC-66)

7.577 The application concerning RR-1445 cotton was first submitted to Spain (lead CA) in June 1997, and was provided to the Commission for circulation to all member States in December 1997. Following a positive opinion by the SCP concerning RR-1445 cotton on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The draft measure was submitted to the Regulatory Committee for a vote using a written procedure on 26 November 1998, with a deadline for the vote of 18 December 1998. The deadline for the vote was extended twice, following requests from various member States, until 22 February 1999. The Regulatory Committee failed to reach a qualified majority decision, and the Commission again launched inter-service consultations on 7 May 1999. 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 application was updated and re-submitted under Directive 2001/18 on 16 January 2003. As of 29 August 2003, no draft measure has been submitted by the Commission to the Council under Directive 2001/18.

7.578 The **United States** argues that the Commission was required under EC law to submit a draft measure to the Council "without delay" following the inability of the Regulatory Committee to reach a decision on 22 February 1999. The United States contends that the Commission refused to do so, however, and, as a result, further consideration of this application was indefinitely suspended as of February 1999. The Commission took no further action on this application for nearly four years, other than purported inter-service consultations, until the applicant was forced to update its application in January 2003 and to re-submit it under Directive 2001/18. The United States contends that only the existence of a moratorium explains the failure of the European Communities to move the application forward after its positive assessment by the relevant EC scientific body.

7.579 **Canada** argues that despite the positive opinion by the lead CA, the positive opinion by the SCP and the failure of the Regulatory Committee to deliver an opinion and despite an express legal obligation to do so, the Commission failed to submit to the Council a draft measure in order to break the deadlock at the Regulatory Committee in accordance with the obligation under Directive 90/220. Canada also argues that inter-service consultations had taken place earlier for this product, prior to the submission of a draft decision to the Regulatory Committee. Following the failure of the Regulatory Committee to reach a decision, the approval procedure for RR-1445 cotton was completely suspended for four years. Canada maintains that the only reasonable explanation as to why an additional four-year inter-service consultation was required is the existence of the moratorium.

7.580 **Argentina** argues that RR-1445 cotton, like other applications with a positive scientific opinion from 1998, was stalled by inter-service consultations. The lack of action on this product by the Commission for four years following the failure of the Regulatory Committee to reach a decision is further evidence of the de facto moratorium.

7.581 The **European Communities** notes that eight member States raised objections or had comments on issues related mainly to compositional analysis, molecular characterization, antibiotic

marker genes, safety and long-term effects on the environment – prior to the assessment and favourable opinion by the SCP. The European Communities argues that the Regulatory Committee failed to reach a qualified majority decision because a number of member States maintained objections, in particular because of concerns related to 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 herbicide tolerant crop management. The updated application submitted in January 2003 by the applicant under Directive 2001/18 was still incomplete with respect to a monitoring plan. The European Communities maintains, therefore, that any delay which has occurred is entirely legitimate and related to risk assessment and management considerations.

7.582 The **United States** responds that the four-year delay following the failure of the Regulatory Committee to reach a decision was not caused by a pending request to the applicant for additional information. The evaluation by the SCP had addressed all of the concerns raised by the member States at the level of the Regulatory Committee, including antibiotic resistance marker genes, toxicity to non-target organisms, and out-crossing from the transgenic plants, and came to the conclusion that the placing on the market of RR-1445 cotton with the purpose of being used as any other cotton was not likely to cause adverse effects on human health or the environment. None of the member States objecting at the Regulatory Committee offered any competing risk assessment or scientific evidence for their objections, nor did they identify any specific inadequacies in the SCP review. Nothing in the record indicates that the Commission communicated any scientific concerns to the applicant or identified any shortcomings in the application following the lack of a decision by the Regulatory Committee in February 1999.

7.583 **Argentina** also considers that all of the concerns identified by member States in their objections at the Regulatory Committee had been fully addressed by the SCP. Furthermore, this product had also received a favourable opinion under Regulation 258/97 on novel foods and food ingredients with respect to oil derived from RR-1445 cotton. The opinion of the Advisory Committee on Novel Foods and Processes was that oil from RR-1445 cotton is substantially equivalent to conventional cottonseed oil in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.

7.584 The **Panel** notes that, following the failure of the Regulatory Committee to reach a decision on 22 February 1999, and the re-launching of inter-service consultations on 7 May 1999, there is no record of any further action on this application before the repeal of Directive 90/220 in October 2002 and its replacement by Directive 2001/18. The record of the consultation of the Regulatory Committee by written procedure regarding a draft Commission Decision concerning the placing on the market of RR-1445 cotton does not contain any indication of a specific request to the applicant for further information.[721]

7.585 Four member States provided statements in support of their votes (Sweden, United Kingdom, Austria and Italy). All of the statements are very brief, and none includes a scientific evaluation or risk assessment in support of the views expressed. The UK competent authority voted against the draft measure stating that its disagreement is with respect to the marketing of the product for use in animal feed, due to the use of an antibiotic resistance marker gene in the product. Furthermore, while raising no concerns in terms of potential risks to the UK environment, the United Kingdom draws the attention of other member States where the cotton may be widely grown to potential negative impacts on biodiversity arising from changes in crop management methods. The Austrian competent authority abstained from voting indicating that the assessment of the risk especially from the use of the

[721] Exhibit EC-66/At. 57.

antibiotic resistance marker has not been sufficient for approval of a product which could be used as feed. Furthermore, Austria indicates that specific labelling requirements should be mentioned in the Commission Decision. The Swedish competent authority voted against the draft measure referring to earlier views that herbicide tolerant crops should not be placed on the market until the long-term effects of such crops on the environment have been better analysed, and common principles for evaluation and monitoring of potential risks connected to the cultivation of herbicide tolerant crops established. Italy, which voted in favour of the decision, stated that the use of Roundup-Ready herbicide on the cotton plant should be authorized only if the glyphosate metabolites and relevant residues were within the limits established by EC regulations.

7.586 We note that the evaluation of the SCP specifically addressed potential risks from the use of the antibiotic resistance marker gene in the product if used as animal feed. The SCP noted that it was "unlikely" that either gene which conferred resistance would survive processing. However, it went on to consider the potential risk if this "theoretically possible" and "extremely unlikely chain of events" occurred, and concluded that the introduction of either resistant gene would not increase existing risks to any significant effect, nor did they identify any potential risks from the "equally remote possibility" that the gene would be transformed and expressed. These findings were subsequently confirmed in a January 1999 report by the French CA, the Commission du Génie Biomoléculaire.

7.587 In response to a question from the Panel, one of the experts advising the Panel, Dr. Squire, observed that the issue of antibiotic resistance was considered in the SCP's opinion and found not to pose a risk. Furthermore, he notes that although there is now a widespread perception that antibiotic resistance should not be introduced through herbicide resistant products, cotton occupies a very small area in Europe and does not present potential problems of the type that might be associated with other crops.[722]

7.588 The SCP also specifically considered risks to non-target organisms and resistance and tolerance concerns. In response to a question by the Panel, another expert advising the Panel, Dr. Andow, stated his view that because the SCP considered that the risks of indirect effects or long-term and spatial scale effects on non-target organisms, and of effects associated with changes in the cropping system or the evolution of resistance in weeds to glyphosate, were inconsequential, the SCP did not propose a monitoring plan. Dr. Andow considered that the scientific issues raised by the objecting member States could be addressed in a monitoring plan, but that the necessity of a monitoring plan could not be determined from these objections.[723] Dr. Squire further noted that neither the applicant nor EC competent authorities had proposed suitable criteria on which to base monitoring.[724]

7.589 Although the European Communities stated that following the positive opinion of the Scientific Committee, the applicant entered into discussions with the lead CA on a further rat feeding study, no evidence was provided to the Panel with regard to these discussions or the possible outcome, nor with respect to whether these discussions were undertaken and/or concluded prior to the scheduled vote in the Regulatory Committee.[725]

7.590 As no qualified majority was reached by the Regulatory Committee, it is reasonable to assume that the purpose of the inter-service consultations launched by the Commission in May 1999 was to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine,

[722] Annex H, para. 480.
[723] *Ibid*, paras. 449-450.
[724] *Ibid*, para. 467.
[725] EC first written submission, para. 232.

in the light of such an analysis, whether it would be appropriate to modify the Commission draft measure before it was sent to the Council.[726]

7.591 However, in the case of RR-1445 cotton it appears that the Commission never completed this task, even though the inter-service consultations were started more than three years before the repeal of Directive 90/220. There is no evidence to suggest that there was any further contact with the applicant following the vote of the Regulatory Committee in February 1999, and even less that any further information was requested from the applicant. The Commission's failure to submit a draft measure to the Council before the repeal of Directive 90/220 contrasts with other approval procedures, in which the Commission was able to prepare and submit draft measures to the Council within a few months of a failure of the Regulatory Committee to reach a decision, despite the fact that some member States voted against the Commission's draft measure in those cases.[727] We are not convinced that either the absence of a qualified majority in the Regulatory Committee or the statements made by the above-mentioned member States explain the Commission's failure, over more than a three-year period, to submit a draft measure to the Council.

7.592 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission launched its inter-service consultations with regard to RR-1445 cotton shortly before the June 1999 declaration by the Group of Five countries. At the time it conducted its inter-service consultations, the Commission thus had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[728] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the contention that the Commission made and followed such a decision.

7.593 In the light of the above considerations, we conclude that the Commission's failure after the February 1999 Regulatory Committee meeting to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

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[726] The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals. We address this further *infra*, paras. 7.1254-7.1261.

[727] 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 maize (Exhibit EC-92) 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.

[728] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

MON809 maize (EC-83)

7.594 The application concerning MON809 maize was first submitted to the competent authority of France (lead CA) in December 1995, with the request for approval of both MON810 and MON809. In March 1996, a new application was submitted concerning only MON809. The application was forwarded to the Commission and to all member States in August 1996. A favourable opinion was issued by the SCP on 19 May 1998. Inter-service consultations were launched on 12 June 1998 and concluded on 19 July 1998. The consultation of the Regulatory Committee was launched on 4 September 1998, and closed on 23 October 1998 without a decision. On 22 April 1999, the Commission launched an internal procedure for the adoption by the Commission of a draft measure to be submitted to the Council, but this procedure was suspended on 29 April 1999. The application was withdrawn by the applicant on 4 October 2002.

7.595 The **United States** observes that this application was forwarded to the Commission with a favourable opinion from the lead CA, and that it received a positive opinion from the SCP. When the Regulatory Committee failed to reach a decision on the Commission's draft measure in October 1998, the Commission refused to submit the measure to the European Council as required by EC law. Because of the failure of the Commission to proceed with this application, the application was withdrawn in October 2002.

7.596 **Canada** notes that this product was assessed both under Directive 90/220 and under Regulation 258/97. The safety assessments undertaken by both the SCP and the Scientific Committee for Food (SCF) concluded that this product raised no concerns with respect to the environment or animal and human health.

7.597 The **European Communities** notes that after assessment by the SCP, the application was withdrawn by the applicant in October 2002. The applicant gave no reason for the withdrawal. The European Communities notes that an important number of applications have been withdrawn by the respective companies because of various commercial reasons and changes in strategies.

7.598 The **United States** argues that this failed application provides direct, compelling evidence of the existence of a general moratorium. This application languished in the approval process for years, for no apparent reason other than the moratorium, and the withdrawal evinces the applicant's frustration with the European Communities' suspension of its approval process. The United States further notes that there was no need to explicitly mention the delays in the notice of withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.599 **Canada** observes that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.600 **Argentina** also argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.601 The **Panel** notes that six months following the failure of the Regulatory Committee to deliver an opinion on this application, on 22 April 1999, the Commission launched an internal written procedure for the adoption by the Commission of a draft measure to be submitted to the Council. This draft measure was for the approval of MON809. In circulating this proposal, the Commission noted that the applicant had undertaken to provide labelling of bags of seeds; to provide a detailed technical guide to purchasers of the seed; and to inform traders regarding the full product description of the modified seeds. Furthermore, the Commission noted that the applicant had developed a management strategy to minimize the development of insect resistance and had offered to inform the Commission and member States of the results of monitoring in this regard. However, one week later, on 29 April 1999, the Commission suspended the written procedure for approval, citing the need to verify the monitoring plan with respect to the development of insect resistance in light of the recommendations adopted in March 1999 by the SCP with respect to surveillance of resistance.[729]

7.602 The chronology of this application, as provided by the European Communities, indicates that additional questions were sent to the SCP, apparently in the context of the safeguard measure adopted by Austria with regard to MON810 maize.[730] Like MON809, MON810 is a modified Bt maize. No evidence has been provided of such additional questions, and by whom these questions were asked. However, in correspondence dated 15 June 1999, the applicant seeking the approval of MON809 maize submitted a further assessment of the likelihood of adverse effects on Lepidoptera species to the French competent authority, apparently in response to a request. The applicant noted that this evidence had previously been provided to the competent authorities of the United Kingdom in the context of the assessment of MON809 for food and feed safety.

7.603 On 24 September 1999, the SCP issued an opinion on Austria's safeguard measure on MON810. The Austrian competent authority had indicated that its safeguard measure was taken in light of a study which addressed possible adverse effects of pollen from genetically modified Bt maize on the monarch butterfly. The SCP considered the evidence available regarding potential undesired effects of the Bt toxin on non-target insects, including on the Lepidopteran species in Europe. The SCP evaluated this evidence not only with respect to MON810, but also with respect to other genetically modified maize lines which had previously been approved (Bt-176 and Bt-11), and with respect to products whose approval was pending, including MON809 and Bt-531 cotton. With respect in particular to MON809, the SCP noted that the protoxin had not been detected in pollen.

7.604 The SCP concluded that there was no reason to change its previous advice to the Commission on the Bt crops which it had previously evaluated. It recalled its previous statement that it would be sensible to conduct monitoring in post-release situations, and endorsed the practice of monitoring, with appropriate and adequately targeted methodology, the large-scale introduction of such crops in order to detect any deleterious impact on non-target insect populations. There was no specific reference in this regard to MON809.

7.605 Given this second favourable opinion by the SCP, it seems reasonable to assume that the Commission would rapidly have proceeded to submit a draft measure to the Council on MON809.

[729] Exhibit EC-83/At. 70.
[730] We discuss this safeguard measure below in Section VII.F of our Report.

This was not the case, however. Neither is there any indication that the applicant was requested to provide any further information on a monitoring plan for potential effects of MON809 on non-target insects. Indeed, there does not appear to have been any further action by the Commission on this application during the three years following the second favourable opinion of the SCP, and in October 2002 the applicant withdrew the application without citing a reason.

7.606 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission did not complete its suspended internal written procedure for the adoption of the draft measure to be submitted to the Council after the June 1999 declaration by the Group of Five countries. Following this declaration, and despite the favourable opinion of the SCP, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[731] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure concerning MON809 to the Council is consistent with the contention that the Commission made and followed such a decision.

7.607 We consider that the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning MON809 maize.

7.608 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning MON809 maize to the Council after the September 1999 favourable opinion of the SCP is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic tomato (EC-84)

7.609 The application concerning the Transgenic tomato is for the planting, growing, harvesting and processing of tomatoes into non-viable products and was first submitted to the competent authority of Spain (lead CA) in November 1996. In November 1997, the application was forwarded to the Commission with a favourable opinion from the lead CA, and circulated to all member States the following month. Another application regarding the same product was also submitted under Regulation 258/97 to the United Kingdom in March 1998 (EC-100). In June 1998, the SCP issued a favourable opinion indicating that there was no evidence that the production and consumption of the transgenic tomato was likely to cause adverse effects on human or animal health or the environment. According to the information provided by the European Communities, Commission inter-service consultations were concluded in October 1998. Consultation of the Regulatory Committee was launched in November 1998, and on 18 December 1998 the Regulatory Committee failed to reach a decision by qualified majority. In February 2002, the application was withdrawn.

[731] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

7.610 The **United States** argues that despite favourable opinions from the lead CA and the SCP, when the Regulatory Committee failed to approve the Commission's draft measure, the Commission refused to submit the measure to the Council, as required by EC law. The United States maintains that this refusal to submit the measure to the Council is evidence of the existence of a general moratorium.

7.611 The **European Communities** notes that in the written procedure for a vote by the Regulatory Committee in December 1998, both Denmark and Italy voted in favour of approval of the transgenic tomato. The European Communities points to the fact that this application was withdrawn prior to the establishment of the Panel and that the applicant gave as the reason for the withdrawal "commercial re-positioning" following a merger with another company.

7.612 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies 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, which the United States maintains results from the moratorium.

7.613 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.614 **Argentina** argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.615 The **Panel** notes that although the Regulatory Committee failed to reach a decision by qualified majority in November 1998, the record of the votes (written procedure) indicates that no member State objected. France failed to submit a vote. Austria, Greece, Ireland, Luxembourg and Sweden abstained and statements were provided by Austria, Greece and Sweden. The Panel remarks that Austria's competent authority concurred that the "state-of-the-art" risk assessment "did not indicate any specific challenges to human health and the environment"; however, Austria suggested that any potential effects of large-scale cultivation be monitored "as generally agreed in discussions on the amendment of Directive 90/220/EEC", and that specific labelling requirements should be mentioned at least in the recitals.[732]

[732] Exhibit EC-84/At. 45.

7.616 On the other hand, the statement submitted by Greece consisted of a single sentence: "We support the idea of a 'Moratorium' for G.M.O.s as presented by some Member-States".[733] Sweden unsuccessfully requested an extension of the vote until the safety of the transgenic tomato as food had been assessed, to ensure co-ordination and coherence between decisions taken with regard to release into the environment and novel foods.

7.617 We note that within two months following the failure of the Regulatory Committee to reach a decision, the applicant provided clarification that the transgenic tomato was bred solely for the processing tomato industry and would not be available directly to consumers. Furthermore, on 23 September 1999, the Scientific Committee on Food (SCF) expressed a favourable opinion regarding the safety of processed products produced form the transgenic tomato in the context of Regulation 258/97 on novel foods.

7.618 We do not consider that any of the specific concerns identified by member States during the consultation of the Regulatory Committee pertain specifically to the safety assessment of transgenic tomatoes for cultivation and processing. Furthermore, all of the concerns previously identified by member States were addressed in the evaluations undertaken by the SCP and the SCF, and the European Communities has not argued that any substantive concerns were raised by any member State subsequent to these assessments. It could therefore be expected that the Commission would have submitted a draft measure to the Council "without delay" with respect to the applications for the cultivation and processing of transgenic tomatoes.

7.619 Indeed, the documentation provided to us indicates that the Commission began preparing a draft measure for submission to the Council in February 1999, and six months later, in August 1999, launched an internal written procedure for the adoption of the draft measure by the Commission. However, there is no indication that this draft measure was ever actually submitted to the Council, and no evidence of any Council action with regard to this application. The European Communities has provided no explanation for the failure to submit this draft measure to the Council, as required by Directive 90/220. No documentation has been provided with regard to any consideration of this application after the 23 September 1999 positive assessment by the SCF of the processed tomato products, until the withdrawal of the application under Directive 90/220 more than two years later, in February 2002.

7.620 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission did not complete its internal written procedure for the adoption of the draft measure to be submitted to the Council after the June 1999 declaration by the Group of Five countries. Following this declaration, and despite the favourable opinion of the SCP (and the SCF), the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[734] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, for a period of more than two years after launching its internal written

[733] *Ibid*.

[734] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

procedure, to submit a draft measure to the Council is consistent with the contention that the Commission made and followed such a decision.

7.621 The European Communities points out that in November 1998, at the Regulatory Committee stage, Denmark and Italy voted in favour of approval of the transgenic tomato under Directive 90/220. In June 1999, these two member States became part of the Group of Five countries supporting a general moratorium. The votes by Denmark and Italy do not support the conclusion that there was systematic member State opposition to final approvals already as from October 1998, but they are not inconsistent with the application of a general moratorium at least as from June 1999.

7.622 Regarding the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application, we have already noted with respect to the application concerning MON809 maize that this is not inconsistent with the Complaining Parties' assertion that a general moratorium on approvals was in effect.

7.623 In light of the above considerations, we conclude that the Commission's failure after August 1999 to submit a draft measure concerning the cultivation and processing of the transgenic tomato to the Council is consistent with the Complaining Parties' assertion that at least as from June 1999 the European Communities applied a general moratorium on final approvals.

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

7.624 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to re-convene the Regulatory Committee for a vote on a draft measure, after the Regulatory Committee had met, but not taken a vote on the draft measure. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[t]he representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter."

Falcon oilseed rape (EC-62)

7.625 The application concerning Falcon oilseed rape was first submitted to Germany (lead CA) in April 1996, and was provided to the Commission for circulation to all member States in December 1996. Following a positive opinion by the SCP concerning Falcon oilseed rape on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed.

7.626 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 in accordance with Article 21 of Directive 90/220, 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. According to the United States, the Commission failed to do so for no other reason than the general moratorium.

7.627 **Canada** argues that this product was stalled at Community level for many years.

7.628 **Argentina** noted that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including Falcon oilseed rape, from moving forward. The application of Falcon oilseed rape was prevented from reaching the Regulatory Committee voting stage as of 4 September 1998 and until June and October 1999, where it was not voted on.

7.629 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 new protein expressed by the GM plant 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.

7.630 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, on the food chain and on the spreading of the gene due to the possibility of crossing between the GM 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 United States' view, Italy's request was not scientifically justified.

7.631 The **Panel** must first address the United States' understanding of Article 21 of Directive 90/220. Article 21 of Directive 90/220 states that if "no opinion is delivered" by the Regulatory Committee, the Commission must submit a draft measure to the Council. The United States suggests that after the March 2000 meeting of the Regulatory Committee, the Commission was required to submit another draft measure to the Regulatory Committee and/or was required to submit a draft measure to the Council.[735] The Commission in this case submitted a draft measure to the Regulatory Committee which was on the agenda of the October 1999 meeting. No vote was held on that measure at that meeting.[736] The record does not indicate that a different draft measure was on the agenda of the March 2000 meeting of the Regulatory Committee. Therefore, the Panel does not see what is the basis for the United States' argument that after the March 2000 meeting, there was a need for the Commission to submit another draft measure, or to re-submit the same draft measure, to the Regulatory Committee.

7.632 The Panel is also not persuaded that in the absence of a vote by the Regulatory Committee, the Commission was required to submit a draft measure directly to the Council. If that were the case, the Commission should have submitted a draft measure to the Council after the Regulatory Committee failed to vote on Falcon oilseed rape at its meeting in October 1999. Instead, the Commission convened another Regulatory Committee meeting in March 2000. In the Panel's understanding, the phrase "no opinion is delivered" is intended to refer to a situation where the

[735] US third written submission, paras. 107-108.
[736] Exhibit EC-62/At. 87.

Regulatory Committee votes on a draft measure, but fails to achieve the required qualified majority in favour or against the measure.[737]

7.633 The Panel agrees with the United States, however, that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the Commission to convene another meeting with a view to obtaining a vote on its draft measure.[738] Therefore, the question to be examined is why this did not happen.

7.634 There is no direct evidence on the record to show why the Regulatory Committee did not proceed to a vote on Falcon oilseed rape at the March 2000 meeting.[739] From other evidence before the Panel, two separate reasons can nevertheless be inferred. One reason appears to be a request for information from the Italian CA. That request was transmitted to the lead CA on 14 March 2000, and the lead CA forwarded it to the applicant.[740] The applicant provided the information requested to the lead CA on 13 November 2000. In its letter, the applicant notes that all the issues on which Italy requested more information "were indeed already addressed by the European Scientific Committee on Plants (SCP)" when evaluating the application in question and that they had also already been addressed in documents provided by the applicant in November 1999.[741]

7.635 The other reason for the Regulatory Committee's failure to vote appears to be a letter sent by the applicant to the Commission the day before the March 2000 Regulatory Committee meeting.[742] As can be gathered from a letter of 20 April 2000 by the German lead CA to the applicant[743], the applicant should have sent its letter to the lead CA rather than the Commission. The Commission apparently shared the applicant's letter with the lead CA at the March 2000 Regulatory Committee meeting, and the lead CA then distributed it to the other member States present at the meeting. According to the letter by the lead CA, the applicant's letter gave rise to confusion. The lead CA's letter states that it was unclear whether the applicant's letter sought to modify the application such that the product would no longer be placed on the market soon after the application was approved, but only as from 2003.[744] The lead CA notes that the uncertainty over the applicant's intentions meant that the decision had to be postponed so that clarification could be sought from the applicant. Consistent with this account, the lead CA's letter ends by asking the applicant for clarification. As

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[737] *See* the result of the consultation of the Regulatory Committee by written procedure in the procedure concerning Bt cotton where member States voted, but the result was that the "Committee did not give an opinion on the measures" (emphasis omitted). Exhibit EC-65/At. 59.

[738] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "*Commission* informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "*Commission* is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

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

[740] Exhibit EC-62/At. 95. 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".

[741] Exhibit EC-62/At. 97.

[742] The record does not contain a copy of that letter.

[743] Exhibit EC-62/At. 96.

[744] According to the lead CA, the applicant's letter of 8 March 2000 expanded on a letter of 28 February 2000 which the applicant sent to the lead CA and which was subsequently forwarded to the other member States. The lead CA notes that while it had not itself understood the February 2000 letter as a request for a modification of the application, some uncertainty nevertheless arose in this respect once other member States became aware of the content of the letter. Exhibit EC-62/At. 96.

already pointed out, the lead CA's letter dates from 20 April 2000. From the record it appears that the applicant did not provide the requested clarification until 29 May 2001.[745] On the same date, the applicant provided the lead CA with a set of documents which it said confirmed that its application was already in line with the main provisions of Directive 2001/18, which had been adopted in March 2001.[746]

7.636 From the foregoing it would appear that as from the end of May 2001, when the applicant provided the clarification sought by the lead CA, the two above-mentioned reasons could no longer explain the Commission's failure to call another meeting of the Regulatory Committee for a vote on Falcon oilseed rape.[747] Directive 90/220 was not repealed until 17 October 2002. In the Panel's view, there would thus have been enough time to convene another Regulatory Committee meeting and for the Commission to adopt its draft measure in the event of a favourable vote.[748]

7.637 We note that the United States considers that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third meeting. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting after May 2001 is consistent with the existence of such a decision by the Commission. 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 it could have considered that the Regulatory Committee would finally vote at the next meeting, but 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 have to complete the procedure by adopting its draft measure.

7.638 In the light of the above considerations, we conclude that the Commission's failure to convene another Regulatory Committee meeting concerning Falcon oilseed rape after May 2001 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

MS8/RF3 oilseed rape (EC-63)

7.639 The application concerning MS8/RF3 oilseed rape was first submitted to Belgium (lead CA) in September 1996, and was provided to the Commission for circulation to all member States in

[745] The applicant stated that once the application concerning Falcon oilseed rape was approved there would initially be large-scale releases in the European Communities that would remain limited to identified users. At the earliest as of 2003, there would be full commercial release of the product in question. Exhibit EC-62/At. 99.

[746] Exhibit EC-62/At. 98.

[747] As noted above, we are not aware of any other reasons.

[748] We note in this regard that the March 2000 Regulatory Committee meeting was held four months after the first Regulatory Committee meeting in October 1999 and that after that October meeting the applicant had also submitted additional information.

January 1997. Following a positive opinion by the SCP concerning MS8/RF3 oilseed rape on 19 May 1998, the Commission on 4 September 1998 launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee . The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed and replaced by Directive 2001/18.

7.640 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.

7.641 **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 the recommendations contained in the SCP opinion, including a monitoring plan. Although the application was discussed at the Regulatory Committee in the summer of 1999, the Commission failed to submit a draft measure for a vote by the Regulatory Committee, and instead imposed the "interim approach". 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.

7.642 Canada also points to the 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. 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. As Directive 90/220 was repealed in October 2002, the application was effectively returned to the member State level, thus causing a 7.5- year delay in processing this application.

7.643 **Argentina** notes that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including MS8/RF3 oilseed rape, from moving forward. The application MS8/RF3 oilseed rape was prevented from reaching the Regulatory Committee voting stage until June and October 1999, where it was not voted on.

7.644 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 Italy raised scientific issues regarding the "effects of the transgenic product on the biogeochemical cycles and on food chains" and the likelihood of spreading. Italy's concerns reflected new information concerning the impact of herbicide regimes associated with cultivation of GM herbicide tolerant oilseed rape on biodiversity which had recently been made public at the time of the meeting. The European Communities further

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.

7.645 **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.

7.646 Canada further notes that at the same time that the Commission submitted a draft proposal to the Regulatory Committee in June 1999, the Environment Council adopted the "Common Position" and five EC member States issued their Declaration openly opposing the approval of any biotech product. The applicant voluntarily agreed to fulfill the requirements of the future legislation set out in the "Common Position".[749]

7.647 The **European Communities** maintains that in the summer of 1999, in view of the proposed modification of the legislation, and on the basis of the Common Position by the Environment Council, the applicant voluntarily committed to anticipate in its application a number of the additional requirements that the proposed modifications were meant to address. The applicant submitted undertakings and commitments on a number of issues including post-market monitoring, traceability and labelling. The lead CA, other member States' CAs and the Commission discussed commitments and undertakings by the applicant, and in particular monitoring plans, into 2002. By then, Directive 2001/18 had been approved and it was decided to continue the evaluation of the dossier under the old legislative regime provided that the provisions of the new Directive were taken into account by the applicant voluntarily and became legally binding. In February 2002, the lead CA asked the applicant to complete the dossier with required data on, *inter alia*, reference material concerning the events MS8 and RF3. The applicant did not reply in that year.

7.648 The **Panel** notes that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the Commission to convene another meeting with a view to obtaining a vote on its draft measure.[750] Therefore, the question to be examined is why this did not happen.

7.649 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.[751] 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.[752] The applicant provided the information requested

[749] Exhibit EC-63/At. 72.

[750] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "Commission informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "Commission is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

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

[752] 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".

by Italy to the lead CA on 13 November 2000. In its letter, the applicant notes that all the issues on which Italy requested more information "were indeed already addressed by the European SCP " when evaluating the application in question and that they were also already addressed in November 1999 documents provided by the applicant.[753] This communication was also circulated to all other CAs and the Commission. We further note that in response to a question from the Panel, one of the experts advising the Panel, Dr. Nutti, expressed the view that the request for further information was not necessary to ensure the conclusions for the safety assessment of the newly expressed protein in the food chain.[754]

7.650 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.[755] 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.[756] 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.[757] There is no indication that the lead CA ever forwarded the new documents to the other member States and to 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.[758] No reason was given for why an opinion had been requested.

7.651 Regarding the clarification provided by the applicant in June 2001, we note that there is nothing in the record to suggest that the Commission was "waiting" for the June 2001 clarification. If the Commission was not waiting for that clarification, then it could not provide an explanation 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 could be expected that the Commission would have inquired with the lead CA whether the applicant had provided clarification. There is no evidence that the Commission did so.

7.652 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 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 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

[753] Exhibit EC-63/At. 88.
[754] Annex H, para. 331.
[755] Exhibit EC-63/At. 92.
[756] Exhibit EC-63/At. 91.
[757] *Ibid*.
[758] Exhibit EC-63/At. 93.

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."[759] 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."[760] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[761]

7.653 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 recall that in the approval procedure concerning Falcon oilseed rape, a different lead CA did not find it necessary to make an assessment of additional information submitted by an applicant to document that its application was already in line with the main provisions of Directive 2001/18.

7.654 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.[762] 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.[763]

7.655 From the foregoing it would appear that at the very latest in the summer of 2002, once the applicant had replied to the last pending question of the BBC in May 2002, the Commission could have re-convened the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape. As Directive 90/220 was not repealed until 17 October 2002, we think there would have been 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.

7.656 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium on the approval of biotech products. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third

[759] Exhibit EC-63/At. 102.
[760] *Ibid*.
[761] *Ibid*.
[762] 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.
[763] 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.

meeting. We recall that in the Complaining Parties' view, the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting after May 2001 is consistent with the existence of such a decision by the Commission. 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 it could have considered that the Regulatory Committee would finally vote at the next meeting, but 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 have to complete the procedure by adopting its draft measure.

7.657 In the light of the above considerations, we conclude that the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape in the summer of 2002 (at the latest) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR fodder beet (EC-64)

7.658 The application concerning RR fodder beet was first submitted to Denmark (lead CA) in February 1997, and was provided to the Commission for circulation to all member States in October 1997. Following a positive opinion by the SCP concerning RR fodder beet on 23 June 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed.

7.659 The **United States** argues that the Commission failed to submit a draft measure to the Regulatory Committee. Later, the United States argues that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission failed to re-submit a draft measure to the Regulatory Committee.

7.660 **Canada** argues that the Commission did not submit a draft measure for a vote by the Regulatory Committee, even though the lead CA issued a positive opinion on the application on 7 October 1997, the SCP issued a positive opinion on the application on 23 June 1998 and the applicant responded to all the questions posed by the lead CA on 27 April 1998.

7.661 **Argentina** noted that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including RR fodder beet, from moving forward. The application for RR Fodder beet was prevented from reaching the Regulatory Committee voting stage until October 1999, when it was not voted on.

7.662 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 – first in October 1999 and then in March 2000. The Regulatory Committee did not vote in October 1999 due to outstanding requests for information.

7.663 The **Panel** recalls that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the

Commission to convene another meeting with a view to obtaining a vote on its draft measure.[764] Therefore, we need to examine why the Commission did not do so.

7.664 There is no direct evidence on the record to show why the Regulatory Committee did not proceed to a vote on RR fodder beet at the March 2000 meeting.[765] One reason appears to be a request for information from the Italian CA. That request was transmitted to the lead CA on 14 March 2000, and the lead CA forwarded it to the applicant.[766] The applicant provided the requested information to the lead CA on 12 July 2000. In its letter, the applicant notes in regard to its answers to the questions raised by the Italian CA that "there are no new data in the document, only clarifications".[767] With its July 2000 letter, the applicant also provided data on molecular characterization which were apparently generated at the request of the United Kingdom's CA. The letter noted the applicant's understanding that the UK experts reached the conclusion that this data did not provide new information after they had reviewed a previously submitted data package which "addressed sufficiently the UK questions".[768]

7.665 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. The applicant therefore requested the lead CA to inform all member States that the application dossier was complete and that a decision should be taken at Community level.[769] The applicant sent a copy of its July 2000 letter to the Commission.

7.666 There is no indication that the lead CA forwarded the new documents to the other member States. In fact, the issue of when the documents were to be forwarded was discussed in a meeting held between the lead CA and the applicant in January 2001.[770] 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).[771] However, the record shows that the lead CA did not follow the applicant's suggestion, and the documents were not provided to other member States while Directive 90/220 was still in force.

7.667 As noted earlier, the Commission received a copy of the applicant's July 2000 letter, and this letter addressed all outstanding issues. Notwithstanding this, 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. We recall in this regard that it was the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure.

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[764] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "Commission informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "Commission is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

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

[766] Exhibit EC-64/At. 116. 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".

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

[768] *Ibid*.

[769] *Ibid*.

[770] Exhibit EC-64/At. 120.

[771] *Ibid*.

7.668 From the foregoing it would appear that after July 2000, once the applicant had provided the additional information sought by the Italian CA, or at the latest as from 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.

7.669 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium on the approval of biotech products. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third meeting. We recall that, in the Complaining Parties' view, the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting is consistent with the existence of such a decision by the Commission. 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 it could have considered that the Regulatory Committee would finally vote at the next meeting, but 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 have to complete the procedure by adopting its draft measure.

7.670 In the light of the above considerations, we conclude that 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 Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

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

7.671 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Regulatory Committee a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[t]he representative of the Commission shall submit to the committee a draft of the measures to be taken".

Transgenic potato (EC-67)

7.672 The application concerning Transgenic potato was first submitted to Sweden (lead CA) in August 1996, and was provided to the Commission for circulation to all member States in June 1998. Following a positive opinion by the SCP concerning the Transgenic potato on 18 July 2002, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. The applicant submitted an updated application under Directive 2001/18 in January 2003, and it was provided to the Commission for circulation to all member States in May 2004.

7.673 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.

7.674 **Argentina** argues that the application concerning the Transgenic potato was stalled and hence never reached the Regulatory Committee stage. Argentina points out in this regard that after the favourable SCP opinion of July 2002, there was neither an inter-service consultation phase in the Commission nor any other movement until Directive 2001/18 entered into force.

7.675 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.

7.676 The **Panel** understands the European Communities to argue that the Commission did not submit a draft measure to the Regulatory Committee because the SCP provided its opinion only three months before the date of repeal of Directive 90/220. This argument presents the issue whether the Commission could have reached the conclusion that three months would be insufficient to approve the application concerning the Transgenic potato.

7.677 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[772]. In our assessment, it is possible that the Commission reached the conclusion that even if all relevant actors proceeded with a sense of urgency, the aforementioned steps could not all be completed within three months.[773] Similarly, it is possible that this was the reason why the Commission did not undertake any steps to move the process forward, *e.g.*, by launching inter-service consultations on a draft measure to be submitted to the Regulatory Committee.[774]

7.678 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning the Transgenic potato the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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. As noted, however, the Commission's failure to forward a draft measure to the Regulatory

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

[773] We nevertheless note that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion. Exhibit EC-76/At. 72. This suggests that if indeed more than three months were necessary, in the best-case scenario, to complete the procedure, it might not have taken much more than that.

[774] From the evidence before us, it seems that unlike in other procedures (*see, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48), the Commission in this procedure did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee.

Committee might also reflect the Commission's conclusion that even in the best of cases the application could not have been approved before the date of repeal of Directive 90/220.

7.679 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning the Transgenic potato to the Regulatory Committee following the issuance in July 2002 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Liberator oilseed rape (EC-68)

7.680 The application concerning Liberator oilseed rape was first submitted to Germany (lead CA) in January 1998, and was provided to the Commission for circulation to all member States in January 1999. 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 before Directive 90/220 was repealed. The applicant provided an updated application under Directive 2001/18 on 16 January 2003.

7.681 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 lengthy delay after the SCP opinion was issued provides compelling evidence of the existence of a general moratorium.

7.682 **Argentina** argues that the application concerning Liberator oilseed rape was stalled for two years and never reached the Regulatory Committee stage. Argentina points out in this regard that after the favourable SCP opinion of November 2000, there was neither an inter-service consultation phase in the Commission nor any other movement until November 2002.

7.683 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".[775] 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.

7.684 The **Panel** understands the European Communities as asserting that the applicant in this case should on its own initiative and without a specific request by the lead CA have presented a code of practice for the field management of the Liberator oilseed rape and that the applicant's failure to do so explains the Commission's failure to submit a draft measure to the Regulatory Committee.

7.685 In considering the European Communities' assertion, the first thing to be noted is that it was the Commission, not the applicant, that requested an opinion from the SCP.[776] Accordingly, when the SCP stated that "[i]t is recommended that the introduction of herbicide tolerant crops should be

[775] Exhibit EC-68/At. 88.
[776] Exhibit EC-68/At. 86.

accompanied by […] an agreed code of practice for field management […]"[777], the SCP was in our understanding recommending that the Commission seek to agree on a code of practice with the applicant. However, there is no evidence that the applicant was ever requested by the Commission or the lead CA to propose a code of practice in accordance with the SCP's recommendation. We therefore see no reason to assume that it was for the applicant to take the initiative and prepare a response to the SCP recommendation.

7.686 The European Communities correctly points out that in the approval procedure concerning Falcon oilseed rape, the applicant wrote a letter to the Commission soon after the SCP had issued its opinion on the product in question. The applicant's letter refers to certain recommendations made by the SCP concerning optimal deployment in agriculture and indicates the applicant's intention to make available to users relevant information on management schemes.[778] However, there is nothing in the applicant's letter to suggest that the applicant was requested to respond to the SCP's recommendations. In the absence of a reference in the letter to a request or requirement, it may be assumed that the letter was sent at the applicant's own initiative. In our view, the letter at issue does not therefore support the EC argument that the applicant in the procedure concerning Liberator oilseed rape was supposed to present a proposal for a code of practice once the SCP had issued its opinion.

7.687 For the reasons set out above, we are not persuaded by the European Communities' explanation that the Commission did not submit a draft measure to the Regulatory Committee because it was waiting for the applicant to propose a code of practice. In any event, the fact that the applicant did not present a proposal in our view was not an obstacle to the Commission launching inter-service consultations on a draft measure. From the evidence before us, however, it seems that unlike in other procedures[779], the Commission in this procedure never even launched such consultations. This further undermines the EC assertion that the Commission was waiting for the applicant.

7.688 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.[780]

7.689 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning Liberator oilseed rape the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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

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

[778] Exhibit EC-62/At. 75. In our view, it is doubtful that the applicant's statement of its intentions with respect to management schemes can be said to amount to a proposal for a code of practice, as the European Communities contends.

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

[780] 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 EFSA issued its opinion. Exhibit EC-76/At. 72.

majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.690 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Liberator oilseed rape to the Regulatory Committee following the issuance in November 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Bt-11 maize (EC-69)

7.691 The application concerning Bt-11 maize (EC-69) was first submitted to France (lead CA) in May 1996, and was provided to the Commission for circulation to all member States in May 1999. The SCP issued a favourable opinion on Bt-11 maize on (EC-69) 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. Under the new Directive, the applicant submitted the updated application on 15 January 2003. As of the establishment of the Panel, the application was still under assessment under Directive 2001/18.

7.692 The **United States** argues that after 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's approval system, the next step after the SCP favourable opinion should have been to submit the application for approval by the EC's Regulatory Committee, but that there is no action on the application for 2 years after the SCP opinion and instead the next entry 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.

7.693 **Argentina** argues that Bt-11 maize (EC-69) received a positive opinion from the SCP on 30 November 2000, but there was no further movement on the application until Directive 2001/18 took effect, and the application had to be resubmitted. The application was thus stalled for two years.

7.694 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 characterisation of the Bt-11 line, taking into account the provisions of the new Directive, *inter alia* on monitoring, traceability and labelling.

7.695 The **United States** responds that the monitoring plan referred to in the SCP opinion is an Insect Resistance Management (IRM) plan, but 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, nor did it 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.

7.696 The **Panel** understands the European Communities as asserting 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 as asserting that the applicant submitted additional information in May 2002, just before the new Directive entered into force.

7.697 Regarding the monitoring plan, we note that the SCP, in its opinion concerning Bt-11 maize (EC-69), stated that "there is no evidence to indicate that the placing on the market for cultivation purposes of maize line Bt-11 […] is likely to cause adverse effects on human health and the environment", but nonetheless concluded that "[t]he SCP should be kept informed of the results of monitoring and research studies in Member States with particular regard to the development of insect resistance"[781]. The SCP, in another paragraph of its opinion, also states that "[s]uch monitoring [as developed by the Expert Group on Monitoring for Insect Resistance to Bt toxins] *should be* carried out in Bt-Maize and should provide an adequate framework to delay the onset of resistance in the target pest."[782]

7.698 Thus, while the European Communities is correct that the SCP recommended monitoring, it is important to recall that it was the Commission, not the applicant, that requested an opinion from the SCP. Accordingly, when the SCP expressed its interest in the implementation of a monitoring plan, the SCP was, in our understanding, addressing itself to the Commission, not the applicant. 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.

7.699 We note that the applicant submitted additional information in May 2002 which included a monitoring plan. However, as the European Communities itself has suggested, it appears this information was submitted with a view to updating the application in anticipation of the entry into force of the new requirements contained in Directive 2001/18.[783]

7.700 For the reasons set out above, we are not persuaded by the European Communities' explanation that the Commission did not submit a draft measure to the Regulatory Committee because the SCP recommended a monitoring plan and the proposal by the applicant remained unsettled. In any event, the fact that the SCP stated that monitoring should be carried out in our view was not an obstacle to the Commission launching inter-service consultations on a draft measure. From the evidence before us, however, it seems that unlike in other procedures, the Commission in this procedure never launched such consultations. This further undermines the EC assertion that the Commission did not forward a draft measure to the Regulatory Committee because the issue of the monitoring plan remained unsettled.

7.701 Regarding the additional information submitted by the applicant in May 2002, we have already observed 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 explain the Commission's failure to submit a draft measure to the Regulatory Committee between November 2000 and May 2002.

7.702 We note 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

[781] Exhibit EC-69/At. 83.
[782] *Ibid*. (emphasis added).
[783] The European Communities provided the Panel with a list of the appendices submitted by the applicant, but not with the accompanying cover letter. Exhibit EC-69/At. 84.

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.[784]

7.703 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning Bt-11 maize (EC-69) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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.

7.704 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Bt-11 maize (EC-69) to the Regulatory Committee following the issuance in November 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

GA21 maize (EC-78)

7.705 The application concerning GA21 maize (EC-78) (C/ES/98/01)[785] was first submitted to Spain (lead CA) in May 1998, and was provided to the Commission for circulation to all member States in June/July 1999. 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. In October 2002, Directive 90/220 was repealed. The applicant submitted an updated application to the lead CA under Directive 2001/18 on 15 January 2003. As of the establishment of the Panel, the application was still being assessed at Community-level deliberation under Directive 2001/18. On 15 September 2003, the application was withdrawn.

7.706 The **United States** argues that even though GA21 maize (EC-78) was forwarded by the lead CA to the Commission with a favourable opinion, and it also received a favourable risk assessment from the SCP, the consideration of this application was indefinitely suspended because the Commission refused to submit a draft measure to the Regulatory Committee.

7.707 **Canada** argues that GA21 maize (EC-78) received a positive opinion from the lead CA in May 1998 and the applicant answered all the questions posed by the lead CA. In addition, GA21 maize (EC-78) received 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. Despite these facts, the Commission failed to submit a draft measure to the Regulatory Committee.

[784] 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 EFSA issued its opinion. Exhibit EC-76/At. 72.

[785] A separate application for approval of GA21 maize was submitted to the United Kingdom (*see* EC-85).

7.708 **Argentina** argues that once the SCP issued its favourable opinion on 22 September 2000, the procedure on this application was suspended. 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.

7.709 The **European Communities** argues that after assessment at both national and European Community level, the application was withdrawn by the applicant on 15 September 2003. The European Communities further notes that the applicant, in its withdrawal letter, gave three reasons for the withdrawal: *first*, the progress in the approval procedure of another Roundup Ready 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.

7.710 The **United States** responds that, once the SCP rendered a favourable opinion on 22 September 2000, all activity unexpectedly ceased at the Commission level and that there was no action or communication by the Commission on this application for the next 3 years, up to the time the application was finally withdrawn by the applicant on 15 September 2003. 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.

7.711 The United States argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies 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, which the United States maintains results from the moratorium.

7.712 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.713 **Argentina** likewise argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the

process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.714 The **Panel** understands the European Communities to argue that after the SCP opinion, the application was being assessed according to the procedures. 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[786], the Commission in this procedure never launched inter-service consultations on a draft measure.

7.715 We note 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."[787] 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 entry into force of the new requirements contained in Directive 2001/18, and not because the applicant was requested to address the SCP opinion.[788] 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.

7.716 We 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.[789] In March 2001, the lead CA informed the Commission that it had no objection to the applicant's request.[790] 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.

7.717 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.[791]

7.718 For the reasons set out above, we are not persuaded by the European Communities' assertion that the application concerning GA21 maize (EC-78) was being assessed according to the procedures until it was withdrawn by the applicant. The fact that the applicant's September 2003 letter withdrawing the application did not specifically state that the application was not being processed according to the procedures provided for in Directive 90/220, and that the letter did not specifically

[786] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[787] Exhibit EC-78+85/At. 90.
[788] Exhibit EC-78+85/At. 94.
[789] Exhibit EC-78+85/At. 91.
[790] Exhibit EC-78+85/At. 92.
[791] 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.

cite a general moratorium as a reason for the withdrawal of the application does not confirm the EC assertion. As we have noted in the context of our discussion of other approval procedures, the Complaining Parties have identified plausible explanations for why an applicant might not mention a moratorium in a withdrawal letter if a moratorium was in effect.

7.719 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall that the Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning GA21 maize (EC-78) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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.

7.720 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (EC-78) to the Regulatory Committee following the issuance in September 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

GA21 maize (EC-85)

7.721 The application concerning GA21 maize (EC-85) was first submitted to the United Kingdom[792] (lead CA) towards the end of 1997[793]. The lead CA forwarded the application to the Commission on 15 October 1999. The Commission circulated the application to all member States in December 1999. After receiving comments and objections from member States, the Commission did not submit a draft measure to the Regulatory Committee and the application was withdrawn by the applicant with a letter of 29 March 2001[794].

7.722 The **United States** argues that the Commission failed to submit a draft measure to the Regulatory Committee after completion of the MS consultation in February 2000.

7.723 **Canada** argues that the Commission failed to submit a draft measure to the Regulatory Committee after completion of the consultations with relevant member States in February 2000.

7.724 **Argentina** argues the procedure had taken 3 years and 5 months without the adoption of a definitive decision concerning its approval. According to Argentina, the application was submitted to the lead CA on 6 November 1997 under Directive 90/220 and still had not reached the Regulatory Committee stage when the Directive 2001/18 entered into force. The application was withdrawn on 29 March 2001.

7.725 The **European Communities** argues that after discussions between the lead CA and the applicant, the application was withdrawn by the applicant with its letter dated 29 March 2001. The

[792] *See also* the approval procedure concerning GA21 maize (Spain) (EC-78) above.
[793] The precise date on which the application was submitted to the United Kingdom is unclear from the information before the Panel.
[794] Exhibit EC-78/At. 93.

applicant referred to "the unexpected commercial constraints" and the parallel application for GA21 maize in Spain as justification for its withdrawal.

7.726 The **United States** maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies 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, which the United States maintains results from the moratorium.

7.727 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium.

7.728 Canada further argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.729 **Argentina** likewise argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.730 The **Panel** understands the European Communities to be asserting that the reason why the Commission did not forward a draft measure to the Regulatory Committee is that the applicant did not sufficiently respond to the comments and objections put forth by the member States.

7.731 The chronology provided to us by the European Communities indicates that some member States submitted comments, questions and objections on this application after it was circulated together with the lead CA's favourable assessment. The applicant on 17 February 2000 provided prompt responses to requests for additional information and for clarification from several member States.[795] On 18 February 2002, additional member States raised objections. These objections do not appear to have included new requests for information or clarification.[796] At any rate, there is no evidence that these objections were conveyed to the applicant and that the applicant indicated that it would respond to them. This is in contrast with the approval procedure concerning the GA21 maize application submitted to Spain (EC-78), in which the Commission sent to the applicant the substance of the objections by the member States and in which the applicant responded to them before the Commission sought an opinion from the SCP.[797]

[795] Exhibit EC-78+85/At. 41.
[796] Exhibit EC-78+85/Ats. 42-44.
[797] Exhibit EC-78+85/At. 77 and 79.

7.732 We note that in cases where member States raised objections to the approval of an application, the Commission routinely sought an opinion from the SCP before submitting a draft measure to the Regulatory Committee, even though there was no legal obligation under Directive 90/220 to do so.[798]. However, the Commission did not send this application to the SCP for review. In contrast, in February 2000, the parallel application submitted to Spain (EC-78) was already being reviewed by the SCP, for it had been sent to the SCP on 29 October 1999.[799] The SCP issued a favourable opinion on GA21 maize (EC-78) on 22 September 2000.[800] Even if it were assumed, *arguendo*, that the Commission saw no need to request an additional and separate SCP opinion on GA21 maize (EC-85) and was waiting for the SCP opinion on GA21 maize (EC-78), the fact remains that the Commission apparently did not launch inter-service consultations on a draft measure concerning GA21 maize (EC-85) even after the SCP had issued its opinion on GA21 maize (EC-78).

7.733 On 29 March 2001, the applicant withdrew its application. Since the last member State objections were filed already in mid-February 2000 and since, assuming it was relevant, the SCP opinion on GA21 maize (EC-78) was issued in September 2000, it is clear to us that the withdrawal of the application in March 2001 does not explain the Commission's failure to launch inter-service consultations and/or to forward a draft measure to the Regulatory Committee.[801]

7.734 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning GA21 maize (EC-85) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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.

7.735 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning GA21 maize (EC-85).

7.736 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (EC-85) to the Regulatory Committee after the member States expressed their views on the dossier in February 2000 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

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[798] EC reply to Panel question No. 133.
[799] Exhibit EC-78/At. 82.
[800] Exhibit EC-78/At. 90.
[801] 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.

T25 x MON810 maize (EC-86)

7.737 The application concerning T25 x MON810 maize was first submitted to the Netherlands (lead CA) in June 1998, and was provided to the Commission for circulation to all member States in May 1999. Following a positive opinion by the SCP concerning T25 x MON810 maize on 6 June 2000, the Commission did not submit a draft measure to the Regulatory Committee. In December 2002, the application was withdrawn.

7.738 The **United States** argues that, despite the SCP's favourable risk assessments, the Commission refused to submit a draft measure to the Regulatory Committee as required by EC law, which led to the withdrawal of the application on 12 December 2002.

7.739 The **European Communities** argues that, after assessment by the SCP, the application was withdrawn by the applicant by its letter dated 12 December 2002, which pointed to "entirely commercial reasons" as the justification for its withdrawal.

7.740 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies 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, which the United States maintains results from the moratorium.

7.741 The **Panel** understands the European Communities as asserting that the Commission did not send a draft measure to the Regulatory Committee because, after the SCP opinion, the application was being assessed according to the procedures and then was withdrawn by the applicant.

7.742 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[802], the Commission in this procedure never launched inter-service consultations on a draft measure.

7.743 We further note that in contrast with other SCP opinions, the SCP opinion on T25 x MON810 maize did not contain any recommendation for monitoring.[803] Moreover, there is no evidence that the Commission had requested, and was waiting for, further information from the applicant. Accordingly, we are not persuaded by the European Communities' explanation that the application was being assessed according to the procedures until it was withdrawn by the applicant in December 2002.

7.744 The SCP opinion in this procedure dates from June 2000. Directive 90/220 was not repealed until more than 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

[802] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[803] Exhibit EC-86/At. 66.

Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[804]

7.745 The United States considers that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning T25 x MON810 maize the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. 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.

7.746 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning T25 x MON810 maize.

7.747 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning T25 x MON810 maize to the Regulatory Committee following the issuance in June 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic red-hearted chicory (EC-77)

7.748 The application concerning Transgenic red-hearted chicory was notified twice under Directive 90/220. The first application (C/NL/94/25) was submitted to the Netherlands (lead CA) in December 1994. This application was approved at the Community level in May 1996. In accordance with an agreement between the lead CA and the Commission, this approval covered only breeding activities, not food or feed uses. In March 2003, the applicant requested the withdrawal of the marketing approval for breeding activities and obtained the requested withdrawal on 24 April 2003.[805]

7.749 Following the 1996 approval for breeding activities, the applicant submitted an application (C/NL/94/25/A) under Directive 90/220 to the Netherlands and the Commission in September 1996 requesting that approval be extended to use of this product for human and animal consumption. At the time of the second application, the Regulation 258/97 had not been adopted, but subsequently, in April 1998, the applicant began the application process for this product under Regulation 258/97 as well, by submitting an application to the Netherlands. Under the Directive, the SCP issued a favourable opinion on Transgenic red-hearted chicory for food and feed use on 18 December 1998, whereas the Scientific Committee on Foodstuffs (SCF) did not complete its assessment.

[804] 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.

[805] Exhibit EC-77/Ats. 43 and 44.

7.750 The **European Communities** argues that the application concerning this product was introduced in the Netherlands in 1996 and that after assessment at both national and European Community level, the application was withdrawn by the applicant in April 2003. The applicant gave two reasons for the withdrawal: *first*, the absence of a market for these products; and *second*, the fact that the applicant preferred not to be associated with GMOs any longer.

7.751 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. In addition, the companies have 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 resulting from the moratorium.

7.752 **Canada** observes that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection

7.753 **Argentina** also argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.754 The **Panel** begins its analysis by noting two factors which complicate the review of the procedure for the approval of the Transgenic red-hearted chicory under Directive 90/220. *First*, the food safety aspects of Transgenic red-hearted chicory were evaluated both under Directive 90/220 (EC-77) and under Regulation 258/97 (EC-97). A number of documents in the later stages of the application were filed in both approval procedures, which indicates that at a certain point in time, these applications began to be processed together. Many of the documents relating to the two applications are identical.[806] Hence, the evaluation of the approval procedure conducted under Directive 90/220 requires consideration of documentation submitted with the chronologies for both Exhibit EC-77 and EC-97.

[806] The following documents are identical: Exhibits EC-77/At. 93 and EC-97/At. 25 (on 14 November 2000); Exhibits EC-77/At. 94 and EC-97/At. 29 (on 11 June 2001); Exhibits EC-77/At. 95 and EC-97/At. 30 (on 18 June 2001); Exhibits EC-77/At. 97 and EC-97/At. 31 (24 July 2001). In addition, the document filed as Exhibit EC-97/At. 23 (on 10 July 2000) can be found amongst the documents filed as Exhibit EC-77/At. 93, and the document filed as Exhibit EC-77/At. 96 (12 July 2001) can be found amongst the documents filed as Exhibit EC-97/At. 31. Moreover, it appears that the entry "SCF review" (24 April 2001) in Exhibit EC-77 is the same as the entry "SCF additional request to the applicant" filed as Exhibit EC-97/At. 28.

7.755 *Secondly*, the same applicant submitted applications for Transgenic green-hearted chicory under both Directives 90/220 (EC-110) and Regulation 258/97 (EC-98) in parallel with the applications for Transgenic red-hearted chicory. The record for Transgenic red-hearted chicory overlaps substantially with that for Transgenic green-hearted chicory. In some cases the documentation submitted by the European Communities for a particular product actually provides information on two products. For example, on 23 April 1998, the Dutch Provisional Commission for Food Safety submitted to the European Commission a positive assessment[807] of both Transgenic green-hearted chicory and red-hearted chicory under the Directive 90/220. Yet this assessment was not included in the EC chronology for Transgenic red-hearted chicory.

7.756 Turning now to examine the procedure for the approval of the Transgenic red-hearted chicory under Directive 90/220, we note that the SCP evaluated feed and food safety aspects of this application under the Directive.[808] The SCP issued an opinion in December 1998, stating that "against the background of available knowledge, there is no evidence to indicate that the placing on the market of [red-hearted chicory] will cause adverse effects on human health and the environment".[809]

7.757 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 Panel notes that, in March 1999 after the SCP's favourable opinion, the Commission circulated an internal proposal for a draft measure to be submitted to the Regulatory Committee on which inter-service consultations were later launched.[810]. These consultations were closed on 26 May 1999.[811] The result of these consultations shows that one of the Commission services concerned expressed the view that the SCF needed to be consulted before the Regulatory Committee would be convened for a vote on the draft measure.[812] While it is clear from the record that the Regulatory Committee was not convened after the Commission completed its inter-service consultations, the record does not indicate that the Commission sought an opinion from the SCF.

7.758 However, documentation contained in Exhibit EC-97 concerning the procedure under Regulation 258/97 indicates that, in the meantime, the Commission had requested an evaluation by the SCF on 29 April 1999, as required by Article 11 of Regulation 258/97.[813] Exhibit EC-97 suggests that in September 2001 the applicant asked the SCF to suspend its assessment of the red-hearted chicory under Regulation 258/97.[814] Subsequently, in May 2003, the applicant requested the SCF to withdraw the dossier altogether.[815] Thus, it is clear that the SCF did not complete its assessment before September 2001, and it appears that it was no longer reviewing the application in question after that date.

7.759 There is no question that the Commission had enough time, once it had completed its inter-service consultations in May 1999, to submit its draft measure to the Regulatory Committee and to adopt its draft measure in the event of a favourable vote in the Regulatory Committee while Directive 90/220 was still in force. Based on the foregoing elements, it may be that the Commission decided not to convene the Regulatory Committee for a vote on its draft measure under

[807] Exhibit EC-110/At. 6.
[808] Exhibit EC-77/At. 86.
[809] *Ibid*., p. 5.
[810] Exhibit EC-77/Ats. 87 and 89.
[811] Exhibit EC-77/At. 90.
[812] *Ibid*.
[813] Exhibit EC-97/At. 19.
[814] Exhibit EC-97 contains no supporting document.
[815] Exhibit EC-97/At. 32.

Directive 90/220 until the SCF had completed its review of the Transgenic red-hearted chicory under Regulation 258/97.

7.760 Regarding the SCF's review of Transgenic red-hearted chicory, we note that in a communication to the SCF of 14 November 2000, the applicant expressed frustration with the progress of evaluation of the product, and in particular with a July 2000 request by the SCF for further information about substantial equivalence.[816] The applicant noted that much information had been provided to permit the determination of substantial equivalence between the transgenic chicory and conventional chicory, and expressed the view that "it does not make sense to continue year after year with experiments without having any indication that there is no substantial equivalence". The applicant also expressed concern that since the SCF had not indicated whether it would accept the new experiments as proposed by the applicant, "this might be a new reason for the SCF to ask the company to do new experiments after the proposed experiments have been finished". The total process would thus take at least three additional years, and the applicant indicated that the time necessary to conduct the required additional field trials would have negative financial implications. The applicant stressed that "the procedure, time, energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity." The applicant provided additional information from various years of field introductions to substantiate its claims of substantial equivalence, and requested that the SCF extract its conclusions and take decisions based on the information available at that time.

7.761 Five months after the communication from the applicant, in April 2001, the SCF informed the applicant that it would accept the data provided regarding field studies, and requested additional information regarding nutritional composition.[817] Dr. Nutti, one of the experts advising the Panel, considered that the information requested by the SCF regarding the nutritional composition was "important for the nutritional evaluation of the product".[818] The Panel accepts Dr. Nutti's view. But it is not convinced that the SCF's information request could not have been made at an earlier stage of the SCF's review. In response to the SCF's new request for information, the applicant indicated that it had not yet decided whether to execute additional experiments.[819] It expressed concern that the question regarding antibiotic resistance markers would need to be resolved before new experiments were started, and requested clarification regarding whether products containing antibiotic resistance markers would be permitted to enter the EC market after the entry into force of Directive 2001/18. In July 2001, the Commission indicated that the provisions of Directive 2001/18 did not include a general legal ban on antibiotic resistance marker genes as such but linked their phasing out to certain qualifiers.[820] The Commission also indicated that consideration of the applications for red-hearted chicory was suspended until the information requested by the SCF had been provided.[821] No further responses came from the applicant after the July 2001 clarifications by the Commission. As previously noted, in September 2001 the applicant asked the SCF to suspend its review of the red-hearted chicory.

7.762 We recall the Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals between October 1998 and August 2003. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and

[816] Exhibit EC-77/ At. 93.
[817] Exhibit EC-97/At. 28.
[818] Annex H, para. 762.
[819] Exhibit EC-77/At. 94. *See also* Exhibit EC-97/At. 29.
[820] Exhibit EC-77/At. 97. *See also* Exhibit EC-97/At. 31.
[821] *Ibid.*

application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. It is pertinent to note in this regard that the Commission's failure to forward its draft measure concerning Transgenic red-hearted chicory to the Regulatory Committee coincided with the June 1999 declaration by the Group of Five countries. In this situation, 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 concerning Transgenic red-hearted chicory would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Therefore, the fact that in the procedure concerning Transgenic red-hearted chicory the Commission did not submit a draft measure to the Regulatory Committee is in principle consistent with the Complaining Parties' contention that a general moratorium on approvals was being applied.

7.763 We have said that the Commission may have decided not to convene the Regulatory Committee for a vote on its draft measure under Directive 90/220 until the SCF had completed its review of the red-hearted chicory under Regulation 258/97. If this was the case, this would neither confirm nor contradict the Complaining Parties' assertion that the Commission was instrumental in the application of a general moratorium on approvals. In our view, it would not confirm the Complaining Parties' assertion because the Commission might also have waited for the SCF opinion if no general moratorium was in effect at the time. We note in this respect the special and unusual circumstance that the food safety of Transgenic red-hearted chicory was being evaluated concurrently under both Directive 90/220 and Regulation 258/97. At the same time, we consider that the possibility that the Commission was waiting for the SCF opinion would not contradict the Complaining Parties' assertion because even if the SCF had completed its review, the Commission might still not have forwarded its draft measure to the Regulatory Committee.[822] This can be seen from the above-mentioned approval procedures, where the Commission failed to submit draft measures to the Regulatory Committee.

7.764 We note the European Communities' argument that the application concerning Transgenic red-hearted chicory was withdrawn in March 2003 without any reference to a moratorium. According to the information before the Panel, what the applicant did in March 2003 was to request the lead CA to withdraw its consent to the placing on the market of Transgenic red-hearted chicory. It is not clear why the applicant would have made a reference to a moratorium on approvals when it had already secured approval. Furthermore, we have seen no evidence of a withdrawal of the application submitted under Directive 90/220 for feed and food uses. At any rate, even if the application submitted under Directive 90/220 for feed and food uses had been withdrawn and the applicant had not specifically cited a general EC moratorium on approvals as a reason for the withdrawal, we think this would not be inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning Transgenic red-hearted chicory.

7.765 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Transgenic red-hearted chicory to the Regulatory Committee following the completion of its inter-service consultations in May 1999 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

[822] We note in this regard that after the applicant had asked the SCF in September 2001 to suspend its review of Transgenic red-hearted chicory under Regulation 258/97, the Commission did not transmit to the Regulatory Committee its draft measure in the approval procedure conducted under Directive 90/220. Exhibit EC-77 does not suggest that a similar request was made in the context of the procedure under Directive 90/220.

Delays at member State level

7.766 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which they say the member State to which the application was submitted – the lead CA – either did not complete its assessment of the relevant application or completed it with considerable delay. We consider these approval procedures below, recalling that Article 12(2) of Directive 90/220 provides that "[a]t the latest 90 days after receipt of the [application], the competent authority shall either: a) forward the dossier to the Commission with a favourable opinion, or b) inform the [applicant] that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected". Article 12(5) of Directive 90/220 further provides that "[f]or the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the applicant shall not be taken into account".

7.767 Since some of the relevant lead CA assessments were made after the entry into force of Directive 2001/18, we further recall that Article 14(2) of Directive 2001/18 similarly provides in relevant part that "[w]ithin 90 days after receipt of the [application], the competent authority shall […] prepare an assessment report and send it to the [applicant]". Article 14(2) further provides that where the assessment report indicates that the product in question may be placed on the market, the competent authority shall "send its report […] to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States". Article 12(4) provides in relevant part that "[f]or the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the [applicant] shall not be taken into account".

Bt-531 cotton (EC-65)

7.768 In the approval procedure concerning Bt-531 cotton, the applicant submitted an updated application to the Spanish CA (lead CA) on 16 January 2003, in accordance with the requirements of Directive 2001/18. When the Panel was established on 29 August 2003, the lead CA had not yet forwarded the application to the Commission.

7.769 **Argentina** argues 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.

7.770 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.

7.771 The **Unites States** responds that the argument by the European Communities that the applicant failed to provide an adequate monitoring plan under Directive 2001/18 is flatly wrong. The applicant had submitted an Insect Resistance Management (IRM) plan as part of its product stewardship, which was deemed "adequate" by the EC's own SCP back in 1998. According to the Unites States, that the application is being discussed at the "staff-level" under Directive 2001/18 – in this case at an arguably delayed pace and on questionable grounds – is entirely consistent with a moratorium adopted on a political level.

7.772 The **Panel** notes that the updated application was submitted to the lead CA in January 2003, and that more than seven months later, in August 2003, *i.e.*, when this Panel was established, the lead CA had not completed its initial assessment.

7.773 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 lead CA requested additional information in relation to the monitoring plan at the beginning of August 2003[823]. Before forwarding this request, the lead CA spent six and a half months evaluating the application without finishing its assessment report. As of the end of August 2003, the applicant had not provided the requested information.

7.774 The European Communities provides no explanation for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the monitoring plan submitted by the applicant was incomplete. Moreover, the European Communities does not suggest that the alleged incompleteness somehow prevented the lead CA from evaluating other aspects of the application. Thus, the alleged incompleteness of the monitoring plan does not in any event explain why the evaluation of these other aspects led the lead CA to exceed the 90-day period.

7.775 As an additional matter, it must be kept in mind that the lead CA in this case was not examining the application concerning Bt-531 cotton for the first time. In November 1997, the lead CA forwarded the application to the Commission with a favourable assessment.[824] Moreover, in July 1998, the SCP provided its own assessment of the application.[825] 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 considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Notwithstanding this fact, the lead CA in this case failed to complete its assessment within the prescribed 90-day period.

7.776 Furthermore, while there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 the Spanish CA had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[826], and that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.777 In the light of the above considerations, we conclude that the time taken by the Spanish CA to assess the application concerning Bt-531 cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

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[823] Exhibit EC-65/At. 64.
[824] Exhibit EC-65/At. 4.
[825] Exhibit EC-65/At. 47.
[826] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved. We note that Exhibit US-80 was also referred to by Argentina.

RR-1445 cotton (EC-66)

7.778 In the approval procedure concerning RR-1445 cotton, the applicant submitted an updated application to the Spanish CA (lead CA) on 16 January 2003, in accordance with the requirements of Directive 2001/18. When the Panel was established on 29 August 2003, the lead CA had not yet forwarded the application to the Commission.

7.779 **Argentina** argues 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.

7.780 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.

7.781 The **Panel** notes that the updated application was submitted to the lead CA in January 2003, and that more than seven months later, in August 2003, *i.e.*, when this Panel was established, the lead CA had not completed its initial assessment.

7.782 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 lead CA requested additional information in relation to the monitoring plan at the beginning of August 2003.[827] Before forwarding this request, the lead CA spent six and a half months evaluating the application without finishing its assessment report. As of 29 August 2003, i.e. less than a month after that request, the applicant had not provided the requested information.

7.783 The European Communities provides no explanation for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the monitoring plan submitted by the applicant was incomplete. Moreover, the European Communities does not suggest that the alleged incompleteness somehow prevented the lead CA from evaluating other aspects of the application. Thus, the alleged incompleteness of the monitoring plan does not in any event explain why the evaluation of these other aspects led the lead CA to exceed the 90-day period.

7.784 As an additional matter, it must be kept in mind that the lead CA in this case was not examining the application concerning RR-1445 cotton for the first time. In November 1997, the lead CA forwarded the application to the Commission with a favourable assessment.[828] Moreover, in July 1998, the SCP provided its own assessment of the application.[829] 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 considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Notwithstanding this fact, the lead CA in this case failed to complete its assessment within the prescribed 90-day period.

[827] Exhibit EC-66/At. 64.
[828] Exhibit EC-66/At. 3.
[829] Exhibit EC-66/At. 43.

7.785 Furthermore, while there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 the Spanish CA had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[830], and that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.786 In the light of the above considerations, we conclude that the time taken by Spain to assess the application concerning RR-1445 cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

RR oilseed rape (EC-79)

7.787 In the approval procedure concerning RR oilseed rape (EC-79), the applicant submitted an application to France (lead CA) on 21 May 1995. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was withdrawn on 15 January 2003.

7.788 The **United States** argues that this application was delayed at the member State level for more than 100 months. 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, based on the applicant's letter of withdrawal, that the lead CA refused to consider the application after February 1996, the date of the lead CA's last request for information.

7.789 **Canada** asserts that after responding to three iterations of questions, the applicant was informally advised that the lead CA would not be proceeding further with the assessment of the application. More particularly, Canada argues that since 1996, the lead CA has taken no further action to complete the approval procedure, meaning that this application was delayed at the member State level for more than 100 months. Canada acknowledges that some of the delays occurred prior to October 1998. Canada submits in this respect that whatever the motivation of France prior to October 1998, RR oilseed rape was the victim of the moratorium after October 1998. Canada further asserts that it was due to the inaction of the lead CA that the applicant on 7 July 1998 submitted a second application, this time to the Netherlands (application concerning RR oilseed rape (EC-70)). According to Canada, this demonstrates that if the delay caused by a particular lead CA is long enough, it has the effect of discouraging applicants from continuing with their applications.

7.790 The **European Communities** notes that the applicant in 2003 gave two reasons for the withdrawal of its application in January 2003: the prolonged inaction by the lead CA with respect to this application and the applicant's consequent focus on commercial activities outside of the European Communities. The European Communities also confirms, however, that a second application was filed in the Netherlands in 1998.

[830] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

7.791 The **Panel** notes that in August 1996 the applicant provided additional information in response to a request of February 1996 from the French "Commission du génie biomoléculaire" (hereafter CGB).[831] The CGB apparently delivered a favourable opinion at the end of 1996.[832] There is no indication that after receiving the CGB's opinion at the end of 1996 the lead CA was waiting for further scientific advice or for additional information from the applicant. In fact, in mid-1997, the applicant wrote to the lead CA to inquire about the progress of the procedure, the modalities of transmission of the dossier to the Commission and the advisability of supplementing the dossier with further information prior to its forwarding to the Commission.[833] It appears that the lead CA never provided a formal response to the applicant's inquiry.[834]

7.792 The United States and Canada argue that the lead CA's failure to complete its assessment of RR oilseed rape (EC-79) is consistent with their view that as of October 1998 the European Communities applied a general moratorium, that is to say, a decision not to allow any application to proceed to final approval. The Panel considers that as of June 1999 the unexplained failure by the lead CA to complete its assessment supports the view of the United States and Canada. It is important to recall in this context that France is one of the Group of Five countries. The countries making up the Group of Five in June 1999 declared that they would use their powers under Directive 90/220 to prevent the approval of applications, pending the adoption of new EC legislation on labelling and traceability. The fact that France as the lead CA in this procedure delayed the completion of the assessment at member State level for several years is in accordance with the June 1999 declaration.[835]

7.793 In the light of the above considerations, we conclude that the failure by France to complete its assessment of RR oilseed rape (EC-79) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR oilseed rape (EC-70)

7.794 In the approval procedure concerning RR oilseed rape (EC-70 – incidentally the same product as in EC-79 where the lead CA is the French CGB), the applicant submitted an application to the Netherlands ((lead CA) 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.

7.795 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

[831] Exhibit EC-79/At. 15.
[832] Exhibit EC-79/At. 30.
[833] Exhibit EC-79/At. 28.
[834] Exhibit EC-79/At. 30.
[835] In the approval procedure concerning Bt-11 maize (EC-69), France was also the lead CA. In that procedure, which was initiated in June 1996, France completed its assessment and forwarded the application to the Commission in early April 1999. Thus, that application was forwarded before the June 1999 declaration by the Group of Five countries. France was also the lead CA in the case of two other oilseed rape applications under Directive 90/220 – MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. These applications were approved at Community level, but France subsequently withheld its consent to the placing on the market of the two products concerned.

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.

7.796 **Canada** notes that in February 2000, the Dutch State Institute for Quality Control of Agricultural Products (hereafter RIKILT-DLO), 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), 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.

7.797 Canada further 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.

7.798 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. 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. The European Communities points out that once the applicant had provided an update, the application moved immediately to the Community level. This indicates that all relevant steps had already been completed, and is inconsistent with the notion that a moratorium was in place.

7.799 The **Panel** understands from the record that in evaluating applications for placing on the market at the time in question, the Netherlands generally took into consideration the application submitted by the applicant, the advice from the COGEM, the opinion of the RIKILT-DLO, where applicable, and comments from other relevant parties. Based on this evaluation, a draft assessment report was then published and was open for public comments for a period of four weeks.[836] In the procedure concerning RR oilseed rape (EC-70), the RIKILT-DLO submitted its favourable opinion in February 2000[837]; the applicant was advised in March 2000 in an e-mail that no further technical

[836] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 3; *see also* Exhibit CDA-57.

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

information for the risk assessment needed to be supplied[838]; and the COGEM provided its favourable advice on 10 January 2001.[839]

7.800 By January 2001 the Netherlands had spent over seven months evaluating RR oilseed rape (EC-70).[840] In other words, the Netherlands had already exceeded the 90 day time-period envisaged for this process in Directive 90/220. The European Communities suggests that all of the time taken 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.[841] However, there is no indication that the COGEM provided its advice only in January 2001 because it needed to resolve scientific or technical issues. 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.[842] The applicant provided the requested information in December 1998.[843] 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 advice.[844]

7.801 In the light of the foregoing, the Panel considers that at the latest in March 2000, when the Netherlands CA confirmed to the applicant by e-mail that no further technical information needed to be submitted, the Netherlands 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, the Dutch 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.[845] However, the Panel does not consider that the March 2000 e-mail from the Netherlands CA constituted a formal request for information which triggered a clock-stop.[846] In any event, in April 2000, the applicant did confirm its legal name and registration.[847] And in mid-May 2000, the applicant sent a draft document to the Netherlands CA to indicate how it intended to modify the original application and to ask for comments and suggestions.[848] The

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

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

[840] The evidence on the record does not permit a precise determination of the period during which the clock was stopped. Nevertheless, it is clear from Exhibit EC-70 that 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 alone during which the clock was not stopped and which are but examples already add up to more than seven months.

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

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

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

[844] 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.

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

[846] 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.

[847] 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.

[848] 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.

Netherlands CA replied that it would communicate its "findings" as soon as possible, probably within less than a fortnight.[849] This estimate demonstrates that the document submitted in mid-May 2000 did not call for a lengthy analysis by the Netherlands CA. Thus, it cannot be said that the additional information submitted in April and May 2000 precluded the Netherlands CA from proceeding to finalize its assessment report as from March 2000.

7.802 Even assuming that the COGEM could not have provided its advice before January 2001, once the COGEM had done so, the Netherlands CA had all the elements to complete its assessment report. Notwithstanding this, the Netherlands CA did not finalize its report at that point. Instead, on 12 March 2001 – on the day Directive 2001/18 was adopted – the Netherlands CA wrote to the applicant saying that in accordance with Directive 2001/18 a detection method "should be provided" to complete the dossier, "to be able to forward the dossier to the EU member states".[850] Although Directive 2001/18 was not to enter into force until October 2002, the applicant provided a detection method on 16 March 2001.[851] The applicant requested, however, that the detection method be treated as confidential. In May 2001, the lead CA asked the applicant to reconsider its request or else 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.[852] 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.[853] 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. As is clear from the foregoing, 8 months were spent clarifying the confidentiality status of the detection method and primer sequences. While the applicant took a total of 3 and a half months to reply to the several requests for further substantiation, it must also be noted that 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.[854] A similar situation arose in September 2001 when the lead CA waited for more than two months before following up with another request.[855]

7.803 In January 2002, the lead CA made a request, "according to the conditions as laid down in Directive 2001/18/EC", that the applicant should provide reference material to verify the primer sequences and detection method.[856] Two weeks later, the applicant informed the lead CA that it was sending the requested materials.[857] According to a statement by the Netherlands, the assessment report was completed before 17 October 2002 but was not forwarded to the Commission due to a change of government following general elections.[858]

7.804 It is clear from the foregoing that there are a number of elements which support the conclusion that the Netherlands could have completed its assessment much earlier than it did: (i) the COGEM apparently did not review information submitted at its request for more than two years, which delayed the finalization of the lead CA's assessment report since the lead CA as of March 2000

[849] Exhibit EC-70/At. 22.
[850] Exhibit EC-70/At. 23.
[851] Exhibit EC-70/At. 24.
[852] Exhibit EC-70/At. 26.
[853] Exhibit EC-70/At. 30.
[854] Exhibit EC-70/At. 28.
[855] Exhibit EC-70/At. 33.
[856] Exhibit EC-70/At. 35.
[857] Exhibit EC-70/At. 36
[858] Exhibit EC-70/At. 66, Statement of the Competent Authority of the Netherlands.

had all other technical information needed for its risk assessment; (ii) when the COGEM finally provided its advice in January 2001, the lead CA did not complete its assessment report but requested additional information based on the provisions of Directive 2001/18, even though the Directive had not yet entered into force; and (iii) during the eight-month exchange with the applicant over confidentiality issues, the lead CA caused delays by not following up promptly with its additional requests for clarification.

7.805 The United States and Canada do not assert that the Netherlands itself was an active participant in the alleged moratorium on approvals and that the time taken by the Netherlands to complete its assessment is a reflection of the Netherlands' support for the moratorium. Rather, their assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States and Canada contend that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment. In the view of the United States and Canada, the Netherlands knew that because of the alleged moratorium the speed of its assessment would have little impact on the eventual date of approval.[859]

7.806 Following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. It is reasonable to assume that the Netherlands was also aware that in the approval procedures concerning Bt-531 cotton and RR-1445 cotton the Commission after May 1999 failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Council. Consequently, the Netherlands could in our view have come to the conclusion that there was no realistic prospect that RR oilseed rape (EC-70) could be approved under Directive 90/220 in 1999 or at any point thereafter until the date of repeal of the Directive. The Netherlands' conduct is consistent with such a view. The COGEM did not provide its advice until shortly before the adoption of Directive 2001/18. Instead of completing its assessment report at that point, the Netherlands on the day of adoption of Directive 2001/18 requested the applicant to provide a detection method, even though the Directive would not enter into force for another 19 months. During the subsequent exchange with the applicant over the confidentiality of the detection method and primer sequences, there were further delays attributable to the lead CA. And even when the applicant provided the requested reference material in early February 2002, the assessment report was not promptly completed and forwarded to the Commission so that the application might still have been approved in the event of no objections within 60 days from other member States.

7.807 The European Communities correctly points out that once the applicant had provided an updated application in December 2002, the application was quickly forwarded to the Commission together with the lead CA's favourable assessment report. We also agree with the European Communities that this indicates that the assessment report was up-to-date in terms of the requirements of Directive 2001/18. But we do not agree that this undermines the claim that a moratorium on approvals was in place. In our view, the fact that under Directive 2001/18 the application promptly moved to the Community level rather supports the opposite view. This is the view that the Netherlands considered that for as long as Directive 2001/18 was not in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of the new Directive, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.808 In the light of the above considerations, we conclude that the time taken by the Netherlands to complete its assessment of RR oilseed rape (EC-70) is consistent with the Complaining Parties'

[859] US reply to Panel question Nos. 193-195; Canada's reply to Panel question No. 189.

assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (EC-71)

7.809 In the approval procedure concerning LL soybeans (EC-71), the applicant submitted an application to Belgium (lead CA) on 28 September 1998. In September 1999, the applicant submitted an application for this same product to Portugal. We will discuss the latter application separately below. When Directive 90/220 was repealed on 17 October 2002, Belgium as the lead CA in the procedure here at issue had not yet forwarded the dossier to the Commission. The applicant updated the application on 15 January 2003. The applicant withdrew the application to Portugal in January 2003. The application to Belgium was withdrawn by the applicant on 29 June 2004. It is important to note as well that in November 1998 the applicant submitted to Belgium an application concerning LL soybeans (EC-93) for approval as a novel food under Regulation 258/97.

7.810 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.

7.811 **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 suspension of the approval procedures, as the "initial reports" were not prepared, and considers this to be a "failure to consider" the application for LL soybeans (EC-71).

7.812 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.

7.813 The **Panel** considers 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.

7.814 In considering the first time period, we understand that in evaluating applications for placing on the market at the time in question, Belgium generally took into consideration the application submitted by the applicant and the advice from the Biosafety Council. Two months after the application was first submitted to the Belgian CA, the Biosafety Council requested a substantial amount of information[860] and the Belgian CA indicated that the approval process would be suspended until the requested information was provided.[861] In a response to this request the applicant noted that some information which was being requested by the Biosafety Council had already been submitted to the Ministry of Public Health.[862] In a later letter dated March 1999, the Biosafety Council acknowledged that the applicant had apparently submitted much of the requested information

[860] Exhibit EC-71/At. 4.
[861] Exhibit EC-71/At. 5.
[862] Exhibit EC-71/At. 12.

regarding herbicides and stated that the Belgian CA had passed this information directly to the High Health Council for evaluation.[863] In this same letter, the 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". Based on the advice by the Biosafety Council the Belgian CA in 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.[864] The applicant did not respond to the May 1999 request until July 2001.

7.815 The second time period begins with the submission by the applicant of a second application concerning LL soybeans (EC-81) to Portugal in September 1999. We note that in a communication to Belgium dated 1 December 2000, the applicant explicitly indicated its intention of maintaining dual applications.[865] 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 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.[866] On 5 September 2001, ten months after confirming the continuation of the evaluation process in Belgium, the lead CA (Belgium) indicated to the applicant that further evaluation of the application would be suspended until the applicant specified a single country to handle the application.[867] The applicant responded by asserting the maintenance of double concurrent applications.[868] 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.

7.816 In relation to the third time period, 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.

7.817 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements. *First*, the applicant took more than two years to provide the information requested by the lead CA in May 1999. *Secondly*, 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.

7.818 Regarding the first element, we note that the United States and Argentina do not assert that at the time of the May 1999 request for additional information, Belgium was an active participant in the alleged moratorium on approvals. Indeed, we recall that in June 1999 Belgium was one of the Group

[863] Exhibit EC-71/At. 16.
[864] Exhibit EC-71/Ats. 17 and 22.
[865] Exhibit EC-71/At. 23.
[866] Exhibit EC-71/At. 24.
[867] Exhibit EC-71/At. 28.
[868] Exhibit EC-71/At. 29.

of Seven countries which declared, not that they would take steps to suspend further approvals, but that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. We consider that Belgium's May 1999 request for additional information could be a reflection of the precautionary approach referred to in the June 1999 declaration of the Group of Seven countries.

7.819 Regarding the second element, 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. 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. We recall in this regard that Belgium indicated to the applicant that it would continue considering the relevant application if the applicant decided to discontinue the application submitted to Portugal. At the same time, it must be noted that a similar issue of parallel applications arose in the approval procedure concerning Bt-11 maize (EC-80). In that procedure, however, the lead CA (Spanish CA) did not appear to consider this a problem.[869]

7.820 Taking account of the foregoing, we consider that the aforementioned two elements do not in themselves provide direct confirmation of the existence of a general moratorium on final approvals. However, we note that the application concerning LL soybeans (EC-71) did not reach the Community level phase of the EC approval process prior to its withdrawal in April 2004. In other words, it never reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval. Therefore, while it is recognized that the two above-mentioned elements which affected the progress of the application concerning LL soybeans (EC-71) at the member State level do not directly confirm that a general moratorium was in effect, the record on this case does not demonstrate that no moratorium on final approvals was in effect during the relevant time period.

7.821 In the light of the above considerations, we conclude that Belgium's failure to complete its assessment of the application concerning LL soybeans (EC-71) prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (EC-81)

7.822 The application concerning LL soybeans (EC-81) was introduced in Portugal (lead CA) in 1999. The applicant withdrew the application on 27 January 2003. As already discussed, an application for the approval of LL soybeans under Directive 90/220 had been previously submitted to Belgium (EC-71, see above) and the evaluation of that application by Belgium was ongoing when the application in Portugal was withdrawn.

7.823 The **United States** claims that this application was delayed at the member State level.

7.824 **Argentina** asserts that in this case, the European Communities blocked the marketing of the product, given the suspension of, or failure to consider, the application. Argentina further notes that

[869] Exhibit EC-80/At. 12.

in the case of this product the European Communities neither processed the application nor conducted the required risk assessment. Argentina asserts that there is no scientific justification for the suspension of the approval procedures, as the "initial reports" were not prepared, and considers this to be a "failure to consider" the application for LL soybeans (EC-81).

7.825 The **European Communities** notes that after discussions between the lead CA and the applicant, the application was withdrawn by the applicant's letter of 27 January 2003. The product had been previously notified in Belgium, and the evaluation of that application in Belgium was ongoing.

7.826 The **Panel** notes that no dossier was submitted as evidence for this application with regard to the approval procedure in Portugal. We understand from the record that in evaluating applications for placing on the market at the time in question, Portugal's CA generally took into consideration the application submitted by the applicant and the advice from the Ministry of Agriculture, the Ministry of Health and the Institute for Experimental and Technological Biology (IBET).

7.827 In a December 1999 opinion on the application concerning LL soybeans (EC-81), the Ministry of Agriculture noted lack of information on environmental impacts and lack of region-specific studies.[870] In January 2000, the Ministry of Health noted that the application was not clear about whether there was an intention to cultivate this product, and that the molecular characterization provided was insufficient.[871] The Ministry of Health also noted the need to have a toxicological study of the associated herbicide. The Ministry of Health asked Portugal's CA to obtain clarification, and so in January 2000 Portugal's CA requested additional information from the applicant. In May 2000, the IBET, in the opinion it provided to Portugal's CA, noted several areas in which the analyses presented were somewhat incomplete and concluded that "having due regard to the grounds for caution and the need to clarify the abovementioned points in doubt, there do not, however, appear to be any objective reasons for regarding these soybeans as 'unsafe' to use, at least when compared with other equivalent products currently on the market".[872] Following IBET's advice, the Portuguese CA sought further clarification from the applicant in May 2000.

7.828 After a 16-month delay, in September 2001, the applicant responded to questions from the Ministry of Health and IBET, providing additional information on nutritional composition and molecular characterization.[873] In October 2001, the Portuguese CA acknowledged receipt of the information and indicated that the information would be assessed by the Ministry of Health and IBET.[874]

7.829 In November 2001, the Portuguese CA proposed to the applicant that it updates the application under Directive 2001/18, which had been adopted in March 2001. The Portuguese CA pointed out that its initiative was in accordance with a July 2000 proposal by the Commission whose aim it was "to allow the different Member States to vote on and approve, where appropriate, the Commission's proposals for decisions authorizing the placing on the market of notified products before the new Directive enters into force." The Portuguese CA's letter further notes that "although the requested reformulation of the application is voluntary, given the complex situation currently prevailing in Europe with regard to authorizations for the placing on the market of new genetically modified products we consider it to be absolutely necessary" in order to present the application for

[870] Exhibit EC-81/At. 2.
[871] Exhibit EC-81/At. 3.
[872] Exhibit EC-81/At. 6
[873] Exhibit EC-81/Ats. 7 and 8.
[874] Exhibit EC-81/At. 9

assessment by the member States.[875] The letter asked the applicant to let the Portuguese CA know whether it accepted the CA's proposal. The applicant responded that it would be providing the requested documentation as soon as possible.[876]. However, the applicant does not appear to have done so.

7.830 In January 2002, the Ministry of Health raised further questions particularly related to molecular characterization.[877] There is no record of a response from the applicant addressing this request for information. In January 2003, one year after the last request for information from the lead CA, the applicant withdrew the application citing "various reasons" for the withdrawal.[878]

7.831 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements: (i) the time taken by the applicant to respond to the January and May 2000 requests for information and (ii) the failure of the applicant to update the application under Directive 2001/18, as proposed by the Portuguese CA in November 2001.

7.832 In considering Portugal's conduct, we note that the United States and Argentina do not assert that at the time of the January and May 2000 requests for additional information or in November 2001, Portugal was an active participant in the alleged moratorium on approvals. Indeed, Portugal was not one of the Group of Five countries. We also note that Portugal was not part of the Group of Seven countries which declared that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products.

7.833 Concerning Portugal's 2001 proposal that the applicant update its application in accordance with the requirements of Directive 2001/18, the first thing to be noted is that Portugal made it clear that doing so was voluntary. However, Portugal also indicated its view that, in view of the "complex situation currently prevailing in Europe", the update was "absolutely necessary" in order for the application to be approved at Community level. The reference to a "complex situation currently prevailing in Europe" could be a reference to a general moratorium on final approvals. Indeed, Portugal suggested that compliance with certain Directive 2001/18 requirements was a necessary condition for approval; it did not suggest that this would lead to approval. But the reference to a "complex situation" could also be a reference to the fact that there was opposition among member States to approving under Directive 90/220 applications which did not meet the main requirements of Directive 2001/18. We recall in this regard that already before Directive 2001/18 had been adopted, in June 1999, the Group of Seven countries stated that to the extent legally possible they wished to see applied the principles, especially regarding traceability and labelling, laid down in the Council's Common Position of June 1999 concerning the revision of Directive 90/220. Therefore, we consider that the November 2001 proposal of the Portuguese CA does not provide confirmation of the asserted fact that the European Communities at the time applied a general moratorium on final approvals. However, it is consistent with that assertion.

7.834 It should be added that as of January 2003, when it was withdrawn by the applicant, the application concerning LL soybeans (EC-81) had not reached the Community level phase of the approval procedure under Directive 90/220. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

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[875] Exhibit EC-81/At. 11.
[876] Exhibit EC-81/At. 12.
[877] Exhibit EC-81/At. 13.
[878] Exhibit EC-81/At. 15.

7.835 In the light of the above considerations, we conclude that the failure of Portugal to complete its assessment of the application concerning LL soybeans (EC-81) prior to January 2003, when the application was withdrawn, is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium on final approvals during the relevant period of time.

LL oilseed rape (EC-72)

7.836 The application concerning LL oilseed rape was submitted to the United Kingdom (lead CA) on 28 January 1999. When Directive 90/220 was repealed on 17 October 2002, the United Kingdom had not yet forwarded the dossier to the Commission. The applicant submitted an updated application on 13 January 2003 in accordance with Directive 2001/18. The application was still pending at the time of establishment of the Panel. It was withdrawn by the applicant on 26 March 2004.

7.837 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 provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed and ultimately suspended consideration or failed to approve the product.

7.838 The **European Communities** argues that the lead CA requested some additional information after having initially received the application. After having received that information, the lead CA forwarded the dossier for a preliminary view to its scientific committee, the Advisory Committee on Releases to the Environment (hereafter ACRE). The ACRE found that the dossier not only showed inconsistent data on molecular characterization but was also generally "rather impenetrable". In December 1999, the dossier was sent back to the applicant for "substantial revision and clarification".

7.839 According to the European Communities, the applicant did not get back to the lead CA on this dossier for almost two years. Contact was only re-established towards the end of 2002 when the applicant inquired about what was needed to up-date the dossier under the new Directive 2001/18. The applicant sent some up-dated documents in January 2003, but not the full dossier. The lead CA requested completion of the up-dated application and the applicant provided further data, which required further clarifications and led the lead CA to suggest that the full dossier should be re-submitted. In March 2004, the applicant withdrew the pending application and submitted a new application a few days later. According to the European Communities, at the time of establishment of the Panel the new dossier was in the course of being assessed by the lead CA. The European Communities maintains that it cannot be responsible for delays arising at the instigation of the applicant.

7.840 The **Panel** understands from the record that the lead CA made some preliminary requests for additional information in the months following receipt of the application. Some, but not all, of the additional requests from the lead CA are included in the information provided to the Panel. For example, a 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; however the annex has not been provided.[879] There is, moreover, no record of a response from the applicant to this request.

7.841 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

[879] Exhibit EC-72/At. 11.

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.[880] 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.

7.842 On 16 January 2003, the applicant submitted an updated application under Directive 2001/18 to the lead CA.[881] 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.[882] 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.[883] On 13 June 2003, the lead CA requested further clarifications and suggested that a complete version of the application be re-submitted.[884] 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).[885] No information was provided to the Panel regarding the assessment of the new application.

7.843 It is clear from the foregoing 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 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.

7.844 We 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.[886] 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.[887]

7.845 Nonetheless, the circumstance that the applicant apparently never responded to the July and December 1999 requests for additional information is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries and the failure by the Commission to complete some of the previously discussed approval procedures, we think the applicant could have believed that the application concerning LL oilseed rape would not be approved while Directive 90/220 was still in force.

7.846 Taking account of the aforementioned elements, we consider that the gap between December 1999 and October 2002 does not in itself provide direct confirmation of the existence of a general

[880] Exhibit EC-72/At. 12.
[881] Exhibit EC-72/At. 15.
[882] Exhibit EC-72/At. 16.
[883] Exhibit EC-72/Ats. 18 and 19.
[884] Exhibit EC-72/At. 28.
[885] Exhibit EC-72/At. 29.
[886] Annex H, Panel Question 29.
[887] Annex H, para. 600.

moratorium on final approvals. But in our view the gap is consistent with the contention that a general moratorium was in effect at the time.

7.847 Regarding the assessment of the application concerning LL oilseed rape under Directive 2001/18, we recall our earlier summary of relevant facts. These facts do not lead us to believe that the lead CA was deliberately delaying the consideration of this application. We also note in this respect that the United States does not assert that the United Kingdom was an active participant in the alleged moratorium on approvals. Indeed, the United Kingdom was not part of the Group of Five countries. However, as of August 2003, when this Panel was established, the application concerning LL oilseed rape had not reached the Community level phase of the approval procedure under Directive 2001/18. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.848 In the light of the above considerations, we conclude that the failure of the United Kingdom to complete its assessment of the application concerning LL oilseed rape prior to August 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium on final approvals during the relevant time period.

BXN cotton (EC-73)

7.849 The application concerning BXN cotton was submitted to the Spanish CA (lead CA) in April 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 on 16 January 2003, in accordance with Directive 2001/18. According to the European Communities, the application was withdrawn after the establishment of the Panel.[888]

7.850 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 provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed and ultimately suspended consideration or failed to approve the product.

7.851 The **European Communities** argues that the lead CA forwarded the dossier to its scientific committee, the National Biosafety Committee, which found that the dossier needed to be improved. A considerable amount of information was missing on issues such as compositional analysis, environmental impact, toxicity, nutritional analysis, and a number of points, such as scope, labelling proposal, etc., had to be clarified. The lead CA forwarded these comments to the applicant in July 1999.

7.852 According to the European Communities, after a first exchange of correspondence, the applicant did not respond to the lead CA for three years, until January 2003, when the company which produced the herbicide to which the cotton is tolerant informed the lead CA that it had assigned this pending application to another company. The new applicant company submitted an up-dated application in accordance with Directive 2001/18 on 16 January 2003.

7.853 The European Communities maintains that the lead CA forwarded the new dossier to the National Biosafety Committee, which found that there were deficiencies in the molecular characterization of the product. The lead CA forwarded these comments to the applicant in October 2003. In November 2003, the lead CA was asked by another company to clarify its request for

[888] There is nothing in the record to confirm this EC assertion.

additional information. The lead CA has provided these clarifications and asked for an explanation of the identity of the applicant. The European Communities notes that a response is still awaited.

7.854 The **Panel** begins its analysis by noting that despite its request in June 2004 that the European Communities provide complete documentation relating to the scientific assessments of all applications, the documentation provided in relation to this application is incomplete. None of the substantive information provided by the applicant, either with respect to the original application in May 1999 or with the resubmission of the application in January 2003, has been made available. This makes it very difficult to put into context the requests for clarification and for further information from the lead CA.

7.855 We note that the application was first submitted in May 1999, and in July 1999 the lead CA submitted questions and requested further information from the applicant. The applicant responded in September 1999, clarifying, *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.[889] The applicant did not respond to this request before an updated application was submitted in January 2003 under Directive 2001/18.[890]

7.856 The communication from the lead CA in February 2000 made five points. One was to note that the National Biosafety Committee saw fit to request the Ministry of Agriculture to register the associated herbicide for use on this cotton product. Another was to instruct that references to the OECD in relation to the certification of varieties be deleted as not relevant. Two of the remaining points appeared to be related to food and feed safety concerns: that new analyses be conducted regarding the nitrilase level in cottonseed oil, and that the studies proposed on animals fed on feed derived from this product be conducted under normal livestock feeding conditions in Spain. The remaining point was to request rewording of the text with reference to gentamicine resistance. Although this would appear to be a concern about potential risks to human or animal health arising from antibiotic resistance, without the text of the application it is not possible to confirm that this is indeed a food safety issue.

7.857 The Panel asked the experts advising it 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.[891] 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.[892] 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

[889] Exhibit EC-73/At. 6.
[890] This is confirmed by Exhibit EC-73/At. 12.
[891] Annex H, Panel Questions 30 and 31.
[892] Annex H, para. 601.

ecotoxicity tests or proposals to manage, monitor and handle the crop to reduce the risk of herbicide resistance in weeds.[893]

7.858 An updated application was submitted in January 2003 under Directive 2001/18 and completed in March 2003. Again, the application itself has not been provided to the Panel. It seems that the application now concerned the importation of seed for processing, but not cultivation.[894] In August 2003, when this Panel was established, the application appears to have been under review by the National Biosafety Committee.[895]

7.859 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.

7.860 We recall that, due to incomplete information, the experts advising us were unable to express definitive views on whether the clarifications requested by the lead CA in February 2000 were necessary to ensure that conclusions of the safety assessment were valid. Nonetheless, the circumstance that the applicant did not respond to the February 2000 request is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries and the failure by the Commission to complete some of the previously discussed approval procedures, we think the applicant could have believed that the application would not be approved while Directive 90/220 was still in force.

7.861 The European Communities has surmised that the failure to pursue this application may be due to the numerous changes in the ownership of the producing company as well as in the rights on the pending application. From information provided by the European Communities it appears that in 1999 and 2001, the applicant from the EU was merged with or taken over by other EU companies. Subsequently, in 2003, the lead CA was informed that the rights to the application had been transferred to a US company. It is unclear when the application was assigned to the relevant US company. Based on the information before us, we think it is conceivable that the aforementioned changes in ownership had an impact on the efforts made by the applicant in pursuit of its application.

7.862 Taking account of the aforementioned elements, we consider that the gap between February 2000 and October 2002 does not in itself provide direct confirmation of the existence of a general moratorium on final approvals. But in our view the gap is consistent with the contention that a general moratorium was in effect at the time.

7.863 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.[896] 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.[897] The applicant provided such a summary on 19 March 2003, and thus the updated application appears to

[893] Annex H, paras. 604-612.
[894] Exhibit EC-73/At. 12.
[895] There is no information about when the application was submitted to the National Biosafety Committee.
[896] Exhibit EC-73/At. 8.
[897] Exhibit EC-73/At. 9.

have been complete as of that date.[898] 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.[899] 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 is 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 report itself required much time.

7.864 While there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 Spain had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals.[900] Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[901], and that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.865 In the light of the above considerations, we conclude that the failure of the Spanish CA to complete its assessment of the application concerning BXN cotton under Directive 90/220 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period. We further conclude that the time taken by Spain to assess the application concerning BXN cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-1507 maize (EC-74)

7.866 The application concerning Bt-1507 maize (EC-74) was first submitted to the Netherlands CA (lead CA) in November 2000. The scope of the application was for import of maize for processing and for use as food and feed. A separate application was submitted to the Spanish CA for the cultivation of the product, which we hereafter refer to as the application concerning Bt-1507 maize (EC-75). We will discuss that application separately below. When Directive 90/220 was repealed on 17 October 2002, the Netherlands CA had not yet forwarded the dossier to the Commission. An updated application was submitted in November 2002 under Directive 2001/18. The lead CA completed its initial assessment of the application and submitted the application to the Commission on 15 August 2003.

7.867 The **United States** argues that this application was delayed at the member State level for several years, and was not submitted for a decision by the Regulatory Committee. The United States

[898] Exhibit EC-73/At. 10.
[899] Exhibit EC-73/At. 12.
[900] Since the application was not complete until March 2003, it would appear that the 90-day period started to run as of that time.
[901] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed 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.

7.868 The **European Communities** argues that following receipt of this application, the lead CA requested additional information on molecular characterization, allergenicity and toxicity of CRY1F, and on labelling. Exchanges with the applicant on these issues went on until almost the end of 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 application 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. 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. The Commission forwarded the dossier to EFSA for an opinion in February 2004, together with a summary of the remaining objections from seven member States. The European Communities argues that the facts demonstrate that there was neither a suspension of consideration nor a failure to approve this product.

7.869 The **Panel** notes that there was frequent communication between the lead CA and the applicant on this application from the time the application was initially submitted under Directive 90/220 until the lead CA sent its assessment report to the Commission on 15 August 2003. Although extensive documentation was provided to us, it was presented in a manner which did not facilitate its consideration (some documents were reproduced up-side down or sideways, others mislabelled or duplicated, for others only the tables of content were provided).

7.870 The United States explicitly questions the justifiability of only one of the requests for additional information made by the lead CA, a request of 13 December 2001 for additional field trial data. Other US arguments concern objections and requests for additional information from other member States which were made subsequent to the establishment of the Panel and hence are not specifically taken into account.

7.871 We note that in response to the 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.[902] 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.[903] 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.[904] 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

[902] Exhibit EC-74/At. 33.
[903] Exhibit EC-74/At. 52.
[904] 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.[905] This was apparently done by the applicant on 24 March 2003.[906]

7.872 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.

7.873 We sought advice from the experts advising us as to whether the field trials in France, Italy and Chile would provide compositional data on maize kernels that would be relevant to evaluating cultivation areas exporting maize to the European Communities. Dr. Nutti drew attention to the Codex Alimentarius *Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*[907] which state that the location of the trials sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature.

7.874 Dr. Nutti considered that the field tests in France, Italy and Chile could be considered as supplementary information to previous tests carried out by the applicant, although she did not consider that they were necessary, in particular since the maize in question was for importation and processing and not for cultivation.[908] Dr. Andow noted that it was likely that for some industrial uses of maize, *e.g.*, as biofuel, there was little need to distinguish among regional sources. However, without data supporting this lack of need to distinguish geographic sources, it was not possible, in his view, to determine if maize from Chile would in fact be representative of maize from other regions of the world. He further observed that the scientific rationale for the request for compositional data was not evident from the written record. He considered it essential that the lead CA provide such a rationale concomitant with the request for information, because many of the possible reasons for requesting such information were not necessary for completing a scientific risk assessment.[909]

7.875 In considering the December 2001 request by the lead CA for further field trials, we note that the United States does not assert that, at that time, the Netherlands was an active participant in the alleged moratorium on approvals. However, the United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected how it assessed applications.

7.876 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on

[905] Exhibit EC-74/At. 84.
[906] Exhibit EC-74/Ats. 87-88.
[907] CAC/GL 45-2003, para. 45.
[908] Annex H, para. 626.
[909] Annex H, para. 635

labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, the Netherlands could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning Bt-1507 maize (EC-74) could be approved prior to the repeal of Directive 90/220.

7.877 Against this background, we accept that it is possible that the lead CA's December 2001 request for further field trials could, as the United States argues, be explained as a way to delay consideration of the application concerning Bt-1507 (EC-74) so that it would not be forwarded to the Commission and the other member States until the entry into force of Directive 2001/18, under which the application might eventually be approved, after the adoption of new EC rules on labelling and traceability. The fact that the applicant's response to the December 2001 request did not come until after the repeal of Directive 90/220 is consistent with this explanation. However, the applicant's response 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 resulting delay is attributable solely to the request for additional field trials.

7.878 It must also be noted 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. In our view, the December 2001 request for additional field trials could also reflect a precautionary approach to evaluating applications. The views expressed by the experts advising us do not appear to rule out this possibility.

7.879 Taking account of the aforementioned elements, we consider that the December 2001 request by the Netherlands for additional field trials does not in itself provide direct confirmation of the existence of a general moratorium on final approvals. But in our view the request is consistent with the contention that a general moratorium was in effect at the time.

7.880 We note that after the applicant had provided an updated application in November 2002, the lead CA requested 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.

7.881 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.

7.882 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.

7.883 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 (EC-74), by the end of March 2003 the lead CA had all the elements to complete its safety assessment. Even 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. By that time, as noted, the confidentiality issue had also been resolved.

7.884 While there is no indication that the Netherlands in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that the Netherlands exceeded the 90-day period even after it had received all necessary information is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[910], and that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.885 Moreover, we note that it was not until 15 August 2003 that the application concerning Bt-1507 (EC-74) reached the Community level phase of the approval procedure under Directive 2001/18. As we have said before, it is only at the Community level that the Group of Five countries and/or the Commission could take action to delay or prevent the final approval of this application.

7.886 In the light of the above considerations, we conclude that 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 contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-1507 maize (EC-75)

7.887 Neither the date of the initial submission of the application concerning Bt-1507 maize (EC-75) to the Spanish CA (lead CA), nor the application itself, have been made available to the Panel. However, the lead CA acknowledged receipt of the application in a letter dated 11 July 2001. The application was for all uses including cultivation. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was updated in December 2002 under Directive 2001/18. On 5 August 2003, the lead CA submitted the application and its assessment report to the Commission; it was circulated to all member States on 20 August 2003.

7.888 The **United States** argues that this application was delayed at the member State level for several years, and was not submitted for a decision by the Regulatory Committee. 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 contests the justifiability of some of the

[910] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

information requested by the lead CA, and particularly of a number of the objections raised by other member States following circulation of the lead CAs' assessment report by the Commission.

7.889 The **European Communities** argues that following a preliminary assessment of this application by the Spanish National Biosafety Committee, the lead CA requested further additional information on 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.[911] 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.

7.890 The European Communities notes that the Commission circulated the application to the member States and received comments and objections from ten of them. These concern issues such as molecular characterization, detection methods, non target organisms, monitoring plans, toxicity, allergenicity and agricultural practices.

7.891 The **Panel** notes that there appeared to be at least two exchanges between the applicant and the lead CA regarding requests for further information before the repeal of Directive 90/220. Unfortunately, although a considerable amount of documentation was provided to us, it was presented in a manner which did not facilitate its consideration. Many of the documents were mislabelled or misrepresented in the chronologies provided by the European Communities; or they did not correspond to the requests for information identified but rather to requests that occurred considerably later.

7.892 As far as we have been able to determine, following the receipt of the application in July 2001, the lead CA consulted with its National Biosafety Committee and on 30 October 2001 requested 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. First and foremost, the lead CA requested that field studies of Bt-1507 maize (EC-75) be conducted in Spain. Other requests concerned molecular characterization, protein expression, effects on target and non-target species, and monitoring of resistance. A response was provided by the applicant on 14 February 2002, including information on field studies undertaken in Spain. Following further advice from the National Biosafety Committee of 13 May 2002, on 17 June 2002, the lead CA submitted requests for additional field studies and other additional information about molecular characterization and protein expression to the applicant. The applicant responded to these requests on 17 December 2002, providing, *inter alia*, information on additional field studies undertaken in Spain. This was after the date of repeal of Directive 90/220.

7.893 The application was apparently updated and re-submitted under Directive 2001/18 on 13 February 2003. The lead CA requested a specific recalculation on the molecular characterization, additional information regarding toxicity studies, and information on herbicide use on 17 February 2003. Following a meeting between the applicant and lead CA on 28 February 2003, the applicant provided the requested information on 7 April 2003. Following another meeting between the applicant and lead CA, the applicant submitted a revised updated application on 28 May 2003. The updated application was forwarded along with a positive assessment by the lead CA to the Commission on 5 August 2003. It was circulated by the Commission to member States on 20 August 2003, with a deadline for comments of 19 October 2003. On the date of establishment of the Panel, the application was thus being reviewed by the member States.

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

7.894 It is clear from the foregoing that the assessment of the application concerning Bt-1507 maize (EC-75) under Directive 90/220 was delayed as a consequence of two requests for information from the lead CA in November 2001 and June 2002, respectively. We sought advice from the experts as to whether the information requested by the lead CA in November 2001 on molecular characterization, allergenicity, toxicity and environmental impact were necessary to ensure that the conclusions of the safety assessment were valid.[912] The experts were unable to assess the original application as it was not provided to the Panel. Dr. Nutti noted, however, that the subsequent explanations and information provided by the applicant with regard to protein toxicity and allergenicity were correct, very well detailed and comprehensive.[913] Dr. Andow opined that the requests for further information on toxicity, including the toxicity of degradation products of Cry1F or PAT proteins, were necessary to ensure that the conclusions of the safety assessment were valid. He also considered that there could be a legitimate basis for requesting studies on non-target species of particular concern to Spain. He noted that there was no scientific consensus regarding the need for field trials to be conducted in the actual location of concern, but he considered the question from the lead CA to be insufficiently specific to guide the applicant in providing a response and therefore concluded that the particular question which was put forward by the lead CA was not necessary to ensure that the conclusions of the safety assessment were valid .[914]

7.895 In connection with the November 2001 and June 2002 requests for information, we further note that on both occasions the lead CA waited for more than one month before forwarding the questions suggested by the National Biosafety Committee. This 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.[915]

7.896 In examining the lead CA's November 2001 and June 2002 requests for information, we note that the United States does not assert that, at that time, Spain was an active participant in the alleged moratorium on approvals. However, the United States contends that Spain was placed in a position of having to recognize the moratorium as a reality and that this affected how it assessed applications.

7.897 We consider that following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, Spain could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning Bt-1507 maize (EC-75) could be approved prior to the repeal of Directive 90/220. Spain's conduct, notably the time taken by the lead CA to forward questions from the National Biosafety Committee, is consistent with such a view, in that it contributed to the application not being forwarded to the Commission and the other member States until after the entry into force of Directive 2001/18.

7.898 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

[912] Annex H, Questions No. 36 and 36(a).
[913] Annex H, paras. 636-637.
[914] *Ibid*, paras. 639-651.
[915] *See, e.g.*, the approval procedure concerning BXN cotton. Exhibit EC-73/Ats. 2-3 and 5 and 6.

have the application approved or rejected while Directive 90/220 was still in force. It should also be noted 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, even if we were to accept, taking account of the views expressed by the experts advising us, that the November 2001 request for information might reflect a precautionary approach to evaluating applications, the delayed transmission of that request cannot, in our view, be said to reflect such an approach.

7.899 We note that under Directive 2001/18, in February 2003, the lead CA requested further information in response to the applicant's replies to the lead CA's request for information of June 2002. The applicant provided a response in April 2003 and a revised updated application in May 2003. The updated application was then forwarded to the Commission together with the lead CA's favourable assessment report within three months, as required by Directive 2001/18. The fact that after obtaining yet further information, the application under Directive 2001/18 appears to have moved promptly to the Community level in our view does not disprove the claim that a moratorium on approvals was in place. As we have said, Spain could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.900 In the light of the above considerations, we conclude that Spain's failure to complete its assessment of the application concerning Bt-1507 maize (EC-75) earlier than in August 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-11 maize (EC-80)

7.901 The application concerning Bt-11 maize (EC-80) was first submitted to the CA of Spain (lead CA) on 29 May 1998. On 30 April 1999, the lead CA forwarded the application with a positive assessment to the Commission. The application was withdrawn by the applicant on 20 May 1999. In withdrawing the application, the applicant referred to the parallel application which had been submitted to France on 28 May 1996 (Bt-11 maize (EC-69)), and which had been forwarded by the French CA to the Commission on 4 April 1999 with a positive assessment.

7.902 The application concerning Bt-11 maize (EC-80) was for approval of the cultivation of this product. It should be noted that Bt-11 maize (EC-163) had been approved in the European Communities as of 22 April 1998 under Directive 90/220 for import and for processing.

7.903 The **United States** argues that this application was delayed at the member State level and was not forwarded for consideration at the Community level. The United States submits that although the applicant provided answers to all of the questions, the member State nonetheless delayed and ultimately suspended consideration or failed to approve the product. The United States considers that the delays in the consideration by the lead CA are evidence of the existence of a moratorium.

7.904 The **European Communities** argues that after discussions between the lead CA and the applicant, this application was withdrawn on 20 May 1999. The applicant gave as the reason for its withdrawal the existence of a parallel application made in France.

7.905 The **United States** argues that the companies 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, which the United States maintains results from the moratorium.

7.906 The **Panel** begins by noting the United States' argument that the application concerning Bt-11 maize (EC-80) was not forwarded for consideration at the Community level. This is incorrect. This application was submitted by the lead CA to the Commission in April 1999 and thus did reach the Community level; however, the applicant withdrew the application within a month of this referral.

7.907 The United States further argues that the delays in the consideration by the lead CA are evidence of the existence of a moratorium. In considering this argument, we first recall that it is the United States' contention that the European Communities applied a general moratorium as of October 1998. From the information provided to us, it appears that between October 1998 and April 1999 the application was under assessment by Spain's National Biosafety Committee and by the Spanish CA. There is no indication that in the period from October 1998 to April 1999 further information was to be submitted by the applicant in response to requests for information. This period exceeds the 90-day assessment period provided for in Directive 90/220. We therefore agree with the United States that between October 1998 and April 1999 there were delays in the consideration of the application concerning Bt-11 maize (EC-80).

7.908 No explanation has been offered by the European Communities of the failure of the lead CA to consider this application within the period of time foreseen in Directive 90/220. The United States does not assert that Spain itself was an active participant in the alleged moratorium on approvals and that the time taken by Spain to complete its assessment is a reflection of Spain's support for the moratorium. Rather, its assertion is that the time taken by Spain reflects the impact of the moratorium.

7.909 We note that the relevant delay in the consideration of this application occurred between October 1998 and April 1999, *i.e.*, before the June 1999 declaration by the Group of Five countries. Spain was not a part of the Group of Five countries. 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. Taking into account these elements, we consider that the delay which occurred between October 1998 and April 1999 neither contradicts nor confirms the existence of a moratorium on final approvals as of October 1998. In our view, a general EC moratorium on final approvals as of October 1998 could explain Spain's conduct after 1998. Spain could have considered that strict compliance with the 90-day deadline was effectively not necessary since in any event a final approval of the application concerning Bt-11 maize (EC-80) would not be granted while the alleged moratorium was in effect. On the other hand, since Spain in June 1999 formally declared that it would take a thoroughly precautionary approach, we think it is also possible that Spain reviewed the application particularly carefully and that this resulted in unintended delays.

7.910 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals as from October 1998. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning Bt-11 maize (EC-80).

7.911 In the light of the above considerations, we conclude that the failure by Spain to complete its assessment of the application concerning Bt-11 maize (EC-80) earlier than in April 1999 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

NK603 maize (EC-76)

7.912 In the approval procedure concerning NK603 maize, the applicant submitted an application to Spain (lead CA) in August 2000. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was forwarded with a positive assessment to the Commission on 14 January 2003. The scope of the application covered import and industrial use, including use as animal feed.

7.913 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.

7.914 **Canada** argues that the total time taken by the lead CA for its review was 25 months, and that only 13 of the 25 months were taken by the applicant to respond to questions. The difference of 12 months exceeds the 3-month period provided for in Directive 90/220.

7.915 **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 favorable 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.

7.916 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.[916]

7.917 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.

7.918 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.

7.919 The **Panel** understands from the record 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.[917] We note that there is no record of these additional studies. The Spanish CA subsequently acknowledged receipt of the letter on 2 January 2001.

[916] Exhibit EC-76/At. 1.
[917] Exhibit EC-76/At. 3.

7.920 It is clear from the record that the progress of this application was adversely affected notably by two elements. *First*, the applicant took more than six months to provide information requested by the lead CA in February 2001. *Secondly*, the applicant took more than five months to provide information requested by the lead CA in October 2001.

7.921 Regarding the February 2001 request for information, we note that the lead CA requested additional information concerning molecular characterization, nutritional analysis and environmental impact of the product in question. 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.

7.922 Given that the application was for import and industrial use in the European Communities and not for cultivation, Dr. Andow indicated that "some information is necessary to consider how gene escape can occur either during processing, storage or transport, but detailed information is not necessary." Thus, he concluded that requests for additional detailed environmental studies were not justified.[918]

7.923 Dr. Nutti noted that the food safety information available to the lead CA seemed sufficient given that substantial equivalence had been demonstrated in several feeding studies.[919] Dr. Nutti stated that "whatever studies were further requested by the lead CA [...] were not necessary to ensure that conclusions of the safety assessment were valid since all the relevant information had already been provided."

7.924 Regarding the October 2001 request for information, we understand from the record that one month after the applicant had submitted new information in response to the request of February 2001, in October 2001, the Spanish CA requested that a Polymerase Chain Reaction (PCR) be conducted, and sought additional information on molecular characterization and details of the potential environmental impact of accidental dissemination or germination.[920] More than five months passed before the applicant responded with additional information. After the applicant had submitted new information in March 2002, the Spanish CA communicated persistent doubts.[921]

7.925 The United States notes that the Spanish CA had stressed that PCR should be used to detect small DNA insertions because PCR provides a greater degree of sensitivity.[922] The United States argues that the use of some PCR-based method to detect additional fragments potentially too small to be seen by a Southern blot analysis was scientifically unjustified.

7.926 The European Communities claims that the request from the lead CA was scientifically valid.[923] According to the European Communities, the additional data provided by the applicant indicates that the use of PCR improved the sensitivity of the molecular characterization in comparison to the data previously provided in the application. Therefore, although the applicant stressed that the conclusion in relation to safety provided in the application was not altered, the European Communities maintains that the lead CA's request for additional information was necessary to ensure that conclusions of the safety assessment were valid.

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[918] Annex H, Dr. Andow's response to Panel Question 37.
[919] Annex H, Dr. Nutti's response to Panel Question 37.
[920] Exhibit EC-76/At. 10.
[921] Exhibit EC-76/At. 14.
[922] Exhibit EC-76/At. 10.
[923] EC Comments on the experts replies, para. 462.

7.927 In relation to PCR, the Panel recalls that Dr. Nutti expressed the view that the initial information regarding food safety seemed sufficient.[924] The Panel understands from the record, however, that the Spanish CA emphasized that the PCR is also considered "essential for product traceability".[925]

7.928 In relation to the additional October 2001 requests for environmental information, Dr. Andow noted that the applicant had not addressed this question of potential environmental impact of any accidental dissemination or germination. He commented that the applicant "believes, probably rightly, that the likelihood of accidental dissemination and germination (exposure to the environment) is small. If this is true, the applicant is arguing that when exposure is small, risk is small. Consequently, the applicant may believe that it was not necessary to address this question."[926] However, Dr. Andow noted that the lead CA could believe that the potential risk associated with accidental dissemination and germination could be large. Dr. Andow therefore concluded that this request for information to be provided by the applicant was justified.

7.929 In considering the lead CA's February 2001 and October 2001 requests for information, we note that the United States and Argentina do not assert that, at the time of these requests, Spain was an active participant in the alleged moratorium on approvals. Indeed, Spain was not part of the Group of Five countries. However, following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[927] In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, Spain could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning NK603 maize could be approved prior to the repeal of Directive 90/220.

7.930 Against this background, we consider that Spain could have been requesting information which it would not otherwise have requested, and that it was not concerned about any delays such requests would entail, as it saw no possibility of the application being approved while Directive 90/220 was still in force. The views expressed by the experts advising us are not inconsistent with this possibility. As indicated previously, notably in the case of the February 2001 request the experts questioned the need for the information that was requested.

7.931 It must also be remembered, however, 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. In our view, the fact that the experts questioned the need for the information that was requested in February 2001 does not rule out the possibility that Spain was taking a precautionary approach to evaluating applications. Therefore, we think the February 2001 and October 2001 requests for additional information could also be a reflection of the June 1999 declaration by the Group of Seven countries.

7.932 Taking account of the aforementioned elements, we consider that Spain's February 2001 and October 2001 requests for additional information do not in themselves provide direct confirmation of the existence of a general moratorium on final approvals. But in our view these requests are consistent with the contention that a general moratorium was in effect at the time.

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[924] Annex H, Dr. Nutti's response to Panel Question 37.
[925] Exhibit EC-76/At. 10.
[926] Annex H, Dr. Andow's response to Panel Question 38.
[927] We recall that the Commission made a proposal for such rules in July 2001.

7.933 We note that at a very early stage, in August 2002, the applicant submitted an updated application to satisfy the new requirements of Directive 2001/18. The applicant appears to have done so at its own initiative.[928] In August 2002, it was already clear, however, that the approval procedure concerning NK603 maize could not be completed under Directive 90/220. Consistent with the fact that the update was submitted early on, the updated application was promptly forwarded to the Commission with the lead CA's favourable assessment report on 14 January 2003.[929] However, the fact that under Directive 2001/18 the application moved to the Community level very quickly in our view does not disprove the claim that a moratorium on approvals was in effect. As we have said, Spain could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.934 In the light of the above considerations, we conclude that the failure of Spain to complete its assessment of NK603 maize earlier than in January 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

GA21 maize (EC-85)

7.935 The application concerning GA21 maize (EC-85) was initially submitted to the United Kingdom (lead CA) on 12 December 1997, for the import of grain and of derived products for animal feed and processing. On 15 October 1999, the lead CA submitted the application to the Commission with its favourable assessment.[930] The application was withdrawn on 27 June 2001.

7.936 The **United States** argues that this application was delayed at the member State level for seven months. In February 1999, the Advisory Committee on Release into the Environment (ACRE) notified the applicant that it would forward the application to the Commission following some amendments to the application.[931] On 23 March 1999 the applicant submitted the final and complete amended application, as agreed between the applicant and the lead CA, which was ready to be forwarded to the Commission as of that date.[932] The application, however, was delayed for more than seven months for no discernible reason before it was finally sent to the Commission on 15 October 1999. More than four months after the positive ACRE opinion, the applicant explicitly inquired about this delay in a letter dated 8 July 1999 to the Minister of the Environment, only to receive a reply back four months later, on 2 November 1999, noting, without explanation, that the application "had recently been forwarded" to the Commission.[933]

7.937 The United States observes that the chronology provided by the European Communities gives the false impression that activity actually occurred on this application after April 1999 by referencing an ACRE meeting on 16 September 1999.[934] As the minutes of that meeting show, however, GA21 maize (EC-85) was not on the agenda and was not discussed. There was no activity during this time period on the side of the lead CA. The United States maintains that these seven months of inaction following the lead CA's positive risk assessment were politically motivated. The exact application as

[928] Exhibit EC-76/At. 18.
[929] Exhibit EC-76/At. 27.
[930] We recall that an application for the same product was submitted to Spain on 29 May 1998 (EC-78).
[931] EC Exhibit 78 + 85/At. 22.
[932] Exhibit US-145.
[933] Exhibit US-146.
[934] Exhibit EC-78 + 85/At. 24.

submitted by the applicant on 23 March 1999 was finally forwarded to the Commission without further discussion or amendment.

7.938 **Canada** argues that the lead CA failed to submit the application to the Commission until November 1999, well after the applicant had made certain amendments to the original application in March 1999 in accordance with the agreement with the lead CA made in February 1999. That is, the lead CA failed to forward the application to the Commission for 7.5 months. Canada argues that this should be considered together with the fact that the lead CA had already spent 15.5 months for its review with regard to the application since the application was submitted by the applicant in November 1997.

7.939 The **European Communities** argues that the delays at the member State level relating to this application were due to the numerous requests for additional information. Furthermore, when the application was withdrawn, the applicant cited as reasons for its withdrawal "unexpected commercial constraints" and the parallel application in Spain.

7.940 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies 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, which the United States maintains results from the moratorium.

7.941 The **Panel** notes that on 16 February 1999 the lead CA informed the applicant that, in light of some of the new data provided by the applicant in response to requests from the lead CA, ACRE had re-reviewed the application, and requested some amendments in order to permit the dossier to be forwarded to the Commission. ACRE indicated that subject to these amendments being made, it was content for the dossier to be forwarded to the Commission with a favourable opinion.[935] The applicant provided an amended application to the lead CA in March 1999.[936] The chronology provided by the European Communities indicates that a meeting of ACRE was held on 16 September 1999. However, as correctly noted by the United States, the minutes of this meeting make no reference to any discussion of the GA21 maize (EC-85) application.[937] The EC chronology shows no further action on this application until it was forwarded to the Commission with a positive assessment report on 15 October 1999. Evidence submitted by the United States shows, however, that on 8 July 1999, the applicant inquired with the lead CA why the application was not being forwarded.[938] The lead CA replied on 2 November 1999, almost four months later, indicating only that the application had meanwhile been forwarded to the Commission.[939]

7.942 The United States does not assert that the United Kingdom itself was an active participant in the alleged moratorium on approvals and that the delay in question is a reflection of the United Kingdom's support for the moratorium. Nevertheless, the United States contends that the fact that the lead CA did not forward the application to the Commission for almost seven months after receiving an amended version was politically motivated. In response to a request for elaboration from the

[935] Exhibit EC78+85/At. 22.
[936] Exhibit EC-78+85/At. 26. Evidence submitted by the United States confirms that the revised application was submitted on 23 March 1999. Exhibit US-145.
[937] Exhibit EC-78+85/At. 24.
[938] Exhibit US-146.
[939] *Ibid*.

Panel, the United States observed that many EC member States, including the United Kingdom, were divided internally on their position related to biotechnology. On the one hand, elements of the UK government have, in the United States' view, been supportive of agricultural biotechnology. On the other hand, the United States argues that certain political figures were not supportive, including the UK Environment Minister at the time of the delay in question. According to the United States, the conduct of the United Kingdom shows that countries other than the Group of Five countries recognized the political reality of the moratorium, and that this reality at times affected the manner in which they conducted their assessments of biotech applications.

7.943 In considering the United States' arguments, we note that it is reasonable to assume that the lead CA needed some time to review the amended application submitted in March 1999 before it could be forwarded to the Commission with a favourable opinion. Nevertheless, the lead CA had previously indicated that there were no other outstanding issues, and so we agree with the United States that a delay did occur between March 1999 and October 1999. Indeed, this period alone resulted in the consideration of this application at the member State level far exceeding the 90-day assessment period allowed under Directive 90/220.

7.944 The precise reasons for the lead CA's temporary inaction are unclear. We note that during the period from March to October 1999, in June, the Environment Council agreed on a Common Position in relation to the revision of Directive 90/220 and the Group of Five countries made their declarations. It may be that the United Kingdom considered that it was not appropriate to forward the application concerning GA21 maize (EC-85) to the Commission and the other member States with a favourable opinion shortly before this important Council meeting, and that after the meeting the United Kingdom took time to evaluate the impact of the Council meeting on the EC approval process, and to see the reaction of the Commission. It may also be that the delay reflects an internal UK policy debate, as suggested by the United States.

7.945 What is clear, though, is that the United Kingdom completed its assessment and in October 1999 forwarded the application to the Commission with a favourable opinion. This is consistent with the circumstance that the United Kingdom was not part of the Group of Five countries which stated that they would take steps to suspend further approvals. The fact that the United Kingdom completed its assessment does not, however, contradict the claim that a general moratorium on final approvals was in effect in October 1999. If a moratorium was in effect, it was only after the application concerning GA21 maize (EC-85) reached the Community level that the Group of Five countries and/or the Commission could take steps to prevent the final approval of the application concerning GA21 maize (EC-85).

7.946 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2001 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning GA21 maize (EC-85).

7.947 In the light of the above considerations, we conclude that the time taken by the United Kingdom to complete its assessment of the application concerning GA21 maize (EC-85) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

MON810 x GA21 maize (EC-82)

7.948 The application concerning MON810 x GA21 maize was initially submitted to Spain (lead CA) on 4 August 1999. This maize is produced by conventionally hybridizing two "parental" biotech products, MON810 maize and GA21 maize. This application was withdrawn by the applicant on 15 September 2003. At that time, the lead CA had not yet submitted the application to the Commission.

7.949 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.[940] 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.[941] 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.[942] 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.[943] None of these studies identified anything that would provide any basis for the concern raised by the member State.

7.950 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.

7.951 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.[944] 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.[945] 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.[946]

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[940] Exhibit EC-82/At. 8.

[941] 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.

[942] 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).

[943] Exhibit EC-82/Ats. 2 and 5.

[944] Exhibit EC-82/At. 18.

[945] Exhibit EC-82/At. 20.

[946] Exhibit EC-82/At. 21.

7.952 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".[947]

7.953 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.

7.954 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.

7.955 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.

7.956 The **Panel** begins by noting that much of the information provided to it has been incorrectly identified. In particular, translations into Spanish of information previously submitted in English have been identified as "additional data", and at times the same document was included as several different attachments. Furthermore, it should be recalled at the outset 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.[948]

7.957 Turning now to Spain's assessment of the application concerning MON810 x GA21 maize under Directive 90/220, we note that the most significant delay in the consideration of this application appears to be due to the time taken by the applicant to provide information in response to a request for additional information from the Spanish CA in November 1999. The applicant did not provide the

[947] The European Communities refers to the United States' response to question 47 of the Panel, table in Annex I.

[948] We recall that the application concerning GA21 maize (EC-78) was withdrawn by the applicant in 2003.

information requested until August 2001, and 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 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.

7.958 In April 2002, the Spanish National Biosafety Committee reviewed 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.[949] 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.

7.959 We note that after receiving 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, there is no evidence that the Spanish CA requested additional or missing information once the National Biosafety Commission had reviewed the Spanish version of the applicant's documents of August 2001. Nor did the Spanish CA complete its assessment after receiving further advice from the National Biosafety Commission in April 2002. From the information before us, it would appear that the 90-day period had already been exceeded by April 2002.

7.960 According to the European Communities, the failure of the lead CA to forward the application concerning MON810 x GA21 maize to the Commission in 2002 can be explained 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, GA 21 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. We are not convinced by this explanation.

7.961 To begin with, as previously noted, the Spanish CA had already favourably assessed the application concerning GA21 maize (EC-78). Furthermore, the SCP in September 2000 had issued a favourable opinion on the application concerning GA21 maize (EC-78).[950] It is not clear, therefore, why the same 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. As a general matter, it may be correct 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 and the assessment would then have been "concluded" at Community level. Thus, 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.

7.962 The United States argues that this application never reached the Community level stage due to the alleged general moratorium on final approvals. More particularly, the United States contends that 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. We recall that the United States does not

[949] Exhibit EC-82/At. 18.
[950] Exhibit EC-78+85/At. 90.

assert that Spain itself was an active participant in the alleged moratorium on approvals or that the time taken by Spain in its assessment is a reflection of Spain's support for the moratorium. Rather, it asserts that Spain was placed in a position of having to recognize the moratorium as a reality, and that this affected the speed with which it conducted its assessment.

7.963 We consider that following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[951] In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note in this regard that the single trait parent application concerning GA21 maize (EC-78) did not progress at Community level after the SCP had issued its favourable opinion in September 2000.[952] In relation to that application, we have previously concluded that the Commission's failure to submit a draft measure concerning GA21 maize (EC-78) to the Regulatory Committee following the issuance in September 2000 of the SCP's opinion is consistent with the United States' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

7.964 Against this background, and in particular in view of the situation with regard to the single trait parent application concerning GA21 maize (EC-78), we consider that Spain could have come to the conclusion in 2002 that there was no realistic prospect that the application concerning MON810 x GA21 maize could be approved prior to the repeal of Directive 90/220. In our view, Spain's failure to complete its assessment prior to the repeal of Directive 90/220 is therefore consistent with the view that a general moratorium on approvals was in effect at the time.

7.965 We note 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, it is not apparent that the Spanish CA's conduct as of April 2002 reflects a precautionary approach. Indeed, the Spanish CA did not follow up with the applicant to seek more information or additional clarifications after receiving further advice from the National Biosafety Commission in April 2002. We recognize that, by that time, 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.[953]

7.966 Furthermore, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2003 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning MON810 x GA21 maize.

7.967 Regarding Spain's assessment of the application concerning MON810 x GA21 maize under Directive 2001/18, we note that the applicant on 16 January 2003 indicated its intention to submit an updated application in accordance with Directive 2001/18. The European Communities has indicated, however, that the updated application was never received by the lead CA. We have seen no evidence

[951] We recall that the Commission made a proposal for such rules in July 2001.

[952] It is reasonable to assume that as the lead CA in the approval procedure concerning GA21 maize (EC-78), Spain was aware of this situation.

[953] Exhibit EC-75/At. 13.

to the contrary. The only other information regarding this application relates to its withdrawal by the applicant on 15 September 2003. Thus, it appears that the application was never considered by the lead CA under Directive 2001/18. This said, without an updated application, the lead CA could not have done so.

7.968 In the light of the above considerations, we conclude that the failure of Spain to complete its assessment of the application concerning MON810 x GA21 maize prior to the repeal of Directive 90/220 in October 2002 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

High-oleic soybeans (EC-87)

7.969 The application concerning High-oleic soybeans was submitted to the Netherlands (lead CA) on 19 June 1998. Following several requests for additional information from the lead CA and responses by the applicant, the application was withdrawn by the applicant on 12 December 2002.

7.970 The **United States** argues that the application for High-oleic soybeans was withdrawn because of the European Communities' excessive delay in carrying out the approval process. The United States maintains that this delay was a manifestation of the moratorium on approvals.

7.971 The **European** Communities argues that when the application was withdrawn by the applicant in December 2002, the justification given for the withdrawal pointed to "entirely commercial reasons".

7.972 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in its reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.973 The **Panel** notes that in a communication dated 7 December 1998, the Netherlands Institute for Food Safety (RIKILT), one of the advisory scientific bodies considering the application, informed the lead CA that not enough information was available to assess the safety of livestock feed made from High-oleic soybeans.[954] The applicant was formally informed of the request for further data in a letter dated 8 January 1999. However, it appears that the RIKILT's questions had been made available to the applicant by e-mail already on 4 December 1998.[955] On 1 July 1999, the applicant provided responses to the RIKILT's questions "from 4 December 1998". The applicant submitted almost 270 pages of replies and studies.[956] The new information was apparently reviewed by the RIKILT, and on 27 October 1999, the Dutch CA on behalf of the RIKILT requested the applicant to provide further substantiation of the compositional analysis it had submitted.[957] The applicant did not provide the requested substantiation, however. There is no indication of any further communications on this application until it was withdrawn by the applicant more than three years later, on 12 December 2002, *i.e.*, after the repeal of Directive 90/220.

[954] Exhibit EC-87/At. 11.
[955] Exhibit EC-87/Ats. 13 and 14.
[956] Exhibit EC-87/At. 14.
[957] Exhibit EC-87/At. 15.

7.974 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements. *First*, the lead CA's request for additional information of December 1998/January 1999 and the time taken by the lead CA to review the additional information once it had been received. *Secondly*, the applicant's failure, over a period of more than three years, to respond to a follow-up request for additional information.

7.975 Regarding the first element, we have asked the experts advising us whether the information requested in December 1998/January 1999 and October 1999 on the composition of the product and the alteration in the protein profile were necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti considered that the data requested in December 1998/January 1999 on the lectin content and composition data for at least two seasons was necessary to ensure that conclusions of the safety assessment concerning human use were valid. She also noted, however, that the changes in the fatty acid composition would not be expected to have an impact on livestock feed safety.[958]

7.976 In considering the requests of December 1998/January 1999, it must also be noted, however, that a few months later, in June 1999, the Netherlands formally declared that it would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. In our view, the December 1998/January 1999 requests might reflect a precautionary approach to evaluating applications.

7.977 On 1 July 1999, the applicant provided the information requested in December 1998/January 1999. Almost four months later, on 27 October 1999, the Dutch CA forwarded additional questions from the RIKILT to the applicant. This means that during that period alone, the Netherlands exceeded the 90 days available to it under Directive 90/220 to assess the application. On the one hand, it should be recalled in this context that the applicant's technical response consisted of a 270-page document. In comparison, the original application contained 170 pages.[959] On the other hand, we consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. It is also reasonable to assume that the Netherlands was aware that after May 1999, in the approval procedures concerning Bt-531 cotton and RR-1445 cotton, the Commission failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Council. Consequently, it is possible, in our view, that the Netherlands considered that the application concerning High-oleic soybeans could not be promptly approved at Community level, and that this affected the speed of its own assessment at the member State level. Hence, we think the Netherlands' conduct is consistent with the view that a general moratorium on approvals was in effect at the time.

7.978 Regarding the second element which contributed to a delay in the completion of this procedure, we note that the reasons for the applicant's failure to provide further substantiation are unclear. In its December 2002 letter of withdrawal, the applicant indicated that there was no safety concern relating to High-oleic soybeans and that the withdrawal was related entirely to commercial reasons.[960] In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2002 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning High-oleic soybeans.

[958] Annex H, paras. 673-674.
[959] Exhibit EC-87/At. 1.
[960] Exhibit EC-87/At. 16.

7.979 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of the application concerning High-oleic soybeans prior to December 2002, when it was withdrawn by the applicant, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR sugar beet (EC-88)

7.980 The application concerning RR sugar beet was submitted for approval in Belgium (lead CA) in December 1998 under Directive 90/220. Following the entry into force of Directive 2001/18, an updated application was submitted by the applicant on 16 January 2003. At the time of establishment of the Panel, the lead CA had not yet submitted its assessment to the Commission. On 16 April 2004, the application was withdrawn by the applicant.

7.981 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 member State declined to forward the application to the Commission. Although the applicant provided answers to all of the questions raised by the lead CA, the member States nonetheless delayed and ultimately suspended consideration or failed to approve this product under Directive 90/220. This product was resubmitted under Directive 2001/18.

7.982 **Canada** argues that the lead CA failed to complete its review with regard to the application, and thus exceeded the 90-day limit provided for by Directive 90/220 by several years. Canada argues that during the review process, the lead CA requested three times (April 1999, November 2000 and January 2001) the applicant to "voluntarily" comply with the requirements provided for by Directive 2001/18, even though Directive 2001/18 would not be in force until October 2002.

7.983 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.

7.984 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in its reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.985 The **Panel** observes that the application was apparently sent to the lead CA in December 1998, however no record of this application is available to us. Also, the lead CA considered the application to be incomplete. After the applicant submitted further information, the lead CA on 1 March 1999 acknowledged receipt of a complete application.[961] Apparently, 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

[961] Exhibit EC-88/At. 3.

food/feed equivalence.[962] The applicant provided responses to some of these questions in July 1999.[963] Other questions were answered in December 1999.[964]

7.986 In October 1999 the lead CA requested additional information on gene transfer in digestive tracts.[965] The applicant provided such information in January 2000.[966] 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.[967]

7.987 In February 2000, the lead CA requested missing bibliographical references. The applicant provided the relevant references in February and March 2000.[968] 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.[969]

7.988 In November 2000, the lead CA requested further clarifications regarding molecular characterization and allergenicity of "event '77'".[970] 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.[971] The applicant apparently did not provide the requested information.

7.989 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.[972] 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.[973] 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.

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[962] Exhibit EC-88/Ats. 8 and 9.
[963] Exhibit EC-88/At. 10.
[964] Exhibit EC-88/At. 13.
[965] Exhibit EC-88/At. 12.
[966] Exhibit EC-88/At. 15.
[967] Annex H, Dr. Nutti's response to Panel Question 42.
[968] Exhibit EC-88/Ats. 17-21.
[969] Exhibit EC-88/At. 22.
[970] Exhibit EC-88/At. 27.
[971] Annex H, Dr. Nutti's response to Panel Question 43.
[972] Exhibit EC-88/At. 29.
[973] Exhibit EC-88/At. 30.

7.990 In January 2003, the applicant submitted an updated application under Directive 2001/18. There was an acknowledgement by the lead CA in February 2003 that the applicant had provided updates and a request for further information.[974] The applicant apparently did not provide the requested information. Instead, in April 2004 the applicant submitted a letter of withdrawal.

7.991 We begin our examination of the lead CA's assessment of the application concerning RR sugar beet by recalling that the applicant did not respond to the lead CA's November 2000 request for additional information.[975] It would therefore appear that after November 2000 the lack of progress under Directive 90/220 is attributable to the applicant. The question to be examined, then, is why the lead CA did not complete its assessment prior to November 2000. We note in this respect that by the end of March 2000 the applicant had provided all additional information requested by the lead CA. 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. 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. We note in this connection that by November 2000, Belgium had already far exceeded the 90-day period provided for in Directive 90/220 for the assessment to be made by a lead CA.

7.992 We also recall that in June 1999 Belgium was one of the Group of Seven countries which declared, not that they would take steps to suspend further approvals, but that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in view of the timing of Belgium's November 2000 request for additional information – it was forwarded more than seven months after the applicant had submitted additional information in March 2000 – we are not convinced that that request was a reflection of the precautionary approach referred to in the June 1999 declaration of the Group of Seven countries.

7.993 We consider that following the June 1999 declaration by the Group of Five countries, Belgium had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, Belgium also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, it is possible, in our view, that Belgium considered that the application concerning RR sugar beet could not be promptly approved at Community level, and that this affected the speed of its own assessment and led it to request information which it might not otherwise have requested.[976] As indicated previously, notably in the case of the clarifications sought concerning allergenicity, Dr. Nutti questioned the need for the information that was requested. The circumstance that the applicant did not respond to the November 2000 request is also consistent with this possibility, for it may indicate that the applicant had lost confidence that its application would be forwarded to the Commission by Belgium while Directive 90/220 was still in force.

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[974] Exhibit EC-88/At. 34.

[975] The lead CA in January 2001 reminded the applicant of its November 2000 request for information. Exhibit EC-88/At. 29.

[976] In fact, as noted earlier, in January 2001 Belgium itself indicated to the applicant that it expected opposition to the approval of the application concerning RR sugar beet if the applicant did not voluntarily comply with certain principles set out in the Common Position on the revision of Directive 90/220.

7.994 Taking account of the aforementioned elements, we consider that Belgium's failure to complete its assessment prior to its November 2000 request for additional information is consistent with the existence of a general moratorium on approvals. This view is not contradicted by the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2004. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning RR sugar beet.

7.995 In the light of the above considerations, we conclude that the time taken by Belgium for its assessment of RR sugar beet is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic green-hearted chicory (EC-110)

7.996 The application concerning Transgenic green-hearted chicory was submitted for approval in the Netherlands (lead CA) on 11 March 1996 under Directive 90/220. On 15 April 2003, the application was withdrawn.

7.997 The **European Communities** has indicated that, after assessment at both national and European Community level, the notification was withdrawn by the applicant on 15 April 2003. The applicant gave two reasons for the withdrawal: first, the absence of a market for these products; and second, the fact that the company preferred not to be associated with GMOs any longer.

7.998 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted and new products were developed, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.999 The **Panel** notes that a draft of a favourable opinion prepared for submission to the European Commission was provided to the applicant for comments on 8 July 1996.[977] Six months later, in January 1997, the applicant submitted a letter requesting that the application not be forwarded to the Commission until there was greater clarity regarding the authorization of Transgenic red-hearted chicory (EC-77).[978]

7.1000 More than two years later, on 25 March 1999, the Dutch advisory body for feed safety, the RIKILT, submitted an assessment report to the Dutch CA. Contrary to the description of this report given by the European Communities, the RIKILT did not request additional information. Rather, the RIKILT stated that given the conclusions of the Provisional Committee For Safety Evaluation of Novel Foods and/or the SCP, there were no indications that occasional use of the modified green-hearted chicory as feed would not be safe. The report did indicate that by current EU standards the data provided on the composition of the modified green-hearted chicory was insufficient to comment on its comparability with non-modified green-hearted chicory. It went on to state, however, that as green-hearted chicory was not a normal ingredient of feed, and in light of the opinion of the Provisional Committee on the Safety of Novel Foods regarding its safety for human consumption,

[977] Exhibit EC-110/At. 4.
[978] Exhibit EC-110/At. 5.

there was no indication that the product would not be safe for both animals and consumers of animal products if occasionally used as feed.[979]

7.1001 On 19 May 1999, the applicant voluntarily provided some supplementary data on food safety aspects "in response to requests by different Member States" in the context of the discussion of the application concerning the same product submitted under Regulation 258/97. The application provided the information, although the application concerning Transgenic green-hearted chicory concerned feed use, not food use.[980] No information was provided to us regarding any further exchanges concerning this application after this date. The application was not re-submitted under Directive 2001/18 and formally withdrawn on 15 April 2003. The withdrawal letters submitted to us are in Dutch and no translation was provided.

7.1002 It is evident from the foregoing that the consideration of this application by the lead CA was not completed within the 90 days foreseen under Directive 90/220. Unfortunately, however, based on the information that was provided to us we are unable to ascertain to what extent any delays which occurred after May 1999, when the applicant voluntarily submitted further information, were attributable to the lead CA. As noted, the evidence seems to suggest that in July 1996, the application was deemed sufficient for the relevant scientific committees within the Netherlands to conclude that the Transgenic green-hearted chicory presented no risk to human or animal health or the environment. But in January 1997, the applicant requested that the application not be forwarded until there was greater clarity about the approval of Transgenic red-hearted chicory. From the evidence before us, it is not clear whether in May 1999, the lead CA was still waiting for the applicant to withdraw its holding request. If that was the case, the failure of the lead CA to complete its assessment after May 1999 and forward the application to the Commission would be the result of the applicant's own request.

7.1003 Even assuming, however, that the lead CA was waiting for the applicant to give it the go-ahead, this would not demonstrate that no moratorium on final approvals was in effect during the relevant time period. As of October 2002, when Directive 90/220 was repealed, the application concerning Transgenic green-hearted chicory had not reached the Community level phase of the approval procedure under Directive 90/220. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1004 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of Transgenic green-hearted chicory prior to October 2002, when Directive 90/220 was repealed, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Member State failure to give consent to placing on the market

7.1005 In support of their assertion that the European Communities applied a general moratorium on approvals the United States and Canada have pointed to approval procedures in which the member State to which the application was submitted – the lead CA – failed to give its written consent to the placing on the market of a biotech product, after that biotech product had been approved by Commission decision. We consider these approval procedures below, recalling that Article 13(4) provides in relevant part that "[w]here the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that

[979] Exhibit EC-110/At. 7.
[980] Exhibit EC-110/At. 8.

the product may be placed on the market". Article 13(5) further provides that "[o]nce a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to".

MS1/RF1 oilseed rape (EC-89)

MS1/RF2 oilseed rape (EC-90)

7.1006 The applications for both MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were submitted to France (lead CA) in April 1995 for cultivation, import and marketing. After consideration by the lead CA and subsequently at Community level, these applications were approved by the Commission on 6 June 1997.[981]

7.1007 The **United States** argues that numerous applications that were blocked under Directive 90/220 were not resubmitted under Directive 2001/18, including MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. These applications languished at the final stage of the process for more than five years because the lead CA withheld its final approval.[982] Both applications were submitted to France in April 1995, which forwarded them with favourable opinions to the European Commission on 27 July 1995. The Commission reviewed the applications and found "no reason to believe that there will be any adverse effect on human health and the environment" from placing MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market.[983] Accordingly, the Commission approved both products on 6 June 1997,[984] consistent with the favourable opinion of the Regulatory Committee.[985] Despite the favourable decision of the Commission, France refused to complete the process by giving its final consent so that MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape could be placed on the market.[986]

7.1008 **Canada** argues that MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have been affected by the moratorium, as these products have been prevented from receiving the approval necessary for the product to be legally marketed in the European Communities. Canada submits that although these products were approved prior to October 1998, these products are the victims of the moratorium after October 1998 as much as any products.

7.1009 Canada notes that the EC decisions approving 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[987], on the basis, in part, that there was no reason to believe that there would be any adverse effects on human health and the environment. However, the lead CA failed to give its consent for either product contrary to this stipulation and Article 13(4) of Directive 90/220 and despite the fact that the same competent authority originally provided a favourable opinion.

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[981] Commission Decision 97/392/EC of 06/06/1997 in OJ L164 of 21/06/1997, p. 38 (Exhibit EC-89) and Commission Decision 97/393/EC of 06/06/1997 in OJ L164 of 21/06/1997, p. 40 (Exhibit EC-90).

[982] Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

[983] Commission Decision 97/392/EC, O.J. 21.6.1997 L164, preamble, fifth recital (Exhibit US-43); Commission Decision 97/393/EC, O.J. 21.6.1997 L164, preamble, fifth recital (Exhibit US-44).

[984] Commission Decision 97/392 (Exhibit US-43); Commission Decision 97/393 (Exhibit US-44).

[985] Commission Decision 97/392, preamble, eighth recital (Exhibit US-43); Commission Decision 97/393, preamble, eighth recital (Exhibit US-44).

[986] Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

[987] Canada refers to Article 1(1) of each Commission Decision, respectively.

7.1010 Canada further notes that on 7 July 1999, the Commission sent a "reasoned opinion" to France in relation to the withholding of consent for these products. This procedural step necessarily precedes any legal proceedings by the Commission against a member State for infringement of EC law before the European Court of Justice.[988] However, the Commission did not pursue this matter any further; it did not bring an infringement procedure. Although Canada requested additional information from the European Communities during consultations, the European Communities has yet to provide any additional information on what steps were actually taken. Furthermore, in a judgment dated 4 November 2000, the French Conseil d'Etat, following the decision of an earlier European Court of Justice ruling in relation to Article 13(4) of Directive 90/220, concluded 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.[989]

7.1011 Canada argues that despite the Commission's decisions to place both products on the market over 6 years ago (and the completion of the most recent favourable risk assessment by an EC scientific body on a closely related use of the same product at least 5 years ago), France has continued to withhold consent to the placement of these products on the market. Accordingly, the applicant has been unable to place either plant variety on the EU market.[990]

7.1012 The **European Communities** argues that from a legal point of view, the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and/or MS1/RF2 oilseed rape on the market. These products have obtained marketing approval by virtue of Commission decisions of 6 June 1997. While those decisions were addressed to France and placed an obligation upon France to grant final consent, they could nevertheless develop a direct effect *vis-à-vis* the applicant as well.

7.1013 According to the European Communities, in the case law of the European Court of Justice, EC member States cannot prevail themselves of the fact that they have not implemented (or refuse to implement) Community obligations addressed to them in order to deny an individual a right granted through those same Community provisions.[991] The individual, therefore, can assert this right by directly relying on the Community law in question. These principles form the so-called doctrine of "direct effect." The Court has based this doctrine on a teleological interpretation of Community law, and in particular, on the so-called "effet utile" principle.

7.1014 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

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[988] European Communities, GMOs: Commission moves against Luxembourg and France, Commission Press Release, IP/99/438, Brussels, 7 July 1999 (Exhibit CDA-52). *See also* European Communities, 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).

[989] European Communities, 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] E.C.R. I-01651 (Exhibit CDA-51).

[990] Canada notes that the processed oil from canola/oilseed rape hybrid MS1/RF1 was approved for placing on the market pursuant to the simplified procedures of Article 5 of Regulation 258/97 as of 24 June 1997 (*see* the summary of Article 5 applications received in 1997, product number 2, contained in Exhibit CDA-25). The application was submitted to the Commission by the United Kingdom following a scientific assessment conducted by its Advisory Committee on Novel Foods and Processes.

[991] *See only* European Court of Justice, Leberpfennig, C-9/70 [1970] ECR 825.

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).

7.1015 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 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.

7.1016 The **United States** maintains that under Directive 90/220, the "Community level" approval is not effective unless and until the member State that initially received the application takes the final step of placing the product on the market. In this case, the lead CA never allowed the product to be placed on the market. Thus, these products in fact were never approved for cultivation, import, and marketing in the European Communities. This is an example of how in certain circumstances a single member State can block a product approval, and is furthermore an example of the existence of the general moratorium. Neither of these products is in fact on the market in the European Communities and EC Customs officials would not admit either of these products without the final step (the French consent) in the approval process. The European Communities has failed to explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market.

7.1017 **Canada** argues that one cannot reasonably conclude that an approval procedure has been brought to an end if an applicant must undergo potentially expensive and time-consuming litigation to enforce its rights.

7.1018 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.[992]

7.1019 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

[992] Exhibits US-43 and -44; CDA-48 and -49.

on the market of the products at issue. Thus, France did not grant its consent for more than five years.[993]

7.1020 The European Communities has suggested 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). The application concerning MS1/RF1 oilseed rape (EC-161) had been submitted to the United Kingdom and was approved for breeding activities in 1996. In considering this 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.

7.1021 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.[994] 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.

7.1022 For all 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.

7.1023 We recall 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. As previously noted, the Complaining Parties argue that one of the steps which the Group of Five countries could take to prevent further approvals was to withhold written consent to the placing on the market of the product to be approved in cases where they were acting as the lead CA. We consider that 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 did what was within its power to prevent these products from being approved.

7.1024 Therefore, we consider that at least as from June 1999, France's failure to give its written consent supports the Complaining Parties' assertion that the European Communities was applying a

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[993] 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.

[994] 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.

general moratorium on final approvals. France's conduct is not inconsistent with the Complaining Parties' assertion that a general EC moratorium was in effect already as from October 1998. However, the fact that France withheld its consent already as from June 1997 could also support the view that although France, for its part, opposed further approvals and used its powers to prevent approvals, no general EC-wide moratorium was in effect in October 1998.

7.1025 We should note that there is 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.

7.1026 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. The United States and 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.

7.1027 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. Therefore, the European Communities' contention does not detract from our view that at least as from June 1999 France's continued failure to give its written consent supports the Complaining Parties' assertion that the European Communities was applying a general moratorium on final approvals.

7.1028 In the light of the above considerations, we conclude that at least as from June 1999 the failure of France to give its written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape supports the contention of the Complaining Parties that the European Communities applied a general moratorium on approvals.

Delays due to changes in the legislative framework

7.1029 As we have noted at the outset, the European Communities acknowledges that delays occurred in some approval procedures which were pending under Directive 90/220. According to the European Communities, these delays occurred as a result of legislative changes which were being made at the time. Specifically, the European Communities refers to the revision of Directive 90/220 which led to the adoption of Directive 2001/18. The European Communities observes that while Directive 90/220 continued to be the basis for the processing of applications, pending applications presented a problem in that they did not generally contain the data/information necessary to address

the concerns which led to the adoption of Directive 2001/18. The European Communities says that it therefore had to find ways to ensure that the applicant provided the necessary data/information. The European Communities points out that most applicants agreed to do so on a voluntary basis. The European Communities submits that with the adoption and entry into force of the new legislation, all relevant concerns have been addressed. The European Communities asserts that, as a consequence, under Directive 2001/18 all approval procedures have been proceeding normally.

7.1030 Thus, the European Communities essentially argues that to the extent there were delays in the processing of Directive 90/220 applications, they were linked to legislative changes which were completed in October 2002 with the entry into force of Directive 2001/18. They were not linked to legislative changes sought by the Group of Five countries and obtained in September 2003 with the adoption of new EC rules on labelling and traceability. In support of this assertion, the European Communities submits that there were delays before the entry into force of Directive 2001/18, but not after.

7.1031 It is apparent from the above review of individual approval procedures that delays occurred which were linked to the adoption of Directive 2001/18 or to its more or less imminent entry into force. In our view, however, these delays are entirely consistent with the Complaining Parties' contention that a general moratorium on approvals was in effect until at least August 2003. We recall in this respect that in June 1999 the Group of Five countries declared that "pending the adoption of [new EC rules ensuring labelling and traceability of GMOs and GMO-derived products]"[995], they would take steps to have any new authorizations for growing and placing on the market suspended. By October 2002, when Directive 2001/18 entered into force, the new EC rules on labelling and traceability had not been adopted.[996] Thus, it is clear from the June 1999 declaration that the Group of Five countries would oppose approvals until the adoption of the new rules, that is to say, until after the entry into force of Directive 2001/18. We also recall the Complaining Parties' assertion that the Commission was instrumental in the adoption and application of the alleged general moratorium on approvals and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. Accordingly, if a general moratorium on approvals was in effect until at least August 2003, it was to be expected that the Group of Five countries (acting as lead CA or through the Regulatory Committee/Council) and/or the Commission would cause delays prior to the repeal of Directive 90/220 so as to prevent applications from being approved while that Directive was still in force.

7.1032 The European Communities claims that after the entry into force of Directive 2001/18, there were no further delays, except for delays which were the result of a clock-stop while further information was awaited. However, as our preceding analysis has shown, there were in fact delays in the processing of applications under Directive 2001/18 which are consistent with the existence of a moratorium on approvals. Such delays occurred at the member State level in the approval procedures concerning Bt-531 cotton, RR-1445 cotton, BXN cotton and Bt-1507 maize (EC-74). Our analysis also showed that in a number of instances, applications moved to the Community level relatively promptly.[997] However, we have said that, in our view, this does not disprove the Complaining Parties' claim that a moratorium on approvals was in effect during the relevant time period. We observed that the lead CA in the relevant cases could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application

[995] Exhibits US-76 and -77; CDA-3; ARG-12.
[996] The Commission did not propose such rules until July 2001.
[997] *See, e.g.*, the approval procedures concerning RR oilseed rape (EC-70), Bt-1507 maize (EC-74), Bt-1507 maize (EC-75) and NK603 maize.

in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability. In other words, the lead CAs had reason to believe that under Directive 2001/18 any delays caused by them at member State level might have an impact on when the relevant applications would be approved.

7.1033 The European Communities' contention that there were and should have been no delays after the entry into force of Directive 2001/18 is also inconsistent with the June 1999 declaration by the Group of Five countries. As noted earlier, the Group of Five countries announced that they would take steps to prevent approvals pending the adoption of the new EC rules on labelling and traceability. Such rules were adopted in September 2003, *i.e.*, after the entry into force of Directive 2001/18. The record shows that Group of Five countries continued to oppose the approval of applications even though they had been updated in accordance with the requirements of Directive 2001/18.[998]

7.1034 Furthermore, we note that, as of August 2003, there had been no case where an approval procedure conducted under Directive 2001/18 reached the stage where the Commission had to submit a draft measure to the Regulatory Committee/Council or adopt a draft measure not adopted by the Council. In other words, there was no procedure which reached the stage where the Commission could have taken action to delay or prevent the final approval of an application. Moreover, the first Commission approval of an application under Directive 2001/18 occurred only in July 2004, that is to say, after the establishment of the Panel and after the entry into force of the new EC rules on labelling and traceability. Hence, as far as the Commission's conduct is concerned, the record does not disprove the Complaining Parties' claim that the Commission had decided not to complete approval procedures for as long as the new EC rules had not been adopted.

7.1035 In the light of the above considerations, we are not persuaded by the European Communities' contention that to the extent there were delays in the processing of applications for deliberate release into the environment, they were attributable in part to legislative changes which were completed in October 2002 with the entry into force of Directive 2001/18, but not to legislative changes sought by the Group of Five countries. We consider that the delays which occurred prior to the entry into force of Directive 2001/18 are entirely consistent with the contention of the Complaining Parties that the European Communities was applying a general moratorium on approvals at least until August 2003. We also consider that the record does not support the European Communities' assertion that under Directive 2001/18 there were no delays or at least none which are consistent with the existence of a moratorium on approvals.

(ii) Novel Foods – Applications submitted under Regulation 258/97

7.1036 The Panel now turns to address those of the relevant applications which were submitted and dealt with under the provisions of Regulation 258/97 concerning novel foods and novel food ingredients. From the information provided to us, it appears that all of the biotech products which were the subject of the relevant Regulation 258/97 applications had also been submitted for approval under Directive 90/220.[999] It is also noteworthy that all Regulation 258/97 applications were submitted after the corresponding Directive 90/220 applications.[1000] Furthermore, the two biotech food products which were approved by the Commission in 2004, Bt-11 sweet maize (food) and

[998] *See, e.g.*, the approval procedures concerning RR oilseed rape (EC-70) (Exhibit EC-70/At. 71) and NK603 maize (Exhibit EC-76/At. 46).

[999] In some cases, the Directive 90/220 and Regulation 258/97 applications were submitted to the same lead CA. In most cases, they were submitted to different lead CAs.

[1000] In some cases, the Regulation 258/97 applications were submitted a few days later, in other cases more than a year later.

NK603 maize (food), were approved after having been approved under Directive 90/220 (Bt-11 maize (EC-163)) and Directive 2001/18 (NK603 maize).

7.1037 Some of the approval procedures we address below are for applications covering foods or food ingredients which contain or consist of GMOs.[1001] It should be noted in this respect that according to Regulation 258/97 "risks to the environment may be associated with novel foods or food ingredients which contain or consist of [GMOs]".[1002] Article 9(1) of Regulation 258/97 therefore requires that applications concerning such foods or food ingredients be accompanied by the technical dossier supplying the relevant information required under Article 11 of Directive 90/220 and the environmental risk assessment based on this information or, where appropriate, the decision approving the placing on the market of the relevant product under Directive 90/220. Article 9(2) provides that the 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]". 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 the corresponding Directive 90/220 application had previously been approved.

7.1038 The Complaining Parties assert that the facts and histories of the relevant approval procedures support their view that the European Communities applied a general moratorium on final approvals of biotech products, including biotech food products. We recall in this respect that in June 1999 the Group of Five countries declared that "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs)", "pending the adoption of [EC rules ensuring labelling and traceability of GMOs and GMO-derived products], in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended".[1003] This declaration was made in the context of the revision of Directive 90/220. However, by its terms, the declaration does not exclude from its scope GMOs which are directly used as foods or food ingredients, GMOs contained in foods or food ingredients, or GMOs from which foods or food ingredients are produced, but which do not contain the relevant GMOs.

7.1039 Furthermore, we note that the new EC rules on labelling and traceability of GMOs and GMO-derived products referred to in the June 1999 declaration by the Group of Five countries clearly include those which were adopted in September 2003 as Regulation 1830/2003. That Regulation, as its title makes clear, concerns "the traceability and labelling of [GMOs] and the traceability of *food and feed products produced from [GMOs]*" (emphasis added). The preamble to Regulation 1830/2003 notes that traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products in accordance with the requirements of Regulation 1829/2003 on genetically modified food and feed, which was also adopted in September 2003. In the light of this link between the two Regulations, and above all in view of the reference in the Group of Five declaration to new EC rules on "labelling [...] of GMOs and GMO-derived products", it is plausible that the Group of Five declaration was intended to cover also Regulation 1829/2003. That Regulation lays down additional labelling requirements for genetically modified food and feed. In particular, unlike Regulation 258/97, it requires labelling of GMO-derived

[1001] In some cases, from the information provided to us, we could not determine whether an application covered foods or food ingredients containing or consisting of GMOs.
[1002] Fifth preambular paragraph of Regulation 258/97.
[1003] Exhibits US-76 and -77; CDA-3; ARG-12.

food products also in cases where the DNA or protein of GM origin is not detectable in the final food products.

7.1040 In relation to Regulation 1829/2003, we should add that Canada and Argentina submitted to us a Council document which indicates that on the issue of "authorization of new GMO food products" Denmark, supported by France, Italy, Austria, Portugal and Luxembourg, in January 2003 pointed to "the conditions for further approval of [GMOs] since a political agreement had been reached at the Council on 28 November 2002 [...] on the proposal for a Regulation on [GM food and feed]". The document further states that "[s]ome of these delegations" considered that "no new procedure of authorization for placing on the market new GMOs should be granted as long as this Regulation had not yet entered into force".[1004] However, we cannot give much weight to this document as it is not clear what is meant by "the conditions for further approval", nor is it clear how many and which of these delegations were against further approvals pending the entry into force of the new Regulation 1829/2003 on GM food and feed.

7.1041 Finally, we note that if the Group of Five countries considered it appropriate, pending the adoption of new EC rules on labelling and traceability, to take steps to prevent the approval under Directives 90/220 or 2001/18 of biotech products which are for cultivation and/or feed use, it would be surprising if they did not oppose on the same grounds the approval under Regulation 258/97 of the identical products for food use, at least where those products contain or consist of GMOs. To recall, Regulation 258/97 indicates that environmental risks may also be associated with the food use of biotech products and requires that food products containing or consisting of GMOs satisfy the environmental safety requirements of Directives 90/220 and 2001/18. In fact, the record shows that Denmark and France have invoked the June 1999 declaration by the Group of Five countries in the context of approval procedures conducted under Regulation 258/97, when raising objections to favourable lead CA assessments of specific applications.[1005]

7.1042 With these observations in mind, we now turn to review the approval procedures conducted for the relevant Regulation 258/97 applications. As with our review of the procedures conducted for the Directive 90/220 applications, we will first focus on the Commission's conduct. Then, we consider the conduct of the SCF. Finally, we examine the conduct of individual member States acting as lead CAs.

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

7.1043 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Regulatory Committee[1006] a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 13(3) of Regulation 258/97 provides in relevant part that "[t]he representative of the Commission shall submit to the Committee a draft of the measures to be taken".

[1004] Press Office of the Council, 2481st Council meeting – Agriculture and Fisheries, Brussels, 27 and 28 January 2003, p. 23 (Exhibit ARG-52). *See also* Exhibit CDA-118.

[1005] Exhibits EC-91/At. 32 (food containing or consisting of GMOs and food produced from, but not containing GMOs); EC-92/Ats. 23 and 27 (food containing or consisting of GMOs); EC-96/At. 27 (food containing or consisting of GMOs and food produced from, but not containing GMOs).

[1006] We recall that the Regulatory Committee established under Article 13 of Regulation 258/97 was the Standing Committee on Foodstuffs.

GA21 maize (food) (EC-91)

7.1044 The application for GA21 maize (food) was submitted to the Dutch CA (lead CA) on 24 July 1998. The initial assessment of the lead CA was provided to the Commission on 21 January 2000, and circulated by the Commission to member States on 18 February 2000. On 18 May 2000, the Commission requested the SCF to evaluate the application; the opinion of the SCF was issued on 27 February 2002. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1045 The **United States** argues 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.[1007] Within less than one month, the applicant provided answers to all questions.[1008] It took a further 11 months for the SCF to issue an opinion on 27 February 2002.[1009] 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"[1010] 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."[1011]

7.1046 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.[1012] 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."[1013]

7.1047 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 feed as well as the labelling of GM products".[1014] 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

[1007] Exhibit EC-91/At. 39.
[1008] Exhibit EC-91/At. 40.
[1009] The United States observes that the current revised regulatory framework recognizes that a period of six months is an achievable timeframe for the European Communities' scientific authority (EFSA GMO Panel) to come to an opinion. Regulation (EC) No. 1829/2003, Article 6.1.
[1010] Exhibit EC-91/At. 43, pp. 11-12.
[1011] Exhibit EC-91/At. 43.
[1012] Exhibit EC-91/At. 44.
[1013] Exhibit EC-91/At. 44.
[1014] Exhibit EC-91/At. 45, p. 1.

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.[1015] 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.

7.1048 **Canada** notes that after GA21 maize received a favourable assessment by the lead CA, other member States raised objections. The SCF was then requested to conduct its own independent risk assessment and specifically "to focus its deliberations on the issues raised in the comments made by member States' authorities."[1016] The risk assessment, taking into consideration the objections raised by member States, concluded that the product in question was as safe as conventional maize. Specifically, the SCF concluded in February 2002:

> "Having reviewed all the information provided by the petitioner and in the light of current published scientific information it is concluded that from the point of view of consumer health maize grain from maize line GA21 and derived products that are the subject of this application are as safe as grain and derived products from conventional maize lines."[1017]

7.1049 Canada notes, however, that GA-21 maize is among those products where no decision has been taken despite having received a favourable opinion from the relevant scientific committee. Since 1998, the Regulatory Committee has not delivered a single favourable opinion in relation to the authorization of biotech products under Regulation 258/97. Canada rejects the European Communities' attempt to rationalize the "delay" in approving this product on the basis that legislative change was required to enable regulators to adopt "risk management". The risk assessment of GA21 maize under Regulation 258/97 did not identify any risks for which risk management measures would be justified. Therefore there is no justification for imposing "risk management" measures, be they labelling, post market monitoring or tools to facilitate the implementation and enforcement of such risk management measures (*e.g.* product tracing or detection). Canada maintains, rather, that the "delays" in approving GA21 maize under Regulation 258/97 are a result of the moratorium on the approval of biotech products.

7.1050 **Argentina** argues that for GA21 maize (food), the risk assessment required by Regulation 258/97 has been completed. However, 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. This means that the process dragged on for a total of 5 years and 2 months since the initial submission of the application without a definitive response.

7.1051 The **European Communities** recalls that in May 2000, the Commission requested the opinion of the SCF. The SCF issued its opinion in February 2002, finding that the application did not contain sufficient information concerning substantial equivalence and toxicity testing, and requested additional information from the applicant.[1018]

[1015] Exhibit EC-91/At. 45, p. 2.
[1016] Exhibit CDA-35-J, p. 2; Exhibit CDA-35-K, p. 2; Exhibit CDA-35-M, p. 11.
[1017] Exhibit CDA-35-K, pp. 11-12; Exhibit EC-91/at.43.
[1018] Exhibit EC-91/At. 17.

7.1052 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 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.

7.1053 Specifically 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 detection and validation 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").

7.1054 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.

7.1055 The **Panel** notes that the lead CA forwarded the application with its positive assessment to the Commission on 21 January 2000. After the circulation of this assessment report to all member States three weeks later, a number of member States submitted comments, requested further data, or raised objections within the 60-day period provided under Regulation 258/97. On 18 May 2000, the Commission requested the SCF to give an opinion regarding potential health concerns related to GA21 maize (food), and to focus specifically on the issues raised in the comments by member States.

7.1056 Shortly after the application was submitted to the SCF, the applicant provided responses to questions from two member States and submitted a revised labelling proposal; all of this possibly new information was, however, available by the end of August 2000. In April 2001, the SCF requested further information from the applicant. The applicant apparently provided the data requested by the SCF within two months. However, another eight months elapsed before the SCF issued its favourable opinion on 27 February 2002.

7.1057 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[1019], and noted that the progress of the application concerning GA21 maize (EC-78) under Directive 90/220 had been suspended for some

[1019] 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]".

time. The applicant was hoping that this move would enable the application under Regulation 258/97 to proceed immediately.[1020]

7.1058 More than a month 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".[1021]

7.1059 The report first addresses the issue of the labelling of foods and food ingredients derived from GA21 maize. It states that the applicant preferred to comply only with the labelling requirements set out in Article 8 of Regulation 258/97, which requires labelling only of foodstuffs where detectable traces of modified DNA or the resulting protein are present (*i.e.*, GM-maize oil was not required to be labelled). According to the report, the applicant believed that this was the scheme which would be in force at the time a decision would be made on this application, and would also avoid that GA21 maize would be treated differently from foods derived from other varieties of GM maize already on the EC market. The report notes that the applicant considered that if and when the labelling scheme was changed, those changes would automatically become obligatory for all authorized foodstuffs derived from any GM-maize variety. However, the Commission observed that it was clear that it would be more difficult to obtain a favourable opinion by a majority of member States if not all foods and food ingredients derived from GA21 maize had to be labelled, recognizing that anticipating the new labelling requirements (before the new legislation was adopted) would require re-consideration of the labelling of foods derived from GM maize already on the market. It was agreed that the Commission and the applicant would meet again to discuss the labelling issue once the European Parliament had debated the proposal for the new legislation in July 2002. There is nothing in the record to indicate that such a meeting took place in July 2002, or that the labelling issue was otherwise pursued further.

7.1060 The report of the meeting then goes on to address the issue of "[d]etection methods, traceability, reference materials [and] identification". The report indicates that the applicant "agreed to provide" the necessary information and materials to the JRC in a timely manner. There is nothing in the record which indicates that this "agreement" from the applicant was not voluntary. The report of the meeting indicates that there should be "no particular problem with respect to the validation. However, the availability of reference material has not been discussed."[1022] 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.

7.1061 In September 2002, another meeting took place between the Commission and the applicant. The report of the meeting indicates that little progress had been made with regard to the validation of a detection method. This was because of a deadlock resulting from a request by the applicant that the method be kept confidential until the date of approval of the application. The report further notes that once a material transfer agreement was reached and a detection method and the necessary materials were available, the validation would take three months.[1023] Apparently, a material transfer agreement was finally signed in late February 2003, but a detection method was not provided until the end of March 2003.[1024] At the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved by the JRC, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

[1020] Exhibit EC-91/At. 44.
[1021] Exhibit EC-91/At. 45.
[1022] Exhibit EC-91/At. 45.
[1023] Exhibit EC-91/At. 46.
[1024] Exhibit EC-91/At. 50.

7.1062 It is clear from the foregoing that after the SCF opinion was issued, the progress of the application was adversely affected by the fact that the Commission waited for more than three months before seeking voluntary commitments from the applicant. As well, the applicant agreed to provide additional information and materials so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. This in turn resulted in further delays, due to the need for validation of a detection method.

7.1063 The Complaining Parties consider that the Commission's failure promptly to submit a draft measure to the Regulatory Committee, without seeking additional commitments from the applicant, reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to suspend approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in April 2002, following the issuance of the SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the Complaining Parties' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1064 In considering the Complaining Parties' contention, we note, first of all, that the Commission could have forwarded a draft measure based on the requirements of Regulation 258/97 only. It did not do so. Instead, the Commission sought voluntary commitments from the applicant with regard to labelling and traceability. The commitments sought were based on legislative proposals for new EC rules on labelling and traceability. In relation to labelling, the Commission specifically pointed out that it would be difficult to obtain a majority without additional commitments. These elements suggest that the Commission wanted to prepare and forward a draft measure which could obtain qualified majority support in the Regulatory Committee or the Council. As pointed out earlier, however, in view of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that no qualified majority could be achieved before the new EC rules on labelling and traceability of GMOs and GMO-derived products were adopted.[1025] It should also be noted in this connection that the record contains no example of an approval procedure, whether it be one conducted under Directives 90/220 and 2001/18 or one conducted under Regulation 258/97, where the Commission adopted its own draft measure prior to the adoption of the new EC rules on labelling and traceability. For these reasons, we consider that the Commission's conduct in the approval procedure concerning GA21 maize (food) is consistent with the Complaining Parties' contention that at least until August 2003 the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications.

7.1065 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (food) to the Regulatory Committee prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

[1025] This view is supported by the fact that Denmark invoked the June 1999 declaration by the Group of Five countries in the approval procedures concerning GA21 maize (food), when raising objections to the lead CA's favourable assessment of the application. Exhibit EC-91/At. 32.

Bt-11 sweet maize (food) (EC-92)

7.1066 A request for the approval of products processed from Bt-11 sweet maize (food) was initially submitted to the Netherlands (lead CA) on 6 April 1998. An amendment submitted on 24 November 1998 extended the scope of the request to cover also the consumption of fresh Bt-11 sweet maize. The documentation for these two requests was joined in a single document, which was submitted to the Commission on 11 February 1999 in accordance with Regulation 258/97. On 12 May 2000, the lead CA forwarded its initial assessment report to the Commission who circulated it to all member States on 15 June 2000. The Commission requested the opinion of the SCF in December 2000; the SCF issued its opinion in April 2002. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1067 Subsequent to the establishment of the Panel, on 10 November 2003, the Regulatory Committee failed to vote on the draft measure submitted by the Commission. On 8 December 2003, the Regulatory Committee voted on the draft measure but failed to reach a qualified majority. On 24 April 2004, the Council failed to reach a qualified majority on the draft measure submitted by the Commission. On 19 May 2004, the Commission adopted its draft measure concerning Bt-11 sweet maize (food).

7.1068 The **United States** notes that Bt-11 sweet maize (food) application was for marketing the maize as a fresh vegetable or after processing, not for cultivation. Moreover, the maize line was derived from an already reviewed and approved version of Bt-11 field maize.[1026] On 10 February 1998, the SCF published an opinion in which it concluded that the use of seed carrying the Bt-11 event was as safe as the use of seed from conventional maize varieties.[1027]

7.1069 The United States argues that following the positive assessment of the SCF in April 2002, there were delays in the processing of this application. The United States notes that the European Communities attempts to justify delays in the processing of the Bt-11 sweet maize (food) application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risk assessment were issued by the Member States, all of which conflicted with the SCF opinion".[1028] 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 in its view submitted during that time period. According to the European Communities' own chronology, the only events that occurred between October to December 2003 were: the finalization of a method validation by the JRC on 2 October 2003;[1029] the applicant's agreement to making public the validation method on 20 October 2003[1030]; a meeting of the Standing Committee on the Food Chain and Animal Health on 10 November 2003;[1031] a comment from France on 27 November 2003;[1032] the vote at the Regulatory Committee on 8 December 2003 (which did not reach a qualified majority);[1033] and a 20 November 2003 letter from the applicant to the Commission releasing technical data.[1034] None of these documents contain any purported risk assessments conducted by

[1026] According to the United States, the key difference between sweet and field maize is that, irrespective of whether it is genetically modified or not, sweet maize has a higher amount of natural sugars.
[1027] Exhibit EC-92/At. 17, p. 1 (referring back to the February 1998 SCP Opinion).
[1028] Responses by the European Communities to the questions posed by the Panel on the 3rd of June, 2004, Response to Question 1.
[1029] Exhibit EC-92/At. 66.
[1030] No document available per the European Communities' chronology.
[1031] Exhibit EC-92/At. 67 (misdated in the EC chronology as November 8).
[1032] Exhibit EC-92/At. 69.
[1033] Exhibit EC-92/At. 70.
[1034] Exhibit EC-92/At. 68.

France, Austria, or Belgium. At the 10 November 2003 meeting of the Standing Committee on the Food Chain and Animal Health,[1035] only a comment was provided by France, not a risk assessment.[1036] At the Regulatory Committee meeting on 8 December 2003, Austria[1037], Belgium[1038] and France[1039] 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 in December 2003 it was because certain member States objected due to the proposed new traceability and labelling regulations (which did not become effective until April 2004).[1040]

7.1070 In May 2004, the novel food application for Bt-11 sweet maize was finally approved. The United States contends that the history of this application confirms the delays resulting from the moratorium, and its ultimate approval does not indicate that the moratorium has finally ended. Rather, in the view of the United States, the Bt-11 approval in May 2004 is entirely consistent with, and in fact supports, the existence of a general moratorium during the period covered within the Panel's terms of reference. Both the Commission and the Council have stated that the entry into force of the new traceability and labelling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on 19 April 2004. The United States considers that the fact that the Commission then approved the application concerning Bt-11 sweet maize (food) just one month later is not mere coincidence. To the contrary, this timing indicates that the EC approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, the United States emphasizes that the Council itself acknowledged the existence of the "moratorium" – using this very word – in a statement concerning the scheduled approval of the application concerning Bt-11 sweet maize (food).[1041]

7.1071 **Canada** argues that Bt-11 sweet maize is one of six products whose approval was delayed for as long as five years, despite having received a favourable assessment from the lead CA, and, in the case of this product, having also received a positive assessment from the SCF. Canada notes that the Regulatory Committee held a vote on the application concerning Bt-11 sweet maize (food) on 8 December 2003, after the establishment of the Panel. However, the Regulatory Committee failed to obtain the qualified majority necessary for approval, despite having received a favourable opinion from the SCF.

7.1072 Canada further argues that it is unjustifiable to fail to approve products under Regulation 258/97 on the basis that the existing legislation does not provide for risk management

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[1035] Exhibit EC-92/At. 67.

[1036] 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.

[1037] Exhibit EC-92/At. 71.

[1038] Exhibit EC-92/At. 73.

[1039] Exhibit EC-92/At. 72.

[1040] Exhibit EC-92/Ats. 67 (noting that "[f]inally, 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 and 76.

[1041] EC first written submission, para. 157.

measures, where the risk assessments for those products have not identified any risks that need to be managed. The SCF concluded in April 2002 that Bt-11 sweet maize (food) is as safe for human food use as its conventional counterparts.[1042]

7.1073 In relation to the Commission's decision of May 2004 to approve the placing on the market of Bt-11 sweet maize (food), Canada observes that the Commission has been forced to adopt a decision authorizing Bt-11 sweet maize (food) only after resort to the exceptional Regulatory Committee procedure. Despite favourable opinions of EFSA and despite the entry into force of the new legislative regime,[1043] member States voted against the Commission's proposal for the approval of the product in question at the Regulatory Committee stage. Moreover, the Council failed to act. Far from demonstrating that the moratorium has been lifted, the fact that approval is granted only at the last possible step is another indication of the existence of the moratorium.

7.1074 **Argentina** argues that although some products, including Bt-11 sweet maize (food), received positive scientific opinions under Regulation 258/97, approval of these products was nonetheless stalled, both before reaching the Regulatory Committee stage and within that stage.

7.1075 The **European Communities** notes that following the submission of this application to the Netherlands in 1999, the lead CA requested additional information relating mainly to the antibiotic resistance marker used (PAT protein) and to the toxicity studies done in relation to this protein. 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 above issues as well as to molecular characterization. The Commission requested an 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.

7.1076 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 of information, 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. Following the finalization of the validation method, the Commission prepared a proposal for a decision on a market authorization. The proposal did not obtain a qualified majority in the Regulatory Committee or in the Council and was adopted by the Commission on 19 May 2004.

7.1077 The European Communities argues that the history of the application concerning Bt-11 sweet maize (food) is an illustration of the fact that the approval process has been steadily proceeding over the past years. The marketing authorization of Bt-11 sweet maize (food) did not occur because of a sudden change in the European Communities' policy on GMOs, but as the result of a normal process of assessment, which has known no suspension and has been conducted taking into account the

[1042] Exhibit CDA-35-J, pp. 9-10.

[1043] Regulation 1829/2003 (GM food and feed) (Exhibit CDA-20) and Regulation 1830/2003 (traceability and labelling) (Exhibit CDA-30) entered into force on 18 April 2004.

reactions of the applicants, the constant evolution of the scientific and regulatory debate concerning GMOs and the entry into force of new legislation resulting from this debate.

7.1078 The **Panel** notes that the lead CA forwarded the application with its positive assessment to the Commission on 12 May 2000. After the circulation of this assessment report to all member States, a number of member States submitted comments, requested further data, or raised objections within the 60-day period provided under Regulation 258/97. On 13 December 2000, the Commission requested the SCF to give an opinion regarding potential health concerns related to Bt-11 sweet maize (food), and to focus specifically on the issues raised in the comments by member States. The SCF apparently considered the application for four months before requesting further information from the applicant on 15 April 2001. It appears that no response was forthcoming from the applicant, and on 12 November 2001 the SCF reminded the applicant that it was awaiting information requested in April. The applicant apparently replied that it expected to provide the requested data in January 2002. On 17 April 2002, the SCF issued its report with the conclusion that Bt-11 sweet maize (food) is as safe for human food use as its conventional counterparts.

7.1079 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".[1044]

7.1080 The report of the meeting addresses the issue of "[d]etection methods, traceability, reference materials [and] identification". The report indicates that the applicant "agree[d] to provide" the necessary information and materials to the JRC in a timely manner.[1045] 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.

7.1081 Apparently, the applicant did not transfer any material until late January 2003. Following unsatisfactory results of the detection methods validation, and further provision of materials for the validation, in January 2003 the JRC indicated that it would provide a template protocol for the validation for use by the applicant.[1046] The JRC continued to find the results unacceptable, and in July 2003 the applicant accepted to use the method proposed by the JRC and submitted materials.[1047] The JRC finalized its method validation in October 2003.[1048] Thus, at the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved by the JRC, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.1082 It is clear from the foregoing that after the SCF opinion was issued the progress of the application was adversely affected by the fact that the Commission waited for more than a month and a half before seeking voluntary commitments from the applicant. As well, the applicant agreed to provide additional information and materials so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. This in turn resulted in further delays, due to the need for validation of a detection method.

[1044] Exhibit EC-92/At. 54.
[1045] *Ibid*.
[1046] Exhibit EC-92/Ats. 56 and 57.
[1047] Exhibit EC-92/Ats. 59 and 63.
[1048] Exhibit EC-92/At. 66.

7.1083 In its responses to questions by the Panel, the European Communities submits that another reason for the delay in the forwarding of a draft measure to the Regulatory Committee was the circumstance that between October and early December 2003 new risk assessments were issued by Austria, Belgium and France, all of which, according to the European Communities, conflicted with the SCF opinion. We note that this explanation concerns a period of time that post-dates the date of establishment of this Panel, and we will therefore not consider this explanation.

7.1084 The Complaining Parties consider that the fact that the Commission did not promptly submit a draft measure to the Regulatory Committee, without seeking additional commitments from the applicant, reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to suspend approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in April 2002, following the issuance of the SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the Complaining Parties' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1085 In considering the Complaining Parties' contention, we note, first of all, that the Commission could have forwarded a draft measure based on the requirements of Regulation 258/97 only. It did not do so. Instead, the Commission sought voluntary commitments from the applicant. The commitments sought were based on legislative proposals for new EC rules on labelling and traceability of GMOs and GMO-derived products. These elements suggest that the Commission wanted to prepare and forward a draft measure which could obtain qualified majority support in the Regulatory Committee or in the Council. As pointed out earlier, however, in view of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that no qualified majority could be achieved before the new EC rules on labelling and traceability of GMOs and GMO-derived products were adopted.[1049] It should also be noted in this connection that the record contains no example of an approval procedure, whether it be one conducted under Directives 90/220 and 2001/18 or one conducted under Regulation 258/97, where the Commission adopted its own draft measure prior to the adoption of the new EC rules on labelling and traceability. We recall that in the case of the application concerning Bt-11 sweet maize (food), the Commission adopted its own draft measure only after the entry into force of the new EC rules. For these reasons, we consider that the Commission's conduct in the approval procedure concerning Bt-11 sweet maize (food) is consistent with the Complaining Parties' contention that at least until August 2003 the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications.

7.1086 We note the European Communities' argument that the approval of the application concerning Bt-11 sweet maize (food) did not occur because of a sudden change in the European Communities'

[1049] This view is supported by the fact that Denmark and France invoked the June 1999 declaration by the Group of Five countries in the approval procedures concerning Bt-11 sweet maize (food), when raising objections to the lead CA's favourable assessment of the application. Exhibit EC-92/Ats. 23 and 27. We also note that even after the adoption of the new EC rules in September 2003, neither the Regulatory Committee in its December 2003 vote nor the Council in its April 2004 vote achieved a qualified majority in favour of the application concerning Bt-11 sweet maize (food).

policy on GMOs, but as the result of a normal process of assessment, which steadily proceeded and knew no suspension. We recall that the Complaining Parties' contention is that the European Communities was applying a general moratorium on final approvals. Thus, "steady progress" of an application short of final approval is not inconsistent with the Complaining Parties' contention. As of August 2003, the application concerning Bt-11 sweet maize (food) had not yet been approved by the Commission. The application was only approved after the entry into force of the new EC rules on labelling and traceability in April 2004, and then only after every procedural step had been exhausted. Neither the Regulatory Committee nor the Council achieved a qualified majority in favour of the application.

7.1087 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Bt-11 sweet maize (food) to the Regulatory Committee prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic tomato (food) (EC-100)

7.1088 The application concerning the Transgenic tomato (food) was initially submitted to the United Kingdom (lead CA) and to the Commission on 2 March 1998. The lead CA forwarded its initial assessment to the Commission on 4 June 1998, and this was circulated to all member States on 22 June 1998. On 23 December 1998, the SCF was requested to evaluate the application; the opinion of the SCF was given on 7 September 2000. The application was withdrawn by the applicant on 24 September 2001.

7.1089 The **United States** argues that after this application received a positive assessment from the SCF, the application was withdrawn because of the excessive delay in carrying out the approval process.

7.1090 The **European Communities** contends that after assessment at the national level, the request was withdrawn by the applicant. As the reason for its withdrawal, the applicant pointed to "commercial re-positioning" following a merger.

7.1091 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.1092 The **Panel** notes that the initial assessment by the lead CA was completed well within the 90-day time period established in Regulation 258/97. Following the circulation of the initial positive assessment to member States, a number of member States submitted comments and objections. On 23 December 1998, after further comments from other member States had been submitted, and responses provided by the applicant, the Commission requested an opinion of the SCF.

7.1093 On 23 September 1999, the SCF gave its opinion and concluded that from the human health point of view, processed tomato products derived from these tomatoes were as safe as products from conventional fruit.[1050] The next step in the procedure was for the Commission to prepare and submit a

[1050] Exhibit EC-100/At. 48.

draft measure on the application to the Regulatory Committee. However, there is no evidence of this step being completed during the eleven months following the SCF opinion.

7.1094 On 7 September 2000, the SCF issued another opinion on the application concerning the Transgenic tomato (food).[1051] Apparently, the Commission had requested this further opinion to obtain the SCF's comments on the relevance of particular studies undertaken in the United States on transgenic tomatoes for fresh consumption. This request was apparently prompted by a question to the Commission from a member of the European Parliament. The SCF concludes that these results have no relevance for the assessment of the safety of the processed tomato products which were to be approved in accordance with the application concerning the Transgenic tomato (food).

7.1095 Even after this second positive assessment by the SCF, the Commission did not forward a draft measure to the Regulatory Committee before the application was withdrawn by the applicant more than one year after the second positive opinion by the SCF. As noted by the European Communities, in the letter of withdrawal the applicant made reference to recent mergers and to its commercial re-positioning.[1052]

7.1096 It is clear from the foregoing that the application concerning the Transgenic tomato (food) did not progress because the Commission did not forward a draft measure to the Regulatory Committee. The SCF gave a favourable opinion of the application on two separate occasions, and no reasons for the lack of progress were provided to us.

7.1097 The United States considers that the Commission's failure, over a period of more than two years, to submit a draft measure to the Regulatory Committee reflects the adoption by the European Communities of a general moratorium on approvals, that is to say, of a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to prevent approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in September 1999, following the issuance of the first SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the United States' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1098 We consider that the Commission's conduct in the approval procedure concerning the Transgenic tomato (food) is consistent with the contention that the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications. In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning the Transgenic tomato (food).

[1051] Exhibit EC-100/At. 49.
[1052] Exhibit EC-100/At. 50.

7.1099 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning the Transgenic tomato (food) to the Regulatory Committee prior to the withdrawal of the application in September 2001 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Failure by the Scientific Committee on Food to complete its review

7.1100 In support of its assertion that the European Communities applied a general moratorium on approvals, the United States has pointed to two approval procedures in which it says the Scientific Committee for Food (SCF) which the Commission consulted with regard to these applications did not complete its review. We consider these approval procedures below, recalling that Article 11 of Regulation 258/97 provides that "[t]he Scientific Committee for Food shall be consulted on any matter failing within the scope of this Regulation likely to have an effect on public health".

Transgenic red-hearted chicory (food) (EC-97)

Transgenic green-hearted chicory (food) (EC-98)

7.1101 The applications concerning Transgenic red-hearted chicory (food) and Transgenic green-hearted chicory (food) for human consumption were initially submitted to the Netherlands (lead CA) in April 1998. The lead CA provided initial positive assessments for both products to the Commission on 23 April 1998, which was circulated to member States as drafts on 13 May 1998. On 27 October 1998, the Commission informed member States that the initial assessments were not draft texts, and that the lead CA was not undertaking any further assessment. A large number of member States submitted comments or objections on these applications, and on 29 April 1999 the Commission requested the SCF to give an opinion. The SCF considered both products at the same time in its evaluation. No opinion had been issued by the SCF at the time these applications were withdrawn on 27 May 2003.

7.1102 The **United States** argues that although these products received favourable initial assessments by the lead CA, as of May 2003, when the application for both was withdrawn, the products had been "under assessment" by the SCF for more than five years. The United States contends that these withdrawn applications are direct evidence of the existence of a general moratorium, and that the withdrawal evinces the applicant's frustration with the suspension of the EC approval process.

7.1103 The **European Communities** notes that after assessment of these products by the lead CA, the request was withdrawn by the applicant with the indication that the applicant preferred to no longer be associated with genetically modified products because of the negative response from the market.

7.1104 The **Panel** notes that the initial assessments by the lead CA were made within the 90-day period foreseen for this purpose under Regulation 258/97. Delays in the consideration of the applications for these two products occurred primarily in the course of the evaluation by the SCF. For example, more than four months went by after the SCF received the request by the Commission to evaluate these products before the SCF requested better quality images of certain analytical results from the applicant. The information provided does not indicate when or if the applicant provided the requested data, but only that, two months later, the SCF requested additional information, and after a 7-month delay, the SCF requested that the applicant provide studies covering two growing seasons and at least six locations. The applicant apparently instead offered to provide data from previous growing seasons, which the SCF indicated might be acceptable.

7.1105 In a communication to the SCF of 14 November 2000, the applicant expressed very apparent frustration with the progress of evaluation of these two products.[1053] The applicant noted that much information had been provided to permit the determination of substantial equivalence between the transgenic chicory and conventional chicory, and expressed the view that "it does not make sense to continue year after year with experiments without having any indication that there is no substantial equivalence".[1054] The applicant also expressed concern that since the SCF had not indicated whether it would accept the new experiments as proposed by the applicant, "this might be a new reason for the SCF to ask the company to do new experiments after the proposed experiments have been finished".[1055] The alternative suggested by the SCF would require the applicant to apply for additional field trials in several countries, and the applicant indicated that it would take at least one year to get permission from all competent authorities. The total process would thus take at least three additional years, and the applicant indicated that this would have negative financial implications. The applicant indicated that it had reached the conclusion that the applications for the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) were a kind of "never ending story", and that "the procedure, time energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity."[1056] The applicant nevertheless provided additional information from various years of field introductions to substantiate its claims of substantial equivalence, and requested that the SCF extract its conclusions and take decisions based on the information now available to it.

7.1106 Five months after the November 2000 communication from the applicant, the SCF informed the applicant that it would accept the data provided regarding field studies, and requested additional information regarding nutritional composition.[1057] The applicant indicated, in response, that it had not yet decided whether to execute additional experiments. It expressed concern that the question regarding antibiotic resistance markers would need to be resolved before new experiments were started, and requested clarification regarding whether products containing antibiotic resistance markers would be permitted to enter the EC market after the entry into force of Directive 2001/18.[1058] In a response dated 24 July 2001, the Commission indicated that the provisions of Directive 2001/18 did not include a general legal ban on antibiotic resistance marker genes as such but linked their phasing out to certain qualifiers. The Commission also indicated that consideration of the applications for the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) was suspended until the requested information on nutritional composition had been provided.[1059] The record does not include any further response from the applicant until the formal withdrawal of the applications on 27 May 2003.[1060] However, the European Communities asserts that the SCF was requested as early as 24 September 2001 to suspend its consideration of the applications concerned.

7.1107 We sought the views of the experts advising us regarding the necessity of the information requested by the SCF on substantial equivalence, molecular characterization and antibiotic resistance marker genes to ensure that the safety assessment was valid.[1061] The only expert who provided a

[1053] Exhibits EC-97/At. 25 and EC-98/At. 35.
[1054] *Ibid.*
[1055] *Ibid.*
[1056] *Ibid.*
[1057] Exhibits EC-97/At. 28 and EC-98/At. 38.
[1058] Exhibits EC-97/At. 29 and EC-98/At. 39.
[1059] Exhibits EC-97/At. 31 and EC-98/At. 41.
[1060] Exhibits EC-97/At. 32 and EC-98/At. 42.
[1061] Annex H, Question 55 and 56.

response to this question, Dr. Nutti, considered that the information requested regarding the establishment of substantial equivalence was necessary, and that the information requested on nutritional composition was also required.[1062]

7.1108 The United States considers that the SCF's failure, for more than two years, to complete its assessment of the applications in question reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We note that the United States does not assert that the SCF was an active participant in the alleged moratorium on approvals and that the time taken by the SCF for its assessment is a reflection of the SCF's support for the moratorium. We understand the United States to argue instead that the alleged general moratorium on approvals affected the manner in which, and the speed with which, the SCF conducted its assessments of the applications in question.

7.1109 It is reasonable to assume that the SCF was aware of the June 1999 declaration by the Group of Five countries, and thus of their declared intention to act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[1063] In our view, it can further be assumed that the SCF was aware of the failure by the Commission in the approval procedure concerning the Transgenic tomato (food) to submit a draft measure to the Regulatory Committee following the two positive SCF opinions. Against this background, it is conceivable that the SCF could have been requesting more information than it would otherwise have requested, notwithstanding the fact that such requests could be expected to result in delays.

7.1110 The November 2000 communication from the applicant, referring to a "never ending story", clearly documents the applicant's frustration with the long delays and repeated requests for information. This communication is therefore consistent with the possibility that the progress of the SCF's assessment was affected by the alleged general moratorium on approvals. In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food).

7.1111 On the other hand, the record shows that in other approval procedures, and during the relevant time period, the SCF completed its assessment of applications within a shorter timeframe.[1064] Furthermore, we recall the advice of Dr. Nutti that the information requested by the SCF may be considered necessary to ensure that the conclusions of the safety assessment of the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) were valid. However, even if it is accepted that the time taken by the SCF may be explained by the need for valid conclusions, this would not contradict the United States' assertion that the European Communities applied a general moratorium on approvals. In June 1999, the Group of Five countries indicated that they would act as a "blocking minority" in the Regulatory Committee and in the Council, and we recall that in the approval procedure concerning the Transgenic tomato (food), the Commission failed to discharge its

[1062] Annex H, paras. 759-760.
[1063] We recall that the Commission made a proposal for such rules in July 2001.
[1064] *See, e.g,* the approval procedure concerning Bt-11 sweet maize (food), where an SCF opinion was requested in December 2000 and provided in April 2002. During that period, the clock was stopped for several months. Exhibit EC-92/Ats. 47-53.

responsibility inasmuch as it did not submit a draft measure to the Regulatory Committee. These acts and omissions affect and concern stages of the approval procedure subsequent to the SCF's involvement. The applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) had not reached these stages as of September 2001, when the SCF was apparently requested to suspend its work.

7.1112 In the light of the above considerations, we conclude that the failure of the SCF to complete its assessment of the applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) prior to September 2001, when the SCF was apparently requested by the applicant to suspend its work, is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Delays at member State level

7.1113 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which they say the member State to which the application was submitted – the lead CA – either did not complete its assessment of the relevant application or completed it with considerable delay. We consider these approval procedures below, recalling that Article 6(3) of Regulation 258/97 provides that "[t]he initial assessment report [by the lead CA] shall be drawn up within a period of three months from receipt of [the application]". Article 6(4) further provides that the lead CA "shall without delay forward the [initial assessment report] to the Commission, which shall forward it to the other Member States."

GA21 maize (food) (EC-91)

7.1114 The application for GA21 maize (food) was submitted to the Netherlands CA (lead CA) on 24 July 1998. The initial assessment of the lead CA was provided to the Commission on 21 January 2000, and circulated to member States on 18 February 2000. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1115 The **United States** argues that the application for GA21 maize (food) under Regulation 257/98 was delayed at the member State level for 18 months while the lead CA completed its risk assessment. The lead CA requested the applicant to perform a further study on compositional analysis. The request was made on 24 February 1999, and the applicant provided its response by 26 October 1999.[1065] Thus, the total time between the first submission, 24 July 1998, and the lead CA's opinion, 17 January 2000, was 18 months. Of those 18 months, 8 were used by the applicant to answer questions.

7.1116 **Canada** argues that the total time taken by the lead CA for its review was 18 months, and that only 8 of the 18 months were taken by the applicant to respond to questions. The difference of 10 months exceeds the 3-month period provided for in Regulation 258/97.

7.1117 The **European Communities** argues that this application was pending at the member State level for about a year and a half due to requests by the lead CA for completion of the dossier and for additional scientific data. The United States ignores the fact that the 18 months spent at member State level were due to the incompleteness of the dossier initially submitted by the applicant and to the need for additional scientific data.[1066]

[1065] Exhibit EC-91/Ats. 11 and 14.
[1066] The European Communities refers to Exhibit EC-91/Ats. 1-6.

7.1118 The **Panel** notes from the record that this application was submitted to the Netherlands in July 1998. A month and a half later, the applicant was apparently requested to complete the dossier. The applicant seems to have provided the missing information in December 1998, although some references were provided only in January 1999. In February 1999, the Dutch Health Council put forward its first substantive request for information. The applicant provided the requested information in March 1999. In June 1999, the Health Council informed the applicant that it needed more data than that provided by the applicant in March. The applicant provided the data in October 1999. The Health Council completed its assessment in December 1999, and the Dutch CA forwarded its initial assessment report in January 2000.

7.1119 We note that the record for this approval procedure is incomplete, but it appears that the Dutch CA did not have a reasonably complete file until December 1998. We also note, however, that the Dutch CA then waited for almost three months before forwarding an initial request for information. After receiving the requested information, the Dutch CA again waited for almost three months before making a follow-up request for more data. Finally, after obtaining the necessary data, the lead CA spent another period of almost three months finalizing its assessment. It is clear, therefore, that the lead CA exceeded the three-month period foreseen in Regulation 258/97 for an initial assessment.

7.1120 The United States and Canada do not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, their assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. According to the United States and Canada, the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1121 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note, however, that the lead CA's initial request for additional information and its follow-up request for more data were made in February and early June 1999, respectively, and thus pre-date the June 1999 declaration of the Group of Five countries. On the other hand, it was after the June 1999 declaration that the lead CA spent an additional three months finalizing its initial assessment report.

7.1122 We also note, however, 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. In particular, we are not convinced that the Dutch CA could not forward its June 1999 follow-up request for more data sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not finalize its initial assessment earlier than in January 2000.

7.1123 It is pertinent to note in this regard that the applicant had submitted two other applications concerning the same product under Directive 90/220, one to the United Kingdom (GA21 maize (EC-85)) and one to Spain (GA21 maize (EC-78)). By the time the Dutch CA was finalizing its assessment report, the two Directive 90/220 applications were under assessment at Community level. As we have noted, following the June 1999 declaration by the Group of Five countries, the Dutch CA in our view had reason to believe that at Community level the Group of Five countries and/or the Commission could take action to delay or prevent the final approval of these applications. Since a

special environmental safety assessment was necessary for the application concerning GA21 maize (food) to be approved under Regulation 258/97[1067], we think it could also be that the time taken by the Dutch CA before forwarding its initial assessment report in January 2000 reflects a view on the part of the Dutch CA that the Directive 90/220 applications concerning GA21 maize would be delayed at Community level.

7.1124 In the light of the above considerations, we conclude that the time taken by the Netherlands for its initial assessment of the application concerning GA21 maize (food), and in particular the time taken by the lead CA as from October 1999 to finalize its initial assessment report, is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (food) (EC-93)

7.1125 The application concerning LL soybeans (food) was submitted to Belgium on 30 November 1998. The application was sent to the Commission on 2 February 1999. At the time of establishment of the Panel, the lead CA had not completed its assessment of the application. In July 2004, the applicant withdrew the application.

7.1126 The **United States** submits that Belgium refused to forward the application for LL soybeans (food) for consideration at the Community level.

7.1127 **Argentina** argues that there was an overall delay of 5 years and 8 months since the application was submitted.

7.1128 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.[1068] 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.[1069] 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.

7.1129 The European Communities submits that the Complaining Parties 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 points out that on 6 July 2004, the applicant withdrew its application.

7.1130 The **Panel** notes 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

[1067] We note that the application concerning GA21 maize (food) as submitted to the Dutch CA *inter alia* concerned foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

[1068] Exhibit EC-93/At. 11.

[1069] Exhibit EC-93/Ats. 16 and 17.

of February 1999.[1070] 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.

7.1131 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.[1071]

7.1132 In March 1999, the Commission circulated the application for information to all member States. The chronology provided by the European Communities indicates that Denmark requested further information from the applicant at that time, however this correspondence was not provided to us.

7.1133 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.[1072] 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.[1073]

7.1134 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 from April 1999.[1074] 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.[1075] The record indicates that as of August 2003, the applicant had still not fully replied to the first request relating to substantial equivalence.[1076] 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.[1077]

7.1135 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

[1070] Exhibit EC-93/Ats. 1 and 3.
[1071] Exhibit EC-93/At. 11.
[1072] *Ibid.*
[1073] Annex H, Dr. Nutti's response to Panel Question 48.
[1074] Exhibit EC-93/At. 14.
[1075] Exhibit EC-93/At. 13.
[1076] Exhibit EC-93/At. 25.
[1077] *Ibid.*

were justified.[1078] 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.[1079] 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.[1080]

7.1136 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.[1081] 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.

7.1137 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.[1082]

7.1138 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.

7.1139 This said, as noted earlier, it appears that the applicant never fully replied to the lead CA's April 1999 request for additional information. It also seems that the responses which were given 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.

7.1140 In considering the applicant's conduct, and in particular its failure to respond to the August 2001 request for clarification, it is important to recall that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also being evaluated by Belgium. As we have noted earlier, however, the consideration of that application – the application concerning LL soybeans (EC-71) – appears to have been suspended as from September 2001 as a result of the applicant's refusal to discontinue another Directive 90/220 application concerning the

[1078] Annex H, Dr. Nutti's response to Panel Question 49.
[1079] Exhibit EC-93/At. 21.
[1080] Exhibit EC-93/At. 22.
[1081] Annex H, Dr Nutti's responses to Panel Question 50.
[1082] Exhibit EC-93/At. 25.

same product, which had been submitted to Portugal. Directive 90/220 was repealed in October 2002. The applicant withdrew its application from Portugal and submitted an updated application to Belgium. Belgium then continued its consideration of the application under Directive 2001/18 as of February 2003.

7.1141 We further recall that Article 9(2) of Regulation 258/97 provides that decisions approving the placing on the market of foods or food ingredients containing or consisting of GMOs 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 noted, the environmental safety assessment under Directive 90/220 was suspended as of September 2001. Since a specific environmental safety assessment was necessary for the application concerning LL soybeans (food) to be approved under Regulation 258/97, it seems plausible that the applicant did not see much use in seeking progress in the Regulation 258/97 procedure as long as the Directive 90/220 procedure was suspended. In relation to the application concerning LL soybeans (EC-71), we said earlier that the fact that Belgium suspended consideration of that application – in response to the applicant's refusal to discontinue one of the two Directive 90/220 applications – does not directly confirm that a general moratorium was in effect in the European Communities.

7.1142 Nevertheless, we consider that the history of the approval procedure concerning LL soybeans (food) at the member State level is consistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. We recall in this regard that in June 1999, the Group of Five countries indicated that they would act as a "blocking minority" in the Regulatory Committee and in the Council, and that in the approval procedure concerning the Transgenic tomato (food), the Commission after October 1999 failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Regulatory Committee following the first SCF opinion of September 1999. These acts and omissions affect and concern the Community level phase of the approval procedure under Regulation 258/97. However, the application concerning LL soybeans (food) as of August 2003 had not reached the Community level.

7.1143 In the light of the above considerations, we conclude that the record of the progress of the application concerning LL soybeans (food) at the member State level is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

MON810 x GA21 maize (food) (EC-94)

7.1144 The application concerning MON810 x GA21 maize (food) was submitted to the Netherlands (lead CA) on 29 February 2000. A summary of the file was circulated by the Commission to all member States on 29 March 2000. At the time of establishment of the Panel, the lead CA had not completed its initial assessment.

7.1145 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.

7.1146 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[1083] and was notified in 1998 on the basis of an opinion of substantial equivalence as required under Regulation 258/97 in 1998.[1084] 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]."[1085] At the time of establishment of the Panel, the approval of GA21 maize (food) under Regulation 258/97 had not yet been granted.

7.1147 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.[1086] 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.

7.1148 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.[1087] 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.

7.1149 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.[1088] The lead CA also

[1083] 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).

[1084] Exhibit US-132.

[1085] Exhibit EC-94/At. 11.

[1086] Exhibit EC-94/At. 12.

[1087] Exhibit EC-82/At. 9.

[1088] 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).

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 transgenic parental lines.[1089] 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.

7.1150 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.[1090] 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."[1091] 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.

7.1151 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).

7.1152 **Canada** argues that the application is still pending with the lead CA.

7.1153 The **European Communities** argues that the lead CA requested additional information from the applicant in July 2000, however the 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. Since the request was made on valid grounds, the delay caused by it cannot be considered "undue." Furthermore, issues such as molecular characterization of inserted DNA from transgenic parent lines, the determination of flanking DNA or compositional analysis still remain unanswered. Finally, 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.

7.1154 The **Panel** notes that under Regulation 258/97 the initial assessment report is to be drawn up by the lead CA within a period of three months from receipt of an application meeting the applicable conditions. When the Commission circulated notice of this application to all member States on 29 March 2000, it indicated that the initial assessment was to be completed by 16 June 2000 at the latest.[1092] However, the lead CA's assessment had not been completed by the time of the establishment of the Panel, that is, three and a half years after submission of the application.

[1089] Exhibit EC-94/At. 2.
[1090] Exhibit EC-94/At. 10.
[1091] *Ibid.*
[1092] Exhibit EC-94/At. 5.

7.1155 The first indication of any contact from the lead CA was a request for additional data sent to the applicant on 17 July 2000.[1093] No specific explanation has been provided as to why this information was not requested much sooner, rather than one month after the normal deadline for completion of the assessment. The response to the July 2000 request was provided by the applicant only on 15 February 2002. Subsequently, there was a five-month delay before the lead CA followed up with the applicant to request additional information on 2 July 2002. No specific explanation has been provided for this further delay. Furthermore, 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.

7.1156 We sought the views of the experts advising us regarding the necessity of the information requested by the lead CA in July 2000 to ensure that the conclusions of the safety assessment were valid.[1094] Dr. Nutti addressed the lead CA's requests regarding the EPSPS protein, the effect of glyphosate treatment on the composition of maize plants, the additional information on the composition of the hybrid, and the additional toxicological feeding study. Dr. Nutti did not consider that any of this requested information was necessary to ensure the validity of the safety assessment, in light of the information already provided in the application and already known about the parental lines. In her view, the responses provided by the applicant in February 2002 confirmed the data previously submitted.[1095] Dr. Andow addressed the requests regarding the effect of glyphosate treatment and toxicology. In his view, the request regarding the glyphfosate treatment was necessary, as he believes the applicant had provided an incorrect statistical analysis. With regard to the toxicology request, Dr. Andow considered that the underlying concern was valid, but he considered that the applicant should have been able to address this concern through other means, and the request for toxicity testing was not necessary to ensure that the conclusions of the safety assessment were valid for MON810 x GA21 maize.[1096]

7.1157 We are cognizant of the fact that the European Communities disagrees with some of the responses by the experts. The European Communities notes that the results of the additional studies were required to confirm the information provided in the application, and that there are different regulatory approaches regarding the comparisons of a GM hybrid and the data requirements needed to assess the safety of these hybrids. In particular, the European Communities argues that the fact that the approach of the lead CA differs from the one preferred by the Panel's experts does not mean it is not valid. Furthermore, the European Communities submits that the lead CA requested information on additional substances in light of the information that had just become available regarding the presence of unintended DNA fragments in a genetically modified glyphosate-resistant soybean.

7.1158 We accept that different regulatory practices may result in differences in perceptions as to what information is necessary to a safety assessment. However, 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 still would not explain the long delays in responses by the lead CA both before and after the July 2000 request.

7.1159 The United States argues that these delays reflect the alleged general moratorium on final approvals. More particularly, the United States contends that the delay in the application for MON810 x GA21 maize (food) was a direct consequence of the delays in the applications for GA21 maize (EC-78) and GA21 maize (food) under the moratorium. We recall that the United States does

[1093] Exhibit EC-94/At. 12.
[1094] Annex H, question 44.
[1095] Annex H, paras. 682-687.
[1096] Annex H, para. 700.

not assert that the time taken by the Netherlands in its assessment of the application concerning MON810 x GA21 maize (food) is a reflection of its support for the alleged moratorium. Rather, the United States asserts that the Netherlands was placed in a position of having to recognize the moratorium as a reality, and that this affected the speed with which it conducted its assessment.

7.1160 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note in this regard that in 2000, when the application concerning MON810 x GA21 maize (food) was submitted, the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food) were both under assessment at Community level. In relation to these single trait parent applications, we have previously noted that the Commission in both procedures failed to submit a draft measure concerning these applications to the Regulatory Committee prior to August 2003, and that this is consistent with the assertion that the European Communities applied a general moratorium on final approvals.

7.1161 Against this background, and in particular in view of the situation with regard to the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food)[1097], we consider that the Netherlands could have come to the conclusion that there was no realistic prospect that the single trait parent applications concerning GA21 maize would be approved prior to the date of repeal of Directive 90/220, and that as long as they were not approved the hybrid application concerning MON810 x GA21 maize (food) would likewise not be approved.[1098] In our view, the time taken by the Netherlands both before and after its July 2000 request for information is therefore consistent with the existence of a general moratorium on approvals.

7.1162 We note 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 forward its July 2000 and July 2002 requests to the applicant sooner than it did even while following a precautionary approach.

7.1163 Regarding the fact that the applicant took more than a year and a half to provide its response to the lead CA's July 2000 request, and that it did not respond to the July 2002 request for information, we consider this is consistent with the United States' suggestion that the applicant thought that the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food) were being delayed at Community level as a result of the alleged moratorium and that the applicant therefore saw little value in actively pursuing the hybrid application for MON810 x GA21 maize (food).

7.1164 In the light of the above considerations, we conclude that the time taken by the Netherlands for its assessment of the application concerning MON810 x GA21 maize (food) is consistent with the

[1097] Since these applications were at Community level, it is reasonable to assume that the Dutch CA was aware of the relevant situation.

[1098] We note that the application concerning MON810 x GA21 maize (food) referenced Article 9 of Regulation 258/97 which applies to foods or food ingredients containing or consisting of GMOs and which requires that the approval decision respect the environmental safety requirements laid down in Directive 90/220.

Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Bt-1507 maize (food) (EC-95)

7.1165 The application concerning Bt-1507 maize (food) was submitted to the Netherlands (lead CA) on 15 February 2001. At the time of establishment of the Panel, the lead CA had not completed its initial assessment. This assessment was completed on 4 November 2003, and the report circulated to all member States by the Commission on 10 December 2003.

7.1166 The **United States** argues that the lead CA refused to forward this application to the Commission.

7.1167 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 characterisation, 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.

7.1168 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.

7.1169 The **Panel** recalls that according to Regulation 258/97, an initial assessment report is to be drawn up by the lead CA within a period of three months from receipt of an application meeting the applicable conditions. In this case, this initial assessment was not completed until 4 November 2003, that is, almost three years after receipt of the application. We note, however, that an initial request for additional data was made by the lead CA on 28 June 2001, that is four months following receipt of the application.[1099] The applicant apparently provided some information in November 2001, although this was not given to us, but did not provide all of the information requested until 12 February 2003.[1100] In March 2003, the lead CA requested further clarifications, which were provided in May 2003.[1101] In June 2003, the lead CA posed questions in relation to the applicant's May 2003 reply.[1102] The applicant provided answers by 9 July 2003.[1103] 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.

7.1170 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

[1099] Exhibit EC-95/At. 8.
[1100] Exhibit EC-95/At. 12.
[1101] Exhibit EC-95/Ats. 13 and 14.
[1102] Exhibit EC-95/At. 15.
[1103] Exhibit EC-95/At. 16.

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.[1104] Dr. Nutti responded to this question and commented specifically on the lead CA's requests related to compositional and toxicological analyses. She considers that some of the information requested, such as three seasons of field tests (as opposed to two seasons as provided in the application), was not necessary to ensure the safety assessment. On the other hand, the request for compositional data regarding certain substances and the oral toxicity study to rule out unintended change in Bt-1507 maize were necessary in her view.[1105] All of this information was provided by the applicant in February 2002, except for the results of the oral toxicity study which was submitted only in February 2003.

7.1171 Even accepting that the information requested by the lead CA in June 2001 was necessary to ensure the validity of the safety assessment, it should be noted that the application concerning Bt-1507 maize (food) had been under review in the Netherlands for almost four and a half months before the Dutch CA forwarded its June 2001 request for information. Similarly, the lead CA on two occasions took a month to analyse responses provided by the applicant and forward follow-up requests for information. And once the applicant had provided information in response to the Dutch CA's last request for information, the lead CA still took several months to complete its initial assessment report.

7.1172 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1173 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1174 We also note, however, 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. In particular, we are not convinced that the Dutch CA could not forward its June 2001 request for information to the applicant sooner than it did even while following a precautionary approach, or that it could not complete its assessment report earlier than in November 2003.

7.1175 It is pertinent to note in this regard that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also under assessment by the Dutch CA. The Dutch CA did not complete its assessment of the application concerning Bt-1507 maize (EC-74) until August 2003. We have previously concluded in this respect that the failure of the Netherlands to complete its assessment of the application concerning Bt-1507 maize (EC-74) earlier than in August 2003 is not inconsistent with the contention that the European Communities applied a general moratorium during the relevant time period. Since a special environmental safety assessment

[1104] Annex H, Question 51.
[1105] Annex H, Dr. Nutti's responses to Question 51.

was necessary for the application concerning Bt-1507 maize (food) to be approved under Regulation 258/97[1106], we think it could also be that the time taken by the Dutch CA before forwarding its June 2001 request or before completing its initial assessment report in November 2003 reflects the delays in the approval procedure concerning Bt-1507 maize (EC-74).

7.1176 Taking account of the aforementioned elements, we consider that the Dutch CA's conduct in the approval procedure concerning Bt-1507 maize (food) is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at the time. It should be recalled, in addition, that the application concerning Bt-1507 maize (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken actions to delay or prevent its final approval.

7.1177 In the light of the above, we conclude that 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 contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

NK603 maize (food) (EC-96)

7.1178 The application for NK603 maize (food) was submitted to the Netherlands (lead CA) in April 2001. The lead CA forwarded its initial assessment report to the Commission in November 2002. In January 2003, the Commission forwarded the initial assessment report by the lead CA to member States for comments and objections.

7.1179 The **United States** argues that although the application concerning NK603 maize (food) eventually received a positive assessment from the lead CA, 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 3½ months were used by the applicant to provide additional information; the lead CA used the remaining 14½ months.

7.1180 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.[1107] 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

[1106] We note that the application concerning Bt-1507 maize (food) applies to foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

[1107] Exhibit EC-96/At. 7.

food safety. The United States observes that the applicant nevertheless conducted the requested test, which identified no adverse effects.

7.1181 **Canada** argues that the total time taken by the lead CA for its review was 18 months, and that only 3.5 of the 18 months were taken by the applicant to respond to questions. The difference of 14.5 months exceeds the 3-month period provided for in Regulation 258/97.

7.1182 **Argentina** argues 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, the delays by the lead CA to complete its initial assessment and forward this application to the Commission were not justified.

7.1183 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 18 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.

7.1184 The **Panel** understands from the record 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.

7.1185 There were two separate requests for additional information before the lead CA forwarded its initial assessment report to the Commission in November 2002. First, the lead CA requested further information in December 2001 on the sequence of the inserted DNA fragment as well as further information on the flanking sequences, semi-chronic toxicity study, and further information on compositional data from the field trials.[1108] A cover letter indicates that the applicant provided this information three months later, however the record does not include the details from the applicant's response.

7.1186 We asked the experts advising us whether the information regarding molecular characterization, toxicity effects of unintended changes and compositional data requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti noted that the applicant had provided all the information usually requested for the food safety assessment, and had also confirmed that the GM maize in question was equivalent in composition and nutrition to the conventional counterpart. She emphasized that "there was no need for requesting a semi chronic toxicity study in mice or rats, using maize grain or meal, in order to rule out possible undesired effects of additional, unidentified changes".[1109] The European Communities contests Dr. Nutti's conclusion that the additional 90-day toxicity study was not necessary. The European Communities indicates that the lead CA provided as rationale for its request for the 90-day study that it would provide additional reassurance of no unintended undesired effects.[1110] The European Communities argues that Dr. Nutti's conclusion should be dismissed on the basis of the available scientific evidence on the relevance of such studies.

7.1187 The second request for information came from Italy in January 2002 in a letter to the Commission. This request asked for further information on the evaluation of substantial equivalence,

[1108] Exhibit EC-96/At. 7.
[1109] Annex H, Dr. Nutti's responses to question 53.
[1110] Exhibit EC-96/At. 7.

molecular characterization, and detection analysis. Italy noted that the request was particularly important as "in the Community context, it has been shown that the simplified procedure needs to be suspended for GMOs".[1111]

7.1188 We again asked the experts whether the information requested by Italy was necessary to ensure that the conclusions of the safety assessment were valid. Dr. Nutti noted that "additional animal feeding studies may be warranted for GM foods if changes in the bioavailability of the nutrients are expected or if the composition of the GM food is not comparable to conventional food".[1112] She considered that the applicant had adequately established the substantial equivalence of the NK603 maize with its conventional counterpart, and that the request from Italy for more animal feeding studies was therefore not necessary to ensure that conclusions of the safety assessment were valid. In any event, there is no evidence on the record that the applicant was ever requested by the lead CA to provide the information sought by Italy. Nor is there any evidence that the applicant submitted information to address the requests made by Italy.

7.1189 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. The Committee concluded that "the consumption of NK603 maize and food and food ingredients derived from this is just as safe for humans as the consumption of non-genetically modified maize and maize products".[1113] It was not until November 2002 that the lead CA forwarded its assessment report to the Commission.[1114]

7.1190 In considering the foregoing, we note that this application was under assessment at the member State level for eighteen months. The lead CA's December 2001 request for information led to a delay, inasmuch as the applicant took three months and a half to respond to the request. 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. However, even accepting that the information requested by the lead CA in December 2001 was appropriate to ensure the validity of the safety assessment, it should be noted that the Netherlands took considerably more time for its assessment than the three months foreseen under Regulation 258/97. 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.[1115] 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.

7.1191 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

[1111] Exhibit EC-96/At. 9.
[1112] Annex H, Dr. Nutti's responses to question 54.
[1113] Exhibit EC-96/At. 7.
[1114] Exhibit EC-96/At. 12.
[1115] The application had been under review for more than four and a half months after receipt of copies of the cited literature and data. These copies were requested by the lead CA two months after receipt of the application.

7.1192 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1193 We also note, however, 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. In particular, we are not convinced that the Dutch CA could not forward its December 2001 request for information to the applicant sooner than it did even while following a precautionary approach, or that it could not forward its completed assessment report earlier than in November 2002.

7.1194 It is pertinent to note in this regard that the applicant had submitted an application concerning the same product under Directive 90/220. That application was under assessment by the Spanish CA during the same time period. The Spanish CA did not complete its assessment while Directive 90/220 was still in force. Under Directive 2001/18, the Spanish CA forwarded its positive assessment report concerning NK603 maize to the Commission on 14 January 2003. We have previously concluded in this respect that Spain's failure to complete its assessment of NK603 maize earlier than in January 2003 is not inconsistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period. Since a special environmental safety assessment was necessary for the application concerning NK603 maize (food) to be approved under Regulation 258/97[1116], we think it could also be that the time taken by the Dutch CA before forwarding its December 2001 request or before forwarding its initial assessment report in November 2003 reflects a view on the part of the Dutch CA that the Spanish CA would not forward the application concerning NK603 maize to the Commission and the other member States until after the entry into force of Directive 2001/18.

7.1195 Taking account of the aforementioned elements, we consider that the Dutch CA's conduct in the approval procedure concerning NK603 maize (food) is consistent with the Complaining Parties' view that a general moratorium on final approvals was in effect in the European Communities at the time. It should also be recalled in this regard that the application concerning NK603 maize (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1196 In the light of the above considerations, we conclude that the time taken by the Netherlands to complete its initial assessment of the application concerning NK603 maize (food) is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

[1116] We note that the application concerning NK603 maize (food) concerns foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

High-oleic soybeans (food) (EC-99)

7.1197 The application concerning High-oleic soybeans (food) was submitted to the Netherlands (lead CA) on 24 July 1998. The application was withdrawn by the applicant on 12 December 2002. At that time, the lead CA had not yet issued its initial assessment of the application.

7.1198 The **United States** argues that the application for High-oleic soybeans (food) was withdrawn because of the European Communities' excessive delay in carrying out the approval process.

7.1199 The **European Communities** argues that after discussions between the lead CA and the applicant, the applicant in December 2002 withdrew its application. The applicant gave as the reason for its withdrawal "entirely commercial reasons."

7.1200 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.1201 The **Panel** observes that in circulating notice of this application to all member States, the Commission indicated that the initial assessment by the lead CA would be available by 5 November 1999 at the latest. In contrast, at the time this application was withdrawn in December 2002, this initial assessment had not yet been completed.

7.1202 It appears that the lead CA requested further references from the applicant sometime before mid-October 1998, which was when these were provided. The information provided is incomplete and does not permit identification of when these references had been requested. Furthermore, in March 1999, the lead CA contacted the applicant to request explanations regarding certain results reported in the initial application.[1117] This was more than seven months after its receipt of the application. No explanation has been provided for this delay. The applicant provided the explanations and information requested in May 1999.[1118] More than three months later, in September 1999, the lead CA requested further clarification of the information provided.[1119] The applicant responded within three weeks, on 22 September 1999.[1120] It appears that the applicant's response addressed all questions asked by the lead CA. There is no indication that subsequent to September 1999 the lead CA sought further information or took any further action on this application until the application was withdrawn more than three years later on 12 December 2002.

7.1203 We note that no explanation has been provided to us for why the lead CA did not complete its assessment during the three years following the applicant's September 1999 response to a request for clarification. The United States argues that this delay was due to the alleged general moratorium on approvals. The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the

[1117] Exhibit EC-99/At. 11.
[1118] Exhibit EC-99/At. 14.
[1119] Exhibit EC-99/At. 15.
[1120] Exhibit EC-99/At. 16.

Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1204 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands at the time also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1205 We also note, however, 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. In particular, we are not convinced that it was not possible for the Dutch CA to complete its assessment before December 2002 even while following a precautionary approach.

7.1206 It is pertinent to note in this context that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also under assessment by the Dutch CA. In the procedure conducted under Directive 90/220, the Dutch CA requested additional information in October 1999.[1121] However, the applicant did not provide a response to that request until it withdrew its application in December 2002. Since a special environmental safety assessment was necessary for the application concerning High-oleic soybeans (food) to be approved under Regulation 258/97[1122], we think it could be that the time taken by the Dutch CA after the September 1999 response by the applicant reflects the delays in the approval procedure concerning High-oleic soybeans. We have previously concluded that the record of the member State level assessment of that application is not inconsistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

7.1207 Taking account of the aforementioned elements, we consider that the unexplained failure by the lead CA to complete its assessment of the application concerning High-oleic soybeans (food) after September 1999 is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time. It should also be recalled in this regard that the application concerning High-oleic soybeans (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1208 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in December 2002 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning High-oleic soybeans (food).

[1121] Exhibit EC-87/At. 15.

[1122] We note that the application concerning High-oleic soybeans (food) concerns foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

7.1209 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of the application concerning High-oleic soybeans (food) prior to December 2002, when it was withdrawn by the applicant, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

T25 x MON810 maize (food) (EC-101)

7.1210 The application concerning T25 x MON810 maize (food) was submitted to the Netherlands (lead CA) on 20 April 2000. The application was withdrawn on 12 December 2002. At that time, the lead CA had not completed its initial assessment. (An application for approval of this product under Regulation 90/220 was also submitted; see EC-86 above.)

7.1211 The **United States** argues that the application for T25 x MON810 maize (food) was withdrawn because of the European Communities' excessive delay in carrying out the approval process.

7.1212 The **European Communities** maintains that after discussions between the lead CA and the applicant, in its letter withdrawing the application the applicant pointed to "entirely commercial reasons."

7.1213 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.1214 The **Panel** notes that in bringing the application to the attention of all member States on 3 May 2000, the Commission stated that the initial assessment was to be concluded by 28 July 2000 at the latest.[1123] However, it was apparently only on 17 July 2000 that the lead CA first contacted the applicant to request additional information.[1124] After the applicant responded on 22 November 2000, another five months lapsed before the lead CA requested further information on 23 April 2001.[1125]

7.1215 In responding to the April 2001 request from the lead CA, on 21 November 2001 the applicant noted that not only had both parental lines been previously approved, but the same hybrid T25 x MON810 maize product had been reviewed under Directive 90/220 and had received a favourable assessment from the Dutch CA and from the SCP in June 2000. Given these circumstances, the applicant questioned the need for providing additional information on molecular characterization. It also noted that the request for a semi-chronic toxicity study was "an unexpected requirement".[1126] Nonetheless, the applicant indicated its intention to provide the information requested by mid-2002, and asked that the Dutch Health Council allow the applicant the opportunity to provide the additional information before completing its safety assessment. It appears from the applicant's November 2001 response that the Health Council had previously indicated its intention to finalize its safety assessment before the end of 2001.

[1123] Exhibit EC-101/At. 4.
[1124] Exhibit EC-101/At. 11.
[1125] Exhibit EC-101/Ats. 13 and 14.
[1126] Exhibit EC-101/At. 15.

7.1216 No evidence has been provided of further correspondence on this application until the letter of 12 December 2002 from the applicant withdrawing the application. We can only presume that the applicant did not provide the information as indicated in its letter of 21 November 2001, and that the lead CA did not explain to the applicant the reasons for its "unexpected requirement" nor otherwise further seek information requested from the applicant.

7.1217 We sought the advice of the experts assisting us as to whether the additional information regarding molecular characterization, field trials, secondary plant metabolites, and toxicological tests requested by the lead CA in April 2001 were necessary to ensure that conclusions of the safety assessment were valid.[1127] Dr. Nutti did not consider that the requests regarding compositional and toxicological analysis were necessary, in light of the information available on the parental lines. She characterized the likelihood of fortuitous changes in the plant metabolism as a result of the conventional cross-breeding of two GMO maizes as being "vanishingly small".[1128]

7.1218 Dr. Andow considered that there is a scientific justification for requiring comparison of T25 maize with and without the pesticide treatment with conventional and untreated maize, although he indicates that there is a scientific debate as to whether all three comparisons are necessary to ensure the safety assessment. With respect to the secondary plant metabolites, Dr. Andow also considers that the likelihood of a change in the plant metabolism may be very small, but that it is difficult to argue how small, and since a potential human health risk could arise from such changes, he considered the requested information to be necessary to ensure a valid safety assessment. Dr. Andow, however, agreed that the requested toxicology study was not necessary for the safety assessment.[1129]

7.1219 Dr. Squire considered that the requests by the lead CA were arguably consistent with the type of information required in the Codex Guideline for the conduct of food safety assessment of food derived from recombinant-DNA plants.[1130]

7.1220 We are cognizant of the European Communities' disagreement with the views of Drs. Andow and Nutti regarding the need for the toxicology study, and with Dr. Nutti regarding the data on herbicide treatment and on secondary compounds. Even accepting that the information requested by the Health Council in April 2001 was necessary to ensure the validity of the safety assessment, this would not explain the time taken by the lead CA before initially requesting additional information in July 2000 (three months), and the time taken to review the information received in November 2000 (five months).

7.1221 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1222 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case

[1127] Annex H, Question 57.
[1128] Annex H, para.766.
[1129] Annex H, para. 772.
[1130] Annex H, para. 774.

of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1223 We also note, however, 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. In particular, we are not convinced that the Dutch CA could not forward its July 2000 request for information to the applicant sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not identify the need for more detailed information earlier than in April 2001.

7.1224 It is pertinent to note, furthermore, that the applicant had submitted an application concerning the same product under Directive 90/220. That application had also been assessed by the Dutch CA. At the time the application concerning T25 x MON810 maize (food) was submitted to the Dutch CA, the application concerning T25 x MON810 maize was being assessed at Community level. In June 2000, the SCP issued a favourable opinion, but the Commission subsequently did not forward a draft measure to the Regulatory Committee prior to the withdrawal of the application in December 2002. We have previously concluded in this respect that the Commission's failure to submit a draft measure concerning T25 x MON810 maize to the Regulatory Committee is consistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals.

7.1225 Taking account of the aforementioned elements, we consider that the time taken by the lead CA before initially requesting additional information in July 2000, and the time taken to review the information received in November 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. It should also be recalled in this regard that the application concerning T25 x MON810 maize (food) as of the date of its withdrawal had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1226 Furthermore, in our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in December 2002 is not inconsistent with the assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning T25 x MON810 maize (food).

7.1227 In the light of the above, we conclude that the time taken by the Netherlands for its initial assessment of the application for T25 x MON810 maize (food) is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR sugar beet (food) (EC-102)

7.1228 The application concerning RR sugar beet (food) was submitted to the Netherlands (lead CA) in November 1999. At the time of establishment of the Panel, the lead CA had not yet completed its initial assessment. The application was withdrawn by the applicant on 16 April 2004.

7.1229 The **United States** argues that the lead CA refused to forward this application to the Commission.

7.1230 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.

7.1231 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly indicated so in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have 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 resulting from the moratorium.

7.1232 The **Panel** notes from the record that this application was submitted to the Netherlands in November 1999. Four months later, in March 2000, the Health Council of the Netherlands requested information from the applicant regarding missing and illegible references and a request for information on the nutritional value of glyphosate-treated RR sugar beet.[1131] The applicant responded one month later and indicated that further studies on DNA and protein detection from sugar produced from RR sugar beet were in process.[1132] In May 2000, the lead CA requested further information on protein toxicity.[1133] The applicant provided a response in December 2000, which included new scientific reports and data.[1134]

7.1233 In January 2001, Denmark requested further information regarding compositional analysis of RR sugar beet treated with herbicide, as well as non-treated, and field management for RR and conventional sugar beet. The Danish CA also requested information on the level of amino acid in treated sugar beet as well as a series of technical reports which were cited in the application, but not provided, by the applicant.[1135] There is no indication on record that the applicant responded to the request from Denmark.

7.1234 In May 2001, after reviewing the additional information provided by the applicant in December 2000, the lead CA requested further information on protein analysis. 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".[1136] No specific study was cited in this regard.

7.1235 There is no indication in the evidence before us that the applicant responded to the requests from the lead CA for further information. Although the European Communities indicates in the chronology it provided on this application that the applicant sent a message regarding the status of the application in November 2001, there is no such document in the record. The next item in the chronology is the withdrawal of the application by the applicant in April 2004.

7.1236 We sought the advice of the experts assisting us as to whether the additional information requested by the lead CA in May 2001 was necessary to ensure that the conclusions of the safety

[1131] Exhibit EC-102/At. 21.
[1132] Exhibit EC-102/At. 22.
[1133] Exhibit EC-102/At. 23.
[1134] Exhibit EC-102/At. 26.
[1135] Exhibit EC-102/At. 31.
[1136] Exhibit EC-102/At. 32.

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".[1137]

7.1237 Even accepting that contrary to the views of Dr. Nutti the information requested by the Health Council in May 2001 was necessary to ensure the validity of the safety assessment, this would not explain 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).

7.1238 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1239 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1240 We also note, however, 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. In particular, we are not convinced that the Dutch CA could not forward its March 2000 request for information to the applicant sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not identify the need for more detailed information earlier than in May 2001.

7.1241 It is pertinent to note, furthermore, that the applicant drew the Dutch CA's attention to an application concerning the same product which the applicant had previously submitted to Belgium under Directive 90/220.[1138] Belgium did not complete its assessment of that application, and the applicant withdrew it in April 2004. We have previously concluded in relation to that application that the time taken by Belgium for its assessment of RR sugar beet is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

7.1242 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. It should also be recalled in this regard that the application concerning RR sugar beet (food) as of the date of its

[1137] Annex H, para. 775.
[1138] Exhibit EC-102/At. 20.

withdrawal had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1243 Furthermore, in our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in April 2004 is not inconsistent with the assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning RR sugar beet (food).

7.1244 In the light of the above, we conclude that the time taken by the Netherlands for its initial assessment of the application concerning RR sugar beet (food) is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

(iii) Conduct of Group of Five countries generally

7.1245 In the preceding analysis, the Panel has addressed certain conduct of one particular Group of Five country, France, in its capacity as lead CA in individual approval procedures.[1139] In what follows, the Panel focuses on the conduct of Group of Five countries in approval procedures in which they were not acting as the lead CA. In particular, the Panel considers how Group of Five countries voted in the Regulatory Committee or Council and whether they raised objections to favourable assessments circulated by the lead CA.

Voting behaviour by Group of Five countries in the Regulatory Committee or Council

7.1246 We begin by considering the voting behaviour by Group of Five countries in the Regulatory Committee or Council. The record makes clear that there was no vote on any application in the Regulatory Committee or the Council between June 1999, when the Group of Five countries made their joint declaration, and August 2003. It is therefore not possible to establish whether, consistent with their June 1999 declaration, the Group of Five countries cast their votes in the Regulatory Committee or the Council in such a way as to prevent the necessary qualified majority from being reached.

7.1247 In response to a question from the Panel, the European Communities pointed out that between October 1998 and June 1999 four votes took place in the Regulatory Committee and that during that time period two Group of Five countries voted in favour of applications.[1140] Specifically, the European Communities mentions that Italy cast a favourable vote in the Regulatory Committee on four applications submitted under Directive 90/220[1141] and that Denmark did the same in relation to one application submitted under Directive 90/220[1142].

[1139] *See* the approval procedures concerning RR oilseed rape (EC-79) and MS1/RF1 oilseed rape (EC-89) as well as MS1/RF2 oilseed rape.

[1140] EC reply to Panel question No. 87.

[1141] The applications in question are those concerning Bt-531 cotton, RR-1445 cotton, MON809 maize and the Transgenic tomato.

[1142] The application in question is that concerning the Transgenic tomato. It should be noted that Denmark voted against the applications concerning Bt-531 cotton and RR-1445 cotton. Exhibits EC-65/At. 59 and EC-66/At. 57. Regarding the application concerning MON809 maize, Denmark abstained. Exhibit EC-83/At. 65.

7.1248 In the Panel's view, the fact that Italy and Denmark voted in favour of a number of applications between October 1998 and June 1999 does not support the inference that if there had been votes between June 1999 and August 2003, these two member States would have voted in favour of additional applications. To begin with, in June 1999 Italy and Denmark declared that they would take steps to prevent new applications from being approved. In addition, between June 1999 and August 2003, Italy and Denmark repeatedly objected to the placing on the market of biotech products which had received a favourable initial assessment from the lead CA.[1143]

7.1249 The European Communities also points out that in February 2004, Italy and France in the Regulatory Committee voted in favour of a Commission draft measure approving the application concerning NK603 maize.[1144] The Panel notes that the vote referred to by the European Communities occurred well after 29 August 2003, the date of establishment of this Panel. As these votes may have been influenced by the establishment of this Panel, it would be inappropriate to infer from these votes that if votes had been held prior to August 2003, Italy and France would have voted in favour of applications.[1145] Also, the voting behaviour by Italy and France in the procedure concerning NK603 maize is consistent with the June 1999 declaration of the Group of Five, in that the new EC rules on labelling and traceability were adopted in September 2003.

Objections by Group of Five countries to favourable assessments by lead CAs

7.1250 We now turn to consider whether the Group of Five countries raised any objections to favourable assessments by lead CAs in the period between June 1999, when the Group of Five countries made their joint declaration, and August 2003. In considering this issue, we first of all recall that under the approval procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97, when the lead CA circulates a favourable assessment report, the other member States have 60 days within which to raise objections to the placing on the market of the biotech product in question. If such objections are maintained, the decision on whether to approve the relevant biotech product must be made at Community level.

7.1251 The record indicates that there were relatively few individual approval procedures in which the 60-day period for objections ended between June 1999 and August 2003. More specifically, it is possible to identify a total of nine applications which fall within this category. They include six applications which were being assessed under Directives 90/220 and/or 2001/18[1146] and three applications which were being assessed under Regulation 258/97[1147].

7.1252 We note that in the case of each of the nine applications in question, there was at least one Group of Five country which raised and maintained an objection to the placing on the market of the biotech product in question. The nine applications include three in which Group of Five country

[1143] *E.g.*, in the approval procedures concerning Bt-11 maize (EC-69) (Denmark and Italy), RR oilseed rape (Denmark and Italy), GA21 maize (EC-85) (Denmark and Italy), T25 x MON810 maize (Denmark and Italy), GA21 maize (food) (Italy) and Bt-11 sweet maize (food) (Denmark and Italy.

[1144] EC first written submission, para. 565; EC reply to Panel question No. 87. It should be noted that other Group of Five countries – Greece, Luxembourg and Denmark – voted against approving the application. Exhibit EC-114.

[1145] For completeness, it should be noted that in February 1999, France in the Regulatory Committee voted against approving Bt-531 cotton and RR-1445 cotton. Exhibits EC-65/At. 59 and EC-66/At. 57.

[1146] The six approval procedures are the approval procedures concerning (i) Bt-11 maize (EC-69), (ii) RR oilseed rape (EC-70), (iii) NK603 maize, (iv) GA21 maize (EC-78), (v) GA21 maize (EC-85) and (vi) T25 x MON810 maize.

[1147] The three approval procedures are the approval procedures concerning (i) GA21 maize (food), (ii) Bt-11 sweet maize (food) and (iii) NK603 maize (food).

objections were raised and maintained under the provisions of Directive 2001/18. We further note that in none of the nine cases did all Group of Five countries raise objections.[1148] It should, however, be recalled in this connection that under Directives 90/220 and 2001/18 as well as Regulation 258/97 an objection from a single Group of Five country was sufficient to force a decision at Community level and hence for the Group of Five countries to obtain the opportunity to use their "blocking minority" in the Regulatory Committee and Council.

7.1253 The fact that at least one Group of Five country raised and maintained an objection in the case of each of the nine relevant applications does not necessarily mean that all of these objections were maintained for the reasons underlying the June 1999 declaration by the Group of Five countries.[1149] Nonetheless, the existence of an objection from at least one Group of Five country in each of the nine cases is consistent with the Complaining Parties' assertion that certain member States intentionally delayed or prevented the final approval of applications. Even if the reason presented by a Group of Five country for its objection differed from the reasons underlying the June 1999 declaration, this fact alone would not contradict the Complaining Parties' assertion. Since this particular Group of Five country raised an objection, it cannot simply be assumed that if the reason offered for the objection had not existed, the country in question would have refrained from objecting on the basis of the June 1999 declaration.[1150]

(iv) Commission conduct prior to the June 1999 declaration by the Group of Five countries

7.1254 We note that Argentina has commented on the conduct of the Commission prior to the issuance of the June 1999 declaration by the Group of Five countries. The conduct in question affected the progress in the approval process of a number of applications which had been submitted under Directive 90/220. In Argentina's view, the Commission's conduct in respect of these applications confirms the existence of a general moratorium on approvals as from October 1998.

7.1255 **Argentina** argues that all applications which had received positive opinions from EC scientific committees in 1998 were prevented by the Commission from progressing in the approval process. The Commission did so by holding lengthy inter-service consultations in September 1998 and May 1999. According to Argentina, a first group of these applications – those concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet – was delayed by inter-service consultations which began in September 1998. The relevant applications did not reach the Regulatory Committee stage until June or October 1999. A second group of applications – those concerning Bt-531 cotton and RR-1445 cotton – reached the Regulatory Committee stage, but failed to achieve a qualified majority vote in the Regulatory Committee in February 1999. The Commission launched inter-service consultations in May 1999 on draft measures to be submitted to the Council, but the Commission did not submit any draft measures, and so the applications in question made no progress

[1148] In three approval procedures there were three Group of Five countries which raised and maintained objections, and in another three approval procedures there were two Group of Five countries which did so.

[1149] In relation to DS291 and DS292, we note that the United States and Canada have demonstrated that in some of the nine relevant approval procedures objections by Group of Five countries were based on reasons which explicitly included those underlying the June 1999 declaration.

[1150] Indeed, if a Group of Five country opposed the placing on the market of a biotech product and it considered there existed, in its view, clear product- or application-specific reasons for doing so, then there was no need for it to fall back on the more general reasons underlying the June 1999 declaration. In other cases, however, the relevant Group of Five country might well have wished to base its opposition to the product in question on the June 1999 declaration. Cases in point are Denmark's first objection concerning Bt-11 maize (EC-69), which was based on product- and application-specific reasons (Exhibit EC-69/At. 66), and Denmark's objection concerning Bt-11 sweet maize (food), which was based on the June 1999 declaration (Exhibit EC-92/At. 27).

until they had to be updated under Directive 2001/18 in January 2003. For Argentina, the September 1998 and May 1999 inter-service consultations undertaken by the Commission are evidence of the existence of a general *de facto* moratorium. Argentina finds further support for this view in the circumstance that the "inter-service consultation" phase was not provided for in Directive 90/220.

7.1256 The **Panel** has already addressed the delays that occurred as from May 1999 as a result of the Commission's inter-service consultations on the applications concerning Bt-531 cotton and RR-1445 cotton. Accordingly, the Panel need only address the inter-service consultations on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet. These consultations were all launched in September 1998. The Panel considers that in addition to these three approval procedures mentioned by Argentina, the approval procedures concerning MON809 maize, the Transgenic tomato, Bt-531 cotton and RR-1445 cotton are also relevant. These additional applications also received favourable opinions from EC scientific committees in 1998[1151], and the Commission launched inter-service consultations on them in or before September 1998[1152]. The following table summarizes the factual situation.

Application	Commission inter-service consultations on draft measure to be submitted to Regulatory Committee	Launch by Commission of vote in Regulatory Committee	Vote in Regulatory Committee	Commission inter-service consultations on draft measure to be submitted to Council
MON809 maize	12/06/1998	04/09/1998	23/10/1998 (absence of qualified majority)	01/02/1999
Transgenic tomato	05/10/1998	26/11/1998	18/12/1998 (absence of qualified majority)	16/02/1999
Bt-531 cotton	04/09/1998	26/11/1998	22/02/1999 (absence of qualified majority)	07/05/1999
RR-1445 cotton	04/09/1998	26/11/1998	22/02/1999 (absence of qualified majority)	07/05/1999
Falcon oilseed rape	04/09/1998	29/06/1999	29/10/1999 (no vote) 09/03/2000 (no vote)	
MS8/RF3 oilseed rape	04/09/1998	30/06/1999	29/10/1999 (no vote) 09/03/2000 (no vote)	
RR fodder beet	04/09/1998		29/10/1999 (no vote)	

7.1257 The above table shows that the Commission on 4 September 1998 began inter-service consultations on five different applications. While in the approval procedures concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet, these consultations apparently went on for almost ten months (or more in the case of RR fodder beet), in the approval procedures concerning Bt-531 and RR-1445 cotton, the consultations were completed much sooner, in less than three months. In considering this discrepancy, account should be taken of the four votes which took place in the Regulatory Committee after 4 September 1998. As is clear from the table, the application concerning MON809 maize was voted on in October 1998, the application concerning the Transgenic tomato in December 1998, and the applications concerning Bt-531 cotton and RR-1445 cotton in February 1999. In each case, the Commission's draft measure approving the relevant application failed to obtain the necessary qualified majority. It may well be that in view of these four successive "defeats" in the Regulatory Committee, the Commission did not find it opportune quickly to launch

[1151] Exhibits EC-83/At. 54; EC-84/At. 42; EC-65/At. 47; EC-66/At. 43.
[1152] Exhibits EC-83/At. 55; EC-84/At. 43; EC-65/At. 48; EC-66/At. 44.

further votes on other applications submitted under Directive 90/220. The timing of the launch of the next votes – 29 June 1999 for Falcon oilseed rape and 30 June 1999 for MS8/RF3 oilseed rape – tends to suggest that the Commission preferred to wait until after the Environment Council meeting of 24/25 June 1999 at which a Common Position was adopted on the proposal to amend Directive 90/220.[1153]

7.1258 The Panel is not convinced that the Commission's conduct in respect of the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet supports Argentina's and the other Complaining Parties' assertion that a general moratorium on approvals was in effect already as from October 1998. It was not until June 1999 that the Group of Five countries announced that they would take steps to suspend new approvals. Moreover, the record of the above-mentioned four votes shows that only some of the five member States which later issued the June 1999 joint declaration voted against the Commission's draft measures.[1154] In the absence of evidence of systematic member State opposition to final approvals, comparable to the kind of opposition announced in June 1999 by the Group of Five countries, there is no apparent reason to believe that the Commission's conduct reflects a decision to prevent the final approval of applications.

7.1259 It might be argued that the Commission's four successive "defeats" in the Regulatory Committee could be evidence of reluctance on the part of certain member States to approve applications under Directive 90/220 which was considered to require amendment. Even accepting this argument, the circumstance that the Commission could have found it increasingly difficult to get member States to vote in favour of applications submitted under Directive 90/220 might provide a rationale for not precipitating further votes. But it does not provide a plausible rationale for the Commission deciding not to make full use of its powers under Directive 90/220 and not to complete approval procedures on its own, if necessary. It is noteworthy in this respect that the Commission eventually did call votes on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet. The Commission did not do so in the case of applications which had obtained favourable opinions from EC scientific committees after the June 1999 declaration by the Group of Five countries. The view that a moratorium on approvals was not already in effect as from October 1998 draws further support from the explanation offered by Greece for abstaining from voting on the Transgenic tomato in December 1998. Greece stated that "we support the *idea* of a 'moratorium' for G.M.O., as presented by some Member-States".[1155] This statement suggests that a moratorium was an idea entertained by some member States at the time, but not that it was a reality.

7.1260 The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals.[1156] It is correct that Commission inter-service consultations were not provided for in Directive 90/220 as a distinct stage in the approval process.[1157] However, as the European Communities explained in response to a question from the Panel, inter-service consultation is a process internal to the Commission, designed

[1153] Particularly in relation to MS8/RF3 oilseed rape and RR fodder beet, some of the delay may also be attributable to additional information supplied by the applicant.

[1154] Regarding MON809 maize, only Greece voted against, with Denmark, France and Luxembourg abstaining. Exhibit EC-83/At. 65. Regarding the Transgenic tomato, no Group of Five country voted against. Greece and Luxembourg abstained. Exhibit EC-84/At. 45. Regarding Bt-531 cotton, Denmark, France and Greece voted against, with Luxembourg abstaining. Exhibit EC-65/At. 59. Regarding RR-1445 cotton, Denmark, France and Greece voted against, with Luxembourg abstaining. Exhibit EC-66/At. 57.

[1155] Exhibit EC-84/At. 45 (emphasis added).

[1156] The United States makes a similar argument about the inter-service consultations launched in May 1999 on the applications concerning Bt-531 cotton and RR-1445 cotton. US second written submission, paras. 56-57; US first oral statement, para. 30.

[1157] *En passant*, the Panel notes that the same is true for Directive 2001/18 and Regulation 258/97.

to ensure that the Commission services with a legitimate interest in the matter on which a Commission decision is being prepared, work in close co-operation and in co-ordinated fashion.[1158] As the European Communities also pointed out, inter-service consultation is mandated by the Commission's rules of procedure for the preparation and implementation of each Commission decision.[1159] It is clear to the Panel, therefore, that the inter-service consultations of September 1998 were not an additional procedural stage devised by the Commission to prevent the approval of biotech products.

7.1261 In the light of the above considerations, the Panel concludes that the time taken by the Commission to submit to the Regulatory Committee draft measures on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet does not support Argentina's and the other Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals already as from October 1998.

(v) Concluding observations

7.1262 The Panel notes that the Complaining Parties did not present detailed arguments in respect of each of the individual approval procedures discussed above. In fact, Canada and Argentina did not present any arguments in respect of some of these approval procedures. The European Communities argues in this regard that addressing only a limited selection of individual approval procedures is not sufficient to prove the existence of an across-the-board moratorium, *i.e.*, of a moratorium which applies to any and all applications which were pending during the relevant time period.[1160] In other words, according to the European Communities, the Complaining Parties cannot sustain their burden of establishing a prima facie case of the existence of a general moratorium on approvals unless they provide detailed evidence and arguments in respect of each and every of the above-mentioned individual approval procedures. In response to a question from the Panel, the Complaining Parties dispute this EC argument.[1161]

7.1263 The Panel agrees with the European Communities that the Complaining Parties could have sought to establish a prima facie case of the existence of a general, or across-the-board, moratorium by offering evidence and argumentation in respect of each and every of the individual approval procedures which were pending between October 1998 and August 2003. But the Panel cannot accept the European Communities' suggestion that this was the only way in which the Complaining Parties could discharge their burden of demonstrating prima facie that the alleged moratorium applied to all pending applications.

7.1264 As is clear from the Panel's preceding analysis, the Complaining Parties have provided other relevant evidence and argumentation to demonstrate the generality of the alleged moratorium. First and foremost, the Complaining Parties demonstrated that not a single biotech application under consideration between October 1998 and August 2003 was approved on or before the date of establishment of this Panel. Moreover, the Complaining Parties relied on the June 1999 declaration by the Group of Five countries, which states that the Group of Five countries "will take steps to have *any* new authorizations for growing and placing on the market suspended" (emphasis added). Finally, the Complaining Parties submitted numerous EC documents and statements by EC or member State

[1158] EC reply to Panel question No. 94. In response to a question from Argentina, the European Communities defined "inter-service consultation" as the process by which the lead service(s) consults with other interested services. EC reply to Argentina's question Nos. 9 and 10.

[1159] *Ibid*.

[1160] EC second written submission, footnote 212.

[1161] Complaining Parties' replies to Panel question No. 179.

officials. The Panel found that these documents and statements support the Complaining Parties' assertion that the European Communities applied a general moratorium during the relevant time period. In the specific circumstances of this case, these elements of proof taken together are sufficient, in the Panel's view, to establish a prima facie case of the generality of the alleged moratorium.

7.1265 Having regard to the individual approval procedures which the Complaining Parties did address, the Panel notes that, according to the Complaining Parties, these approval procedures confirm that certain member States and/or the Commission did cause delays or prevent the final approval of applications in the manner alleged by the Complaining Parties. The relevant approval procedures support this contention. To illustrate this, the Panel recalls below its findings on member States' and the Commission's ability to delay or prevent the final approval of applications and indicates whether it has been established that member States and/or the Commission actually did delay or prevent the approval of applications in this manner. The Panel begins with the relevant member State actions and/or omissions:

(a) The Panel found that the lead CA could delay the completion and circulation of its initial assessment. The United States and Canada have established that a Group of Five country delayed the completion and circulation of its initial assessment, so much so that the applicant withdrew the application.[1162] The European Communities has correctly pointed out, however, that the same Group of Five country in another approval procedure[1163] in April 1999 transmitted to the Commission a favourable initial assessment and that it confirmed that assessment in June 2003, after the application had been updated in accordance with the requirements of Directive 2001/18.[1164] To the extent this is viewed as inconsistent behaviour[1165], it suggests that in situations where the relevant Group of Five country acted as the lead CA, it was not in all cases prepared to assume the possible consequences of delaying or blocking action[1166].

[1162] The approval procedure in question is that concerning RR oilseed rape (EC-79).

[1163] The approval procedure in question is that concerning Bt-11 maize (EC-69).

[1164] EC reply to Panel question No. 87.

[1165] A special circumstance which should be pointed out is the previously mentioned fact that the biotech product at issue – Bt-11 maize – had already been approved for marketing in the European Communities in April 1998, although not for cultivation (Bt-11 maize (EC-163)), which was the use at issue in the approval procedure concerning Bt-11 maize (EC-69).

[1166] By failing to complete its initial assessment, a lead CA exposes itself to the risk of legal action being instituted against it under its own domestic law. EC first written submission, para. 186. There is no such risk, or less of a risk, where a Group of Five country avails itself of its right to object to an initial assessment prepared by a lead CA, or exercises its right to vote against a draft measure submitted by the Commission to the Regulatory Committee or to the Council. For this reason, the Panel does not consider that the fact that France in April 1999 and June 2003 transmitted a favourable initial assessment of Bt-11 maize (EC-69) to the Commission is necessarily inconsistent with the June 1999 declaration by the Group of Five countries. France may have considered that other Group of Five countries, and even the Commission, would take the necessary steps to delay or prevent Bt-11 maize (EC-69) from being approved at member State level or at Community level.

With reference to DS291, the Panel notes that the United States submitted a July 1999 news report which is consistent with the view that Group of Five countries which acted as lead CAs might not always have been willing to face the possible legal consequences of delaying or blocking action. The news report states that "the Commission pointed out on 15 July 1999 that France and Denmark have GMO applications pending, even though they were the leading proponents of GMO moratorium in June". The news report then reports the spokesman for then-Environment Commissioner Ritt Bjerregard to have said that "[w]e cannot understand why

(b) The Panel found that member States other than the lead CA could object to the placing on the market of a biotech product following a favourable assessment by the lead CA. The record establishes that one or more Group of Five countries raised and maintained an objection in each of the approval procedures in which the deadline for raising objections expired in the period between June 1999, when the Group of Five countries made their joint declaration, and August 2003.

(c) The Panel found that a group of member States that constituted a blocking minority could prevent the appropriate Regulatory Committee or the Council from reaching the qualified majority necessary to adopt a draft measure proposing approval of an application. The Panel also found that the Group of Five countries constitute such a group of member States and that the formation of that group was announced in June 1999 in a joint declaration. In this respect, the record makes clear that there was no vote on any application in the Regulatory Committee or the Council between June 1999 and August 2003. It is therefore not possible to establish that consistent with their June 1999 joint declaration, the Group of Five countries cast their votes in the Regulatory Committee or the Council in such a way as to prevent the necessary qualified majority from being reached.

(d) The Panel found that the lead CA could refuse to give its consent to the placement on the market of a biotech product after the Commission has approved an application. The United States and Canada have established that one Group of Five country refused to give its consent to the placement of a biotech product after the Commission had approved the application.[1167]

7.1266 The Panel now turns to relevant Commission actions and/or omissions:

(a) The Panel found that the Commission could delay the submission of a draft measure to the appropriate Regulatory Committee, or it could fail to convene the Regulatory Committee for a vote on a draft measure which has been submitted. The United States, Canada and Argentina have established that the Commission failed to submit draft measures to the appropriate Regulatory Committee.[1168] The United States and Canada have further established that the Commission failed to re-convene the Regulatory Committee for a vote on a draft measure which had been previously submitted, but on which no vote was held.[1169]

(b) The Panel found that the Commission could delay the submission of a draft measure to the Council where the Regulatory Committee was unable to reach the qualified

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these countries do not withdraw their applications after all the statements they made at the Council of Ministers. [...] It is one thing to make all these grand declarations and go before the press and assert their desire for a moratorium. But it seems to be another to take the step of withdrawing their applications. Until these applications are withdrawn, the Commission has a clear legal obligation to pursue the procedures set out in the EEC/90/220 directive". The news report also quotes the spokesman as saying that "[w]e are basically asking the member states to put their money where their mouth is". "EU Official Calls on Members to Pull GMO Applications in Light of 'Moratorium'", International Trade Reporter, 21 July 1999, p. 1214 (Exhibit US-96).

[1167] *See* the Panel's earlier analysis of the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape.

[1168] *See* the Panel's earlier analysis of various approval procedures under the sub-headings "Failure by the Commission to submit a draft measure to the Regulatory Committee".

[1169] *See* the Panel's earlier analysis of various approval procedures under the sub-heading "Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft".

> majority necessary to deliver an opinion. The United States, Canada and Argentina have established that the Commission failed to submit draft measures to the Council in a situation where the Regulatory Committee was unable to reach the qualified majority necessary to deliver an opinion.[1170]

7.1267 As a final matter, the Panel recalls the European Communities' assertion that the Complaining Parties' claims in respect of the general moratorium would collapse when the facts and history of each approval procedure are considered. The European Communities contended that an analysis of the relevant facts would show that during the relevant time period there were no acts and/or omissions which stalled applications at key decision-making stages in the approval process. In the alternative, the European Communities argued that even if the delays that occurred could be viewed as the result of a moratorium, that moratorium ended with the entry into force in January 2003 of Directive 2001/18.

7.1268 The Panel has undertaken an extensive analysis of each individual application discussed by the European Communities as well as of those applications which were withdrawn during the time period in question. As is clear from the above analysis, the facts and histories of the relevant approval procedures do not demonstrate that there were no acts and/or omissions which stalled applications at key decision-making stages in the approval process. To the contrary, for the time period from June 1999 to August 2003, the facts and histories of all approval procedures which have been examined are consistent with the Complaining Parties' assertion that during that time period Group of Five countries and/or the Commission were delaying or preventing the final approval of applications.

7.1269 Moreover, the Panel's analysis does not bear out the European Communities' alternative contention that any acts and/or omissions which might have served to prevent the final approval of applications prior to the entry into force of Directive 2001/18 ended when that Directive entered into force in January 2003. The Panel found in this regard (i) that at the member State level there were delays in the processing of applications under Directive 2001/18 which are consistent with the existence of a moratorium on final approvals, (ii) that Group of Five countries continued to oppose the approval of applications even though they had been updated in accordance with the requirements of Directive 2001/18; and (iii) that, as of August 2003, no procedure had reached the stage where the Commission could have taken action to delay or prevent the final approval of an application.[1171]

7.1270 It follows from the foregoing that the Panel's analysis of individual approval procedures does not lead to the "collapse" of the Complaining Parties' claim that the European Communities applied a general *de facto* moratorium on approvals. Nevertheless, while the Panel considers that the facts and histories of individual approval procedures are consistent with the Complaining Parties' contention that a general moratorium was in effect in August 2003, the Panel was not persuaded that the facts and histories of these procedures support the Complaining Parties' claim that a general moratorium was in effect already before June 1999, and, more specifically, as from October 1998.

(f) Overall conclusions

7.1271 The Panel has now completed its consideration of the various elements it said it would address. To determine to what conclusion these elements lead, it is useful to recall the Panel's main findings:

[1170] *See* the Panel's earlier analysis of various approval procedures under the sub-heading "Failure by the Commission to submit a draft measure to the Council".

[1171] *See supra*, paras. 7.1032-7.1034.

(a) The Panel found that during the relevant time period (October 1998 to August 2003) member States and the Commission had the ability and opportunity to prevent or delay the approval of applications in the manner identified by the Complaining Parties.

(b) The Panel found that the June 1999 joint declaration by the Group of Five countries constitutes direct evidence of an intention on the part of the relevant five member States (Denmark, Italy, France, Greece and Luxembourg) to do what was within their power to prevent the approval of further applications, pending the adoption of EC rules concerning labelling and traceability of biotech products. The Panel also found that because of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that it could no longer approve applications with the (qualified majority) support of the member States. The Panel found it plausible that the systematic opposition by the Group of Five countries was an issue for the Commission, and that this situation, while it continued, could have affected the Commission's readiness to make full use of the relevant procedures to complete the approval process.

(c) The Panel found that no applications were approved between October 1998 and August 2003. This is despite the fact that a large number of applications were pending and that many of these had received one or more favourable scientific assessments. The Panel also noted that before October 1998 ten agricultural biotech products had been approved and that after August 2003 three applications were approved. The Panel highlighted the fact that the post-August 2003 approvals were granted when the present panel proceedings were already under way.

(d) The Panel found that each of the Complaining Parties had submitted numerous official and internal EC documents and statements by high-ranking officials which explicitly state that the reason for the absence of approvals was a general *de facto* moratorium on approvals. The Panel also found that the documents and statements submitted by each Complaining Party permit the inference that a general moratorium was in effect between June 1999 and August 2003. The Panel was not convinced that they warrant the inference that a general moratorium was in effect already as from October 1998, or that it ended in January 2003, when Directive 2001/18 entered into force.

(e) The Panel found that the facts and histories of individual approval procedures confirm that Group of Five countries and/or the Commission did cause delays or prevent final approvals in the manner alleged by the Complaining Parties.

(f) The Panel found that for the time period from June 1999 to August 2003 the facts and histories of all approval procedures examined by the Panel are consistent with the Complaining Parties' assertion that the final approval of applications was intentionally being prevented by Group of Five countries and/or the Commission. The Panel was not persuaded that it can be inferred from the facts and histories of the relevant approval procedures that a general *de facto* moratorium was in effect already as from October 1998, or that it ended in January 2003, when Directive 2001/18 entered into force.

7.1272 The Panel considers that all of these findings taken together lead logically to the following conclusion:

(i) that a moratorium on approvals was in effect in the European Communities between June 1999 and August 2003, when this Panel was established;

(ii) that this moratorium was generally applicable, *i.e.*, to all applications for approval which were pending between June 1999 and August 2003 under Directives 90/220 and/or 2001/18 or under Regulation 258/97; and

(iii) that this moratorium was applied *de facto*, *i.e.*, without having been adopted through a formal EC rule- or decision-making process, and, more particularly, that the final approval of applications was prevented by the Group of Five countries[1172] and/or the Commission through their actions and/or omissions.

7.1273 The Panel also considers that the record supports the inference that the Group of Five countries and the Commission prevented the final approval of applications pursuant to decisions which were intended to be generally applicable. In the case of the Group of Five countries, it can be inferred from their June 1999 joint declaration that they decided to use their powers in the approval process so as to prevent any and all new applications from being approved, until new EC rules on labelling and traceability were adopted. The actual conduct of these countries in the context of individual approval procedures is consistent with the existence of such decisions. During the relevant time period (June 1999 to August 2003), numerous applications received favourable initial assessments from the lead CA. But in each case, one or more Group of Five countries objected to the placing on the market of the relevant biotech product, sometimes explicitly invoking the Group of Five declaration as a reason for their objection. This meant that no application was approved at member State level. At Community level, the Regulatory Committee or the Council did not proceed to a vote on any application between June 1999 and August 2003. There thus exists no information about the voting behaviour of the Group of Five countries during that time period.

7.1274 Regarding the Commission, the Panel made the point that the Commission was faced with highly exceptional circumstances when in June 1999 the Group of Five countries formally signalled its systematic opposition to final approvals. In the Panel's view, it is plausible that the Commission in those circumstances effectively decided not to make full use of the relevant procedures to complete the approval process. In fact, during the relevant time period there was no case where the Commission completed the approval process. Moreover, the Panel's analysis of the facts and histories of individual approval procedures reveals a clear and repeated pattern of inaction, or delayed action, by the Commission at certain stages of the EC approval processes. It shows that the Commission repeatedly failed to forward draft measures to the Council in situations where the Regulatory Committee did not reach the required qualified majority. It also shows that the Commission repeatedly failed to submit a draft measure to the Regulatory Committee, or failed to call a vote in the Regulatory Committee. In the Panel's assessment, the aforementioned elements – the exceptional circumstances presented by the formation of the Group of Five, the fact that the Commission did not approve a single application during the relevant time period, and the fact that during the same time period there was an observable pattern of inaction by the Commission – warrant the inference that the

[1172] The Panel's reference to the Group of Five countries is not intended to suggest that there were no member States other than the Group of Five countries which took steps, during part of the relevant time period (June 1999 to August 2003), with a view to delaying or preventing the final approval of any and all applications. It should be recalled in this respect that Canada submitted evidence which shows that in February 2001 Austria formally expressed its support for the June 1999 declaration by the Group of Five countries, and that the United States submitted a document which suggests that Belgium as of December 2001 also supported the June 1999 declaration by the Group of Five countries.

Commission's conduct was the result of an effective decision not to make full use of the relevant procedures to complete the approval process.[1173]

7.1275 The European Communities appears to argue that the described pattern of inaction by the Commission should rather be considered as a practice in the sense of a pattern of similar responses to a similar set of circumstances.[1174] The European Communities' concept of practice implies that the Commission was engaged in case-by-case decision-making to formulate and develop policy, and that the Commission's conduct in specific cases was subsequently repeated in similar cases, with the consequence that this conduct crystallized into a practice.

7.1276 The Panel is not persuaded that the Commission's conduct reflects nothing more than a practice as that term is understood by the European Communities. True enough, a pattern of inaction could point to the existence of a Commission practice. But it may equally be the consequence of a generally applicable decision by the Commission. Furthermore, the mere fact that the record contains no document embodying such a Commission decision does not imply that no such decision existed and that the described pattern of inaction amounted to a practice. It is important to bear in mind in this regard that the Commission had to respond to decisions of the Group of Five countries which were applicable to all pending and new applications. In these circumstances, the most logical course of action was for the Commission to define and establish a policy which was likewise applicable to all pending and new applications. This was not a situation where the Commission lacked the necessary information to make a general decision and where it was therefore advisable to proceed on a case-by-case basis. The June 1999 declaration by the Group of Five countries provided the Commission with a clear and predictable scenario of how the Group of Five countries would exercise their powers in the context of the EC approval process.

7.1277 Without prejudice to the preceding remarks, the Panel would accept that, in one sense, the Commission's conduct might be considered to reflect a practice. The practice the Panel is referring to relates to the implementation of the Commission's effective decision not to make full use of the relevant procedures to complete the approval process. It is reasonable to assume that there was no predetermined general policy with regard to implementation, as implementation necessarily had to take account of attendant circumstances, including, most notably, the stage in the relevant EC approval procedure to which particular applications had progressed. Indeed, the record shows that the Commission's conduct varied according to the procedural stage reached by a given application.[1175] Another indicator that there was no predetermined general policy with regard to implementation is the circumstance that at one point the Commission changed its conduct in relation to applications which

[1173] For present purposes, it matters little whether the Commission's effective decision was intended to establish Commission policy for several years or whether the decision was tacitly renewed from time to time. Regarding the 2004 approvals of Bt-11 maize (food), NK603 maize and NK603 maize (food), it should be noted that there is no evidence on record which would demonstrate that the Commission decided before 29 August 2003 to complete the approval process in respect of the aforementioned applications. In the case of Bt-11 sweet maize (food), a draft measure was on the agenda of the relevant Regulatory Committee on 8 November 2003. The record does not indicate when the Commission forwarded the draft measure. Exhibit EC-92/At. 67. In the case of NK603 maize, the Commission launched inter-service consultations on a draft measure only on 8 December 2003. Exhibit EC-76/At. 71. Finally, in the case of NK603 maize (food), a draft measure was presented to the Regulatory Committee on 30 April 2004. Here again, the record does not indicate when the Commission forwarded the draft measure. Exhibit EC-96/At. 42. In the light of the evidence on record, there is therefore no reason to doubt that a general *de facto* moratorium was still in effect on 29 August 2003.

[1174] EC first written submission, paras. 566 *et seq.*; EC second written submission, footnote 213.

[1175] For instance, the Commission did not forward draft measures to the Council when the Regulatory Committee did not reach the required qualified majority. In contrast, the Commission initially did forward draft measures to the Regulatory Committee for a vote.

had reached a certain procedural stage. Specifically, the Commission initially forwarded draft measures to the Regulatory Committee for a vote.[1176] Subsequently, however, the Commission stopped doing so.[1177] This shift from one pattern of conduct to another could be interpreted as a change in implementation practice. Such a change in implementation practice would in no way be inconsistent with the view that there was an effective decision by the Commission not to complete the approval process with respect to any pending or new application.[1178]

7.1278 The Panel now turns to address the European Communities' argument that in cases where, as here, the actions and/or omissions of different entities are alleged to be part of a single measure, it is necessary to show that these entities follow a common plan or course of action. The European Communities asserts in this respect that the term "measure" is defined as "a plan or course of action intended to achieve some object".

7.1279 The Panel considers that by not making full use of its powers to complete the approval process, the Commission knowingly entered into effective (*de facto*) co-operation with the Group of Five countries. Indeed, in the Panel's view, the absence of final approvals during the relevant time period is a direct consequence of effective co-operation between the Group of Five countries and the Commission. The Group of Five countries could not have imposed the desired general moratorium on approvals without the co-operation of the Commission. And it is most unlikely that the Commission would have been dissuaded from making full use of the approval procedures if it had not been of the view that the Group of Five countries constituted a credible and stable "blocking minority".

7.1280 It is important to mention that there is nothing in the record to suggest that the Commission unqualifiedly supported the decision of the Group of Five countries to prevent the final approval of applications pending the adoption of new EC rules on labelling and traceability. To the contrary, the "interim approach" developed by the Commission in July 2000 was intended to allow for the resumption of approvals.[1179] But the record shows that even after July 2000 the Commission failed to make full use of the approval procedures.[1180] In other words, the record supports the conclusion that even after July 2000 there continued to be effective co-operation between the Commission and the Group of Five countries.

7.1281 Based on the foregoing observations, the Panel considers that between June 1999 and August 2003 the Group of Five countries and the Commission did follow a common "plan or course of action".[1181] The relevant "plan" consisted in preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability. The fact that the Commission might have disliked the "plan", or sought to change it, is immaterial as long as the Commission did not actually follow a different "plan". As noted, there is no indication that this was the case.

[1176] For instance, in the case of the approval procedure concerning Falcon oilseed rape.

[1177] For instance, in the case of the approval procedure concerning Bt-11 maize (EC-69).

[1178] There would be no inconsistency even if it were assumed that the Commission initially sought to test the resolve of the Group of Five countries to abide by their June 1999 declaration, by launching votes in the Regulatory Committee. There is no indication in the record that the Commission was the initiator of a moratorium on approvals. The Commission's willingness to implement its effective decision not to complete the approval process with respect to any pending or new application may well have been contingent on the Group of Five countries acting in accordance with their June 1999 declaration.

[1179] For an explanation of the "interim approach", *see supra*, footnote 637.

[1180] *See, e.g.*, the approval procedures concerning Bt-531 cotton, RR-1445 cotton , MON809 maize and the Transgenic tomato.

[1181] The Panel is not convinced that the Group of Five countries and the Commission followed a common "plan" prior to June 1999.

7.1282 The European Communities submits, however, that it is not enough for the Group of Five countries and the Commission to have followed a common "plan or course of action". According to the European Communities, the Group of Five countries and the Commission must also have treated their plan of preventing the final approval of applications as *de facto* binding. Otherwise, the European Communities' argument implies, the application of separate decisions by the Group of Five countries and the Commission could not be considered to have produced a new and intended measure, *i.e.*, a general moratorium on approvals.

7.1283 The record does not indicate that either the Group of Five countries or the Commission followed their common plan of preventing the final approval of applications as *de facto* binding. However, there were clear incentives for the common plan to be followed. As we have said earlier, the Group of Five countries could not have imposed the desired general moratorium on approvals without the co-operation of the Commission. And the Commission had grounds for believing that if it did not co-operate with the Group of Five countries, it would have to complete on its own all approval procedures concerning pending applications, due to the "blocking minority" held by the Group of Five countries.

7.1284 At any rate, the European Communities does not explain the basis for its view that the Group of Five countries and the Commission needed to treat their common plan as *de facto* binding. We can see that the question of whether or not the Group of Five countries and the Commission were following their common plan as binding might possibly have an impact on the stability and "lifespan" of the general moratorium on approvals. But we do not consider that, in the case before us, the question of whether the plan at issue was viewed as binding determines whether or not the general moratorium constitutes a measure. We perceive no meaningful difference between a general moratorium on approvals that is applied by the relevant EC entities "voluntarily" and one that is applied pursuant to an enforceable agreement. In neither case, final approvals are granted while the moratorium is being applied. In view of this equivalence of effects, we see no force in the argument that a "binding" moratorium on approvals constitutes a measure for WTO purposes, but that a "voluntary" moratorium on approvals does not. Indeed, were we to accept this argument, Members could evade WTO disciplines governing the application of a moratorium on approvals by applying a "voluntary" rather than a "binding" moratorium.

7.1285 In the light of the above, the Panel reaches the following overall 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 applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

(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 applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

(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 applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

3. Whether the Panel may and should make findings on the WTO-consistency of the general *de facto* moratorium on approvals

7.1286 According to the **European Communities**, even if the Panel finds, as it has, that a general *de facto* moratorium on approvals was being applied by the European Communities between June 1999 and August 2003, this would not automatically mean that the Panel may, or should, make findings on the WTO-consistency of the general moratorium. More particularly, the European Communities argues that the Panel may only make findings on the WTO-consistency of the general moratorium if the moratorium is a challengeable measure under the *WTO Agreement*. And even if that is the case, the Panel should not, in the European Communities' view, make findings on the WTO-consistency of the general moratorium if the moratorium ceased to exist after the date of establishment of the Panel. The European Communities considers that in such circumstances the issue of the WTO-consistency of the general moratorium would be moot and the Panel should refrain from making a ruling on the moratorium.

7.1287 The **Panel** considers that the issues raised by the European Communities are pertinent, and it will therefore examine below (i) whether the moratorium on approvals is a challengeable measure, and if so, (ii) whether the Panel should decline to make findings on the WTO-consistency of the moratorium on approvals if subsequent to the establishment of the Panel the moratorium ceased to exist.

(a) Whether the moratorium on approvals is a challengeable measure

7.1288 The European Communities has argued that the general *de facto* moratorium on approvals cannot be challenged under the *WTO Agreement* because, in its view, the Complaining Parties are not challenging a measure, but a practice – a repeated pattern of suspending consideration of individual applications. The Panel has already dealt with this argument, finding that the general d*e facto* moratorium was the result, not of a mere practice by the Group of Five countries and the Commission, but of separate decisions by these same EC entities, which were intended to be generally applicable.

7.1289 Nevertheless, since the issue was put before us by the European Communities, it is still useful to consider whether the moratorium on approvals, when understood as a measure rather than as a practice, is a challengeable measure. By "challengeable measure" we mean a measure which can be the subject of WTO dispute settlement proceedings. In *US – Carbon Steel*, the Appellate Body had this to say about the measures which may be challenged before a WTO panel:

> "In principle, any act or omission attributable to a WTO Member can be a measure of that Member for purposes of dispute settlement proceedings. The acts or omissions that are so attributable are, in the usual case, the acts or omissions of the organs of the state, including those of the executive branch."[1182]

[1182] Appellate Body Report, *US – Carbon Steel*, para. 81 (footnotes omitted).

7.1290 What sets the moratorium on approvals apart from most other measures challenged before WTO panels are two elements: (i) it is a *de facto* measure, *i.e.*, a measure which was not adopted through a formal EC rule- or decision-making process, and (ii) it is the result of the application of separate decisions by the Group of Five countries and the Commission.

7.1291 We first consider the circumstance that the moratorium is a d*e facto* measure. We note in this regard the Appellate Body's reference to "*any* act or omission attributable to a WTO Member" (emphasis added). In our view, the broad phrase "any act or omission" can encompass both *de jure* measures and *de facto* measures. Reinforcing this view is the circumstance that if *de facto* measures could not be challenged, Members could circumvent their WTO disciplines. For they could then achieve through *de facto* measures what they would not be allowed to achieve through *de jure* measures.

7.1292 As noted, the other particularity of the moratorium is the fact that the moratorium is the result of the application of separate decisions by the Group of Five countries and the Commission. In other words, the moratorium is a measure which is the result of other measures (decisions) applied separately by the Group of Five countries and the Commission. The *WTO Agreement* nowhere says that a measure which is the result of several separate measures is not a challengeable measure. Moreover, the GATT panel in *Japan – Semi-Conductors* found that an inconsistency with Article XI:1 of the GATT 1994 could result from a combination of separate measures:

> "All these factors led the Panel to conclude that an administrative structure had been created by the Government of Japan which operated to exert maximum possible pressure on the private sector to cease exporting at prices below company-specific costs. This was exercised through such measures as repeated direct requests by MITI, *combined with* the statutory requirement for exporters to submit information on export prices, the systematic monitoring of company and product-specific costs and export prices and the institution of the supply and demand forecasts mechanism and its utilization in a manner to directly influence the behaviour of private companies. [...] The Panel considered that the *complex of measures* exhibited the rationale as well as the essential elements of a formal system of export control. [...] The Panel concluded that the *complex of measures* constituted a coherent system restricting the sale for export of monitored semi-conductors at prices below company-specific costs to markets other that the United States, inconsistent with Article XI:1."[1183]

7.1293 We therefore consider that the mere fact that the moratorium is the result of the application of separate decisions by the Group of Five countries and the Commission does not prevent it from being a challengeable measure.

7.1294 We recall, however, the Appellate Body's statement in *US – Carbon Steel* that a measure of a Member can only be challenged if the measure is attributable to that Member. Thus, for the general *de facto* moratorium on approvals to qualify as a challengeable EC measure, it must be attributable to the European Communities. We note that both the Commission and the individual member States which are part of the Group of Five from the perspective of public international law are organs of the European Communities. Accordingly, there can be no doubt that the general moratorium, which is the result of the application of separate decisions by these different EC organs, is attributable to the European Communities.

[1183] GATT Panel Report, *Japan – Semi-Conductors*, para. 117 (emphasis added).

7.1295 In the light of the foregoing considerations, we conclude that the general *de facto* moratorium on approvals constitutes a challengeable EC measure.

(b) Whether the Panel should decline to make findings on the WTO-consistency of the moratorium on approvals if subsequent to the establishment of the Panel the moratorium ceased to exist

7.1296 We now turn to examine the European Communities' further argument that even if the Panel may in principle make findings on the WTO-consistency of the moratorium on approvals because it is a challengeable measure, the Panel nevertheless should not do so if subsequent to the establishment of the Panel the moratorium ceased to exist.

7.1297 Specifically, the **European Communities** argues that if the Panel were to find that as of August 2003 the European Communities applied a general *de facto* moratorium on final approvals, the Panel would need to go on to determine whether that measure subsequently ceased to exist. The European Communities submits that if a measure is no longer in existence, any issues which may have been raised in relation to that measure are moot and a panel should not rule on that measure.[1184]

7.1298 The **United States** argues that the concept of mootness is not relevant to the claims related to the general moratorium on approvals. The measure the United States is requesting the Panel to examine and make findings on is the general moratorium as it existed in August 2003. Any issues relating to whether or not steps taken by the European Communities after August 2003 have brought the European Communities into compliance with its WTO obligations are not before the Panel. In any event, according to the United States, this is not a case in which the measure at issue has terminated. The United States does not agree that two token product approvals – the approvals concerning Bt-11 sweet maize (food) and NK603 maize[1185] – suffice to signal that the European Communities has begun to process other outstanding applications without undue delays. The United States points out that all other applications caught up in the moratorium remain unapproved. The United States submits that biotech product approvals remain a controversial political issue in the European Communities, and the recent expansion of the European Communities from 15 to 25 member States has not simplified the situation. In addition, a number of member States believe that yet additional legislation must be adopted before the granting of new biotech product approvals. And the European Communities has yet to approve a single biotech product for planting in the European Communities. Accordingly, the possibility is substantial that the European Communities – once freed from the pressure of this WTO proceeding – would halt all further approvals. In the view of the United States, it is thus of great import that the Panel issue a finding that the politically-based moratorium is not consistent with WTO rules.

7.1299 Like the United States, **Canada** argues that the question of mootness is not relevant to the claims related to the moratorium, as the moratorium has not ceased to exist. Despite recent Commission Decisions authorizing the placing on the market of two products, Bt-11 sweet maize (food) and NK603 maize, the evidence suggests that the approval of biotech products continues to be delayed and thwarted by the European Communities.[1186] In relation to the two products that have been authorized, the Commission has been forced to adopt decisions authorizing these products after

[1184] The European Communities has also argued that the concept of mootness is not relevant to the claims relating to the general moratorium. However, the European Communities said so under the hypothesis that the Panel finds that a general moratorium never existed.

[1185] We recall that the Commission in 2004 approved the application concerning NK603 maize under Directive 2001/18 and the application concerning NK603 maize (food) under Regulation 258/97.

[1186] Canada's third written submission, para. 196.

failures by both the Regulatory Committee and the Council to take decisions. Canada submits that as long as approvals are invariably granted only after products have gone through every conceivable procedural hoop, the moratorium must be considered to remain in effect. In any event, the continued intransigence on the part of member States, coupled with the complicated political and legal relationship between the member States and the Commission, reflect a very real possibility that, even if it could be said that the moratorium has been lifted, the moratorium could be reinstituted in the future.

7.1300 **Argentina** argues that the approval of Bt-11 sweet maize (food) did not imply the end of the *de facto* general moratorium on approvals. Argentina notes that there are in any event no assurances that the moratorium has ended. Argentina points out in this regard that the approval of Bt-11 sweet maize (food) may have occurred solely because of the establishment of this Panel.

7.1301 The **Panel** notes that the question it is mandated to answer is whether on the date of its establishment, that is to say, on 29 August 2003, the European Communities applied a general *de facto* moratorium on approvals. We have answered this question in the affirmative. The European Communities argues, however, that we should not review the WTO-consistency of that measure on the grounds that the measure has since ceased to exist.

7.1302 At the outset, we examine whether the record of this case indicates that the issue raised by the European Communities – whether the measure at issue, *i.e.*, the general *de facto* moratorium on approvals, ceased to exist after 29 August 2003 – is not merely hypothetical. If the case record indicates that this issue is not merely hypothetical, we think further examination of the EC argument would be warranted.

7.1303 The record shows that the applications concerning Bt-11 sweet maize (food) and NK603 maize (food) were definitively approved by the Commission under Regulation 258/97. Thus, it is not in doubt that after the Panel had been established at least two biotech products – Bt-11 sweet maize (food) and NK603 maize (food) – were definitively approved and hence could be placed on the EC market for specified uses.

7.1304 We note that the moratorium on approvals as alleged by the Complaining Parties was one under which applications were not allowed to move to a positive final approval decision. The Complaining Parties have also alleged that the moratorium applied *across-the-board, i.e.*, that it was applicable to *any and all* applications pending between October 1998 and August 2003. We further note that the Complaining Parties referred to the *absence of a single* approval between October 1998 and December 2003 as critical evidentiary support for their claim that the European Communities applied a general moratorium on approvals. In our earlier findings, we determined that the record supported these assertions by the Complaining Parties.[1187]

7.1305 In view of the foregoing, we consider that there is indeed an issue whether the general *de facto* moratorium on approvals which we found to have existed in August 2003 ceased to exist as a measure generally applicable to all biotech products with pending applications when the definitive approvals for Bt-11 sweet maize (food) and NK603 maize (food) were granted in 2004. Indeed, the applications concerning Bt-11 sweet maize (food) and NK603 maize (food) were applications which *were* allowed to move to a positive final approval decision. Therefore, a more detailed examination of the EC argument is, in our view, warranted.

[1187] *See supra*, para. 7.1285.

7.1306 We begin our examination by noting the following statement by the panel in *India – Autos*:

> "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."[1188]

7.1307 A similar statement was made by a previous panel in *Indonesia – Autos*:

> "[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."[1189]

7.1308 It follows from these statements that in principle we have the authority to make findings on a measure within our terms of reference even if that measure subsequently ceased to exist. We note that the European Communities does not appear to contest this.[1190]

7.1309 The question which remains to be examined, therefore, is whether we should make use of our authority to review the WTO-consistency of the general moratorium on approvals as it existed in August 2003, if the general moratorium later ceased to exist. 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.[1191] 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".

7.1310 The Complaining Parties attach considerable importance to our offering findings on the moratorium as it existed in August 2003, even if it later ceased to exist. They note that most of the applications pending as of August 2003 are still awaiting final approval decisions. The United States and Canada also contend that there is a very real possibility that a general moratorium could subsequently be reintroduced. We consider these to be valid arguments. As numerous applications which were pending in August 2003 have not yet reached the stage of final decision-making, the approvals which were granted in 2004 do not fully address the concerns of the Complaining Parties.[1192] Moreover, the three approvals which were granted in 2004 were possible only because the Commission decided to make full use of the relevant EC approval procedures to complete the

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[1188] Panel Report, *India – Autos*, para. 7.26.

[1189] Panel Report, *Indonesia – Autos*, para. 14.9.

[1190] The European Communities states that the Panel "should" not rule on such a measure, not that it does not have the authority, in principle, to rule on such a measure. EC second written submission, para. 151; EC reply to Panel question No. 7, paras. 26, 28 and 29.

[1191] This approach is consistent with that of the panel in *Chile – Price Band System.* The panel in that case 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.

[1192] We note, as an additional matter, that the European Communities does not argue that the relevant applications were approved in 2004 in order to address the concerns expressed by the Complaining Parties and, hence, to resolve the dispute in relation to the treatment of the relevant applications. The European Communities argues that the approvals which were granted in 2004 are simply the consequence of these applications having reached the final decision-making stage after being assessed at member State and Community level.

approval process. In all three cases, the relevant Regulatory Committee and the Council failed to achieve the required qualified majority. Also, the votes in all three cases were held after the European Communities adopted new EC rules on labelling and traceability, and in some cases even after these rules had entered into force. Notwithstanding this, some Group of Five countries continued to vote against approvals or abstained. Moreover, the Complaining Parties submit that certain member States stated that there needed to be new rules concerning coexistence and environmental liability before they could approve new applications.[1193]

7.1311 In addition to noting the continuing existence of opposition to approvals amongst member States, we also recall the informal, *de facto* nature of the general moratorium on approvals, which means that it can be re-imposed just as soon as it can be ended. In these circumstances, we agree that that even if the general moratorium ceased to exist after August 2003, if we were to find that the European Communities acted inconsistently with its WTO obligations by applying a general moratorium in August 2003, this could help prevent a WTO-inconsistent general moratorium from being reintroduced and, in this way, secure a positive solution to this dispute.[1194]

7.1312 In the light of the above, we do not agree with the European Communities that we should refrain from making findings on the general *de facto* moratorium on approvals as it existed in August 2003 in the event that it later ceased to exist. For the reasons mentioned, we find it appropriate to offer findings on the WTO-consistency of the general moratorium in effect in August 2003 irrespective of whether that measure subsequently ceased to exist.

7.1313 We now turn to consider the issue raised by the European Communities from the perspective of Article 19.1 of the DSU which states that "where a panel [...] concludes that a measure is inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement". The United States argues that when a panel finds that a measure is WTO-inconsistent, it must recommend pursuant to Article 19.1 that the responding party bring that measure into conformity with its WTO obligations, regardless of whether the measure has ceased to exist after the panel was established. It should be noted in this connection that in *US – Certain EC Products*, the Appellate Body has stated that "the Panel erred in recommending that the DSB request the United States to bring into conformity a measure which the Panel has found no longer exists".[1195] The United States emphasises that the measure in that case had been terminated shortly before the panel was established. This is correct. But the Appellate Body nowhere suggested that the situation could be different in a case where a measure ceased to exist in the course of panel proceedings.[1196]

7.1314 We further note the panel report on *Canada – Wheat Exports and Grain Imports* wherein the panel refrained from making a recommendation in relation to a WTO-inconsistent measure which had

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[1193] *See supra*, para. 7.530. *See also*, Exhibit EC-69/At. 125.

[1194] We note that if we were not to make findings on the general moratorium, there would effectively be a possibility of shielding it from scrutiny by a panel because this type of *de facto* measure could be ended shortly before or during panel proceedings and promptly re-imposed thereafter.

[1195] 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.

[1196] The Appellate Body stated that "[a]s we have upheld the Panel's finding that [...] the measure at issue in this dispute [...] *is* no longer in existence, we do not make any recommendation to the DSB pursuant to Article 19.1 of the DSU. Appellate Body Report, *US – Certain EC Products*, para. 129 (emphasis added). In our view, if the Appellate Body had intended to distinguish between measures which ceased to exist before a panel was established and measures which ceased to exist in the course of panel proceedings, it would have used a phrase like "the measure at issue in this dispute was no longer in existence when the panel was established".

been amended in the course of the panel proceedings.[1197] Similarly, in *Dominican Republic – Import and Sale of Cigarettes*, the panel did not find it "appropriate" to make a recommendation in relation to a WTO-inconsistent measure concerning the determination of the tax base for cigarettes because that measure was "no longer in force" as a result of amendments which were made after the panel was established.[1198] While these cases concerned amendments, we think the same approach is logically applicable in a situation where a measure ceased to exist in the course of panel proceedings.[1199] Indeed, the panel in *EC – Commercial Vessels* stated that its recommendation to the European Communities that it bring the relevant measures into conformity with its obligations under the DSU did not apply to certain EC member State aid schemes which had expired soon after the panel had been established. However, the panel's recommendation did cover these expired schemes to the extent they continued to be operational.[1200]

7.1315 Finally, we note that the Appellate Body in *Dominican Republic – Import and Sale of Cigarettes* found that a tax stamp requirement maintained by the Dominican Republic was WTO-inconsistent. It also observed that the parties were in agreement that the tax stamp regime as a whole had been altered by a new decree which came into force after the panel had issued its final report to the parties. The Appellate Body then went on to recommend that the tax stamp requirement be brought into conformity with the GATT 1994 "if, and to the extent that, the [...] modifications to the tax stamp regime have not already done so".[1201]

7.1316 The foregoing WTO jurisprudence supports the inference that panels are to avoid making recommendations which would apply to measures that are no longer in existence or have been amended. Therefore, should we find that the general *de facto* moratorium on approvals was WTO-inconsistent as of August 2003, in formulating any recommendations, we would take appropriate account of the issue raised by the European Communities – that the general moratorium which was in existence in August 2003 might subsequently have ceased to exist.

7.1317 We consider that, in the specific circumstances of this case, we could avoid making recommendations which would apply to measures that are no longer in existence by qualifying any recommendations that we would make in relation to the general moratorium. We recall in this regard that the Appellate Body in *Dominican Republic – Import and Sale of Cigarettes* qualified its recommendation by recommending that the Dominican Republic bring the tax stamp requirement into conformity with the GATT 1994 "if, and to the extent that, the [...] modifications to the tax stamp regime have not already done so".[1202] In the present case, if we were to find that the European Communities breached its WTO obligations by applying a general moratorium, we would similarly recommend that the European Communities bring the general moratorium into conformity with the relevant WTO obligation(s), if, and to the extent that, that measure has not already ceased to exist.[1203]

[1197] Panel Report, *Canada – Wheat Exports and Grain Imports*, paras. 6.258-6.259, 7.3 and 7.6.

[1198] Panel Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 7.363.

[1199] Canada appears to agree with this view. Canada's third written submission, para. 195.

[1200] Panel Report, *EC – Commercial Vessels*, para. 8.4.

[1201] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 129.

[1202] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 129. We recall that the panel in *EC – Commercial Vessels* also offered a qualified recommendation, stating that its recommendation that the European Communities bring certain EC member State aid schemes into conformity with its obligations under the DSU did not apply to aid schemes which had expired after the establishment of the panel, except to the extent that those expired schemes continued to be operational. Panel Report, *EC – Commercial Vessels*, para. 8.4.

[1203] We recall that the issue raised by the European Communities is whether the general moratorium which we found to have existed in August 2003 has since ceased to exist, and not whether that measure, if it were found to be WTO-inconsistent, has already been brought into conformity with the *WTO Agreement.*

Accordingly, we are of the view that so long as we appropriately qualify our recommendations, there is no need to decide, in the context of the present proceedings, whether the general moratorium which we found to have existed in August 2003 subsequently ceased to exist.

7.1318 In the light of this, even if we were to agree with the European Communities that we may decide whether the general moratorium which we found to have existed in August 2003 subsequently ceased to exist, we are not convinced that it would be necessary to do so in the context of the present proceedings. We are also not convinced, in view of the findings and conclusions offered by us, that a decision on whether the general moratorium ceased to exist would be necessary to enable the DSB to make sufficiently precise recommendations to the European Communities. We consider that in the circumstances of this case a qualified recommendation would safeguard and preserve the rights and interests of all Parties and hence would be consistent with the aim of securing a positive solution to the dispute referred to the Panel.[1204] We also note in this regard that in the interim review phase of these proceedings, Canada and Argentina stated that the Panel should not determine whether the general moratorium which we found to have existed in August 2003 continued to exist after the date of establishment of the Panel. The United States considers that the Panel is not charged, in these proceedings, with determining whether the general moratorium continues to exist.

7.1319 Thus, on the basis of all of the above considerations, we decline the European Communities' request to decide, in the context of the present proceedings, whether the general moratorium on approvals which was in effect in August 2003 subsequently ceased to exist. As a result, we undertake no further examination of this issue.

4. Claims of inconsistency raised by the Complaining Parties

7.1320 The Complaining Parties have each presented a series of claims of inconsistency in relation to the European Communities' general *de facto* moratorium on final approvals.

7.1321 The **United States** claims that the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1205]

(a) Annex C(1)(a) and, consequently, Article 8;

(b) Annex B(1) and, consequently, Article 7;

(c) Annex C(1)(b) and, consequently, Article 8;

(d) Article 5.1 and, consequently, Article 2.2; and

(e) Article 5.5 and, consequently, Article 2.3.

7.1322 **Canada** claims that the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1206]

Furthermore, it is worth clarifying that if there were no issue in this case whether the general moratorium on approvals applied by the European Communities in August 2003 subsequently ceased to exist, there would, in our view, be neither a need nor a sufficient justification for a qualified recommendation.

[1204] For further relevant considerations, *see supra*, paras. 6.80 *et seq*.

[1205] The claims are listed in the order in which they were developed in the first written submission of the United States.

(a) Article 5.1 and, consequently, Article 2.2;

(b) Article 5.6 and, consequently, Article 2.2;

(c) Article 5.5 and, consequently, Article 2.3;[1207]

(d) Annex C(1)(a) and, consequently, Article 8; and

(e) Annex B(1) and, consequently, Article 7.

7.1323 **Argentina** claims the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1208]

(a) Article 5.1 and, consequently, Article 2.2;

(b) Article 5.5 and, consequently, Article 2.3;

(c) Article 7 and Annex B(1); and

(d) Article 10.1.

7.1324 The **European Communities** argues that none of the claims presented by the three Complaining Parties are founded, and that it has not acted inconsistently with any of the provisions of the *SPS Agreement* which are being invoked by the Complaining Parties.

7.1325 Since it is the European Communities' view that all of the Complaining Parties' 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 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*, the procedural claims under Annex C of the *SPS Agreement* and Argentina's claim that it was denied special and differential treatment contrary to the provisions of Article 10 of the *SPS Agreement*.

5. Consistency of the general *de facto* moratorium on approvals with Article 5.1 of the *SPS Agreement*

7.1326 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement*.

7.1327 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."

[1206] The claims are listed in the order in which they were developed in the first written submission of Canada.

[1207] Canada's claim under Article 5.5 is put forth as an alternative to its claim under Article 5.6.

[1208] The claims are listed in the order in which they were developed in the first written submission of Argentina.

7.1328 The **Complaining Parties** submit that the general moratorium on approvals constitutes a "sanitary or phytosanitary measure" (hereafter "SPS measure") because it is applied, in their view, to protect against certain of the risks identified in Annex A of the *SPS Agreement*. They further allege that the European Communities has not put forth a risk assessment in support of the general moratorium and that the general moratorium is, therefore, an SPS measure which is not "based on" a risk assessment as required under Article 5.1.

7.1329 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1209] According to the European Communities, Article 5.1 contains obligations relating to the development of SPS measures, not their application. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1) of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1210]

7.1330 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.1 does not contain obligations relating to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.1.

7.1331 The **Panel** notes that, by its clear terms, Article 5.1 applies to SPS measures. Accordingly, for a particular measure to be subject to Article 5.1 it must be an SPS measure. The European Communities contests that the general moratorium on approvals constitutes an SPS measure within the meaning of Article 5.1. It is therefore necessary to examine this issue in detail.

(a) "Sanitary or phytosanitary measure"

7.1332 Article 1 of the *SPS Agreement* states that for the purposes of the *SPS Agreement*, "the definitions provided in Annex A shall apply". Annex A(1) of the *SPS Agreement* contains a definition of the term "sanitary or phytosanitary measure". The definition provided reads as follows:

> *Sanitary or phytosanitary measure* - Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

[1209] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1210] For the text of Article 8 and Annex C(1), *see infra*, sections VII.C.11 and VII.C.12.

> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

7.1333 It is clear from the above definition that all measures are not SPS measures. In other words, not every measure that qualifies as a measure within the meaning of the DSU constitutes, *ipso facto*, an SPS measure.

7.1334 Whether a particular DSU measure constitutes, at the same time, an SPS measure is to be determined, according to the above definition, by reference to such criteria as the objective of the measure, its form and its nature. Regarding the objective of SPS measures, subparagraphs (a) through (d) indicate that SPS measures must "be applied" to protect against certain enumerated risks. Regarding the form of SPS measures, the second paragraph of the definition provides that SPS measures include "all relevant laws, decrees [and] regulations". This enumeration suggests that the *SPS Agreement* does not prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Finally, in relation to the nature of SPS measures, the second paragraph stipulates that SPS measures include "requirements and procedures". The second paragraph then goes on to mention, by way of example, a number of relevant substantive requirements (prescribed end product criteria, prescribed quarantine treatments, certain packaging and labelling requirements, etc.) and procedures (testing procedures, inspection procedures, certification procedures, approval procedures, etc.). We note that the term "requirements" is broad in scope. For instance, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements", in that one is effectively a requirement to permit the marketing of a product and the other a requirement to ban the marketing of a product.

7.1335 Still in relation to the reference in the second paragraph of Annex A(1) to "requirements and procedures", we note that no reference is made to the "application" of "requirements and procedures".[1211] This omission suggests that whereas requirements and procedures as such may constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure. The provisions of the *SPS Agreement* support the view that the omission of a reference to "application" is deliberate, for there are several provisions which establish

[1211] We agree with the European Communities that Article 1.1 of the *SPS Agreement*, which states that SPS measures shall be "developed and applied" in accordance with the provisions of the *SPS Agreement*, confirms that the distinction between SPS measures as such and the application of SPS measures is a relevant one for the purposes of the *SPS Agreement*.

obligations specifically with regard to the "application" of SPS measures. For instance, Article 2.3, second sentence, states that SPS measures "shall not be applied in a manner which constitute a disguised restriction on international trade". Similarly, Article 10.1 states in relevant part that "[i]n the preparation and application of [SPS] measures, Members shall take account of the special needs of developing country Members". Finally, we note that Article 8 draws a distinction between, on the one hand, the "operation" of procedures and, on the other hand, the "procedures", which, themselves, are defined in Annex A(1) as SPS measures.[1212]

7.1336 It should be added in this context that the term "requirements" as it appears in the second paragraph of Annex A(1) is unqualified and thus is applicable both to requirements which are generally applicable and to requirements which have been imposed on specific products.[1213] In our view, the application of a generally applicable SPS "requirement" (e.g., a pre-marketing approval requirement for biotech products) to a specific product may result in a different, product-specific SPS "requirement" (e.g., a ban on the marketing of a specific biotech product). In other words, there may be cases where the application of an SPS "requirement" and, hence, of an SPS measure, may give rise to a new SPS requirement and, hence, a new SPS measure. Applying these considerations to Article 5.1, it could be argued that a generally applicable SPS requirement as set out, *e.g.*, in a law and a product-specific decision based on that requirement might both constitute SPS measures which must be based on a risk assessment.

7.1337 Before proceeding further, a final point should be made. It is important to keep in mind that Annex A(1) is intended to provide a general definition of the term "SPS measure". This general definition must not be applied in mechanistic fashion. In particular, we note that the mere fact that a measure within the meaning of the DSU meets the definition of an "SPS measure" set out in Annex A(1) does not mean that it is, *ipso facto*, subject to every provision of the *SPS Agreement* which applies to "SPS measures". A good illustration of this point is afforded by the chapeau of Annex C(1)(a) of the *SPS Agreement*, which states that "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of [SPS] *measures*, that such procedures are [...] completed without undue delay" (emphasis added). The definition of "SPS measures" given in Annex A says that "SPS measures" include "procedures". Clearly, however, Annex C cannot be read as meaning that "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of [SPS] *procedures*, that such procedures are [...] completed without undue delay". Rather, the term "SPS measures" in Annex C(1)(a) must be interpreted as meaning substantive "SPS requirements".[1214] It is clear from this example that in interpreting the term "SPS measure(s)", in addition to the Annex A(1) definition, account should also be taken of the specific context within which that term appears.

[1212] Article 8 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 (emphasis added).

[1213] We note in this respect that the footnote to Annex B(1) defines "[SPS] regulations" as "[SPS] measures [...] which are applicable generally". It follows, *a contrario*, that there can be SPS measures which are not applicable generally.

[1214] This view draws support from a parallel provision in the *TBT Agreement*. Annex 1(3) of the *TBT Agreement* defines conformity assessment procedures as "[a]ny procedure used, directly or indirectly, to determinate that *requirements* in technical regulations […] are fulfilled" (emphasis added).

(b) Nature of the general *de facto* moratorium on approvals

7.1338 For the purposes of establishing whether the general *de facto* moratorium on approvals constitutes an "SPS measure" within the meaning of Annex A(1) and Article 5.1, it is key, in our view, to determine its nature. More particularly, consistent with the language used in Annex A(1), it must be determined whether the general moratorium is a substantive SPS "requirement", a "procedure" or a measure of a different nature.

(i) Was the decision to apply a general moratorium on approvals a decision to reject all applications or did it predetermine such rejections?

7.1339 To determine the nature of the general moratorium on approvals, it is well to recall our earlier findings. We found, *inter alia*:

(a) that the Group of Five countries decided to use their powers in the approval process so as to prevent any and all new applications from being finally approved, until new EC rules on labelling and traceability were adopted, and

(b) that the Commission responded by not making full use of the relevant procedures to complete the approval process, and that in so doing, it knowingly entered into effective co-operation with the Group of Five countries, and

(c) that, consequently, the Group of Five countries and the Commission followed an inexplicit common "plan or course of action" which consisted in preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability.

7.1340 Based on these findings, and the relevant supporting arguments and evidence, we are of the view that the decisions by the Group of Five countries and the Commission to prevent applications from reaching final approval and thus to apply a general moratorium on approvals were, in essence, decisions to delay final positive approval decisions on individual applications until certain conditions were met.[1215] Consistent with what we have done earlier in our findings, we will hereafter refer, not to decisions by the Group of Five countries and the Commission, but to a decision by the European Communities.

7.1341 In principle, it would also be correct to describe the decision to delay final approval decisions as a decision not to approve individual applications until certain conditions were met. We prefer not to use that description, though. This is because the term "decision not to approve applications" could be understood as referring to a decision to reject all applications. However, as we explain below, the decision to apply a general moratorium was not a substantive decision to reject all applications.

7.1342 By deciding to apply a general moratorium, the European Communities did not give a negative substantive reply to the question "May the biotech products with pending or future applications be marketed in the European Communities?". Rather, the reply the European Communities effectively gave to that question was that certain conditions needed to be met before it could provide positive substantive replies.[1216] In that sense, it can be said that the decision to apply a

[1215] To recall, as of August 2003, relevant conditions (new EC rules on labelling and traceability) had not been met.

[1216] We note that, in the meantime, pending and subsequent applications were subject to a provisional marketing ban. However, as we will explain in detail below, that provisional ban was a consequence, not of the

general moratorium was a procedural decision not to make final and favourable substantive decisions on applications until certain conditions were satisfied.

7.1343 Thus, the decision to apply a general moratorium on approvals did not itself constitute a substantive decision to reject all applications. For completeness, we should examine, in addition, whether the decision to apply a general moratorium on approvals predetermined negative substantive decisions on pending and future applications. The June 1999 declaration by the Group of Five countries said that the relevant member States would take steps to "suspend" new approvals, pending the adoption of EC rules on labelling and traceability. The June 1999 declaration did not imply that once the new EC rules were adopted, the Group of Five countries would seek to complete all pending and new approval procedures with a negative approval decision. We note that there are Group of Five countries which subsequently indicated that additional conditions needed to be met before new approvals could be granted.[1217] However, these additional conditions identified by some Group of Five countries did not predetermine the outcome of approval procedures any more than the conditions set out in the June 1999 declaration. At any rate, there is no evidence to suggest that the Commission's effective decision not to complete approval procedures until the adoption of new EC rules on labelling and traceability predetermined the outcome of individual approval procedures. More particularly, there is no evidence to suggest that the Commission would complete all pending and new approval procedures with a negative decision once the new EC rules were adopted. Accordingly, the decision to apply a general moratorium on approvals cannot be considered to have predetermined negative final decisions on all pending and future applications.

7.1344 Whereas it is clear from the foregoing considerations that we are of the view that the European Communities' decision to apply a general moratorium on approvals can be properly characterized as a decision to delay final positive approval decisions[1218], the Complaining Parties are of the view that this is not the most appropriate legal characterization. In the light of this, we suspend a final conclusion on this issue until after we have examined whether the Complaining Parties have offered a more appropriate legal characterization of the European Communities' decision to apply a general moratorium on approvals. The Complaining Parties have put forward two alternative legal characterizations: (i) that the European Communities' decision to apply a general moratorium on approvals was a decision to impose an effective marketing ban on all biotech products subject to approval, and (ii) that the decision in question established a new procedure or amended the existing EC approval procedure. We first these two characterizations in turn.

(ii) Did the decision to apply a general moratorium on approvals impose an effective marketing ban?

7.1345 The **United States** argues that the general moratorium is, effectively, a marketing ban that affects any and all biotech products. More particularly, the United States submits that a decision to delay completion of approval procedures for biotech products for an indefinite period of time – in this case from late 1998 up through at least August 2003 – is effectively equivalent to a decision to adopt a ban on the marketing of all biotech products subject to the EC approval procedures.

7.1346 **Canada** recalls that the European Communities' own pre-marketing approval requirement effectively imposes a ban on biotech products until they are approved. According to Canada, the

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European Communities' decision to apply a general moratorium on approvals, but of the EC pre-marketing approval requirement.

[1217] *See supra*, para. 7.530. *See also*, Exhibit EC-69/At. 125.

[1218] In order to avoid verbiage, we will hereafter be using the phrase "a decision to delay final approval decisions" rather than the longer, more complete phrase "a decision to delay final positive approval decisions".

general moratorium is a conscious decision on the part of the European Communities not to approve biotech products for an unspecified period of time. In Canada's view, the general moratorium thus effectively renders inoperative the EC approval procedures, resulting in an indefinite suspension of the placing on the market of biotech products. This indefinite suspension converts the pre-marketing approval requirement established by EC legislation into a complete, rather than conditional, marketing ban.

7.1347 **Argentina** argues that the general moratorium functions as a ban on the marketing of biotech products.

7.1348 The **European Communities** argues that the Complaining Parties are improperly characterizing the alleged general moratorium as a marketing ban. The only ban in place in the European Communities is the prohibition to market biotech products that have not undergone prior assessment in accordance with the requirements of EC law. The fact that biotech products cannot be marketed until approved is an intrinsic feature of EC legislation and, indeed, of any approval system. The WTO-consistency of the applicable EC legislation, the EC approval system and the ban on the marketing of non-approved biotech products is not an issue before the Panel as none of these measures have been identified in the Complaining Parties' requests for the establishment of a panel.

7.1349 The European Communities submits that the acts of which the Complaining Parties are complaining should be characterized as delay – they cannot, therefore, amount to a ban. The Complaining Parties' submissions blur this fundamental point, and they seem to insinuate that the EC approval procedures for biotech products are little more than a façade to prevent the marketing of biotech products. The European Communities rejects any such allegation as EC legislation and policy are not intended to prevent the marketing of biotech products.

7.1350 The **Panel** notes that, according to the Complaining Parties, the European Communities' decision to apply a general moratorium on approvals should be characterized, for the purposes of the Panel's legal analysis, as a decision to adopt an across-the-board marketing ban on biotech products requiring approval. In considering this argument, it is important to bear in mind that the decision to apply a general moratorium on approvals was made in the context of a pre-marketing approval system. Therefore, before addressing the merits of the Complaining Parties' argument, it is useful to recall the main features of the European Communities' pre-marketing approval system. EC legislation does not provide for a blanket ban on the marketing of biotech products. EC legislation provides that the marketing of biotech products is subject to approval, or authorization.[1219] In other words, EC legislation imposes a pre-marketing approval requirement. Like any pre-marketing approval system, the EC pre-marketing approval system for biotech products envisages a case-by-case assessment of the products for which marketing approval is sought. Consistent with this case-by-case approach, the European Communities conducts a risk assessment for each individual biotech product which is submitted for marketing approval.[1220]

7.1351 As a result of the EC pre-marketing approval requirement, a biotech product for which marketing approval is sought cannot be legally marketed in the European Communities until the time a final substantive decision has been made on whether or not to approve the marketing of the product. In other words, the pre-marketing approval requirement imposes a provisional ban on the marketing

[1219] Articles 6, 10, 11 and 13 and preambular paragraphs 17, 18 and 20 of Directive 90/220; Articles 4, 6, 13, 15 and 19, and preambular paragraphs 28 and 47 of Directive 2001/18; Articles 3, 4, 6 and 7 and preambular paragraph 2 of Regulation 258/97.

[1220] Articles 12 and 13 of Directive 90/220; Articles 4, 14 and 18 of Directive 2001/18; and Articles 6 and 7 of Regulation 258/97.

of a biotech product for which marketing approval is sought.[1221] The provisional ban remains in effect until a final approval decision has been made.[1222]

7.1352 While applicable EC legislation imposes some deadlines on EC entities charged with carrying out approval procedures, in our understanding, EC legislation does not provide that if approval procedures are not completed within a specified maximum time-period, the relevant application must, as a matter of law, be accepted or rejected. This means, for example, that a failure by a relevant EC entity to observe deadlines imposed on it, while possibly constituting a breach of EC legislation, will normally translate into a delay in the completion of the relevant approval procedure.[1223] Simply put, it can thus be said that in the European Communities the marketing of biotech products is subject to a provisional ban until such time as a final approval decision has been made, regardless of how long it takes to reach a final approval decision.

7.1353 It is important to note that the Complaining Parties in this case chose not to challenge the EC pre-marketing approval system as such. In other words, they chose not to challenge the fact that the European Communities maintains a pre-marketing approval requirement for biotech products. Thus, for the purposes of these proceedings, we must presume that the pre-marketing approval requirement is WTO-consistent. One of the consequences which flows from the EC pre-marketing approval requirement is the fact that the marketing of biotech products for which approval is sought is provisionally banned until such time as a final approval decision has been made. Since this is a direct and necessary consequence of the EC pre-marketing approval requirement, logic dictates that if the pre-marketing approval requirement must be presumed to be WTO-consistent, the same holds true for the provisional ban.

7.1354 With the foregoing observations in mind, we now turn to address the merits of the Complaining Parties' argument that the European Communities' decision to apply a general moratorium on approvals was effectively a decision to adopt an across-the-board marketing ban. Canada has gone furthest in developing this argument. According to Canada, the European Communities' decision to apply a general moratorium on approvals "converted" the EC pre-marketing approval requirement into a definitive marketing ban.[1224] As we understand it, the core of this argument is that as a result of its decision to apply a general moratorium on approvals, the European Communities no longer operated a pre-marketing approval system, but imposed an outright marketing ban. Canada argues that the decision to apply a general moratorium on approvals essentially rendered the EC approval procedure irrelevant, in the sense that it prevented the biotech products with outstanding applications from being approved regardless of the scientific evidence.

7.1355 As an initial matter, we recall our view that, properly understood, the decision to apply a general moratorium on final approvals was a decision to delay final approval decisions. We found that the Group of Five countries and the Commission followed a common "plan", which consisted in

[1221] Instead of saying that the European Communities maintains a pre-marketing approval requirement, one could say with equal justification that the European Communities maintains a conditional marketing ban on biotech products, with the applicable condition being the absence of formal EC marketing approval.

[1222] We use the term "provisional ban" to reflect the fact that this is a provisional measure which is replaced by a final, or definitive, measure upon completion of the approval procedure for the biotech product in question.

[1223] We recall in this context that both at Community and at member State level applicants have the possibility of seeking judicial review of the legality of the actions/inaction by relevant EC entities.

[1224] We note that Canada does not use the term "definitive ban", but instead refers to a "complete, rather than conditional, ban". Canada's reply to Panel question No. 67. We find the term "complete ban" problematic in that it might suggest that the provisional ban effectively imposed by the pre-marketing approval requirement is something other than a complete ban.

preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability. Thus, the "plan" was precisely to prevent final, or definitive, approval decisions. It is consistent with this view that between June 1999 and August 2003 no applications were rejected, and that it was not until after the adoption of the aforementioned EC rules that the Commission approved three applications. In fact, Canada itself acknowledges that the European Communities' decision to apply a general moratorium on final approvals was a "decision not to decide", or a "decision not to approve" applications, and that this type of decision is not the same as a substantive decision definitively to reject any and all applications.[1225] In the light of this, we do not consider that the European Communities' decision to apply a general moratorium on final approvals was designed to convert the pre-marketing approval requirement into a definitive marketing ban.

7.1356 The question thus becomes whether the decision to apply a general moratorium on approvals, while not designed to convert the pre-marketing approval requirement into a definitive marketing ban, nonetheless had the effect of doing so. It is therefore necessary to consider the effect of the decision to apply a general moratorium on approvals. In this regard, we recall once more that the decision we are concerned with in essence was a decision to delay final approval decisions. The decision to delay final approval decisions had the effect of extending the time-period during which non-approved biotech products were subject to the provisional marketing ban flowing from the pre-marketing approval requirement.[1226] For clarity, two observations should be made in relation to this effect. *First*, the effect in question is not an inherent effect of a decision to delay final approvals. If the decision to delay final approval decisions effectively extended the time-period during which the provisional ban was in effect for individual applications, this was because that decision was made in the context of the EC pre-marketing approval system. Had the European Communities opted for a system under which biotech products could be provisionally marketed until a final approval decision was made, a decision to delay final approvals would not have had the effect of extending a provisional marketing ban, but of extending a provisional marketing authorization. *Secondly*, the effect in question is an indirect one. The direct effect of the decision to delay final approval decisions was to delay the completion of individual approval procedures. Under the EC pre-marketing approval system, the marketing of biotech products is banned until it has been approved. Hence, if a decision is made to delay final approvals, this indirectly has an effect, via the principle of "banned until approved", on how long the marketing of the relevant biotech products is provisionally banned.

7.1357 It is clear from the preceding paragraph that the decision to delay final approval decisions and the decision provisionally to ban biotech products are separate and distinct measures. It is also clear that the decision to delay final approval decisions did not impose a new ban. The decision to delay final approval decisions merely had the effect of extending the duration of the provisional ban on the marketing of all non-approved biotech products. That ban was already there, as a consequence of the pre-marketing approval requirement. The provisional marketing ban did not expire prior to the European Communities' decision to delay final approval decisions, and that decision consequently cannot be said to have re-imposed it.

7.1358 It follows from the foregoing considerations that the decision to delay final approval decisions did not have the effect of converting the pre-marketing approval requirement into a definitive

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[1225] *See, e.g.*, Canada's reply to Panel question No. 172.

[1226] We recall that under the European Communities' general moratorium on final approvals, applications were allowed to make some progress in the approval process. Thus, for all those applications which were not affected by the decision to delay final approvals, there was no effective extension of the provisional marketing ban. In contrast, for all applications which as of August 2003 had been affected by the decision to delay final approvals, there had been an effective extension of the provisional marketing ban, but its duration varied from application to application.

marketing ban in the sense of imposing a new ban. But the decision in question had an effect on an already existing ban, the provisional marketing ban flowing from the pre-marketing approval requirement. Accordingly, we need to examine whether, through its effect on the provisional marketing ban, the European Communities' decision to delay final approval decisions converted the EC pre-marketing approval requirement into a definitive marketing ban. More specifically, we need to examine whether the decision to delay final approval decisions effectively converted the pre-marketing approval requirement into an instrument with the same effect as a definitive marketing ban.

7.1359 We note in this regard that if the provisional marketing ban effectively imposed by the EC pre-marketing approval requirement is applied for three years, the practical effect of this is much the same as that of a definitive marketing ban imposed for three years. In either case, the producer seeking to market the relevant biotech product cannot lawfully do so for a three-year period.[1227] Similarly, if a provisional ban is in effect indefinitely, practically speaking, this is little different from a definitive ban imposed for an indefinite period of time.[1228] Thus, the EC pre-marketing approval requirement inherently produces very similar effects as a definitive marketing ban. The European Communities' decision to delay final approval decisions had an effect on the time-period during which the provisional marketing ban was applicable. But it did not lead to the EC pre-marketing approval requirement producing a different kind of effects. Consequently, it cannot be said that the European Communities' decision to delay final approval decisions "converted" the EC pre-marketing approval requirement into an instrument with the same effect as a definitive marketing ban.

7.1360 We accept that the European Communities' decision to delay final approval decisions for an unspecified period of time had the indirect effect of extending the provisional marketing ban for an unspecified period of time. However, as we have stated, the source of the provisional marketing ban, including of the effectively extended ban, is not the decision to delay, but the EC pre-marketing approval requirement. Or to put it differently, what prevents applicants from marketing their biotech product at a given point in time is the European Communities' substantive decision to ban biotech products until they have been approved. If the Complaining Parties had been of the view that the effective extension of the provisional marketing ban in some instances rendered the imposition of that ban inconsistent with Article 5.1, it was open to them to challenge the imposition of that ban (*i.e.*, the pre-marketing approval requirement as the source of the provisional marketing ban). The Complaining Parties chose not to do so in this case.

7.1361 Instead, the Complaining Parties decided to challenge the European Communities' decision to delay final approval decisions. The fact that this procedural decision had an impact on how long the provisional marketing ban resulting from the EC pre-marketing approval requirement was in effect for each application does not turn that decision into a substantive decision provisionally to ban biotech products. A procedural decision to delay final approval decisions does not cease to be procedural merely because it has a substantive impact. Indeed, procedural decisions virtually always have some substantive impact.

7.1362 Within this context, we need to address another argument put forward by Canada. According to Canada, a decision to delay final approval decisions, if it gives rise, as in the present case, to

[1227] We note that while in the case of the provisional marketing ban, the ultimate approval decision could be positive or negative, in the case of the three-year definitive marketing ban, the relevant product could be lawfully marketed upon expiry of the three-year period, unless the ban was re-imposed.

[1228] We note that an indefinite definitive marketing ban, on the one hand, and an indefinite provisional marketing ban, on the other, may have a different economic impact on producers of biotech products. For example, the adverse effect on long-term investments might be smaller in the case of the provisional ban, provided applicants expect that approval decisions will be resumed at some point in the future.

prolonged delays, may be equated with a substantive decision to ban biotech products on the basis that, at some point, a delay effectively becomes a ban. In support of this argument, Canada points to the fact that numerous applications were withdrawn between June 1999 and August 2003. While this is correct, it should also be noted that almost none of the applicants withdrawing their applications cited undue delays in the processing of their application as a reason for the withdrawal.[1229] Nonetheless, we agree with Canada that the absence of a reference to the moratorium or to undue delays does not necessarily indicate that undue delays did not cause, or contribute to, the withdrawals.

7.1363 Canada notes that some applicants in their letters of withdrawal invoked "commercial reasons" and submits that this is a reference to the limited commercial life of biotech products. Canada contends that the biotech products at issue in this dispute have a short life-cycle, such that if they are not approved within reasonable periods of time, the marketing of these products may no longer be of any commercial interest. While this may well be true for some biotech products, the record does not support the view that this is the case generally. In fact, many applicants maintained their applications despite lengthy delays in their processing.[1230] Furthermore, while numerous applications were withdrawn between June 1999 and August 2003, quite a few others were submitted for approval during the same time-period.[1231] If these applicants did not believe that they would eventually be able to have their applications approved, it is difficult to see why the applicants would spend time and money on these applications. Thus, in our view, the facts do not support the general conclusion that, practically speaking, there is no distinction between the European Communities' procedural decision to delay final approval decisions and a substantive decision definitively to ban all biotech products for which approval had been sought.

7.1364 As we have said, we recognize the possibility that, due to short product life-cycles, prolonged delays in the completion of approval procedures could, in some instances, leave applicants with no choice but to withdraw their applications. However, this potential effect of a procedural decision to delay final approval decisions does not provide sufficient grounds for equating that decision with a substantive decision to ban biotech products. The distinction between substance and procedure is a fundamental legal distinction and we see no justification for disregarding it in this case. Annex C(1)(a) of the *SPS Agreement* specifically requires Members to complete their approval procedures without undue delay. A Member is therefore not allowed to cause prolonged delays in the completion of an approval procedure, unless there is a justification for doing so. And if there is a justification, we do not think it would be appropriate to equate delay with a negative substantive decision based on product life-cycle considerations. Where a Member has legitimate reasons for delaying an approval decision, *e.g.*, in order to obtain scientific information required in order to complete a risk assessment, it should not be deemed to have completed its approval procedure with a negative decision (and thus be exposed to the risk of a successful challenge to that presumed decision based on Article 5.1 of the *SPS Agreement*) merely because the applicant's product is nearing the end of its life-cycle. Provided a Member completes an approval procedure without undue delay, the fact that the time taken significantly diminishes the applicant's market opportunities is of no particular relevance.

7.1365 In conclusion, we note that, for the reasons set out above, we are unable to accept the Complaining Parties' argument that the European Communities' decision to apply a general moratorium on approvals was effectively equivalent to a decision to impose an across-the-board marketing ban.

[1229] The application concerning RR oilseed rape (EC-79) is a notable exception. Exhibit EC-79/At. 30.

[1230] For instance, the application concerning Bt-531 cotton was submitted in December 1996 and was still pending in August 2003 and beyond.

[1231] *See, e.g.*, Exhibits EC-94, EC-95, EC-96, EC-104, EC-106 and EC-107.

(iii) Did the decision to apply a general moratorium on approvals itself establish a procedure or amend the existing EC approval procedures?

7.1366 In addition to asserting that the decision to apply a general moratorium on approvals effectively banned the marketing of all biotech products with pending or future applications, the Complaining Parties present arguments which present the issue of whether that decision could be considered either to have established a new procedure or to have amended the existing EC procedures. As this issue is directly relevant to the legal characterization of the decision to apply a general moratorium on approvals, it is necessary to address it.

7.1367 The **United States** argues that the decision to apply a general moratorium on approvals modified the European Communities' approval regime. More specifically, the United Stats argues that the suspension by the European Communities of the consideration of applications for, or granting of, approval of biotech products is a procedure within the meaning of Annex A(1) of the *SPS Agreeme*nt, although an unwritten one. The United States points out in this regard that the *New Shorter Oxford English Dictionary* defines the term "procedure" as a "particular mode or course of action" or a "set of instructions for performing a specific task which may be invoked in the course of a [computer] program".

7.1368 **Canada** does not argue that the decision to apply a general moratorium on approvals established an unwritten procedure. Canada contends, however, that that decision led to a significant departure from the existing EC approval procedure in that it resulted in the European Communities moving from approvals based on risk assessment to no approvals regardless of the scientific evidence. According to Canada, the decision to apply a general moratorium on approvals amounted to a mis- or non-application of the applicable legislation and essentially rendered the approval procedure irrelevant. Canada submits that the moratorium superseded the EC approval procedure as the measure that exerted effective control over applications.

7.1369 Like Canada, **Argentina** does not argue that the decision to apply a general moratorium on approvals established an unwritten procedure. Argentina nevertheless argues that that decision modified the existing EC approval procedures by introducing additional procedural stages not envisaged in the relevant legislation. Specifically, Argentina contends that the inter-service consultations launched and held by the Commission in the context of some individual approval procedures have no legal basis in the legislation.

7.1370 The **Panel** begins by recalling its view that the decision to apply a general moratorium on approvals was a decision to delay final approval decisions. The first issue to be examined in view of the United States' argument is whether the decision to delay final approval decisions laid down a "procedure". Relevant dictionary definitions of the term "procedure" are: "[a] particular mode or course of action"[1232] or "an established or official way of doing something"[1233].

7.1371 In our view, the decision to delay final approval decisions did not itself establish a procedure for approving biotech products or, more to the point, for preventing the final approval of biotech products. To begin with, it did not establish "[a] particular mode or course of action" to be followed by the Group of Five countries and/or the Commission. Nor did it establish an "[un]official way" of approving, or not approving, applications. It is instructive in this regard to recall the June 1999 declaration by the Group of Five countries, which states in relevant part that "in exercising the powers

[1232] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2, p. 2363.

[1233] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Clarendon Press, 1999), p. 1139.

vested in them regarding the growing and placing on the market of genetically modified organisms […] they [the Group of Five countries] will take steps to have any new authorizations for growing and placing on the market suspended".[1234] The declaration itself does not establish a procedure, as it does not specify the steps to be taken to bring about a suspension of approvals. We also recall that the general moratorium on approvals was given effect through various types of action and/or omission by the Group of Five countries and/or the Commission. But the record does not support the conclusion that the relevant acts and/or omissions were a reflection of an established procedure.[1235]

7.1372 It remains to be examined, then, whether the decision to delay final approval decisions effectively amended the relevant EC approval procedures. The relevant approval procedures are set out in Directive 90/220 and its successor, Directive 2001/18, as well as Regulation 258/97. The main elements and similarities of these approval procedures have been described earlier in Section VII.C.

7.1373 We do not consider that the decision to delay final approvals resulted in the European Communities applying a different type of approval procedure between June 1999 and August 2003. Indeed, it can be seen from our earlier findings that applications continued to be assessed in accordance with the procedures set out in Directives 90/220 and 2001/18, as well as Regulation 258/97. Accordingly, applications were still being assessed first at member State level and subsequently at Community level. Lead CAs continued to prepare initial assessment reports. The Commission continued to seek the assistance of EC scientific committees and, at least initially, submitted draft measures to the Regulatory Committee for a vote. While it is correct that the Commission conducted inter-service consultations in the context of some of the approval procedures in question, we have previously found that such consultations were not an additional procedural stage devised by the Commission to prevent the approval of biotech products.[1236]

7.1374 Moreover, it has not been explained to us precisely how the decision to delay final approval decisions would have modified the approval procedures set out in the applicable EC legislation. It is not clear to us what was the particular "mode or course of action" to be followed under the supposedly modified EC approval procedures, or what was the newly established "[un]official way" of approving, or not approving, applications. As we have noted, the June 1999 declaration by the Group of Five countries does not predetermine any particular "mode or course of action" to be followed. The mere fact that some applications did not reach Community level or were not put to a vote in the Regulatory Committee, and that no approval procedure was completed with a final approval decision does not demonstrate that the European Communities applied a different type of approval procedure. In our view, a more appropriate conclusion to be drawn from the absence of final approvals and the delays in the processing of applications is that the European Communities applied its existing approval procedures, but that it intentionally did not make full use of these procedures to complete the approval

[1234] Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations, 2194th Council Meeting - Environment-, Luxembourg, 24/25 June 1999. Exhibits US-76 and 77; Exhibit CDA-3; Exhibit ARG-12.

[1235] We have noted earlier that the Commission's conduct might possibly be considered to reflect an (evolving) implementation practice. *See supra*, para. 7.1277.

[1236] *See supra*, para. 7.1260. We note that these earlier findings concerned inter-service consultations held in the context of an approval procedure conducted pursuant to Directive 90/220. However, the same considerations apply equally to inter-service consultations held in the context of an approval procedures conducted pursuant to Directive 2001/18 and Regulation 258/97.

process.[1237] To our minds, this is a natural and logical way of implementing a decision to delay final approval decisions.

7.1375 Canada argues that the decision to delay final approval decisions led to "a significant departure from the existing EC approval procedure" or "superseded the EC approval procedure as the measure that exerted effective control over applications". As we see it, the decision to delay final approval decisions neither led to a departure from the existing approval procedures nor superseded them. Based on the information on the record, we are of the view that the decision to delay final approval decisions was implemented through, and within the framework of, the existing approval procedures. As pointed out by Canada, this resulted in at least a partial "non-application" of the existing approval procedures. However, non-application of one particular approval procedure does not logically imply application of a different approval procedure.

7.1376 We note, as an additional matter, Canada's contention that "the measure that exerted effective control over applications" was the decision to delay final approval decisions, and not the existing approval procedures. The first observation to be made in relation to this contention is that, legally speaking, applications remained fully subject to the approval procedures in force. However, it is clear that the approval procedures set out in the applicable EC legislation left member States and the Commission a degree of discretion with regard to the application, or operation, of these approval procedures. A decision by a relevant EC entity relating to the application, or operation, of the applicable approval procedures may have – and, indeed, may be intended to have – an impact on the manner and/or speed of assessment of applications. If it does, that decision plainly would exert a degree of "effective control" over applications.

7.1377 In our analysis, the European Communities' decision to delay final approval decisions was such a decision relating to the application, or operation, of the EC approval procedures.[1238] It essentially was a decision to operate the EC approval procedures in such a way that there would be no final approval decisions until certain conditions were met. Moreover, since the objective of that decision was to delay final approval decisions, it is inevitable that it exerted a degree of effective control over individual applications. However, as we have noted above, we do not think that applications were effectively no longer controlled, at all, by the EC approval procedures set out in the legislation. If in practice the decision to delay final approval decisions nonetheless exerted a significant degree of effective control, this was in part a consequence of the objective of that decision, which was to prevent final approval decisions. Quite possibly, the fact that applicants chose not to seek judicial review, either before member State courts or the European Court of Justice, of action taken, or not taken, by lead CAs or the Commission in the context of individual approval procedures was another reason why in practice the decision to delay final approval decisions exerted a significant degree of effective control over individual applications.[1239]

7.1378 In the light of the foregoing, we conclude that the European Communities' decision to apply a general moratorium on approvals did not itself establish a procedure for approving, or not approving, applications, and that it did not effectively amend the existing EC approval procedures either. We

[1237] We recall in this regard the European Communities' argument that the EC legislation which sets out the relevant approval procedures was considered inadequate by some member States and segments of public opinion.

[1238] We recall that the EC approval procedures as such have not been challenged by the Complaining Parties.

[1239] We recall that according to an uncontested statement by the European Communities no complaints were brought before the European Court of Justice in respect of the products subject to these proceedings. Only one case was instituted before a member State court, but that case concerned a member State safeguard measure.

nonetheless consider that the decision to apply a general moratorium on approval was procedural in nature, in that it was a decision relating to the application, or operation, of the existing EC approval procedures.

(iv) Conclusion

7.1379 It is clear from the preceding analysis that we are unable to accept either of the alternative legal characterizations of the general moratorium on approvals which the Complaining Parties have put forward. Accordingly, we confirm the view and conclusion we offered at the beginning of our analysis, namely that the European Communities' decision to apply a general moratorium on approvals should be characterized as a procedural decision to delay final substantive approval decisions. The decision was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures.

7.1380 We recall that the second paragraph of Annex A(1) of the *SPS Agreement* provides that SPS measures include "requirements and procedures". We have stated above that in order to establish whether the general moratorium on approvals constitutes an "SPS measure" within the meaning of Article 5.1 and Annex A(1), it must be determined whether the general moratorium is a substantive SPS "requirement", a "procedure" or a measure of a different nature. Our findings above on the nature of the general moratorium on approvals enable us to make that determination.

7.1381 We have found above that the decision to apply a general moratorium on approvals did not impose an effective marketing ban. If it had, it could have been considered to impose a substantive "requirement", on the basis that a ban is effectively equivalent to a negative requirement, *i.e.*, a requirement not to permit the marketing of a product. We further found that the decision to apply a general moratorium on approvals neither established nor amended a procedure. If it had established or amended a procedure, it might have been considered to lay down a "procedure".

7.1382 We have characterized the decision to apply a general moratorium on approvals as a procedural decision to delay final substantive approval decisions. In our assessment, this procedural decision did not impose a substantive "requirement" in relation to biotech products with pending or future applications. It neither approved nor rejected applications. Similarly, we are of the view that the decision to delay final substantive approval decisions cannot appropriately be viewed as providing for a "procedure", considering that it did not itself establish a new procedure or amend the existing EC approval procedures. We have said that the decision to delay final approval decisions was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures. However, the mere fact that the decision in question related to the application, or operation, of procedures does not turn that decision into a procedure for the purposes of Annex A(1).[1240]

7.1383 Based on these considerations, we conclude that the European Communities' decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of procedures. As such, it did not provide for "requirements [or] procedures" within the meaning of Annex A(1).

[1240] We recall in this regard that the second paragraph of Annex A(1) makes no reference to the "application" of "[substantive] requirements and procedures".

(c) Applicability of Article 5.1 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1384 Having ascertained the nature of the European Communities' decision to apply a general moratorium on approvals, we can now proceed to determine whether that decision was an "SPS measure" within the meaning of Article 5.1 and Annex A(1). We recall in this regard that for a particular measure to be subject to Article 5.1 it must be an "SPS measure".

7.1385 In relation to the Annex A(1) definition of the term "SPS measure", we note once again that the second paragraph of Annex A(1) of the *SPS Agreement* provides that SPS measures include "requirements and procedures". We have found above that the European Communities' decision to apply a general moratorium on approvals did not provide for "requirements [or] procedures" within the meaning of Annex A(1). We found that the decision in question was a decision concerning the application, or operation, of "procedures".

7.1386 We have observed earlier that the second paragraph of Annex A(1) does not refer to the "application" of "requirements and procedures" and that this omission must be given meaning in view of the distinction made in various provisions of the *SPS Agreement* between SPS measures and their "application", or "operation". We consequently found that although requirements and procedures as such may in accordance with the Annex A(1) definition constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure.[1241] Since we determined that the European Communities' decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of the EC approval procedures, it follows from the preceding considerations that that decision does not meet all of the constitutive elements of the definition of the term "SPS measure" as provided in Annex A(1).

7.1387 The Annex A(1) definition is directly applicable to Article 5.1. However, we have stated earlier that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we now go on to analyse whether the provisions of Article 5.1 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1388 Article 5.1 requires that an SPS measure applied by a Member be based on a risk assessment. In our view, the term "SPS measure" in Article 5.1 should be taken to refer to a measure applied for achieving the relevant Member's appropriate level of sanitary or phytosanitary protection. We note in this regard that Article 5.3 of the *SPS Agreement* provides in relevant part that "[i]n determining the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection, Members shall take into account [certain] economic factors". Thus, Article 5.3 establishes a link between the assessment of risk and the determination of "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from *such* risk" (emphasis added). Indeed, as we see it, one of the purposes of a risk assessment is to allow the importing Member to determine "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection".[1242] And one of the purposes of the requirement that SPS measures be based on a risk assessment is to ensure that the measure

[1241] We have pointed out, however, that in some circumstances the application of a requirement may result in another requirement.

[1242] We note that Annex A(4) of the *SPS Agreement* defines the term "risk assessment" as meaning an assessment of risk "according to the [SPS] measures which might be applied".

actually applied for achieving the appropriate level of sanitary or phytosanitary protection bears a rational relationship to the risk.[1243]

7.1389 The view 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 draws further support from Article 5.6. Pursuant to Article 5.6, "when establishing or maintaining *[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection*, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" (emphasis added). We think that Article 5.6 states explicitly what is implied in Article 5.1 and that the two provisions therefore use the term "SPS measures" in the same sense. We note in this regard that Article 5.6 follows Article 5.1 and builds on it, inasmuch as Article 5.6 lays down an obligation that goes beyond the obligation laid down in Article 5.1. Indeed, an SPS measure applied for achieving a Member's appropriate level of protection may be based on a risk assessment, but at the same time may be more trade-restrictive than required to achieve the appropriate level of protection.

7.1390 It follows from the preceding observations that we need to examine whether the European Communities' decision to apply a general moratorium on approvals was a measure applied to achieve the European Communities' appropriate level of sanitary or phytosanitary protection. In addressing this issue, we recall that the European Communities' decision was made in the context of the EC pre-marketing approval system. In our view, the pre-marketing approval requirement which results in a provisional marketing ban may be properly considered a measure that is applied for achieving the European Communities' appropriate level of protection. Moreover, it is not open to doubt that final substantive approval decisions on individual applications are also measures applied for achieving the European Communities' appropriate level of protection.[1244]

7.1391 In contrast, we do not consider that the European Communities' decision to apply a general moratorium on approvals was, as such, a measure applied to achieve the European Communities' appropriate level of protection. We recall in this regard that that decision was a procedural decision to delay final approval decisions. As we explained above, the practical effect of that decision was to extend the time-period during which non-approved biotech products were 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 decision to delay final approval decisions. By itself, the procedural decision to delay final approval decisions did not achieve or imply a particular level of protection.[1245]

[1243] According to the Appellate Body, the requirement of a risk assessment "was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection". Appellate Body Report, *EC – Hormones*, para. 177.

[1244] We recall our view that the application of a "requirement" may result in another "requirement" within the meaning of Annex A(1) of the *SPS Agreement*. Specifically, the application of the EC pre-marketing approval requirement to a specific biotech product for which marketing approval has been sought results in a final approval decision on that product which may be considered a "requirement" – either a requirement to permit the marketing of the relevant product or a requirement to prohibit the marketing of the relevant product.

[1245] Had the European Communities opted for a system under which biotech products could be provisionally marketed until a final approval decision was made, a decision to delay final approval decisions would not have had the effect of extending a provisional marketing ban, but of extending a provisional marketing authorization. But in this scenario as well, it would be the decision to grant provisional marketing authorization which achieves a particular level of sanitary or phytosanitary protection, not the decision to delay final approval decisions.

7.1392 As the European Communities' decision to apply a general moratorium on approvals was not, itself, 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. As a result, the provisions of Article 5.1 do not cast doubt on the provisional conclusion we have reached on the basis of the Annex A(1) definition. Rather, they reinforce our provisional conclusion.

7.1393 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Article 5.1 and Annex A(1). It follows that since only "SPS measures" are subject to the provisions of Article 5.1, the provisions of Article 5.1 are not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1394 In view of this conclusion, we need not continue our analysis of the Complaining Parties' claim under Article 5.1.

(d) Conclusions

7.1395 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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

6. Consistency of the general *de facto* moratorium on approvals with Article 5.6 of the *SPS Agreement*

7.1396 Canada claims that by applying a general *de facto* moratorium on approvals between June 1999 and August 2003, the European Communities has acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement*.

7.1397 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)

7.1398 **Canada** submits that the general moratorium on approvals is more trade-restrictive than required to achieve the European Communities' appropriate level of protection. According to Canada, an obvious alternative measure to the moratorium is for the European Communities to comply with its existing approval legislation and permit biotech products to be considered for, and granted or denied, approval. For the purposes of its claim with respect to Article 5.6, Canada assumes that the European Communities' appropriate level of protection is that which the European Communities has expressed in its approval legislation for biotech products. The EC approval procedures continue to serve as an adequate framework for determining whether biotech products pose risks to human health and the environment. In Canada's view, it is therefore reasonable to conclude that the European Communities' own approval procedure, properly functioning, would achieve its appropriate level of protection. Finally, Canada submits that compliance by the European Communities with its own approval procedures would be significantly less trade-restrictive than the existing moratorium.

7.1399 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1246] According to the European Communities, Article 5.6 contains obligations relating to the development of SPS measures, not their application. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1) of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1247]

7.1400 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.6 does not contain obligations relating to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.6.

7.1401 The **Panel** notes the European Communities' argument that the European Communities' decision to apply a general moratorium on approvals does not fall to be assessed under Article 5.6. In view of this argument, we must first examine whether the provisions of Article 5.6 are applicable.

[1246] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1247] For the text of Article 8 and Annex C(1), *see infra*, section VII.C.11 and VII.C.12.

(a) Applicability of Article 5.6 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1402 We note that, by its clear terms, Article 5.6 applies to "[SPS] measures". Accordingly, for a particular measure to be subject to Article 5.6 it must be an SPS measure. Pursuant to Article 1 of the *SPS Agreement*, the Annex A(1) definition of the term "SPS measure" is directly applicable to Article 5.6. We have found above that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term "SPS measure" as it appears in Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we proceed to analyse whether the provisions of Article 5.6 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1403 When analysing the Complaining Parties' claim under Article 5.1, we have highlighted the fact that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". It is therefore clear that the SPS measures at issue in Article 5.6 are those applied for achieving the appropriate level of protection.

7.1404 We found above that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve the European Communities' appropriate level of protection.[1248] It follows that that decision cannot be considered an "SPS measure" within the meaning of Article 5.6. Reinforcing this view is the fact that the procedural decision to delay final approval decisions did not itself restrict trade. Trade was restricted as a result of a distinct measure, namely, the pre-marketing approval requirement which imposes a provisional marketing ban on biotech products. Consequently, the provisions of Article 5.6 support rather than undermine the provisional conclusion we have reached on the basis of the Annex A(1) definition.

7.1405 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Article 5.6 and Annex A(1). As only "SPS measures" are subject to the provisions of Article 5.6, we consider that the provisions of Article 5.6 are not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1406 In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.6.

(b) Conclusions

7.1407 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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

[1248] *See supra*, para. 7.1371.

7. Consistency of the general *de facto* moratorium on approvals with Article 5.5 of the *SPS Agreement*

7.1408 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement*.

7.1409 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. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision."

7.1410 The **Complaining Parties** submit that the European Communities has adopted different appropriate levels of protection in three different situations that can be compared. The United States argues that the European Communities has identified a different level of protection for biotech products and products produced with biotech processing aids. Canada and Argentina argue that the European Communities has identified a different level of protection for biotech products that have been stalled as a result of the general moratorium, biotech products that were approved for marketing prior to the imposition of the general moratorium, and novel non-biotech products such as those produced by conventional plant breeding techniques. The Complaining Parties further argue that the identified differences in appropriate levels of protection in comparable situations are "arbitrary or unjustifiable". Finally, the Complaining Parties argue that the general moratorium as the measure embodying the differences in the levels of protection has resulted in discrimination or a disguised restriction on international trade.

7.1411 **Canada** notes that it is making a claim under Article 5.5 in the alternative, in the event that contrary to Canada's assumption, the European Communities' appropriate level of protection is reflected, not in the applicable EC approval legislation, but in the general moratorium itself.

7.1412 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1249] According to the European Communities, Article 5.5 is premised on, and requires, the existence of an SPS measure. It does not refer to the application 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 Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1)

[1249] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1250]

7.1413 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.5 does not refer to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.5.

7.1414 The **Panel** notes the European Communities' argument that the European Communities' decision to apply a general moratorium on approvals is not subject to the provisions of Article 5.5. In view of this argument, we must first examine whether the provisions of Article 5.5 are applicable.

(a) Applicability of Article 5.5 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1415 Article 5.5 contains obligations relating to the application of the concept of the appropriate level of sanitary or phytosanitary protection. However, we note that the "Guidelines to Further the Practical Implementation of Article 5.5", adopted by the SPS Committee in accordance with the second sentence of Article 5.5, state in this regard that "the concept of appropriate level of protection is applied in practice through sanitary or phytosanitary measures".[1251] This statement is consistent with relevant Appellate Body jurisprudence. In *EC – Hormones*, the Appellate Body found that three elements must be demonstrated to establish an inconsistency with Article 5.5:

> "The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those *levels of protection* exhibit arbitrary or unjustifiable differences ('distinctions' in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the *measure* embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade."[1252]

7.1416 In the light of this, we consider that although Article 5.5 does not explicitly refer to "SPS measures", implicitly it envisages that the "measure complained of" is an "implementing measure"[1253]. In other words, the measure complained of must be an SPS measure applied for achieving a particular level of sanitary or phytosanitary protection. In this respect, there is therefore no difference between Article 5.5, on the one hand, and Articles 5.1 and 5.6, on the other hand.

7.1417 If, as Appellate Body jurisprudence leads us to believe, Article 5.5 implies a reference to "SPS measures", the general definition of that term set out in Annex A(1) of the *SPS Agreement* must

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[1250] For the text of Article 8 and Annex C(1), *see infra*, section VII.C.11 and VII.C.12.
[1251] G/SPS/15, B.1.
[1252] Appellate Body Report, *EC – Hormones*, para. 214 (italics in original; underlining added).
[1253] *Ibid.*, para. 215.

be applicable in the context of Article 5.5 as well. We have found above that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term "SPS measure" as it appears in Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we proceed to analyse whether the provisions of Article 5.5 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1418 As we have pointed out, the SPS measures at issue in Article 5.5 are those applied for achieving a particular level of protection. We found above that the pre-marketing approval requirement which results in a provisional marketing ban may be properly considered a measure which is applied for achieving the European Communities' appropriate level of protection. Similarly, we found that final substantive approval decisions on individual applications are measures applied for achieving the European Communities' appropriate level of protection. But, most importantly, we found that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve a particular level of protection, and did not imply a particular level of protection either. That decision cannot, therefore, be considered an "implementing measure". This being so, it is clear that the provisions of Article 5.5 as interpreted by the Appellate Body and the SPS Committee do not undermine, but reinforce the provisional conclusion we have reached on the basis of the Annex A(1) definition.

7.1419 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an implementing "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body. As Article 5.5 implies that the measure complained of is an implementing "SPS measure", we consider that Article 5.5 is not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1420 In view of this conclusion, we need not continue our analysis of the Complaining Parties' claim under Article 5.5.

(b) Conclusions

7.1421 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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8. Consistency of the general *de facto* moratorium on approvals with Article 2.2 of the *SPS Agreement*

7.1422 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals between June 1999 and August 2003, the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement*.

7.1423 Article 2.2 of the *SPS Agreement* provides in relevant part:

> "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."

7.1424 It is apparent from the text of Article 2.2 that this provision contains three separate requirements: (i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health; (ii) the requirement that SPS measures be based on scientific principles; and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence.

7.1425 The **Complaining Parties** consider that Article 2.2 is applicable to the general moratorium on approvals. The United States submits that the general moratorium is inconsistent with the second and third requirements in Article 2.2, while Canada and Argentina submit that it is inconsistent with all three requirements contained in Article 2.2.

7.1426 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1254] According to the European Communities, Article 2.2 contains obligations concerning the development of SPS measures, not their application. The European Communities submits that by challenging the way in which applications are dealt with under the EC approval system, the Complaining Parties are challenging the application of an SPS measure. The European Communities therefore considers that Article 2.2 is not applicable to the alleged general moratorium on approvals.[1255]

7.1427 The **Panel** will first analyse the claims under the first requirement in Article 2.2. The claims under the second and third requirements will be analysed subsequently, in a joint subsection.

[1254] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1255] It should be noted that the European Communities initially remarked that one could argue on whether Article 2.2 contains obligations relating to the application of an SPS measure rather than to its development. The European Communities submitted that the question could be left open in this case.

(a) First requirement in Article 2.2

7.1428 **Canada** argues that there is a relationship between the first requirement in Article 2.2 and Article 5.6. Canada notes that the panel in *Australia – Salmon* stated that "Article 5.6 should, in particular, be read in light of Article 2.2".[1256] Canada also submits that Article 5.6 is a more specific expression of the general obligation found in Article 2.2 that SPS measures may be applied only to the extent necessary to protect human, animal or plant life or health. Canada considers, therefore, that an SPS measure found to be in violation of Article 5.6 must be presumed to violate the first requirement in Article 2.2. As previously noted, in Canada's view the general moratorium on approvals is inconsistent with Article 5.6. Canada concludes from this that the general moratorium must also be presumed to be contrary to the first requirement in Article 2.2.

7.1429 **Argentina** considers that the requirement that SPS measures be applied only "to the extent necessary" applies to the imposition of an SPS measure and is valid for any SPS measure. Regarding the general *de facto* moratorium on approvals, Argentina notes that it has been implemented generally, that is to the extent of all biotech products. Argentina argues that the general moratorium is therefore an SPS measure which has been applied to an unjustifiably broad extent. Argentina points out in this regard that the applicable EC legislation itself states that the safety of biotech products must be assessed on a case-by-case basis. In Argentina's view, the unjustifiably broad application of the general moratorium is contrary to the first requirement set out in Article 2.2.

7.1430 The **Panel** begins its analysis with Canada's claim. Canada's claim based on the first requirement in Article 2.2 is in the nature of a consequential claim. Canada submits that an inconsistency with the first requirement in Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.6. We begin our consideration of Canada's claim by recalling our earlier finding that Article 5.6 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.6 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.6, and since Canada's claim under the first requirement in Article 2.2 is premised on the existence of a breach of Article 5.6 by the European Communities, Canada's claim under the first requirement in Article 2.2 cannot succeed.

7.1431 We now turn to consider Argentina's claim. Argentina claims that the European Communities' general *de facto* moratorium on approvals is a measure that has been applied to an unjustifiably broad extent, and that this is contrary to the first requirement in Article 2.2. More specifically, Argentina argues that the moratorium should not have been applied to all biotech products in respect of which applications were pending during the relevant time period, given that the EC approval legislation states that the safety of biotech products should be assessed on a case-by-case basis.

7.1432 Argentina argues that for the purposes of its claim under the first requirement in Article 2.2 the general *de facto* moratorium on approvals should be considered as an "SPS measure". However, based on the Annex A(1) definition of the term "SPS measures", we have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it

[1256] Panel Report, *Australia – Salmon*, para. 8.165.

did not constitute an "SPS measure" within the meaning of Annex A(1).[1257] This view seems to us to be appropriate also in the specific context of the first requirement in Article 2.2.

7.1433 We note in this regard that the panel in *EC - Hormones* stated that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2.[1258] Furthermore, the panel in *Japan – Agricultural Products II* stated that the more specific language of Article 5.6 should be read in the light of the more general language in the first requirement of Article 2.2.[1259] If, as the aforementioned panels suggested, Article 2.2 and Article 5.6 are to be read together, and if Article 5.6 is a specific application of the first obligation provided for in Article 2.2, then our previous considerations as to why we believe the provisions of Article 5.6 are not applicable to the European Communities' decision to apply a moratorium are relevant also in the context of the first requirement of Article 2.2. Therefore, as is the case with Article 5.6, we are of the view that the first requirement in Article 2.2 is applicable to measures applied for achieving a Member's appropriate level of sanitary or phytosanitary protection.[1260]

7.1434 We have already found that the European Communities' procedural decision to delay final approval decisions did not itself constitute a measure which is applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Accordingly, we consider that that decision does not constitute an SPS measure within the meaning of Article 2.2. It follows that the particular claim presented by Argentina under the first requirement of Article 2.2 cannot succeed.

(b) Second and third requirements in Article 2.2

7.1435 The **United States** and **Canada** note that the Appellate Body in *Australia – Salmon* agreed with the panel in that case that "in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence".[1261] As previously noted, in the United States' and Canada's view the general moratorium on approvals is inconsistent with Article 5.1. The United States and Canada conclude from this that the general moratorium must also be presumed not to be based on scientific principles and to be maintained without sufficient scientific evidence, contrary to Article 2.2.

7.1436 **Argentina** argues that the European Communities has no scientific basis for maintaining a general moratorium on approvals. Argentina submits that there is no known scientific evidence that might support the moratorium. In Argentina's view, the lack of any scientific basis means that the general moratorium is inconsistent with Article 2.2. Argentina further argues that according to the Appellate Body there must be a reasonable relationship between the SPS measure at issue and the scientific evidence.[1262] Argentina argues that the general moratorium has been maintained for a period of more than five years (1998 – 2004) without sufficient scientific evidence. Argentina considers that this demonstrates the lack of the required reasonable relationship.

[1257] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 2.2.

[1258] Panel Report, *EC – Hormones* (*Canada*), para. 8.96.

[1259] Panel Report, *Japan – Agricultural Products II*, para. 8.71.

[1260] We note that Argentina is not arguing that for the purposes of its claim under the first requirement in Article 2.2 the EC approval procedures are the relevant SPS measures. Therefore, we need not, and do not, determine whether approval procedures as such can be subject to the first requirement in Article 2.2.

[1261] Appellate Body Report, *Australia – Salmon*, paras. 137-138.

[1262] Argentina refers to Appellate Body Report, *Japan – Agricultural Products II*, para. 73.

7.1437 The **Panel** first considers the United States' and Canada's claim based on the second and third requirements in Article 2.2. This claim is in the nature of a consequential claim. The United States and Canada submit that an inconsistency with the second and third requirements in Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.1. It is correct that the Appellate Body in *Australia – Salmon* found that by maintaining an SPS measure in violation of Article 5.1, Australia as the responding party in that case, by implication, also acted inconsistently with the second and third requirements in Article 2.2.[1263] However, we have determined above that Article 5.1 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.1 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.1, and since the United States' and Canada's claim under the second and third requirements in Article 2.2 is premised on the existence of a breach of Article 5.1 by the European Communities, the United States' and Canada's claim under the second and third requirements in Article 2.2 cannot succeed.

7.1438 Argentina claims that the European Communities maintained its general *de facto* moratorium on approvals without sufficient scientific evidence, contrary to the third requirement in Article 2.2. Under this claim, the general *de facto* moratorium on approvals is considered as an "SPS measure". Based on the Annex A(1) definition of the term "SPS measures", we have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it did not constitute an "SPS measure" within the meaning of Annex A(1).[1264] This view seems to us to be appropriate also in the specific context of the second and third requirement in Article 2.2.

7.1439 We note in this regard that in *EC - Hormones* the Appellate Body agreed with a statement by the panel in that case that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 and that Articles 2.2 and 5.1 should "constantly be read together".[1265] If Article 2.2 and Article 5.1 must be read together, and if Article 5.1 is a specific application of the second and third obligations provided for in Article 2.2, then our earlier considerations as to why we believe the provisions of Article 5.1 are not applicable to the European Communities' decision to apply a moratorium on approvals are relevant also in the context of the second and third requirements of Article 2.2. Therefore, we are of the view that the second and third requirements in Article 2.2 are applicable to measures applied for achieving a Member's appropriate level of sanitary or phytosanitary protection.[1266]

7.1440 We have already found that the European Communities' procedural decision to delay final approval decisions did not itself constitute a measure which is applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Accordingly, we consider that that decision does not constitute an SPS measure within the meaning of Article 2.2. It follows that the particular claim presented by Argentina under the second and third requirements of Article 2.2 cannot succeed.

[1263] *Ibid*., para. 138.

[1264] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 10.1.

[1265] Appellate Body Report, *EC – Hormones*, para. 180. *See also* Appellate Body Report, *Japan – Agricultural Products II*, para. 82.

[1266] We note that Argentina is not arguing that for the purposes of its claim under the second and third requirements in Article 2.2 the relevant SPS measures are the EC approval procedures. Therefore, we need not, and do not, determine whether approval procedures as such can be subject to the second and third requirements in Article 2.2.

(c) Conclusions

7.1441 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 European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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 not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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 not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

9. Consistency of the general *de facto* moratorium on approvals with Article 2.3 of the *SPS Agreement*

7.1442 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement*.

7.1443 Article 2.3 of the *SPS Agreement* provides in relevant part:

> "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."

7.1444 The **Complaining Parties** note that, according to the Appellate Body, in cases where all three elements under Article 5.5 of the *SPS Agreement* have been fulfilled, and, therefore, Article 5.5 has been violated, the relevant SPS measure, by implication, necessarily violates the more general obligations set out in Article 2.3.[1267] The Complaining Parties recall their view that the European Communities has, by maintaining the general *de facto* moratorium on approvals, acted inconsistently

[1267] The Complaining Parties refer to Appellate Body Report, *Australia – Salmon*, paras. 248-252.

with its obligations under Article 5.5. The Complaining Parties submit that, in the light of this, the European Communities has, by implication, also acted inconsistently with its obligations under Article 2.3.

7.1445 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1268] According to the European Communities, Article 2.3 contains obligations concerning the development of SPS measures, not their application. The European Communities submits that by challenging the way in which applications are dealt with under the EC approval system, the Complaining Parties are challenging the application of an SPS measure. The European Communities therefore considers that Article 2.3 is not applicable to the alleged general moratorium on approvals.[1269]

(a) Evaluation

7.1446 The **Panel** notes that the Complaining Parties' claim under Article 2.3 is in the nature of a consequential claim. The Complaining Parties submit that an inconsistency with Article 2.3 follows by implication from a demonstrated inconsistency with Article 5.5. We note that this argument draws support from Appellate Body jurisprudence, for in *Australia – Salmon*, the Appellate Body observed that "a finding of violation of Article 5.5 will necessarily imply a violation of Article 2.3, first sentence, or Article 2.3, second sentence".[1270]

7.1447 We have determined above that Article 5.5 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.5 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.5, and since the Complaining Parties' claim under Article 2.3 is premised on the existence of a breach of Article 5.5 by the European Communities, the Complaining Parties' claim under Article 2.3 cannot succeed.

(b) Conclusions

7.1448 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 European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

[1268] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1269] It should be noted that the European Communities initially remarked that one could argue on whether Article 2.3 contains obligations relating to the application of an SPS measure rather than to its development. The European Communities submitted that the question could be left open in this case.

[1270] Appellate Body Report, *Australia – Salmon*, para. 252.

(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 not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(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 not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

10. Consistency of the general *de facto* moratorium on approvals with Article 7 and Annex B(1) of the *SPS Agreement*

7.1449 All three Complaining Parties claim that the European Communities has failed to publish the existence of the general *de facto* moratorium on approvals and that it has thereby acted inconsistently with its obligations under Article 7 and Annex B(1) of the *SPS Agreement*.

7.1450 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."

7.1451 Annex B(1) of the *SPS Agreement* provides:

> "Members shall ensure that all sanitary and phytosanitary regulations[1271] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them."

7.1452 The **Complaining Parties** submit that the general moratorium on approvals is subject to the publication requirement in Annex B(1). *First*, the general moratorium is an "adopted" measure as it has existed since October 1998 and remains in effect. *Secondly*, the general moratorium is "applicable generally", in that it has applied to all new biotech products subject to the EC approval procedures. *Thirdly*, the general moratorium constitutes a "sanitary or phytosanitary regulation". The Complaining Parties recall in this regard that, in their view, the *de facto* general moratorium is an "SPS measure" and has a similar effect as a law, decree or ordinance. The Complaining Parties further contend that the existence of the general moratorium has not been published, let alone "promptly". The Complaining Parties argue that by failing to publish promptly the existence of the general moratorium, the European Communities has acted inconsistently with its obligations under Annex B(1) and Article 7.

[1271] (*original footnote*) Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

7.1453 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 Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedures. Delay of this kind cannot constitute an SPS measure within the 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 general moratorium on approvals is not subject to Article 7.

7.1454 The **Panel** notes that the Complaining Parties allege an inconsistency of the general *de facto* moratorium on approvals with Annex B(1) and use the alleged inconsistency with Annex B(1) to make a consequential claim of inconsistency under Article 7. Accordingly, we will begin our analysis with the Complaining Parties' claim under Annex B(1).

(a) "Sanitary and phytosanitary regulations"

7.1455 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". That SPS regulations are "SPS measures" is confirmed by Article 7 which states that Members must notify changes in their "SPS measures" and provide information on their "SPS measures" "in accordance with the provisions of Annex B". It can be inferred from this that the "SPS regulations" at issue in Annex B(1) are a sub-category of "SPS measures". Regarding the meaning of the term "SPS measures", we recall Article 1 of the *SPS Agreement*. It states that for the purposes of the *SPS Agreement*, "the definitions provided in Annex A shall apply". We further note that Article 1.3 of the *SPS Agreement* states that the annexes to the *SPS Agreement* – which include Annex B – are an integral part of the *SPS Agreement*. This means that the reference in the footnote to Annex B(1) to "SPS measures" must be interpreted in accordance with the Annex A(1) definition of the term "SPS measures".

7.1456 It follows from the foregoing that a threshold issue before us is whether the general *de facto* moratorium on approvals was a generally applicable "SPS measure" which had been adopted. It is clear from our earlier findings that the moratorium on final approvals was applicable generally inasmuch as it was applicable to all applications which were pending between June 1999 and August 2003.

7.1457 Our earlier findings have also addressed in detail the question of whether the general *de facto* moratorium on approvals met the definition of an "SPS measure" set out in Annex A(1). We found that it was a measure relating to the application, or operation, of the existing EC approval procedures and that such a measure did not constitute an "SPS measure" within the meaning of Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we now go on to analyse whether the provisions of Annex B(1) render the conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1458 Annex B(1) read in conjunction with the accompanying footnote provides that a generally applicable "SPS measure" which has been adopted must be published promptly. We recall that according to Annex A(1) the term "SPS measures" includes "requirements and procedures". It can be deduced from this that a generally applicable measure imposing a substantive SPS requirement or establishing an SPS procedure is to be published, since such a measure would itself be an "SPS measure". In contrast, neither Annex B(1) nor its accompanying footnote suggests that a generally

applicable measure concerning the administration, or operation, of an SPS measure – such as a measure providing for a particular operation of an SPS approval procedure – is, also, to be published.

7.1459 Article 7 supports this view. It requires Members to notify changes in their "SPS measures" and provide information on their "SPS measures". It does not require Members to notify changes in the administration of SPS measures and provide information on the administration of their SPS measures.

7.1460 We attach meaning to the absence in the text of Annex B(1) and Article 7 of any reference to the administration, or operation, of SPS measures. We find instructive in this regard the provisions of Article 18.5 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*, which parallel those of Article 7. Article 18.5 provides that "[e]ach Member shall inform the [Anti-dumping] Committee of any changes in its laws and regulations relevant to this Agreement and in the *administration* of such laws and regulations" (emphasis added). In view of the provisions of Article 18.5, it has to be assumed that where the publication requirement was intended to extend to the administration of generally applicable measures, this was made explicit in the text of the relevant WTO provision.[1272]

7.1461 The Appellate Body in *Japan – Agricultural Products II* stated that the scope of application of the publication requirement of Annex B(1) "should be interpreted in the light of [its] object and purpose".[1273] According to the Appellate Body, "[t]he object and purpose of paragraph 1 of Annex B is 'to enable interested Members to become acquainted with' the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures".[1274] We would agree that extending the publication requirement contained in Annex B(1) to measures concerning the administration, or operation, of SPS regulations would serve the purpose of enhancing transparency. But the object and purpose of Annex B(1) does not entitle us to expand the scope of the publication requirement negotiated by Members, even if we were to consider that it might in principle be desirable to do so.[1275] At any rate, the Appellate Body has made it clear that the principles of treaty interpretation set out in Article 31 of the *Vienna Convention* "neither require nor condone the imputation into a treaty of words that are not there".[1276] As we have said, neither the text of Annex B(1) nor that of Article 7 refers to the administration, or operation, of SPS regulations or SPS measures.

7.1462 In view of the above considerations, we find our earlier conclusion – that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) – to be appropriate also in the specific context of Annex B(1) and Article 7. We thus determine that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of the footnote to Annex B(1). Consequently, we also find that the general *de facto* moratorium on approvals was not an "SPS regulation" within the meaning of Annex B(1). This finding in turn makes it unnecessary for us to consider whether the general *de facto* moratorium on approvals had been "adopted" within the meaning of Annex B(1). Since the provisions of Annex B(1) apply only to "SPS regulations", and since the European Communities' general *de facto* moratorium on approvals was not

[1272] We note that the text of Article 32.6 of the *Agreement on Subsidies and Countervailing Measures* is identical to that of Article 18.5 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*.

[1273] Appellate Body Report, *Japan – Agricultural Products II*, para. 106.

[1274] *Ibid*., para. 106.

[1275] Pursuant to Article 19.2 of the DSU, panels cannot add to the obligations provided in the covered agreements.

[1276] Appellate Body Report, *India – Patents (US)*, para. 45.

an "SPS regulation", it follows that the provisions of Annex B(1) are not applicable to the general moratorium.

7.1463 We recall that the Complaining Parties seek 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 general *de facto* moratorium on approvals, there can be no inconsistency with these provisions. Under the approach followed by the Complaining Parties, there can then logically be no inconsistency with Article 7 either, even assuming that Article 7 is applicable to the general moratorium.

7.1464 In connection with the preceding findings, it is well to point out that Annex C(1) of the *SPS Agreement* contains additional transparency requirements which apply specifically to the operation of approval procedures. In particular, Annex C(1)(b) provides that "upon request, the applicant [must be] informed of the stage of the procedure, with any delay being explained". Thus, to the extent the application by the European Communities of a general *de facto* moratorium on approvals led to delays, the European Communities was under an obligation to explain, upon request from an applicant, that these delays were the consequence of a general moratorium. Accordingly, the European Communities was required to provide information on the general moratorium to those directly affected by it. We note that only the United States has alleged that the European Communities has acted inconsistently with the aforementioned transparency requirement of Annex C(1)(b) by applying a general *de facto* moratorium on approvals.[1277]

(b) Conclusions

7.1465 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 Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

(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 Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

(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 Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

[1277] *See infra*, para. 7.1571.

11. Consistency of the general *de facto* moratorium on approvals with Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*

7.1466 The United States and Canada, but not Argentina, claim that the general *de facto* moratorium on approvals has led to a failure by the European Communities to comply with the requirements of Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*.

7.1467 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."

7.1468 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 [...]."

7.1469 The **United States** argues that the European Communities' approval procedures for biotech products must comply with Article 8 and Annex C(1)(a), which refers to "undue delay". The United States notes that the ordinary meaning of "undue" is "inappropriate, unsuitable, improper; unrightful; unjustifiable[;] [g]oing beyond what is warranted or natural; excessive; disproportionate".[1278] The United States further notes that the ordinary meaning of "delay" is "hindrance to progress; (a period of) time lost by inaction or inability to proceed".[1279] Thus, in the United States' view, the ordinary meaning of "undue delay" under Annex C(1)(a) is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. According to the United States, the ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

7.1470 The United States argues that although it may be difficult in particular cases to decide whether approval procedures are undertaken without undue delay, an across-the-board suspension of final approvals must be considered an "undue delay" under Annex C(1)(a). The United States submits that it has been recognized by EC officials that there was no scientific basis for the failure to move forward under the procedures and timelines provided in the European Communities' own legislation.[1280] The United States also notes that many of the biotech products caught up in the general moratorium on approvals have been subject to positive assessments by the lead CA and the European Communities' own scientific committees.

7.1471 The United States considers that where the European Communities' own legislation provides procedures and timelines for the approval of biotech products, an indefinite suspension of that

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[1278] The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3480.

[1279] *Ibid*., Vol. I, p. 623.

[1280] The United States refers to the above-mentioned October 2001 news report about a statement attributed to Environment Commissioner Wallström.

approval procedures, without any scientific justification, must be considered "undue delay" under Annex C(1)(a). In the light of this, the United States submits that the imposition of a general moratorium on approvals has resulted in the European Communities breaching Annex C(1)(a) and, as a consequence, Article 8.

7.1472 **Canada** argues that the EC approval procedures suspended by the general moratorium on approvals are "approval procedures" to "check and ensure the fulfilment of sanitary or phytosanitary measures" and that the European Communities must therefore comply with Annex C(1)(a). Canada notes that Annex C(1)(a) requires that the European Communities both "undertake" and "complete" the approval procedures without "undue delay". Regarding the term "undertake", Canada submits that that term should be interpreted in the light of the steps that WTO Members are obligated to take in processing an approval application outlined in Annex C(1)(b). Annex C(1)(b) provides that Members shall ensure that:

> "[T]he 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."

7.1473 Thus, in Canada's view, in undertaking an approval procedure, the European Communities is obligated to take the steps outlined in Annex C(1)(b) in the processing of applications under that procedure. In respect of the approval of biotech products, the European Communities is obligated to ensure that an application is examined and that the applicant is informed promptly of deficiencies identified in the application that may hinder progress through the procedure. Canada notes that the European Communities is also obligated to "complete" the approval procedures for biotech products. According to Canada, "complete" in the sense used in Annex C(1)(a) means to take a decision as to whether or not the biotech product in question will be permitted to be placed on the market.

7.1474 Regarding the term "undue delay", like the United States, Canada considers that the ordinary meaning of "undue delay" under Annex C(1)(a) is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. Canada considers that this interpretation suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

7.1475 Canada is of the view that the requirements of Annex C(1)(b) are relevant to determining whether a delay is excessive. Canada notes that Annex C(1)(b) obligates Members to ensure: that standard processing times are published; that the competent body *promptly* examines the applications for completeness and informs the applicant of deficiencies; that the competent body transmits the results of the procedures *as soon as possible*; that where there are deficiencies the competent body proceeds as far as practicable with the procedure; and that any delay is *explained* to the applicant. According to Canada, the purpose of Annex C(1)(b) is to ensure that the processing of an application proceeds as promptly as possible in the circumstances. Thus, the competent body reviewing the application is obligated to undertake the specific steps outlined in Annex C(1)(b) to process the application, in particular, the obligation to explain any delay. Canada notes that, to its knowledge, the

European Communities has failed to provide applicants for biotech products with a justifiable explanation for the delay in processing biotech approvals.[1281]

7.1476 Canada further submits that in the context of Annex C(1), the justification for a delay must be consistent with the provisions of the *SPS Agreement*, namely, that SPS measures must be based on scientific evidence. Article 2.2 of the *SPS Agreement* specifically requires that all SPS measures be "based on scientific principles" and not "maintained without sufficient scientific evidence". Thus, a delay in undertaking and completing an approval procedure is "unjustified" if the delay is caused by a measure that is not based on scientific evidence.

7.1477 According to Canada, there is no sound justification for the European Communities' failure to undertake and complete the approval procedures for biotech products. Canada considers that there is no scientific evidence upon which the general moratorium on approvals is based. Rather, the moratorium undermines the scientific inquiry required as a part of the approval procedures. Canada submits that not only is there no scientific evidence to justify the across-the-board moratorium, for many of the pending applications there is scientific evidence from the European Communities' own experts which support the approval of the product in question. Thus, in Canada's view, the delay, resulting from the moratorium, in undertaking and completing the approval procedures for biotech products is "unjustified" and "excessive". Canada considers that the fact that the general moratorium has been in place for more than five years compounds the excessiveness of the delay.

7.1478 Canada submits that, in the case of the general moratorium, the delay in undertaking and completing the approval procedures for biotech products was caused by a general suspension of those procedures. According to Canada, the *SPS Agreement* does not permit a Member to suspend existing SPS approval procedures, thereby effectively banning products with pending applications, every time that Member seeks to update its legislation. Canada considers that a suspension of an approval regime may be warranted in some circumstances, for example, if there was credible scientific evidence that the continued processing of applications under the existing regime would give rise to actual risks to human health or the environment. However, in Canada's view, this is not the case here. Canada submits that the legislative amendments, for the most part, were to implement measures to identify the occurrence of hypothetical adverse effects or to facilitate the removal of a product from the marketplace in the unlikely event of a hypothetical risk materializing, *e.g.*, monitoring for unanticipated adverse effects.

7.1479 For these reasons, Canada is of the view that, as a result of the general moratorium, the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay in violation of Annex C(1)(a). Canada further submits that as Article 8 of the *SPS Agreement* requires Members to observe the provisions of Annex C, the failure by the European Communities to adhere to the requirements of Annex C(1)(a) to undertake and complete the approval procedures for biotech product without undue delay violates Article 8.

7.1480 The **European Communities** accepts that, to the extent it addresses risks coming under Annex A(1) of the *SPS Agreement*, the approval system set up under the relevant EC legislation is a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1). Regarding the meaning of the term "undue delay", the European Communities argues that out of the rather lengthy list of meanings of the words "undue" and "delay" as offered by the *New Shorter Oxford English Dictionary*, the United States and Canada arbitrarily

[1281] Canada notes that the unjustifiable delay to which it refers does not include the time necessary for the applicant to respond to *bona fide* questions from the competent authority or bodies responsible for the approval procedure.

settle on the choice of "an unjustifiable and excessive hindrance". While not objecting to the choice of "unjustifiable", the European Communities does not see the necessity of adding "excessive", nor does it agree with the choice of "hindrance" as opposed to, for example, "period of time lost by inaction or inability to proceed". It does, however, agree that both the reason for the delay and its duration are relevant considerations in determining whether any delay is "undue".

7.1481 Regarding Canada's argument based on Annex C(1)(b), the European Communities argues that the purpose of Annex C(1)(b) is one of transparency and is not linked in any way to the concept of "undue" in Annex C(1)(a). Annex C(1)(b) only requires Members to publish the "standard", *i.e.*, average or indicative, processing period, or to communicate to the applicant the anticipated processing period. The European Communities notes that nowhere does it say that Members must always abide by the standard processing periods foreseen in their legislation.

7.1482 The European Communities also rejects the United States' argument that an "undue delay" exists when and because the procedural deadlines set forth in the EC legislation have been exceeded. The European Communities considers it clear from a plain reading of Annex C(1)(a) that the meaning of the words "undue delay" is not to be inferred from the domestic legislation of the Members. Had the drafters of the *SPS Agreement* intended to give the words "undue delay" meaning by reference to domestic law, they would have used different wording. The European Communities submits that it is not the purpose of the *SPS Agreement* to elevate national legislation to the level of international law. Equally, it is not the role of the dispute settlement organs (but that of national courts) to enforce that legislation.

7.1483 The European Communities believes that the question of when a period of time becomes a delay is a matter of fact to be established on a case-by-case basis. In particular, in the case of approval procedures for novel products, each specific product presents characteristics and specificities that are peculiar to it. These also vary according to the specific habitat/environment in which the product is to be produced and/or marketed. In the European Communities' view, the question of time cannot, therefore, be separated from the scientific issues associated with an individual product. For the European Communities, this also confirms that any time-limits provided for in legislation setting up an approval procedure cannot be but "standard".

7.1484 The European Communities rejects the United States' and Canada's assertion that a delay is "unjustified" if it is caused by a measure that is not based on scientific evidence. The European Communities submits that delays may occur for reasons completely outside the realm of science. The European Communities offers the example of a case of *force majeure*: an earthquake destroying the building of a competent authority including all archives containing the pending applications. In the European Communities' view, any delays in re-constituting the application files would not be considered "undue" or "unjustifiable". The European Communities argues that, for the same reason, other causes for delay of a non-scientific nature, such as legislative changes or lack of resources, need to be assessed on their own merits.

7.1485 The European Communities further submits that delays caused by legitimate requests for additional information are justified and therefore not "undue". In the European Communities' view, it is legitimate to request additional information necessary for the completion of a risk assessment and/or the compliance with certain standards of risk management and risk communication which have been established by a regulator and which apply to the product in question. According to the European Communities, this applies *a fortiori* when the product at issue is based on a new technology which is generally untried and untested and which is recognised by the international community to have characteristics which inherently require prudence and caution. The European Communities

submits in this regard that the precautionary principle is to be taken into account when assessing "undueness" under Annex C(1)(a).

7.1486 In relation to the United States' and Canada's assertions that an unjustified general suspension of an approval procedure is on its face an "undue delay" within the meaning of Annex C(1)(a), the European Communities submits that, in the present case, no "undue delays" have occurred in any of the pending applications. More specifically, none of the relevant applications for the approval of biotech products has been subject to a "general suspension", and none were stalled in the approval process. In all cases, there have been scientifically valid reasons to delay the approval procedure.

7.1487 The European Communities argues that what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to the applicants. The European Communities submits that all of these requests were related to issues of risk assessment, risk management and sometimes risk communication concerning the individual product in question. Those requests were justified on the basis of standards of risk assessment, risk management and risk communication which not only the European Communities, but the international community has endorsed.[1282] Some of the requests focussed on risk issues falling outside the scope, others on risk issues coming within the scope of Annex A(1) of the *SPS Agreement*. Some requests were based on existing legislation, others on (stricter) requirements as set out in the European Communities' new legislation. Where requests were based on new legislation at a time where that legislation had not yet entered into force, they were conditioned on the applicant's voluntary agreement or were slightly delayed to await the entry into force of that legislation.[1283] According to the European Communities, there is nothing unusual about such an approach, which is common to many legal systems facing transitional arrangements where one set of rules is to be replaced by another.

7.1488 Moreover, the European Communities contends that to the extent there were delays, sometimes this was for reasons lying in the sphere of the applicant. In the European Communities' view, delays caused by the applicant would be justified. Where delays were caused by requests for additional information, the European Communities considers that only those delays which were caused by requests focussing on risk issues falling within the scope of Annex A(1) of the *SPS Agreement* can be reviewed by the Panel in the light of Annex C(1)(a).

[1282] The European Communities refers to the example of Codex Alimentarius, *Principles for the risk analysis of foods derived from modern biotechnology* (Exhibit EC-44). The European Communities notes that these Principles provide (i) that "a pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of a quantity that would withstand scientific peer review" (paragraph 12); (ii) that "risk management measures may include, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring" (paragraph 19); and (iii) that "specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials" (paragraph 21). The European Communities submits that it is clear from the detailed chronologies submitted by the European Communities that the delays – if any – in the processing of applications for the authorization of GM food under Regulation 258/97 in most, if not all, cases result either from the failure or time taken by the applicant in supplying either the qualitatively or quantitatively appropriate data for the purpose of the safety assessment, and/or the reference materials, and/or the analytical methods required for the purpose of risk management measures.

[1283] In the European Communities' view, the question of whether or not such requests could be made under the existing legislation is a question of EC law and, as such, a matter for courts in the European Communities. The European Communities submits that for the Panel, the question is whether such requests are legitimate under the standards of the *SPS Agreement*.

7.1489 Further, the European Communities submits that even if any "undue delays" may have occurred in the past, which the European Communities denies, no such "undue delays" are occurring under the new EC legislative framework.

7.1490 The **Panel** notes that the claims by the United States and Canada under Article 8 are in the nature of consequential claims. The United States and Canada claim that the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, and that, as a consequence, the European Communities has also acted inconsistently with the provisions of Article 8. Therefore, the Panel will begin its analysis with the claims under Annex C(1)(a).

(a) Annex C(1)(a), first clause

7.1491 Annex C(1) establishes obligations "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have determined earlier that Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer) are SPS measures within the meaning of Annex A(1). We have also determined that Directives 90/220 and 2001/18 as well as Regulation 258/97 set out procedures to check and ensure the fulfilment of one or more SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market. It follows from these previous findings 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). As such, they are subject to the provisions of Annex C(1), and notably those of Annex C(1)(a), first clause. Therefore, in accordance with the provisions of Annex C(1)(a), the European Communities was required during the relevant time-period (June 1999 to August 2003) 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".

7.1492 We understand the United States and Canada to claim that the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay, as a result of the adoption and application of the general *de facto* moratorium on approvals. Thus, the measure being challenged is the general *de facto* moratorium on approvals, since the United States and Canada allege that the general moratorium has been the cause of undue delays in the processing of applications under the relevant EC approval legislation.

7.1493 Before evaluating the merits of the claim put forward by the United States and Canada under Annex C(1)(a), first clause, we address a number of interpretative issues.

(i) Interpretation

7.1494 Annex C(1)(a), first clause, requires Members to ensure that approval procedures are "undertaken and completed without undue delay". We first consider the meaning of the phrase "undertake and complete". The verb "undertake" makes clear that Members are required to begin, or start, approval procedures after receiving an application for approval.[1284] The verb "complete", on the

[1284] The dictionary meanings of the verb "undertake" include "[t]ake on (an obligation, duty, task, etc.); commit oneself to perform; begin (an undertaking, enterprise, etc.)". The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3476. The French and Spanish versions of Annex C(1)(a), first clause, also support this reading. The French version uses the verb "engager", the Spanish version the verb "iniciar". We also note that Annex C(1)(b) requires Members to ensure, *inter alia*, that "when receiving an application, the competent body promptly examines the completeness of the documentation and

other hand, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded.[1285] Thus, in our view, the phrase "undertake and complete" covers all stages of approval procedures and should be taken as meaning that, once an application has been received, approval procedures must be started and then carried out from beginning to end.

7.1495 It is clear from the text of Annex C(1)(a), first clause, that not every delay in the undertaking or completion of approval procedures which is caused by a Member is contrary to the provisions of Annex C(1)(a), first clause. Only "undue" delay is.[1286] Regarding the meaning of the phrase " undue delay", we consider that of the dictionary meanings of the term "delay" which have been identified by the United States, there is one which fits naturally with the provisions of Annex C(1)(a), first clause, namely, "(a period of) time lost by inaction or inability to proceed"[1287]. So far as concerns the term "undue", of the dictionary meanings referred to by the United States we find two to be particularly relevant in the specific context of Annex C(1)(a), first clause – "[g]oing beyond what is warranted […]" and "unjustifiable". We note that the United States, Canada and the European Communities have all identified "unjustifiable" as a relevant meaning of "undue". This view is supported also by the French version of Annex C(1)(a), first clause, which refers to "retard injustifié". Thus, based on the ordinary meaning of the phrase "without undue delay", we consider that Annex C(1)(a), first clause, requires that approval procedures be undertaken and completed with no unjustifiable loss of time.

7.1496 According to the United States, Canada and the European Communities, both the reason for a delay and its duration are relevant considerations in determining whether a delay is "undue". We recall in this regard that, in our view, Annex C(1)(a), first clause, requires that there not be any unjustifiable loss of time. Thus, what matters is whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such. Accordingly, if a Member causes a relatively short, but unjustifiable delay, we do not consider that the mere fact that the delay is relatively short would, or should, preclude a panel from finding that it is "undue".[1288] Similarly, we do not consider that a demonstration that a particular approval procedure has been delayed by, say, two years would always and necessarily be sufficient to establish that the relevant procedure has been "unduly" delayed. Having said this, we note that a lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is "undue".

7.1497 In our view, a determination of whether a particular approval procedure has been undertaken and/or completed "without undue delay" must be made on a case-by-case basis, taking account of relevant facts and circumstances. We therefore consider that it would be neither possible nor useful to attempt to define the reasons which would render a given delay "undue", and those which would not render it "undue". Nevertheless, it may be noted that a Member is not legally responsible for delays

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informs the applicant in a precise and complete manner of all deficiencies". Thus, it is clear that approval procedures are "undertaken" upon receipt of an application from an applicant.

[1285] The dictionary meanings of the verb "complete" include "[b]ring to an end, finish, conclude". The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 460. The French and Spanish versions of Annex C(1)(a), first clause, also support this reading. The French version uses the verb "achever", the Spanish version the verb "ultimar".

[1286] Indeed, if this had been the intended result, the text of Annex C(1)(a), first clause, would have stated that approval procedures must be undertaken and completed "without any delay".

[1287] We note that the phrase "inability to proceed" may refer to an objective inability to proceed or a perceived inability to proceed.

[1288] Indeed, we consider that where there is no justification for a delay, the provisions of Annex C(1)(a), first clause, do not permit a Member deliberately to proceed at a delayed pace, even if this is done for only a short period of time. In addition, we note that the cumulative effect of a series of short, but unjustifiable delays could be equally prejudicial to the interests of applicants as the effect of a single, long delay.

which are not attributable to it. Hence, delays attributable to action, or inaction, of an applicant must not be held against a Member when a determination is made regarding whether that Member has undertaken or completed approval procedures "without undue delay".

7.1498 Furthermore, it is pertinent to call attention to the introductory paragraph of Annex C(1). It indicates that approval procedures serve to "check and ensure the fulfilment of [SPS] measures". We consider that if approval procedures serve to check and ensure the fulfilment of SPS requirements, then Members applying such procedures must in principle be allowed to take the time that is reasonably needed to determine with adequate confidence whether their relevant SPS requirements are fulfilled, at least if these requirements are WTO-consistent. Put another way, we view Annex C(1)(a), first clause, essentially as a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking account of the need to check and ensure the fulfilment of their relevant SPS requirements. Consequently, delays which are justified in their entirety by the need to check and ensure the fulfilment of a Member's WTO-consistent SPS requirements should not, in our view, be considered "undue". To offer an example, if new or additional information becomes available at a late stage in an approval procedure and that information may appropriately be considered to have a potential impact on a Member's determination on whether an application fulfils that Member's relevant SPS requirements, it might be justifiable for the Member concerned to delay the completion of the procedure and give itself the additional time needed to assess the information.

7.1499 On the other hand, to offer another example, if the time taken by a Member to complete an approval procedure, or a particular stage thereof, exceeds the time that is reasonably needed to check and ensure the fulfilment of its relevant SPS requirements, for instance because the Member concerned did not proceed as expeditiously as could be expected of it in the circumstances, the delay caused in this way would, in our view, be "undue". This interpretation of Annex C(1)(a) is supported by the object and purpose of the *SPS Agreement*. The fourth preambular paragraph of the *SPS Agreement* states that one particular object and purpose of the *SPS Agreement* is "the establishment of a multilateral framework of rules and disciplines to guide the […] enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade". Annex C(1)(a), first clause, establishes disciplines concerning the "enforcement" of SPS measures, namely, approval procedures. If Annex C(1)(a), first clause, were interpreted to mean that Members need not undertake and complete their approval procedures as soon as possible under the circumstances, we think the object and purpose of minimizing negative trade effects of approval procedures could not be achieved.

7.1500 Canada argues that a delay in undertaking and completing an approval procedure must be considered "undue" if the delay is caused by a measure which is not based on scientific evidence. We would agree that delays caused by measures which are not based on scientific evidence may in some cases be considered "undue".[1289] However, we do not agree that such delays must in all cases be considered "undue". A delay in undertaking and completing an approval procedure may be caused by a temporary government shutdown in the wake of a natural disaster or civil unrest. Likewise, if a Member is confronting an unforeseeable and sharp increase in the number of products submitted for approval, this could cause a short delay in the processing of some or all pending applications, due to the need for that Member to reallocate existing resources, or to obtain additional resources, to deal

[1289] This could be the case, for example, if a delay is caused by a request for additional information which has nothing to do with the issue of whether the relevant product meets the SPS requirements concerned.

with the new situation.[1290] In both examples provided, the delay would be caused by government action, or inaction, which is not supported by scientific evidence. Yet, in our view, there is a convincing argument to be made that the delay would be needed for the Member to be able to check and ensure the fulfilment of relevant SPS requirements. Therefore, we consider that, in both cases, the delay in undertaking and completing approval procedures could properly be viewed as not "undue" and hence not inconsistent with Annex C(1)(a), first clause.

7.1501 There is one additional aspect of Annex C(1)(a), first clause, which it is appropriate to address before examining the merits of the claims before us. The phrase "without undue delay" follows the phrase "undertake and complete". We consider that the phrase "without undue delay" relates, not just to the immediately preceding verb "complete", but to both elements of the phrase "undertake and complete". In other words, we consider that Annex C(1)(a), first clause, should be read as requiring that Members must "undertake" approval procedures "without undue delay" and, subsequently, "complete" them "without undue delay". Were it otherwise, a Member could easily circumvent the requirement to complete approval procedures without undue delay by causing undue delay in the undertaking of approval procedures.

7.1502 The view that the phrase "without undue delay" relates to both elements of the phrase "undertake and complete" implies that if a Member causes undue delay at any stage in an approval procedure, this would constitute a breach of the provisions of Annex C(1)(a), first clause. In our view, there would be a breach of Annex C(1)(a) even if the Member concerned completed one or more previous stages of the approval procedure sooner than could be expected. If, contrary to our view, a Member could balance undue delay in the completion of a particular procedural stage against a period of time "saved" at an earlier stage in the approval procedure, the implication would be that in some cases a Member could temporarily delay the completion of an approval procedure even though there is no need to do so. We consider that such an interpretation of Annex C(1)(a), first clause, would not be supported by the object and purpose of the *SPS Agreement.* In particular, we consider that interpreting Annex C(1)(a), first clause, as permitting a Member temporarily to delay the completion of an approval procedure even when there is no need for a delay would not be consistent with the previously mentioned object and purpose of minimizing negative trade effects of approval procedures.

(ii) Application

7.1503 We now proceed to examine the claims of "undue delay" presented by the United States and Canada. As we have observed earlier, we understand the United States and Canada to claim that, as a result of the general *de facto* moratorium on approvals, the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay and therefore has acted inconsistently with the requirements of Annex C(1)(a), first clause. As we have also pointed out, the United States and Canada are challenging the general moratorium because they view it as a measure which has caused undue delay in the processing of applications under the relevant EC approval legislation. We recall that, for the purposes of the present dispute, the relevant EC approval legislation consists of Directives 90/220 and 2001/18 as well as Regulation 258/97.

7.1504 We consider that for the United States' and Canada's claims to succeed, the United States and Canada need not establish that each and every approval procedure which was pending at some point between June 1999 and August 2003 (the time-period for which we accepted the Complaining Parties'

[1290] Needless to say, it is Members' responsibility to allocate sufficient resources to their competent authorities so that they are in a position to discharge the obligations they have assumed under the *WTO Agreement*.

assertion about EC application of a general *de facto* moratorium on approvals) had been unduly delayed as a result of the general *de facto* moratorium on approvals. In our view, for the purposes of establishing that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, it is sufficient for the United States and Canada to establish that the general *de facto* moratorium on approvals caused undue delay in at least one instance, that is to say, that it caused undue delay in the undertaking or completion of at least one approval procedure conducted in respect of a biotech product at issue in this dispute.

7.1505 We will begin our analysis by examining whether the United States and Canada have established that at least one approval procedure conducted under Directive 90/220 and/or 2001/18 was unduly delayed. If this were the case, it would have been established that, as a result of applying a general *de facto* moratorium on approvals, the European Communities acted inconsistently with its obligations under Annex C(1)(a), first clause, and we would end our inquiry under Annex C(1)(a), first clause. Otherwise, we would go on to examine, in addition, whether the United States and Canada have established that at least one approval procedure conducted under Regulation 258/97 was unduly delayed.[1291]

7.1506 Before turning to examine a particular approval procedure, however, it is well to consider whether the European Communities' reason for applying a general moratorium on final approvals could provide a justification for any delays which may have occurred in individual approval procedures as a result of the application of the moratorium.

Reason for general EC moratorium as a justification for delay

7.1507 Initially, we recall that the European Communities categorically denied that it applied a general *de facto* moratorium on approvals between June 1999 and August 2003.

7.1508 In determining the reason behind the application of the general EC moratorium, we find instructive the June 1999 declaration by the Group of Five countries. As noted by us previously, the Declaration states that, pending the adoption of new EC rules ensuring labelling and traceability of GMOs and GMO-derived products, in accordance with preventive and precautionary principles, the Group of Five countries will take steps to have any new authorizations for growing and placing on the market suspended. We infer from this that the Group of Five countries perceived the EC approval legislation in force at the time as inadequate and considered that in these circumstances prudence and caution warranted the suspension of new final approvals.[1292] Regarding the Commission, we recall our view that there is nothing to suggest that it unqualifiedly supported the decision of the Group of Five countries to prevent the final approval of applications pending the adoption of new EC rules on labelling and traceability, but that it nonetheless effectively (*de facto*) co-operated with the Group of Five countries by not making full use of the relevant, mandatory procedures to complete the approval process.

7.1509 Furthermore, we note the European Communities' assertion before this Panel that during the relevant time period (June 1999 to August 2003) relevant science was evolving and in a state of flux,

[1291] It is useful to recall that regardless of the number of approval procedures we need to examine in order to reach a conclusion on whether the application of the general EC moratorium on approvals has led to a breach of the provisions of Annex C(1)(a), first clause, there are numerous approval procedures which we are required to address in the light of the provisions of Annex C(1)(a), first clause, as part of our evaluation of the Complaining Parties' product-specific claims. *See infra*, Section VII.E.

[1292] We recall our view that the June 1999 declaration by the Group of Five countries was intended to also apply to applications concerning biotech products submitted for approval under Regulation 258/97.

and that the European Communities therefore applied a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from biotech products for which marketing approval had been sought.

7.1510 In view of these elements, we will address below whether (i) the perceived inadequacy of then-existing EC approval legislation and (ii) evolving science and the application of a prudent and precautionary approach would provide a justification for delays which might have occurred as a result of the application of the general EC moratorium on final approvals.

Perceived inadequacy of EC approval legislation in force between June 1999 to August 2003

7.1511 We turn first to address the perceived inadequacy of the EC approval legislation in force between June 1999 to August 2003. As is clear from the June 1999 declaration by the Group of Five countries, the perceived inadequacy of the then-existing EC approval legislation related to the absence of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products.[1293] The concern appears to have been that under the existing EC approval legislation it was not possible for the European Communities to impose, as a condition attached to the granting of marketing approval for GMOs and GMO-derived products, adequate requirements regarding the labelling and traceability of these products.

7.1512 Thus, the issue presented is whether it was justifiable for the European Communities to delay the completion of its approval procedures until the date of adoption of the new EC legislation ensuring labelling and traceability of GMOs and GMO-derived products.[1294] In addressing this issue, we note at the outset that, during the relevant time period (June 1999 to August 2003), approval legislation was in force in the European Communities. As the European Communities has repeatedly stated, the application of the approval legislation in question had never been suspended by a formal EC decision, *e.g.*, by the Commission or the Council and European Parliament. Nor had the granting of final approvals ever been suspended by a formal EC decision.

7.1513 We have stated above that in principle the European Communities was entitled, in conducting approval procedures concerning the biotech products at issue in this dispute, to take the time reasonably needed to determine with adequate confidence whether its relevant SPS requirements were fulfilled. However, given that the new legislation on labelling and traceability was not adopted until September 2003, any requirements set out therein were not EC requirements the fulfilment of which the European Communities could have checked during the relevant time period (June 1999 to August 2003).[1295] Furthermore, the lack of EC-level legislation ensuring labelling and traceability did not affect the European Communities' ability to *check* the fulfilment of its existing SPS requirements. Finally, even if the European Communities considered that new and additional requirements relating to labelling and traceability needed to be imposed as conditions attached to approval decisions, to *ensure* the fulfilment of existing SPS requirements (*e.g.*, the requirement to avoid long-term adverse

[1293] We recall that both Directives 90/220 (and subsequently Directive 2001/18) and Regulation 258/97 contained labelling provisions, and that Directive 2001/18 imposed a traceability obligation on member States. However, these provisions were considered inadequate.

[1294] We recall that the new legislation in question was not adopted until September 2003.

[1295] We note that Annex C(1)(h) of the *SPS Agreement* refers to "applicable" SPS regulations with which compliance is to be ensured. We further note that the European Communities did not claim that it effectively imposed the requirements later included in the new EC legislation. Rather, the European Communities stated that it sought voluntary commitments from applicants which would have ensured the labelling and traceability of GMOs and GMO-derived products.

effects on the environment), there is no reason for believing that the need for, and modalities of, such conditions could only be established in September 2003.

7.1514 Thus, we are of the view that delays in the completion of approval procedures which might have occurred as a result of the lack of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have been delays which were justified by the need to check and ensure the fulfilment of the European Communities' relevant SPS requirements.

7.1515 If the European Communities considered that it was important not to grant final approvals without imposing additional requirements of the type set out in the new EC legislation ensuring labelling and traceability of GMOs and GMO-derived products, it was open to it to try to obtain from applicants either voluntary commitments or a request for suspension of the relevant approval procedure pending the adoption of the new EC legislation.[1296] Alternatively, it could have imposed such requirements as conditions attached to approval decisions, provided the imposition of such requirements was WTO-consistent. We note the possibility that the existing EC approval legislation did not provide a clear or sufficient legal basis for imposing such new and additional requirements relating to labelling and traceability of GMOs and GMO-derived products, and that imposing such requirements might have exposed the European Communities to the risk of a domestic legal challenge. However, the European Communities has repeatedly told this Panel that it should not enforce EC law, and that the issue of compliance of certain EC action, or inaction, with EC law was a matter for EC courts to address, not this Panel. We agree and consider that following the same logic we should not make our determination of EC compliance with the requirements of Annex C(1)(a), first clause, turn on whether or not EC law permitted the European Communities to impose the new and additional requirements regarding labelling and traceability prior to the entry into force of the new legislation. The constraints imposed by EC law would not provide a justification for delays which might have occurred for this reason in the completion of approval procedures.

7.1516 Two further considerations militate in favour of our view that the lack of legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have provided an *eo ipso* justification for delays which might have occurred for this reason in the completion of approval procedures. To begin with, putting in place new legislation is by nature a time-consuming process which not infrequently takes one or more years to complete.[1297] The European Communities itself stated that completing and updating its legislation "inevitably took quite some time to be completed in the light of the serious social and political debate on the issues linked to GMOs and GM food production".[1298] We also note the EC statement that legislation concerning GMOs and GMO-derived products needs to keep pace with the "constant evolution of the scientific and regulatory debate"[1299] on these products, which suggests that a need for regular adjustment and amendment of relevant legislation is to be expected. The evolution of relevant EC legislation would appear to support this statement. In these circumstances, we are concerned that if a Member could suspend and, consequently, delay the granting of final approvals essentially every time it completes and updates its approval legislation, there might be frequent and long periods of time during which final approval decisions are suspended. Incidentally, given the time required to revise legislation, a need for further revision and updating might in some cases be identified even before the previous revision has made its way through the legislative process.

[1296] The record shows that the European Communities did so in a number of approval procedures.

[1297] We note that proposals for new legislation need to be elaborated, the legislation needs to be passed by the legislature and, in some countries, there may also be a need for a popular vote on the legislation before it can be finally adopted.

[1298] EC first written submission, para. 195.

[1299] *Ibid*.

7.1517 The other consideration to be noted relates to the use of procedural delay as an instrument to manage or control risks. It is useful to illustrate this using an example. For instance, if the European Communities delayed the completion of a particular approval procedure because existing legislation precluded it from imposing a traceability requirement for a GMO which would facilitate the withdrawal of the product in the event of unforeseen adverse effects on human health or the environment, the European Communities would effectively use procedural delay as a substitute for a substantive risk management measure (the traceability requirement) that would not be imposable under existing approval legislation. In our view, however, the pursuit of a risk management objective would not justify a delay in the completion of an approval procedure and hence would be inconsistent with Annex C(1)(a), first clause. If procedural delay could be used, directly or indirectly, as an instrument to manage or control risks, then Members could evade the obligations to be observed in respect of substantive SPS measures, such as Article 5.1, which requires that SPS measures be based on a risk assessment. Clearly, we cannot interpret Annex C(1)(a), first clause, in a manner which would nullify or impair the usefulness and intended effect of other provisions of the *SPS Agreement*. Indeed, as we see it, a central purpose of Annex C(1)(a), first clause, is precisely to prevent a situation where Members avoid the substantive disciplines which Articles 2 and 5 of the *SPS Agreement* impose with respect to substantive SPS decisions by not reaching final substantive decisions on applications for marketing approval.

7.1518 In the light of the above, we conclude that the lack of EC legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have provided a justification for delays which might have occurred for this reason between June 1999 and August 2003 in the completion of approval procedures.

Evolving science and application of a prudent and precautionary approach

7.1519 We now turn to consider whether evolving science and the consequent application by the European Communities of a prudent and precautionary approach would provide a justification for delays which may have occurred due to the European Communities' general suspension of final approvals between June 1999 and August 2003.

7.1520 According to the European Communities, GMOs are characterized by scientific complexity and uncertainty. The European Communities contends that during recent years scientific understanding of, and knowledge about, risks potentially arising from GMOs and GMO-derived products has evolved, but remains incomplete. The European Communities notes that many questions remain unanswered, and that there is limited experience with GMOs in terms of time and quality. The European Communities points out in this regard that only very few systematic studies have so far been conducted on indirect and long-term effects of large-scale cultivation of GMOs.

7.1521 The European Communities observes that, in view of the fact that the underlying science is still in a great state of flux, it has chosen to apply a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products for which marketing approval has been sought.

7.1522 As an initial matter, we note that, in our view, Annex C(1)(a), first clause, does not preclude the application of a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products. As we have said, we consider that Annex C(1)(a), first clause, allows a Member to take the time that is reasonably needed to determine with adequate confidence whether its relevant SPS requirements are fulfilled. Consistent with this, we consider that a Member which finds it appropriate to follow a prudent and precautionary approach in assessing and approving applications concerning GMOs and GMO-derived

products, might, for instance, be justified in requesting further information or clarification of an applicant in a situation where another Member considers that the information available is sufficient to carry out its assessment and reach a decision on an application.[1300] Whether a particular request is a reflection of genuine caution and prudence or whether it is a pretext to delay the completion of an approval procedure would need to be determined in the light of all relevant facts and circumstances.

7.1523 It is apparent from the foregoing observations that we perceive no inherent tension between the obligation set out in Annex C(1)(a), first clause, to complete approval procedures without undue delay and the application of a prudent and precautionary approach to assessing and approving GMOs or GMO-derived products. Nevertheless, it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by Annex C(1)(a), first clause. Indeed, if a Member could endlessly defer substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications, Annex C(1)(a), first clause, would be devoid of any meaning or effect. In applying the provisions of Annex C(1)(a), first clause, it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application.

7.1524 The European Communities argues that in the case of applications concerning GMOs and GMO-derived products it is difficult to come to a decision, in view of evolving science and a body of available scientific information and data that is still limited. Even if we were to accept this as an accurate description of the situation as it prevailed between June 1999 and August 2003, we consider that in the light of the provisions of Annex C(1)(a), first clause, this situation in and of itself would not warrant delays in the completion of approval procedures.

7.1525 We note in this regard that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A(1) of the *SPS Agreement* and as required by Article 5.1 of the *SPS Agreement*, pursuant to Article 5.7 of the *SPS Agreement*, a Member may provisionally adopt an SPS measure on the basis of available pertinent information.[1301] Contrariwise, in situations where relevant scientific evidence is sufficient to perform a risk assessment, a Member must base its SPS measure on a risk assessment. Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (*e.g.*, uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken.[1302] In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the *SPS Agreement*, such as Article 5.6.

7.1526 As is clear from the preceding paragraph, evolving science, scientific complexity and uncertainty, and limited available scientific information or data are not, in and of themselves, grounds for delaying substantive approval decisions, and that the *SPS Agreement* does not envisage that Members in such cases defer making substantive SPS decisions. Indeed, even in cases where relevant scientific evidence does not permit the performance of a risk assessment, the *SPS Agreement*

[1300] We recall that pursuant to Annex C(1)(c) of the *SPS Agreement* information requirements must be limited to what is necessary for appropriate approval procedures.

[1301] For further analysis and explanation of the provisions of Article 5.7, *see infra*, Section VII.F.

[1302] For further analysis and explanation of the provisions of Article 5.1, *see infra*, Section VII.F.

envisages that Members take substantive SPS decisions. Certainly, such factors as evolving science and limited availability of scientific evidence affect the confidence which Members can have in the results of their assessments. But they do not inherently affect a Member's ability to reach substantive decisions on an application, particularly since a Member may take account of such factors in reaching substantive decisions.

7.1527 It is quite possible that in the situation described by the European Communities where science evolves and there is limited available scientific evidence, a deferral of substantive decisions might allow for better decisions at a later point in time, provided that appropriate analyses and research are undertaken. However, we do not consider that Annex C(1)(a), first clause, can or should be interpreted to allow Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data. As we have stated earlier, the core obligation implied by Annex C(1)(a), first clause, is for Members to come to a substantive decision. This view is entirely consistent, and fits well with the aforementioned provisions of Article 5.1 and Article 5.7.[1303] It is important to note in this regard that the *SPS Agreement* nowhere states that substantive decisions on applications need to give a straight yes or no answer to applicants. Members may in principle grant time-limited approvals or approvals subject to other appropriate conditions. Alternatively, they may in principle decide to reject an application subject to the possibility of a review of that decision if and when relevant circumstances change. Relevant circumstances could include the state of scientific knowledge. Thus, there is no reason to consider that our interpretation of Annex C(1)(a), first clause, would prejudice Members' ability to take differentiated, proportionate action to protect human health and/or the environment from potential risks arising from GMOs or GMO-derived products.

7.1528 The European Communities argues that it did not go as far as certain other States (or parts of States) which actually adopted outright bans on trade in, and cultivation of, GMOs and/or GMO-derived products. We accept that in certain circumstances an applicant might conceivably prefer it if instead of making a prompt, but negative final approval decision, the European Communities held off on making a final approval decision and undertook further analysis, etc., which might lead to a positive approval decision. However, in our view, this does not provide a justification for delays which might have occurred as a result of the European Communities' decision unilaterally to suspend all final approval decisions. If a Member considers that a delay in the completion of an approval procedure might allow for a positive decision, it can communicate this assessment to the applicant which can then decide whether to accept a delay and ask for a suspension of the approval procedure.

7.1529 In view of the foregoing considerations, we do not consider that the mere fact that science may have been evolving during the relevant time period (June 1999 to August 2003) and the consequent adoption by the European Communities of a prudent and precautionary approach would provide a justification for delaying the completion of approval procedures by imposing a general EC moratorium on final approvals.

Conclusion

7.1530 We have concluded that (i) the perceived inadequacy of the existing EC approval legislation and (ii) evolving science and the application of a prudent and precautionary approach would not

[1303] Indeed, if a Member could delay a final approval decision on the grounds that available scientific evidence is insufficient, that Member could avoid the disciplines imposed by Article 5.7, including the requirement to seek to obtain additional information and to conduct a review of a provisional measure within a reasonable period of time.

provide a justification for delays which might have occurred as a result of the application of the general EC moratorium on final approvals.

7.1531 This conclusion does not imply, however, that the general EC moratorium on final approvals led to undue delay in the undertaking or completion of particular approval procedures. Therefore, our conclusion above does not dispense with the need to go on to examine whether the general EC moratorium led to undue delay in the undertaking or completion of at least one approval procedure conducted under Directive 90/220 and/or 2001/18.

7.1532 Before undertaking this task, we wish to note that our conclusion above should not be construed to mean that it would under no circumstances be justifiable, in the light of the provisions of Annex C(1)(a), first clause, to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products. We consider that there may conceivably be circumstances where this could be justifiable. For instance, if new scientific evidence comes to light which conflicts with available scientific evidence and which is directly relevant to all biotech products subject to a pre-marketing approval requirement, we think that it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence. The resulting delay in the completion of approval procedures might then be considered not "undue".

Approval procedure concerning MS8/RF3 oilseed rape

7.1533 We now turn to examine whether the United States and Canada have established that the general *de facto* moratorium on approvals led to undue delay in the undertaking or completion of a particular approval procedure conducted under Directive 90/220 and/or 2001/18. The United States and Canada did not express a view on which of the many relevant approval procedures conducted under Directive 90/220 and 2001/18 we should examine first. For the sake of efficiency, we have decided to begin our examination with the approval procedure concerning MS8/RF3 oilseed rape, since both the United States and Canada have also presented a product-specific claim that the completion of this particular approval procedure has been unduly delayed, contrary to the requirements of Annex C(1)(a), first clause. We will analyse these product-specific claims in Section VII.E below, when we address the various product-specific measures being challenged by the Complaining Parties.

Relationship of the approval procedure conducted under Directive 90/220 and that conducted under Directive 2001/18

7.1534 Prior to considering whether the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed as a result of the general *de facto* moratorium, we need to address the fact that like many other approval procedures, the approval procedure concerning MS8/RF3 oilseed rape was begun under Directive 90/220 but not completed by the date of repeal of Directive 90/220 (17 October 2002). To recall, 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.[1304] In the case of MS8/RF3 oilseed rape, approval procedures were undertaken under Directive 2001/18 after the applicant had complemented its application.[1305]

7.1535 The question arises 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 completed under Directive 90/220. In considering this issue, we find instructive that applications which were pending on the date of repeal of Directive 90/220 had to be "complemented" in accordance with Directive 2001/18. According to the European Communities, this means that applicants had to provide certain additional information as required under Directive 2001/18. They did not need to re-submit their applications in their entirety. This contention is consistent with the ordinary meaning of the term "complement". The European Communities further told the Panel that in principle a new assessment under Directive 2001/18 was required only for the additional information submitted in accordance with Directive 2001/18. Based on these elements, we consider that 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.

7.1536 The factual determination that an approval procedure not completed under Directive 90/220 was continued under Directive 2001/18 if the applicant complemented its application leads us to the view that, for the purposes of Annex C(1)(a), first clause, an approval procedure begun under Directive 90/220 and continued under Directive 2001/18 constitutes one single approval procedure. It follows that for the purposes of our inquiry under Annex C(1)(a), first clause, it is not necessary 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 was continued under Directive 2001/18. In either case, the relevant approval procedure would have been unduly delayed. Accordingly, we consider that in the case of the approval procedure concerning MS8/RF3 oilseed rape, a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of the impact of the general moratorium on that approval procedure when it was conducted pursuant to the provisions of Directive 90/220. Likewise, a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of the impact of the general moratorium on the approval procedure concerning MS8/RF3 oilseed rape when it was conducted pursuant to the provisions of Directive 2001/18.

Adoption of Directive 2001/18 as a justification for delay

7.1537 An additional issue relating to the revision of Directive 90/220 which we briefly need to consider is whether the adoption in March 2001 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.

7.1538 We note that this issue is similar to the one we have already examined above concerning the lack of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products, and we therefore offer only a few additional observations.

[1304] Article 35 of Directive 2001/18. None of the Complaining Parties questioned the WTO-consistency of Article 35.

[1305] It should be noted, however, that in the case of MS8/RF3 the applicant had voluntarily updated its Directive 90/220 application to comply with requirements set out in Directive 2001/18 even before the entry into force of Directive 2001/18.

7.1539 We have stated above that in principle the European Communities was entitled, in conducting approval procedures concerning the biotech products at issue in this dispute, to take the time reasonably needed to determine with adequate confidence whether its relevant SPS requirements were fulfilled. However, given that Directive 2001/18 did not enter into force until October 2002, any requirements set out therein were not, in our view, EC requirements the fulfilment of which the European Communities needed to check and ensure as of March 2001 in order to complete approval procedures pending under Directive 90/220, the Directive in force at the time.[1306] We further note that the European Communities did not claim that it effectively imposed the requirements of Directive 2001/18 as of the time of their adoption in March 2001.[1307] Rather, the European Communities stated that it sought voluntary commitments from applicants.

7.1540 Thus, we consider that the adoption in March 2001 of Directive 2001/18 could not 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, given that such delay would not have been needed to check and ensure the fulfilment of the European Communities' relevant SPS requirements. However, we consider that in those cases where approval procedures could not be completed while Directive 90/220 was still in force, delays in the completion of these procedures might have been justifiable.

Examination of the approval procedure concerning MS8/RF3 oilseed rape

7.1541 With the preceding observations in mind, we now turn to examine whether the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed, and if so, whether this was as a result of the application of the general *de facto* moratorium, as the United States and Canada claim.

7.1542 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.

7.1543 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. In contrast, the application concerning MS8/RF3 oilseed rape had been pending for almost seven years on the date this Panel was established. The United States contends 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.

[1306] We note that Annex C(1)(h) of the *SPS Agreement* refers to "applicable" SPS regulations with which compliance is to be ensured. We further note that the European Communities did not claim that it effectively imposed the requirements later included in the new EC legislation. Rather, the European Communities stated that it sought voluntary commitments from applicants which would have ensured the labelling and traceability of GMOs and GMO-derived products. Finally, we note that if the European Communities effectively imposed such requirements, then compliance would these requirements should have resulted in the completion of relevant approval procedures. However, the record does not indicate that this was the case.

[1307] We note that if the European Communities had effectively imposed such requirements, then compliance would these requirements should have resulted in the completion of relevant approval procedures. However, the record does not indicate that this was the case, even though there were applicants which voluntarily complied with requirements set out in Directive 2001/18.

7.1544 **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 efforts 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.

7.1545 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.

7.1546 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.

7.1547 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".

7.1548 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.

7.1549 **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.

7.1550 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.

7.1551 We recall in this regard 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.

7.1552 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.[1308] 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.[1309] 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 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.[1310]

7.1553 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.[1311] 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.[1312] 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.[1313] 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.[1314] No reason was given for why an opinion had been requested.

[1308] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[1309] 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".

[1310] Exhibit EC-63/At. 89 and 90.

[1311] Exhibit EC-63/At. 92.

[1312] Exhibit EC-63/At. 91.

[1313] *Ibid.*

[1314] Exhibit EC-63/At. 93.

7.1554 The Panel notes that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to take action. Specifically, Article 21 of Directive 90/220 indicates that the action to be taken by the Commission was 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.

7.1555 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.

7.1556 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.

7.1557 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 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 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."[1315] 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."[1316] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[1317]

7.1558 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.[1318]

[1315] Exhibit EC-63/At. 102.
[1316] *Ibid*.
[1317] *Ibid*.
[1318] *See* our earlier analysis in Section VII.D of the approval procedure concerning Falcon oilseed rape.

7.1559 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.[1319] 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.[1320]

7.1560 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.[1321]

7.1561 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.

7.1562 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

[1319] 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*.

[1320] 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.

[1321] 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 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 might 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.

measure would achieve a qualified majority in the Regulatory Committee.[1322] 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.

7.1563 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.

7.1564 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.

7.1565 Turning now to the reason for the Commission's failure to act, we recall the United States' and Canada's claim that the approval procedure concerning MS8/RF3 oilseed rape was delayed as a result of the application by the European Communities of the general *de facto* moratorium on approvals. We recall in this respect 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 moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States and Canada that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1566 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 address other arguments put forward by the United States and Canada in support of their assertion that the approval procedure concerning MS8/RF3 oilseed rape was unduly delayed as a result of the application of a general *de facto* moratorium on approvals.

Conclusions

7.1567 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.

[1322] 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.

Based on these findings, the Panel accepts the United States' contention that the application by the European Communities of a general *de facto* moratorium on approvals led to "undue delay" in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, consequently, to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, 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 Canada's contention that the application by the European Communities of a general *de facto* moratorium on approvals led to "undue delay" in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, consequently, to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement*.

7.1568 Since we have concluded that the general *de facto* moratorium on approvals led to undue delay in the completion of at least one approval procedure conducted in respect of a biotech product at issue in this dispute, we need not, and thus do not, proceed to examine whether the general *de facto* moratorium on approvals led to undue delay in the undertaking or completion of other individual approval procedures conducted under either Directives 90/220 and 2001/18 or Regulation 258/97.

(b) Article 8

7.1569 We recall that the United States and Canada seek to establish an inconsistency with Article 8 of the *SPS Agreement* on the basis of an inconsistency with Annex C(1)(a). 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. We have determined above that, as a result of the general *de facto* moratorium on approvals, the European Communities has failed, in at least one approval procedure conducted under Directives 90/220 and 2001/18, to observe the provisions of Annex C(1)(a), first clause. Accordingly, we conclude that in respect of the aforementioned approval procedure, the European Communities has, by implication, also acted inconsistently with the provisions of Article 8.

(c) Overall conclusions

7.1570 The foregoing findings and conclusions lead the Panel to the following overall 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 as a result of the application of a general *de facto* moratorium on approvals between June 1999 and August 2003 the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, has also acted inconsistently with its obligations under Article 8 of the *SPS Agreement*.

(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 as a result of applying a general *de facto* moratorium on approvals between June 1999 and August 2003 the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, has also acted inconsistently with its obligations under Article 8 of the *SPS Agreement*.

12. Consistency of the general *de facto* moratorium on approvals with Article 8 and Annex C(1)(b) of the *SPS Agreement*

7.1571 Only the United States claims that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 8 and Annex C(1)(b) of the *SPS Agreement*.

7.1572 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."

7.1573 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 [...]."

7.1574 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.

7.1575 The **United States** argues that the general moratorium on approvals is an unpublished, non-transparent measure under which the European Communities does not allow its approval procedures to proceed to conclusion. As such, the general moratorium is inconsistent, in the United States' view, with each of the related procedural obligations in Annex C(1)(b) and, consequently, with Article 8 as well.

7.1576 Regarding the *first obligation* (publication or communication of processing period), the United States submits that although the applicable EC approval legislation contain processing periods, under the general moratorium on approvals those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the moratorium, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

7.1577 Regarding the *second obligation* (completeness of documentation), the United States argues that under the general moratorium on approvals 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.

7.1578 Regarding the *third obligation* (transmission of results), the United States argues that under the general moratorium on approvals 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.

7.1579 Regarding the *fourth obligation* (processing of deficient applications), the United States argues that under the general moratorium on approvals the European Communities does not proceed as far as practicable in the approval process. Instead, applications are stalled in the approval process.

7.1580 Regarding the *fifth obligation* (explanation of delay), the United States argues that under the general moratorium on approvals delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the general moratorium.

7.1581 The **European Communities** submits that the United States has 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). The United States 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, in the European Communities' view, 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.

7.1582 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).

7.1583 The measure being challenged by the United States is the European Communities' general *de facto* moratorium on approvals. We understand the United States to claim that the adoption and application of the general *de facto* moratorium on approvals has resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b).

7.1584 We also note that the United States relies on the alleged breach of the provisions of Annex C(1)(b) to make a consequential claim of inconsistency under Article 8. Accordingly, we will begin our analysis with the United States' claims under Annex C(1)(b).

(a) First obligation in Annex C(1)(b) (publication or communication of processing period)

7.1585 In relation to the first obligation contained in Annex C(1)(b) (publication or communication of processing period), the United States puts forward two main arguments. The first argument is that as a result of the general moratorium on approvals, 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 periods have not been published.

7.1586 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.

7.1587 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, and that the general moratorium on approvals effectively modified the European Communities' published standard processing periods, the fact that they were unpublished would not be a consequence of the measure at issue, *i.e.*, the general moratorium. Rather, it would be a consequence of a separate and independent failure by the European Communities to publish the new standard processing periods. This is confirmed by the fact that the European Communities could apply the general moratorium on approvals and at the same time publish any new standard processing periods.

7.1588 In the light of this, we conclude that the United States has failed to establish its claim under the first obligation contained in Annex C(1)(b), insofar as that claim is based on the requirement to publish standard processing periods.

7.1589 The United States' second argument in support of its claim under Annex C(1)(b) is that since the European Communities does not acknowledge the moratorium, the anticipated processing period is not communicated to the applicant. 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 the general moratorium on approvals. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not communicating the anticipated processing periods to applicants upon request. The European Communities could apply the general moratorium on approvals and at the same communicate to applicants the anticipated processing periods upon request.

7.1590 In the light of this, we conclude that the United States has failed to establish its claim under the first obligation contained in Annex C(1)(b), insofar as that claim is based on the requirement to communicate to applicants anticipated processing periods.

(b) Second obligation in Annex C(1)(b) (completeness of documentation)

7.1591 Concerning the second obligation contained in Annex C(1)(b), the United States argues that because of the general moratorium on approvals the European Communities did not promptly examine the completeness of documentation and inform applicants of any deficiencies.

7.1592 We note that the United States has identified no concrete evidence to support this assertion.[1323] Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not examining promptly the completeness of documentation and not informing applicants of any deficiencies. The European Communities could apply the general moratorium on approvals and at the same time examine the completeness of documentation and inform applicants of deficiencies in the documentation submitted.[1324]

7.1593 In the light of this, we conclude that the United States has failed to establish its claim under the second obligation contained in Annex C(1)(b).

(c) Third obligation in Annex C(1)(b) (transmission of results)

7.1594 With regard to the third obligation contained in Annex C(1)(b), the United States argues that under the general moratorium results of procedures were not promptly communicated to applicants so that corrective action could be taken.

7.1595 We note that the United States has not identified any results of procedures which were not transmitted to an applicant as soon as possible and in a precise and complete manner. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not transmitting as soon as possible, and in a precise and complete manner, the results of approval procedures. Furthermore, it should be recalled that under the general moratorium, the European Communities prevented final results from being achieved. Thus, there were no final results which could have been communicated to applicants.

7.1596 In the light of this, we conclude that the United States has failed to establish its claim under the third obligation contained in Annex C(1)(b).

(d) Fourth obligation in Annex C(1)(b) (processing of deficient applications)

7.1597 In relation to the fourth obligation contained in Annex C(1)(b), the United States argues that under the general moratorium the European Communities did not proceed as far as practicable in the approval process.

[1323] It is well to recall in this context that it is not incumbent on us to search the record for evidence which would assist the United States in establishing a prima facie case of inconsistency with one or more of the obligations contained in Annex C(1)(b).

[1324] It is well to recall that the United States itself has stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals". US second written submission, para. 51 (emphasis in original).

7.1598 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 the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not proceeding as far as practicable with procedures if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time proceed as far as practicable with procedures upon request.[1325]

7.1599 In the light of this, we conclude that the United States has failed to establish its claim under the fourth obligation contained in Annex C(1)(b).

(e) Fifth obligation in Annex C(1)(b) (explanation of delay)

7.1600 Regarding the fifth obligation contained in Annex C(1)(b), the United States argues that under the general moratorium delays were not explained.

7.1601 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 and of a relevant EC entity denying an explanation of any delay because of the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not informing applicants of the stage of procedures and not explaining any delays, if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time inform applicants of the stage of procedures and explain any delays.

7.1602 In the light of this, we conclude that the United States has failed to establish its claim under the fifth obligation contained in Annex C(1)(b).

(f) Article 8

7.1603 Turning now to the United States' claim under Article 8, we recall that the United States seeks 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 has failed to establish its claims under Annex C(1)(b). Under the approach followed by the United States, this means that the consequential claim under Article 8 has not been established either.

(g) Overall conclusion

7.1604 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 United States has not established that the European Communities has acted inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and,

[1325] Here again, it is useful to recall that the United States itself has stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals". US second written submission, para. 51 (emphasis in original).

consequently, with its obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

13. Consistency of the general *de facto* moratorium on approvals with Article 10.1 of the *SPS Agreement*

7.1605 Argentina claims that the general *de facto* moratorium on approvals applied by the European Communities has failed to take account of Argentina's special needs as a developing country Member and thus is inconsistent with Article 10.1 of the *SPS Agreement*.

7.1606 Article 10.1 provides:

> "In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members."

7.1607 **Argentina** argues that Article 10.1 required the European Communities to take positive action in favour of developing countries. According to Argentina, in preparing and applying a general *de facto* moratorium on approvals, the European Communities should have provided preferential market access for developing country products or implemented its obligations in a manner beneficial, or less detrimental, to the interests of developing country Members. Argentina argues that the general moratorium on approvals had the effect of preventing Argentina's biotech products from having access to the EC market. According to Argentina, this had implications particularly for Argentina's economic development as Argentina is: (i) highly dependent on agricultural exports, (ii) the world's second-largest producer of biotech products, (iii) the world's leading developing country producer of biotech products. Argentina further points out that the EC market is an integrated market consisting of twenty-five member State markets and that the EC market is therefore of great importance for Argentina. Argentina considers that the fact that the general moratorium on approvals prevented its biotech products from having access to the EC market demonstrates that the European Communities has not taken account of the special needs of Argentina.

7.1608 The **European Communities** states that it bears in mind the provisions concerning special and differential treatment of developing country Members when developing and applying its legislation, including, where relevant, its approval legislation for biotech products. The European Communities notes that Argentina's argument seems to be that since the European Communities, in Argentina's view, has violated other WTO provisions and this affects Argentina as a developing country, the European Communities has consequently also failed to comply with Article 10.1. Furthermore, the European Communities does not accept the factual assertion of Argentina that the measure it is complaining about restricts exports of developing country Members to the European Communities. Trade statistics show that imports from developing countries that produce agricultural biotech products have not decreased. On the contrary, imports into the European Communities from Argentina or Brazil of commodities likely to contain genetically modified organisms have steadily increased since 1995/96.

7.1609 **Argentina** does not agree that Article 10.1 needs to be observed only "where relevant". It does not give Members the discretion to take account of the needs of developing country Members or not. Argentina further argues that the European Communities has not provided any evidence proving that it has taken into account Argentina's special needs as a developing country Member when preparing and applying its legislation. The legislation does not contain any reference to the special needs of developing country Members. Moreover, for the entire period of application of the general *de facto* moratorium on approvals, Argentina cannot identify any evidence which would permit the

conclusion that the European Communities has taken account of Argentina's special needs in the context of the approval procedures of interest to Argentina. In addition, the European Communities is incorrect when it suggests that Argentina is making a consequential claim under Article 10.1. Finally, Argentina notes that the trade statistics referred to by the European Communities have not been submitted to the Panel. In any event, those statistics cannot relate to trade in agricultural biotech products after 1998 as no such products have been approved since that date. Argentina further submits that WTO rules protect competitive expectations, not volumes of trade.

7.1610 The **Panel** notes that it is less than clear precisely what Argentina's claim is. We must, therefore, address this issue before we analyse whether the European Communities has breached Article 10.1.

(a) Argentina's claim

7.1611 Article 10.1 applies to the "preparation and application of [SPS] measures". Argentina's submissions do not indicate clearly what, in Argentina's view, is the SPS measure at issue. On the one hand, Argentina argues that the European Communities has failed to comply with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals.[1326] This suggests that, as far as Argentina is concerned, the SPS measure at issue is the general *de facto* moratorium on approvals. On the other hand, Argentina appears to argue that the European Communities has failed to comply with Article 10.1 because of the way it has applied the relevant EC approval legislation.[1327] This suggests that the SPS measure at issue is the relevant EC approval legislation.[1328] We think that both ways of framing a claim under Article 10.1 are possible.

7.1612 Judging by the entirety of Argentina's submissions, we think that Argentina intended to claim that the general *de facto* moratorium on approvals constitutes the relevant "SPS measure". We will examine that claim below. In view of the fact that Argentina's submissions on this issue are less than fully clear and that Article 10.1 is a provision on differential and more favourable treatment for

[1326] Argentina's first written submission, paras. 182 (referring to the "ordering and applying a general moratorium") and 189 (referring to "the decision and subsequent application of the 'de facto' moratorium"); Argentina's first oral statement, para. 77 (referring to the "deciding on and applying the 'de facto' moratorium"); Argentina's second written submission, para. 123 (referring to "the application of the 'de facto' moratorium").

[1327] Argentina's second written submission, paras. 116 (referring to the time of "elaborating and applying its legislation related to agricultural biotech products") and 125 (asserting that there is no evidence that "during the proceedings [*i.e.*, individual approval procedures] the EC has effectively taken into account Argentina's special needs").

[1328] It is pertinent to note that in the context of its challenge to various product-specific measures Argentina makes similar claims under Article 12.3 of the *TBT Agreement.* Article 12.3 provides:

> Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

It is clear from Argentina's submissions that Argentina's claims under Article 12.3 are in respect of the application by the European Communities of its approval legislation, which Argentina says may be considered as laying down "conformity assessment procedures" within the meaning of Article 12.3. Argentina's first written submission, p. 144 (heading) and paras. 445 and 450. However, as indicated, Argentina's claims under Article 12.3 relate to the product-specific measures, whereas we are concerned here with a claim concerning the general *de facto* moratorium on approvals.

developing country Members, we will, however, offer alternative findings. For the purposes of these alternative findings, we will assume that Argentina intended to make the additional claim that the EC approval legislation also constitutes a relevant "SPS measure".

(b) General *de facto* moratorium on approvals as "SPS measure"

7.1613 As indicated, we first examine Argentina's claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals. Under this claim, the general *de facto* moratorium on approvals is considered as an "SPS measure".

7.1614 We have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it did not constitute an "SPS measure" within the meaning of Annex A(1).[1329] However, as we have done in other cases, we also consider the specific provisions of Article 10.1 before reaching a definitive conclusion on whether the general *de facto* moratorium on approvals was an "SPS measure".

7.1615 Article 10.1 provides that in the "preparation and application of [SPS] measures" Members must take account of the special needs of developing country Members. According to Annex A(1), the term "SPS measures" includes "requirements and procedures". It makes sense to say that in the "preparation and application" of "requirements and procedures" Members must take account of developing country Members' needs. In contrast, if the application, or operation, of approval procedures were considered to be an "SPS measure" within the meaning of Article 10.1, Article 10.1 would impose an obligation on Members with regard to the "application" of the "application of an approval procedure". Clearly, such a reading of Article 10.1 would be unreasonable and contrary to logic.[1330] It is no answer to say that in cases where the measure is the "application of an approval procedure", the separate reference in Article 10.1 to the "application" of SPS measures is unnecessary. It is well established in WTO jurisprudence that a treaty interpreter must give meaning and effect to all the terms used in a treaty provision and must avoid interpretations which render treaty terms redundant.[1331]

7.1616 In view of the above considerations, we find our earlier conclusion that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) appropriate in the specific context of Article 10.1. We thus determine that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Article 10.1. Since the claim we are considering is based on the premise that the general *de facto* moratorium was an "SPS measure", it is clear that this claim cannot succeed.

7.1617 Accordingly, we find that Argentina has failed to establish its claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals.

[1329] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 10.1.

[1330] It is instructive to note in this regard that the equivalent provision of the *TBT Agreement*, Article 12.3, refers to the "preparation and application" of "conformity assessment procedures". This supports our reading of Article 10.1 of the *SPS Agreement*.

[1331] Appellate Body Report, *US – Gasoline*, p. 23.

(c) EC approval legislation as "SPS measure"

7.1618 As indicated above, we will offer alternative findings on the assumption that Argentina intended to make the additional claim that the EC approval legislation also constitutes a relevant "SPS measure". Thus, for the purposes of our alternative inquiry, we understand Argentina to claim, in addition, that by adopting and applying a general *de facto* moratorium on approvals, the European Communities has failed to apply its approval legislation in a manner which takes account of developing country Members' needs.

7.1619 Argentina argues that some of the products affected by the European Communities' general moratorium on approvals are of particular export interest to Argentina as a major developing country exporter of those products. Argentina considers that the European Communities should have provided preferential market access for its and other developing countries' products, or implemented its approval legislation in a manner beneficial, or less detrimental, to the trade interests of developing country Members.

7.1620 Argentina's argument implies that when an importing Member applies a measure which (i) treats exports originating in the territory of developing country Members in the same way as exports originating in the territory of developed country Members and (ii) has a significant adverse effect on the developing countries' exports, the importing Member is acting inconsistently with its obligation under Article 10.1. Argentina suggests that in such situations the exports of developing country Members are entitled under Article 10.1 to special and differential treatment *vis-à-vis* the exports of developed country Members. However, the obligation laid down in Article 10.1 is for the importing Member to "take account" of developing country Members' needs. The dictionary defines the expression "take account of" as "consider along with other factors before reaching a decision".[1332] Consistent with this, Article 10.1 does not prescribe a specific result to be achieved. Notably, Article 10.1 does not provide that the importing Member must invariably accord special and differential treatment in a case where a measure has lead, or may lead, to a decrease, or a slower increase, in developing country exports.

7.1621 The fact that there is no indication that between June 1999 and August 2003 the European Communities accorded Argentina special and differential treatment – *e.g.*, by approving the marketing of biotech products exported from Argentina – does not in and of itself constitute prima facie evidence that the European Communities has failed to "take account" of Argentina's needs. While the European Communities must take account of the interests of developing country Members in applying its approval legislation, the European Communities may at the same time take account of other legitimate interests, including those of its own consumers, its environment, etc. There is nothing in Article 10.1 to suggest that in weighing and balancing the various interests at stake, the European Communities must necessarily give priority to the needs of Argentina as a developing country. We therefore think it is conceivable that the European Communities "took account" of Argentina's needs when adopting and applying its general *de facto* moratorium on approvals, but ultimately determined that applications concerning products of export interest to Argentina warranted no special and differential treatment.[1333] Accordingly, we consider that the fact that the European Communities did not accord Argentina special and differential treatment *vis-à-vis* other developed country exporters does not demonstrate, by itself, an inconsistency with Article 10.1.

[1332] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Clarendon Press, 1999), p. 8.

[1333] We recall Argentina's statement that its claim under Article 10.1 is not a consequential claim, but an autonomous claim. Thus, for the purposes of our analysis of Argentina's claim under Article 10.1, we must assume that, but for a possible inconsistency with Article 10.1, the general de facto moratorium on approvals is WTO-consistent.

7.1622 Argentina argues that the European Communities has not provided any evidence which would prove that it has taken into account Argentina's special needs as a developing country Member. This argument lacks merit, for it is incumbent on Argentina as the Complaining Party to adduce evidence and argument sufficient to raise a presumption that the European Communities has failed to take into account Argentina's special needs as a developing country Member.[1334]

7.1623 Argentina also contends that there is no reference in the EC approval legislation to the special needs of developing country Members. However, the absence of a reference to developing country needs in the text of the EC approval legislation does not demonstrate that that legislation itself fails to take account of these needs[1335], or that the European Communities is precluded from taking account, or has not taken account, of these needs when applying that legislation. We therefore consider that it is not sufficient, for the purposes of establishing a claim under Article 10.1, to point to the absence in the EC approval legislation of a reference to the needs of developing country Members.

7.1624 Argentina further argues that for the entire period of application of the general *de facto* moratorium on approvals it could not identify any evidence supporting the conclusion that the European Communities has taken account of Argentina's special needs. We note that Argentina has merely asserted the absence of relevant evidence, without specifying what efforts it has undertaken to collect such evidence. Moreover, we note that Article 10.1 does not specifically require the importing Member to document how it has complied with Article 10.1. In these circumstances, we do not consider that Argentina's argument provides a sufficient basis for us to find that Argentina has met its burden of establishing an inconsistency with Article 10.1.

7.1625 Even considering all of Argentina's arguments together, we are not satisfied that Argentina has met its burden. We recognize that Argentina may not have ready access to information about whether and to what extent the European Communities "took account" of Argentina's needs as a developing country Member. However, there is no evidence on record to show that Argentina ever approached the European Communities and sought information on how the European Communities complied with its obligation under Article 10.1 when applying its approval legislation to applications concerning biotech products of export interest to Argentina. We do not mean to suggest that it is Argentina's duty specifically to request the European Communities to take account of Argentina's needs as a developing country Member. But under well-established rules on burden of proof it is for Argentina to prove its claim that the European Communities did not take account of developing country Members' needs.

7.1626 In the light of the above considerations, we find, in the alternative, that Argentina has failed to establish its claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has applied its approval legislation between October 1998 and August 2003.

[1334] It is worth noting in this context that Argentina has not explained how the European Communities would in the present case have known that a particular application concerned a biotech product of export interest to Argentina. As far as we are able to determine, in none of the many approval procedures affected by the general moratorium was the applicant an Argentinean company or individual. Typically, the applicant was a biotech company of a developed country nationality. While such applicants may have provided information on actual or potential exporting countries as part of the information submitted with their applications, neither Argentina nor the European Communities has confirmed that they were required to do so, or if not, that they have consistently done so.

[1335] We note, however, that Directive 2001/18 in its 13th preambular paragraph states that the content of the Directive "duly takes into account" the European Communities' "international trade commitments". Argentina did not acknowledge this paragraph.